COVID-19 Vaccines

Pandemic Provider Educational Packet
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Summary of Recent Changes

Revisions were made on May 21, 2021

Moderna COVID-19 Vaccine Storage and Handling

- Moderna COVID-19 Vaccine Storage and Handling Summary
- TN COVID-19 Vaccine Storage and Handling Guidance

Moderna COVID-19 Vaccine Administration

- Moderna COVID-19 Vaccine Preparation and Administration Summary
- Moderna COVID-19 Vaccine Standing Orders for Administering Vaccine

Healthcare Educational Information

- Update the COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Providers

Appendix

- Updated COVID-19 Vaccine Consent Template Card (English)
- COVID-19 Vaccine Consent Template Card (Spanish)
Before you proceed, please read the following:

- COVID-19 vaccines are **only** to be placed in a refrigerator or freezer that has been **pre-approved** by the Tennessee Department of Health’s Immunization Program (VPDIP).
- COVID-19 vaccines are not to be taken off-site unless a mobile clinic plan has been submitted and **pre-approved** by VPDIP.
- COVID-19 vaccines must **ALWAYS** be placed in a refrigerator, freezer, or transport cooler that is continuously monitored with a **pre-approved** digital data logger or integrated temperature monitor.
- Never administer vaccines that have experienced temperatures outside of the accepted range. Mark them “DO NOT USE” and contact temperature.health@tn.gov.
- COVID-19 vaccines are **NEVER** to be placed in a dorm-style refrigerator or freezer or in the freezer space of a combination refrigerator/freezer unit.
- COVID-19 vaccines are not to be transferred to another site without the consent of VPDIP.
- Ensure there is an emergency plan for the storage of vaccines in the event there is failure of the primary storage unit.

**Failure to comply with the directions listed above may result in spoilage of vaccines and re-vaccination of vaccine recipients.**

Questions may be directed to VPDIP.pandemic@tn.gov.
**For new COVID-19 providers:**

TennIIS Team adds iWeb, Mass Immunization and VOMS permissions to the Primary and Secondary Points of Contact that are listed on the COVID-19 Provider Agreement.

**For other requests:**

When asking for help, please be specific in your email. Please include a screenshot and explain what exactly is not working. Please copy and paste or take a screenshot of any error messages you’re receiving.

### TennIIS and VOMS Support for non-Public Health users

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<td><a href="mailto:TennIIS.VOMS@tn.gov">TennIIS.VOMS@tn.gov</a> – for VOMS permissions. <a href="mailto:TennIIS.training@tn.gov">TennIIS.training@tn.gov</a> for TennIIS user access and Mass Immunizations permissions.</td>
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<td><strong>TennIIS Mass Immunization Module</strong></td>
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<td><a href="mailto:TennIIS.Training@tn.gov">TennIIS.Training@tn.gov</a></td>
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<td><strong>Vaccine Storage and Handling Questions</strong></td>
<td><a href="mailto:Vaccine.Storage@tn.gov">Vaccine.Storage@tn.gov</a></td>
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Updated: 4/6/2021
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| **TennIIS-VOMS Inventory Management**  | TennIIS Help Desk  
(844) 206-9927  
TennIIS.Help@tn.gov                  | TennIIS.VOMS@tn.gov                      |
| • VOMS user permissions               |                                                                                         |                                        |
| • Accept inventory                    |                                                                                         |                                        |
| • Reconcile Inventory                 |                                                                                         |                                        |
| • Add bonus doses using “Dose Count Variance” |                                                                                       |                                        |
| **Transfer Doses in TennIIS-VOMS Inventory** | TennIIS.VOMS@tn.gov                                                                      | TennIIS.VOMS@tn.gov                      |
| **Temperature Excursion:** When a vaccine storage unit goes out of temperature range | Temperature.health@tn.gov                                                              | Temperature.health@tn.gov (9 am-6pm)    |
| **Transporting Vaccine:** for mobile clinics or for offsite events.  
*Must have a VPDIP-approved plan in place before transporting vaccine.* | Vaccine.Transport@tn.gov                                                                |                                        |

If you need to speak to someone immediately after hours or on the weekends, please call 615-741-7247.
Moderna COVID-19 Vaccine

Vaccine Storage and Handling
Basics

- Store vaccine in a freezer or refrigerator. See guidance below for each storage unit.
- Each box contains 10 multidose vials. Vaccine is supplied in two presentations:
  - Maximum of 11 doses per vial
  - Maximum of 15 doses per vial
- Each box is approximately 2 inches by 2 inches by 5.4 inches

Vaccine

1. The vaccine will arrive frozen between -50°C and -15°C (-58°F and 5°F).
2. Examine the shipment for signs of damage.
3. Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine).
4. Check the TagAlert temperature monitoring device by pressing the blue "start and stop" button.
   - Left arrow points to a green checkmark: The vaccine is ready to use. Store the vaccine at proper temperatures immediately.
   - Right arrow points to a red X: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label DO NOT USE! Call the phone number indicated in the instructions or your jurisdiction’s immunization program IMMEDIATELY!
5. The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
   - Scan the QR code located on the outer carton, or
   - Go to www.modernatx.com/covid19vaccine-eua/.

Ancillary Supply Kit

An ancillary kit with supplies will be provided for administering the vaccine. It includes enough supplies to administer 100 doses of vaccine (10 doses per vial).

Administration supplies include needles, syringes, sterile alcohol prep pads, vaccination record cards (shot cards), and some PPE.

The kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities.

Freezer

Unpunctured vials may be stored in the freezer between -50°C and -15°C (-58°F and 5°F).

- Store in the original carton.
- Protect from light.
- Do not store with dry ice or below -50°C (-58°F).
Storage unit temperatures must be monitored regularly and checked and recorded at the beginning of each workday to determine if any excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature daily using a temperature log and one of the options below:

Option 1: Minimum/Maximum Temperatures (preferred)
Most DDLs display minimum and maximum (min/max) temperatures. Check and record the min/max temperatures at the start of each workday.

Option 2: Current Temperature
If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

For CDC temperatures logs, see https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html.

Transporting Vaccine
Moderna COVID-19 vaccine may be transported at frozen and refrigerated temperatures using a portable unit or container qualified to maintain appropriate temperatures.

Detailed guidance can be found in CDC’s Storage and Handling Toolkit COVID-19 addendum and Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations.

Disposal
Once vaccine has reached its expiration or beyond-use date, contact the manufacturer for guidance on whether it can still be used. If instructed to dispose of vaccine, dispose of the vial (with any remaining vaccine) and packaging as medical waste according to your local and state regulations. Contact your jurisdiction’s immunization program for guidance (https://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html).

*Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.
Store Moderna COVID-19 vaccine between -58°F and 5°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC’s Vaccine Storage and Handling Toolkit, COVID-19 Addendum, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)
1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature
1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "x" in the row that corresponds to the freezer temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.

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Temperatures lower than -58°F and higher than 5°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

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For additional information, see the vaccine manufacturer’s product information at https://www.modernatx.com/covid19vaccine-eua/  Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log
Modern COVID-19 Vaccine
Temperature Log for Frozen Vaccine Storage (Fahrenheit) Days 16-31

Store Moderna COVID-19 vaccine between -58°F and 5°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC’s Vaccine Storage and Handling Toolkit, COVID-19 Addendum, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)
1. Most DDLS display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature
1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the freezer temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.

If the temperature is out of range, TAKE ACTION!
1. Do NOT discard the vaccine.
2. Label the vaccine "Do Not Use."
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.

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Temperatures lower than -58°F and higher than 5°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

For additional information, see the vaccine manufacturer’s product information at https://www.modernatx.com/covid19vaccine-uaa/ Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log
**Store Moderna COVID-19 vaccine between -50°C and -15°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum, for additional information.**

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**Temperatures lower than -50°C and higher than -15°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.**

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For additional information, see the vaccine manufacturer's product information at [https://www.modernatx.com/covid19vaccine-eua/](https://www.modernatx.com/covid19vaccine-eua/)
Modern COVID-19 Vaccine
Temperature Log for Frozen Vaccine Storage (Celsius) Days 16–31

Store Moderna COVID-19 vaccine between -50°C and -15°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC’s Vaccine Storage and Handling Toolkit, COVID-19 Addendum, for additional information.

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If the temperature is out of range, **TAKE ACTION!**

1. Do **NOT** discard the vaccine.
2. Label the vaccine **“Do Not Use.”**
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.

Temperatures lower than -50°C and higher than -15°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

<table>
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<tr>
<th>Time</th>
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For additional information, see the vaccine manufacturer's product information at [https://www.modernatx.com/covid19vaccine-eua/](https://www.modernatx.com/covid19vaccine-eua/)  
Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log.
Use this tracking tool to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. When the current expiration date gets close, contact the manufacturer before discarding vaccine. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. Keep this document for 3 years or longer if required by your jurisdiction.

**Product name:** ____________________  **Manufacturer:** ____________________  **Original Expiration Date:** ____________________

**Expiration date info is available at** (include all available information from manufacturer, website, app, phone number)

<table>
<thead>
<tr>
<th>Date</th>
<th>Lot Number</th>
<th>Updated Expiration Date</th>
<th>Info Source</th>
<th>Name</th>
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</thead>
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<tr>
<td><strong>Example:</strong> 09/01/2020</td>
<td>ABC123DE456</td>
<td>06/30/2021</td>
<td>✨ Website □ Barcode</td>
<td>Susie Smith RN</td>
</tr>
</tbody>
</table>
Modern COVID-19 Vaccine

Beyond-Use Date/Time (BUD) Tracking Label for Vaccine During Refrigerator Storage

Once thawed, Moderna COVID-19 vaccine has specific beyond-use dates/times for refrigerated storage and transport. Use these labels to ensure beyond-use dates/times are followed.

**Storing Vaccine in the Refrigerator**

Moderna COVID-19 vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days.

- Remove the vaccine vials from the freezer.
- Complete the information on the top portion of the label and attach it to the box or container holding the vaccine vials.
- Once labeled, store vaccine vials upright in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days. Use vaccine vials stored in the refrigerator BEFORE removing additional vials from the freezer.
- As the 30-day deadline approaches, contact the manufacturer for guidance if you will not be able to use vaccine. If directed to discard vaccine, follow manufacturer and jurisdiction guidance for proper disposal.

**Transporting Vaccine Between 2°C and 8°C (36°F and 46°F)**

Moderna COVID-19 vaccine may be transported for 12 cumulative hours (e.g., vaccine transported for 2 hours today has 10 hours of transport time remaining). Follow transportation guidance for Moderna COVID-19 vaccine in CDC’s Storage and Handling Toolkit, COVID-19 Addendum.

- When you have completed vaccine transport for the day, remove any remaining vials from the transport container.
- Complete the information on the bottom portion of the label indicating the time in transport and hours remaining for transport, if needed.
- Once you have completed this information, store vaccine upright in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to the indicated BUD.

Note: Storage labels on page 2 are formatted to print on 4” x 3-1/3” adhesive labels. We are unable to format for other size labels. If this size label is not available, print on paper and affix to container holding the vaccine.
When transporting refrigerated vaccines, use:
- A portable refrigerator or vaccine storage container qualified to maintain temperatures between 2°C and 8°C (36°F and 46°F).
- A digital data logger (DDL) with a thermal buffer and external temperature display (preferred). Place the probe as close as possible to the vaccine.
- This temperature log to document temperatures and how long the vaccine is in the portable storage container.

Temperature monitoring and transport time frames:
- Most DDLs display minimum/maximum (min/max) temperatures. *
- Record the time and min/max temperatures:
  - At the start of transport
  - Every time the portable storage container is opened
  - When transport is completed
- The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.*
- Beyond-use date/time (BUD), if applicable, are included in transport time. For example, if the vaccine may be stored at refrigerated temperature for 120 hours, transport is included in this time frame.

### Temperature Log when Transporting Vaccine at Refrigerated Temperatures

<table>
<thead>
<tr>
<th>Today's date:</th>
<th>Transport start time:</th>
<th>Transport end time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider name:</td>
<td>Facility name:</td>
<td>PIN number:</td>
</tr>
</tbody>
</table>

**Temperatures measured in (circle one):** Celsius Fahrenheit

<table>
<thead>
<tr>
<th>Time</th>
<th>Min/max temperatures</th>
<th>Temps lower than 2°C (36°F) and higher than 8°C (46°F) are out of range. * Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.</th>
</tr>
</thead>
</table>

- After packing the vaccine, open the portable storage container only when necessary.
- If using a company or personal vehicle, transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Avoid leaving the portable storage container in direct sunlight or unattended.
- If needed, transport diluents with their corresponding vaccines to ensure there are equal amounts of vaccines and diluents. Follow the manufacturer’s guidance for specific temperature requirements for diluents.

- Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC’s Vaccine Storage and Handling Toolkit for additional guidance.
- Refer to CDC’s Vaccine Storage and Handling Toolkit for additional guidance when transporting vaccines.

* If the DDL does not measure min/max temperatures, check and record temperatures hourly.
* Follow the manufacturer’s guidance if it differs from this time frame.
**Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations**

**Procedure**
Follow storage and handling best practices outlined in CDC’s *Vaccine Storage and Handling Toolkit* to maintain the cold chain when packing and transporting vaccine.

CDC recommends transporting Moderna COVID-19 vaccine at frozen or refrigerated temperature using a portable freezer or refrigerator unit or a container/packout qualified to maintain the recommended temperatures.

To monitor vaccine temperatures, use a digital data logger with a buffered temperature probe that displays current, minimum, and maximum temperatures.

Upon arrival at clinic, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures.

Temperature monitoring: Record time and min/max temperatures:
- At the start of transport
- Whenever the transport container is opened
- When transport concludes

![Flowchart of vaccine transport process]

**General Information**
- Vaccine vials may be transported more than once.
- Transport thawed vaccine at refrigerated temperatures. Once thawed, vaccine should not be refrozen.
- Do NOT use dry ice when transporting vaccine.
- Both punctured and unpunctured vials may be transported.

**Frozen transport: Between -50°C and -15°C (-58°F and 5°F)**
- Only unpunctured vials may be transported frozen.
- Frozen transport is preferred if vaccine must be transported.
  - Do not freeze thawed vaccine.

**Refrigerated transport: Between 2°C and 8°C (36°F and 46°F) for up to 12 total hours**
- **Unpunctured vials**: Vaccine may be stored at refrigerated temperatures for up to 30 days.
  - Time used for transport counts as part of the 30-day limit.
- **Punctured vials**: Punctured vials may be transported at refrigerated temperatures
  - Once punctured, the vaccine must be used within 12 hours.
  - Time used for transport counts as part of the 12-hour time limit.
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopoeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.
- The 12-hour transport time frame is cumulative. Monitor and record all transport time to ensure this time frame is not exceeded.
  - **Example**: If the vaccine is transported for 1 hour to a clinic and for 1 hour back to the primary storage unit, the returned vials can be transported for an additional 10 hours.
  - **Use CDC’s beyond-use date (BUD) labels** to track BOTH the refrigerator storage and transportation time frames.
- Take care that vaccine is not refrozen during transport.

**Best Practices for Transporting mRNA Vaccines**
- Protect vaccines as much as possible from drops, shocks, and vibration.
- To minimize movement, transport vials in the carton whenever possible.
- If individual vials must be transported:
  - Place vials with padding material like bubble wrap or similar materials to prevent breaking.
  - Secure storage containers during transport.
  - Keep vaccine vials upright whenever possible.

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COVID-19 Vaccine Storage and Handling Guidance

Tennessee Vaccine-Preventable Diseases and Immunization Program
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Section One: Introduction

Vaccines must be stored and handled properly in order to prevent and eradicate vaccine-preventable diseases. Failure to properly store and handle vaccines results in financial loss, revaccination, and reduced public confidence in vaccines. Vaccines that have been exposed to improper conditions have reduced potency, resulting in inadequate immune response and poor protection against disease.

The temperature-controlled environment used to maintain and transport vaccines in optimal condition is called the vaccine cold chain. The cold chain begins with the storage unit at the manufacturing plant, extends to the transport and delivery of vaccine and storage at a clinic, and ends with administration of the vaccine to a patient.

Every time a vaccine is exposed to improper conditions (e.g., overexposure to heat, cold, or light), its potency is reduced. If a refrigerated vaccine is exposed to freezing temperature just once, its potency can be destroyed.

This document is designed to assist providers in properly storing and handling federal COVID-19 vaccine as part of the Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP) COVID-19 Vaccination Program. It is a modified version of the Centers for Disease Control and Prevention (CDC) Storage and Handling Toolkit, which you are highly recommended to review in order to fully understand the breadth of information, recommendations, and resources available to assist you in properly storing and handling your vaccine supply. CDC’s You Call the Shots Module Ten is also a recommended training for understanding vaccine storage and handling.

Always refer to the manufacturer information and package inserts or contact the manufacturer directly for detailed storage and handling protocols for individual vaccines.

The Tennessee Department of Health are not authorized to assess, validate, verify, or endorse products or services of private companies. When purchasing storage and handling equipment, keep in mind that products labeled as “CDC-compliant” have not been reviewed by the CDC or the Tennessee Department of Health.

Always contact the Tennessee Vaccine-Preventable Diseases and Immunization Program if you are unsure if a specific product meets requirements.

DRAFT: updated 05/20/2021
Section Two: Staff and Training

Clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs) will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. SOPs should be maintained near vaccine storage units where staff can find them. Additionally, well-trained staff are necessary for implementing SOPs at the facility. Staff should be trained on storage and handling procedures as part of new employee orientation, annually, whenever new vaccines are added to the inventory, and whenever storage and handling recommendations change. A template Routine and Emergency Vaccine Management Plan (REVMP) may be found in Appendix A.

At a minimum, SOPs should contain plans and information for three major areas:

1) **General**: contact information for vaccine manufacturers, equipment service providers, and important facility staff; job descriptions; regularly used forms; and staff training requirements
2) **Vaccine inventory management**: ordering vaccines, monitoring storage, etc.
3) **Emergency**: steps to take in the event of equipment malfunctions, power failures, or other emergencies that can compromise storage conditions

A **primary vaccine coordinator** should be designated for ensuring all vaccines are stored and handled correctly. A **back-up vaccine coordinator** should also be appointed to act in the absence of the primary coordinator. Both coordinators should be responsible for:

- Ordering vaccine (once available) and overseeing receipt/storage of deliveries
- Maintaining all documentation, such as vaccine inventory and temperature logs
- Monitoring operation of vaccine storage equipment and systems
- Organizing vaccines in storage units, including rotating stock at least weekly so vaccines with earlier expiration dates are used first and removing expired vaccines
- Monitoring temperature data on storage units, including:
  - Setting up temperature monitoring devices (TMDs)
  - Checking minimum/maximum temperatures for the last 24 hours in the morning and checking current temperatures in the morning and afternoon
  - Reviewing temperature data weekly for shifts in temperature trends
  - Responding to and reporting temperature excursions
- Organizing vaccine-related training and ensuring staff complete training
- Overseeing vaccine transport when necessary

DRAFT: updated 05/20/2021
Overseeing emergency procedures, such as tracking inclement weather conditions and ensuring appropriate handling of vaccines during a disaster or power outage

VPDIP requires completion of CDC’s COVID-19 Vaccine Training Modules for all primary and back-up coordinators at all sites enrolled in the COVID-19 Vaccination Program. Pharmacists signing the Storage and Handling portion of the COVID-19 Provider Agreement are also required to complete the training modules. Continuing Education Units (CEUs) are available upon completion of each module and must be provided to VPDIP for review. Current training modules are listed below and may be found on [CDC's COVID-19 Vaccine Training Modules Homepage](https://www.cdc.gov/vaccines/).

- COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
- Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know
- Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know
- Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know

**Section Three: Equipment**

**Vaccine Storage Unit Recommendations**

**Purpose-built or pharmaceutical grade units** are designed specifically for storing biologics such as vaccines. These units:

- Can be compact, under-the-counter style or large
- Often have microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistant temperature detector [RTD], or thermistor)
- Often have fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature

**Household grade units** can be an acceptable alternative under the right conditions. When using these units, the freezer compartment of a combination unit should never be used to store vaccines, and certain areas of the refrigerated compartment should be avoided as well. Separate standalone freezers are necessary for storing frozen vaccine.

If a **manual defrost freezer** is used, an appropriate back-up freezer must be available to store vaccine in when the main freezer is being defrosted. A defrost plan should be
included in the storage and handling SOPs, and the unit should be defrosted when the unit has accumulated to a thickness of approximately 1 cm.

**Dormitory-style and bar-style units** may **never** be used to store vaccine. These units have a single external door and evaporator plate (cooling coil) that is usually located in the “freezer” within the refrigerator. These units place vaccine at high risk of freezing.

**Storage Unit Placement**
Vaccine temperature stability requires air circulation around the outside of the storage unit. Recommendations for where to place refrigerators and freezers include:

- Unit should be in well-ventilated room with standard room temperatures (between 20°C and 25°C [68°F and 77°F]) and space between the unit, ceiling, and walls
- Nothing should block the cover of the motor compartment
- Unit should be firm and level, with bottom of unit above floor
- Door should be able to open and close smoothly and fit squarely against unit body

**Stabilizing Temperatures in New and Repaired Units**
Prior to storing vaccines in a new or repaired unit, check and record the minimum and maximum temperatures each workday for two to seven days. Once you have **two consecutive days** of temperatures within the recommended range, the unit is stable and can be used for vaccine storage.

**Recommended Temperature Ranges**
Different COVID-19 vaccines have different recommended temperature ranges.

- **Refrigerated vaccines** should be stored in refrigerators maintained at temperatures between 2°C and 8°C. **Frozen vaccines** should be stored in freezers maintained at temperatures between -25°C and -15°C. **Ultra-cold vaccines** should be stored in freezers or dry ice shipping container in which product is received between -95°C and -60°C.

**Temperature Monitoring Devices (TMD)**
All storage units must be equipped with a specific type of TMD known as a digital data logger (DDL). DDLs provide details on all temperatures the unit has reached at preset intervals. DDLs should have the following features:

- Detachable, buffered probe (or digitally buffered device that mimics buffered probe)
- Alarms (audible or visual) for out-of-range temperatures, with parameters set as:
  - Refrigerator low alarm (too cold) set to trigger after 15 consecutive minutes or longer below 2.0°C

DRAFT: updated 05/20/2021
Certificates of Calibration Testing should also include:

- Refrigerator high alarm (too warm) set to trigger after 60 consecutive minutes or longer above 8.0°C
- Freezer high alarm (too warm) set to trigger after 60 consecutive minutes or longer above -15°C
- Low-battery indicator
- Active display outside of unit that allows current, minimum, and maximum temperatures to be monitored without opening unit door
- Recommended uncertainty of +/- 0.5°C
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
- Ability to easily download data for review
- Ability to report temperatures in Celsius
- A current and valid Certificate of Calibration

A back-up DDL with a valid and current Certificate of Calibration must also be available on-site and readily available in case a primary DDL malfunctions or requires re-calibration. The back-up DDL should be stored outside of the storage unit until needed, and it should have a different calibration re-testing date than the primary DDLs so that one may be used while the other is being replaced or sent out for re-calibration.

Certificate of Calibration Testing
Calibration testing ensures the accuracy of DDLs against nationally accepted standards. Calibration testing should be done every one or two years or according to the manufacturer’s suggested timeline. Certificates of Calibration testing should indicate one or more of the following about the testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Manual Recognition Arrangement (MRA) signatory body
- Traceable to standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Certificates of Calibration Testing should also include:

DRAFT: updated 05/20/2021
• Model/device name or number
• Serial number
• Date of calibration (report or issue date)
• Confirmation that the instrument passed testing (or instrument is in tolerance)
• Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less

The following TMDs should not be used
• Alcohol or mercury thermometers
• Bimetal stem TMDs
• TMDs used for food
• Chart recorded
• Infrared TMDs
• TMDs that do not have a current and valid Certificate of Calibration testing

Temperature Probe Placement
The DDL probe should be placed in the middle area of the storage unit with the vaccines. Anchoring the probe will prevent it from being moved. It should not be placed in the doors, near or against the walls, close to vents, or on the floor of the unit as temperatures in these locations may differ significantly from the temperature in the zone where vaccine is stored.

Monitoring Vaccine Temperature and Equipment

Daily Checks
Current temperatures should be reviewed for each storage unit twice a day (once in the morning and once in the afternoon). During the morning temperature check, the minimum and maximum temperature for the past 24 hours should also be reviewed.

If your DDL can record twice daily readings, use this function and document readings on the Vaccine Storage Unit Digital Data Logger Sign-off Sheet. If your DDL can document the initials of the person that completes the reading, the sign-off sheet does not need to be completed. If your DDL cannot document readings on the DDL report at all, use the Refrigerator and Freezer Temperature Logs to document checks.

Weekly Checks
Additionally, DDL reports must be printed, reviewed, and signed by the Vaccine Coordinator each week and maintained with temperature logs for three years.
Power Supply

The following precautions must be taken to protect the unit’s power supply:

- Plug in only one unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged
- Post “DO NOT UNPLUG” signs at outlets and on units
- Post “DO NOT TURN OFF” signs on fuses and circuit breakers
- Use caution when using power outlets that can be tripped or switched off and avoid using built-in circuit switches which may have reset buttons, outlets that can be activated by a wall switch, and multi-outlet power strips
  - If built-in current switches or power strip surge protection must be used, make sure the power strip is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer.

Organizing and Storing Vaccine

**Store vaccines in their original packaging with lids closed until ready for administration.** Loose vials or syringes may be exposed to unnecessary light and may be more difficult to track for expiration dates. Not storing vaccines in the original packaging affects inventory management and increases the risk of administration errors. Best practices for correct storage of vaccines within a refrigerator or freezer include:

- Store each type of vaccine/diluent in original packaging and in a separate container
- Position vaccines/diluents 2-3 inches from unit walls, ceilings, floor, and door.
  - If using a household-grade unit, do not store vaccines/diluents directly under cooling vents; in deli, fruit, or vegetable drawers; or on refrigerator door shelves. These areas may expose vaccines to unstable temperatures and insufficient air flow.
- Label shelves/containers to identify where each type of vaccine/diluent is stored.
- Store vaccines/diluents with similar packaging/names or with pediatric/adult formulations on different shelves.
- Store diluents with the corresponding refrigerated vaccine. Never store diluent in a freezer. Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.
  - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccine.
o Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.

o The freezer of a combination household-grade unit may be used for non-vaccine, medical storage, as long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.

- Arrange vaccines/diluents in rows and allow space between them to promote air circulation.
- Place vaccines/diluents with the earliest expiration dates in front of those with later expiration dates.
- Place water bottles on the top shelf, floor, and in the door racks. Putting water bottles help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure.
  o Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

Regular Maintenance of Equipment
Vaccine storage units and DDLs require regular maintenance to ensure proper operation. On a regular basis, check seals and door hinges, clean coils and other compartments per manufacturer direction, defrost manual-defrost freezers when the frost exceeds either 1cm or the manufacturer's suggested limit (when defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures), clean the interior of each unit to discourage bacterial and fungal growth, and test any back-up generator quarterly and have it served annually.

Section Four: Pfizer/BioNTech COVID-19 Vaccine Storage

Using the Thermal Shipping Container for Vaccine Storage
Vaccine that is stored in a thermal shipping container should maintain temperatures between -80°C and -60°C (-112°F to -76°F). The thermal shipping container should be stored at 15°C–25°C (59°F –77°F). **Thermal shipping containers may not be used for vaccine storage beyond 30 days.** Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
A Digital Data Logger (DDL) capable of monitoring ultra-cold temperatures must be placed in the location of the vial tray if the thermal shipping container is being used for storage. CDC will provide a temporary DDL with each thermal shipper that may be activated while utilizing the container for vaccine storage. All DDLs purchased separately must have a current, valid Certificate of Calibration.

The thermal shipping container should be re-iced every five days. Re-icing every 5 days helps maintain the level of dry ice and the temperature of the vaccine product. The thermal shipping container should not be opened more than 2 times per day and should not be opened for more than three (3) minutes at a time. Strict adherence to this guideline will ensure the thermal shipping container can maintain ultra-cold storage conditions.

To properly replenish the container, add dry ice to the maximum lines within the payload insert areas and dry ice pod. The thermal shipper and Controlant temperature data logger should be returned to Pfizer within 30 business days of delivery.

Vaccine vials should be protected from light and kept in the original packaging. Vials should always remain upright in trays during storage. If a vial is touched, it is considered “thawed” and is to be moved to the refrigerator for use within 5 days. If the lid of the vial tray is opened, it must be returned to ultra-cold storage within three (3) minutes and must stay in ultra-cold storage for two (2) hours before the tray is opened again. When transferring between ultra-cold environments, the 195-vial box may be at room temperature for up to five (5) minutes if the lid is closed and intact.

Vaccine that is stored in the thermal shipping container with the temporary DDL provided will be continuously monitored. Providers using this method of vaccine storage will not be required to document minimum and maximum daily temps, as the DDLs provided will not have a temperature display. Instead, providers utilizing this method of vaccine storage should review and print the DDL reports provided by Pfizer and/or Controlant to each Primary and Back-up Vaccine Coordinator listed on the COVID-19 Provider Agreement.

Using an Ultra-cold Freezer for Vaccine Storage
Vaccine that is stored in an ultra-cold freezer should be stored between -80°C and -60°C (-112°F to -76°F). Pfizer/BioNTech COVID-19 vaccine may be stored in ultra-cold freezers for up to six (6) months. Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
Vaccine vials should be protected from light and kept in the original packaging. Vials should always remain upright in trays during storage. If a vial is touched, it is considered “thawed” and is to be moved to the refrigerator for use within 5 days. If the lid of the vial tray is opened, it must be returned to ultra-cold storage within three (3) minutes and must stay in ultra-cold storage for two (2) hours before the tray is opened again. When transferring between ultra-cold environments, the 195-vial box may be at room temperature for up to five (5) minutes if the lid is closed and intact.

Vaccine stored in ultra-cold freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the Vaccine Storage Unit Digital Data Logger Sign-off Sheet to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

**Using a Freezer for Vaccine Storage**

Pfizer/BioNTech COVID-19 vaccine that is stored in a freezer should be stored between -25°C and -15°C (-13°F to 5°F). Pfizer/BioNTech COVID-19 vaccine may be stored in a freezer for up to two (2) weeks. **NOTE: Vaccine should never be placed into the freezer compartment of a combination refrigerator/freezer unit.** Vaccine stored at frozen temperatures must be stored in a separate, approved standalone freezer. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Frozen vials stored or transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). This includes vials that are held up to two weeks at -25°C to -15°C (-13°F to 5°F), and at risk of not being used in time. Any time that the vials are stored or transported at -25°C to -15°C count against the two-week limit. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed two weeks. CDC is updating Pfizer Beyond-Use Date Labels to track this two-week timeframe.

Vaccine stored in freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine.
storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the Vaccine Storage Unit Digital Data Logger Sign-off Sheet to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Using a Refrigerator for Vaccine Storage
Pfizer/BioNTech COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Pfizer/BioNTech COVID-19 vaccine may be stored in a refrigerator for up to 1 month (31 days). Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the Vaccine Storage Unit Digital Data Logger Sign-off Sheet to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Section Five: Moderna COVID-19 Vaccine Storage

Using a Freezer for Vaccine Storage
Moderna COVID-19 vaccine that is stored in a freezer should be stored between -50°C and -15°C (-58°F to 5°F). Moderna COVID-19 vaccine may be stored in a freezer for up to six (6) months. **NOTE: Vaccine should never be placed into the freezer compartment of a combination refrigerator/freezer unit.** Vaccine stored at frozen temperatures must be stored in a separate, approved standalone freezer. Unpunctured vials may be stored

DRAFT: updated 05/20/2021
between 8° to 25°C (46° to 77°F) for a total of 24 hours. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture. Vaccine stored in freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the Vaccine Storage Unit Digital Data Logger Sign-off Sheet to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Using a Refrigerator for Vaccine Storage
Modern COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Moderna COVID-19 vaccine may be stored in a refrigerator for up to thirty (30) days. Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture. Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the Vaccine Storage Unit Digital Data Logger Sign-off Sheet to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Section Six: Janssen COVID-19 Vaccine

Using a Refrigerator for Vaccine Storage
Janssen COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Do not store Janssen COVID-19 vaccine in a freezer or ultra-cold freezer.
Janssen COVID-19 vaccine may be stored in a refrigerator for up to three (3) months. Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

Providers may use the Vaccine Storage Unit Digital Data Logger Sign-off Sheet to record daily min/max temperatures, actions taken, and responsible staff initials. DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Section Seven: Temperature Excursions (TEs)

Temperature excursions (TEs) occur when there is a temperature reading outside of the recommended temperature range for a vaccine. When a TE occurs, VPDIP must be notified as quickly as possible at 800-404-3006 during business hours or the next business morning (Monday – Friday, 8:00 AM – 4:30 PM CT) and before any vaccine is administered.
If a TE occurs, follow these steps:

1. Troubleshoot to see if you can identify why unit went out-of-range (e.g., unit is unplugged, unit door is open or not sealed adequately, thermostat is set incorrectly, probe has been moved from center of unit, or coils and vents have excess dust) and attempt to return vaccine to proper storage conditions if still out-of-range by.
   a. If outside of business hours and temperature is still out-of-range and cannot be restored to proper temperatures, execute emergency plan.
2. Label vaccines “Do not use until notified by VPDIP,” and do not use until approved.
3. Call VPDIP for further instruction.
4. Download DDL report, noting how long the temperature has been out of range and the minimum/maximum temperatures.
5. Send the DDL report/temperature log by fax to (615) 401-6829 or by email to Temperature.Health@tn.gov. Include facility PIN and name on report.
6. Wait for notification from VPDIP whether the vaccine can be used.

Section Eight: Vaccine Inventory Management

The vaccine cold chain becomes the provider’s responsibility once delivery is made to the facility. The following section provides information on ensuring that vaccines are unpacked, stored, prepared, administered, and transported correctly.

Scheduling and Receiving Deliveries

Staff members who may accept deliveries should be trained to immediately notify the vaccine coordinator or other designated personnel when deliveries arrive.

Unpacking Deliveries

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after arrival. Check the shipment to ensure:
• No damage occurred to the package during transport
• The correct types and quantities of vaccines (and diluents, if applicable)
• No expired or soon-to-expire products were shipped
• No TEs occurred during transit (using the cold chain monitor [CCM])

Unopened/unpacked boxes should not be placed in a storage unit because the cool packs shipped with the vaccine can make the vaccine too cold if placed inside the storage unit.

Ultra-cold vaccine may be shipped in coolers packed in dry ice. These coolers should be repacked with dry ice within 24 hours of receipt and repacked again within 5 days or per manufacturer recommendations.

Stock Rotation and Removal
On a regular basis, vaccine stock should be rotated and checked for expired doses. Expired vaccines and diluents should be removed immediately to avoid inadvertent administration. Vaccines with earlier expiration dates should be placed in front of those with later expiration dates.

Preparing Vaccines for Administration
Preparing vaccines is the final step in the cold chain before administering to the patient. Best practices for handling vaccines include:

• Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
• Only prepare vaccines when you are ready to administer them.
• Check expiration dates and confirm that you have selected the correct vaccine.
• Only administer vaccines you have prepared.

Section Nine: Vaccine Transport

Vaccine Transport to Offsite PODs or Mobile Clinics
Vaccines should never be transported to an offsite clinic, POD, or mobile clinic without written approval from the VPDIP Program. It is imperative that your facility has the appropriate equipment and processes in place to ensure the vaccine cold chain is maintained before, during, and after transport. Please contact Vaccine.Storage@tn.gov if your facility intends to conduct mobile or offsite clinics. A vaccine storage and handling expert will evaluate your proposed equipment and protocols to ensure vaccine can be

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safely transported offsite. Required equipment includes a portable plug-in vaccine refrigerator and/or freezer and approved DDLs with valid Certificates of Calibration. Written protocols for vaccine transport will also be required.

**Emergency Vaccine Transport**

**Vaccines should not be routinely transported.** However, **emergencies** such as storage unit failure or power outage may require vaccine transport; in these instances, ensure precautions are taken to protect your supply by using the appropriate packing materials and procedures. CDC’s [Packing Vaccines for Transport during Emergencies](https://www.cdc.gov/vaccines/health-providers/managing/transport/index.html) is a useful tool that details proper procedures for doing so. Highlights include:

- **Diluents should be included with their corresponding vaccines during transport to ensure there is always an adequate amount for reconstitution.**
  - If diluents typically stored at room temperature (20°C to 25°C [68°F to 77°F]) will be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines. Diluents should **never** be frozen, even during transport. When packing vaccines and diluents for transport, place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.

- **Maintain a sufficient supply of materials needed for emergency vaccine transport of your maximum inventory.** Materials include:
  - Portable vaccine refrigerators/freezer units (preferred)
  - Qualified containers and packouts
  - Hard-sided insulated containers or Styrofoam™
  - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4°C to 5°C
    - Follow manufacturer’s instructions for use to reduce the risk of freezing vaccines during transport
  - Insulation materials such as bubble wrap and corrugated cardboard – enough to form two layers per container
  - DDLs for each container

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures. In an emergency situation, a system with conditioned water bottles can be used.
Never use commercially available soft-sided food or beverage coolers, and only use the original shipping materials that vaccines were initially shipping on or conditioned water bottle transport systems as a last resort in emergencies. In no situation should the frozen gel packs or coolant packs from the original shipments be re-used.

Planning and Preparing for Transport
Emergency vaccine packing and transport protocols should be included within your facility’s SOPs to ensure you are prepared for a situation in which your vaccine supply must be transported.

- Staff should be trained to pack vaccines correctly.
- Prior to transport, take an inventory of vaccines and record actions to protect vaccines during transport.
- Use the COVID-19 vaccine Transport log in Appendix B to record the time vaccines are removed from the storage unit and placed in the transport container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.
- When in transport, only open unit doors when necessary and only after all preparation for packing and moving vaccines has been completed.
- Avoid leaving containers where they may be exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility and store vaccines at recommended temperatures immediately.

Monitoring Temperatures During and After Transport
While in transport, vaccines should still be continuously monitored using a DDL. DDLs used in vaccine transport have the same requirements as the ones used during routine storage and handling. Upon arrival at the destination, vaccines should be immediately stored in a storage unit with a DDL. A DDL report from the DDL used in transport should be printed, reviewed for TEs, and maintained with COVID-19 vaccine records for three (3) years.

Section Ten: Emergency Vaccine Storage and Handling
Equipment failures, power outages, severe weather conditions, and natural disasters can happen without warning and may compromise vaccine storage conditions. In addition to vaccine transport planning, additional plans should be in place for emergencies.

You may choose to have a backup storage unit within your facility where vaccine can be stored if the primary storage unit fails. Additionally, you may have a generator that is
activated if power is compromised to the facility. However, even if a generator is available, additional backup plans should be in place for transport out of the facility.

**Alternative Storage Facility**
A working agreement should be established with at least one alternative storage facility as part of emergency vaccine storage and handling planning. This agreement should include 24-hour access to this facility.

**After Hours Facility Access**
A relationship with your facility's building manager and/or security staff should be maintained to ensure that you are able to access your vaccine supply outside of normal business hours. Relevant staff should maintain copies of information regarding building access and security procedures at home.
KEEP YOUR MANAGEMENT PLAN NEAR VACCINE STORAGE UNITS

The Tennessee Vaccine-Preventable Diseases and Immunization Program (VPDIP) requires COVID-19 Vaccination Program providers to maintain a vaccine management plan for routine and emergency situations. This document is a template for information, such as guidelines, protocols, contact information, and staff training, about your practice. None of the information included in this template may be excluded in the plan.

Review and update your plan at least once a year, when COVID-19 Vaccination Program requirements change, and when staff with designated vaccine management responsibilities change. Key practice staff must sign and acknowledge the signature log annually and whenever your plan is revised.

CDC Site Visit Reviewers may ask to review your plans during routine and drop-in site visits.

STAFF ROLES AND CONTACT INFORMATION

Facility Name: _____________________________________________________________________________________________________

Facility Address: ___________________________________________________________________________________________________

Facility Phone Number: ____________________________________________ COVID PIN: _________________________

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<th>Role/Responsibility</th>
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<td>Chief Medical Officer</td>
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Please refer to Page 3 of this document for descriptions of the key duties assigned to designated vaccine management staff.

Staff must sign and date the Acknowledgement and Signature Log at the end of this document to confirm that they understand and agree to the duties assigned to them.
COVID-19 REQUIRED TRAINING LOG

Please list designated vaccine management personnel and have them sign and acknowledge that they have completed required training.

Primary and Back-up Vaccine Coordinators must complete CDC’s COVID-19 Vaccine Training Modules. Additionally, if a pharmacist is listed as the signatory under the Storage and Handling section of the COVID-19 Provider Agreement, this individual must complete the training modules. These modules include a General Overview of Immunization Best Practices, Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, and Pfizer COVID-19 Vaccine. Staff at your facility that routinely handle or administer COVID-19 vaccine are recommended to also participate in these trainings, in case of staff turnover.

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KEY DUTIES FOR DESIGNATED VACCINE MANAGEMENT STAFF

All staff who work with COVID-19 vaccines should be familiar with all requirements outlined in the COVID-19 Vaccination Program Provider Agreement. Below are highlights of key duties for designated vaccine management staff.

**CMO/CEO:**
- ☐ Complies with all federal vaccine management requirements, including key areas outlined in this plan
- ☐ Oversees designated vaccine management staff to ensure COVID-19 program requirements are being met
- ☐ Designates one employee as Primary Vaccine Coordinator
- ☐ Designates one employee as Back-up Vaccine Coordinator
- ☐ Authorizes and reports changes to Primary and Back-up Vaccine Coordinators, CEO, or CMO to the COVID-19 Onboarding Team at Vaccine.Onboarding@tn.gov as soon as possible following any changes
- ☐ Meets and documents required training for designated vaccine management staff
- ☐ Ensures designated vaccine management staff are skilled and knowledgeable regarding VPDIP Program requirements for temperature monitoring and storage equipment
- ☐ Ensures practice's vaccine inventory management is consistent with VPDIP Program requirements
- ☐ Ensures practice's vaccine storage units and temperature monitoring devices meet VPDIP program requirements
- ☐ Updates and revises vaccine management plans at least annually and whenever necessary
- ☐ Reviews VPDIP program requirements and management plans with staff at least annually and whenever necessary

**Primary Vaccine Coordinator:**
- ☐ Completes all required training modules
- ☐ Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents

**Back-up Vaccine Coordinator:**
- ☐ Completes all required training modules
- ☐ Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents

**Pharmacist (only required if a pharmacist signed Storage and Handling section of Provider Agreement):**
- ☐ Completes all required training modules
- ☐ Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement, as well as all VPDIP requirements outlined in guidance documents
The Primary Vaccine Coordinator should review and acknowledge the following requirements by checking the box next to each item:

VACCINE STORAGE EQUIPMENT

**Equipment:**

☐ This facility uses VPDIP-compliant and approved vaccine storage refrigerator(s) and/or freezer(s)

☐ Vaccine storage units maintain recommended unit temperature ranges:
  - Refrigerator: between 2 and 8 °C
  - Freezer: between -15 °C and -25 °C
  - Ultra-cold Freezer: between -96 °C and -60 °C

☐ Vaccine storage units have adequate capacity to store vaccine supply at all times

☐ Vaccine storage units are routinely cleaned inside, kept dust-free outside, and have proper seals on the doors

☐ This facility keeps maintenance and repair records for vaccine storage units on file and makes them available to review upon request by VPDIP or CDC Site Visit Reviewers

**Power Supply:**

☐ Each vaccine storage unit is directly plugged into a wall outlet

☐ No vaccine storage unit is controlled by a light switch, power strips, or surge protectors with on/off switch

☐ Extension cords are never used to connect storage units to an outlet

☐ Plug guards are used to prevent power interruption

☐ “DO NOT UNPLUG” signs are posted at each outlet and at the circuit breakers

**Set-up:**

☐ Vaccine storage units are set up according to requirements outlined in the [CDC Storage and Handling Toolkit](#)

☐ Vaccine storage units are located away from direct sunlight and away from walls to allow air circulation

☐ Vaccines are never stored in the doors, drawers, or bins of storage units

☐ Drawers/deli crispers are removed from vaccine storage units

☐ Vaccines are stored 2-3 inches away from the walls, air vents, and floors of vaccine storage units to allow space for air circulation

☐ To stabilize temperatures, frozen cold packs are kept in standalone freezers and water bottles are kept on the top shelf, in the door, and on bottom of refrigerators where vaccines cannot be stored.

☐ The freezer compartment of a combination refrigerator/freezer storage unit is NEVER used for vaccine storage

☐ Dorm-style units are NEVER used for vaccine storage

☐ Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine

☐ Buffered DDL probes are placed in the center of the vaccine storage units, near the vaccines

☐ DDL displays are securely attached on the outside of vaccine storage units

☐ Vaccines are stored in their original packaging until administered

☐ Food, beverages, and laboratory specimens are never stored in vaccine storage units

☐ When medication or biologic media (not inoculated) are stored in the same unit as vaccines, they are placed on the shelves below vaccines

TEMPERATURE MONITORING EQUIPMENT

**Digital Data Loggers (DDLs):**

☐ Each vaccine storage unit has a continuous temperature monitoring device with the following capabilities:
  - Data that can be routinely downloaded
Active display that is placed on the outside of the unit door to allow for reading temperatures without opening the unit door

Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature

Alarm for out-of-range temperatures

Low battery indicator

Accuracy of +/- 0.5°C

Memory storage of at least 4,000 readings

User-programmable logging interval (or reading rate)

Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature

Each DDL has a current and valid Certificate of Calibration (also known as a Report of Calibration Testing)

Each DDL has a digital display of current, minimum, and maximum temperatures

Each DDL displays temperatures in degrees Celsius (°C)

Each DDL is set to alarm when:
  - Temperature in refrigerator goes above 8°C or below 2°C
  - Temperature in freezer goes above -15°C or below -25 °C

Probes are placed in the center of vaccine storage units and never in the unit doors, near or against the walls, underneath air vents, or on unit floors

DDL batteries are replaced every six months or as needed

There is at least one back-up DDL that is readily available on-site to ensure that temperature assessment and recordings can be performed twice a day

**DDL Calibration:**

- All primary and back-up DDLs are calibrated as recommended by the manufacturer
- DDL calibration is done by either a laboratory accredited by an ILAC MRA signatory body or an entity that provides documentation demonstrating that calibration testing meets ISO/IEC 17025 International standards for calibration testing and traceability
- Certificates of Calibration are maintained in a readily accessible area, until expiration, and presented to VPDIP staff for review upon request
- DDLs are replaced on or before expiration date listed on device
- DDLs are replaced when no longer accurate within +/- 0.5°C

**Safeguarding Vaccines, Handling, and Reporting Temperature Excursions:**

- When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage
- Temperature excursions are reported immediately to 800-404-3006 or Temperature.Health@tn.gov
- Vaccines involved in temperature excursions are labelled “Do Not Use Until Further Notice”
- This facility has an Emergency Vaccine Management Plan to follow in case of power outage, appliance malfunction, severe weather conditions, or human error that may affect vaccine viability
- When necessary to transport vaccine to another storage unit or to a predetermined site, facility always follows CDC’s Packing Vaccines for Transport during Emergencies Job Aid

**Temperature Monitoring and Documentation:**

- Vaccine storage unit temperatures are read twice a day, when the clinic opens and before it closes
  - Minimum and maximum temperatures are read and recorded once each day
  - AM temperatures are read and recorded before opening vaccine storage units
☐ PM temperatures are read and recorded at the end of each day, allowing time for corrective actions in the event of out-of-range unit temperatures
☐ Vaccine Storage Unit Digital Data Logger Sign-off Sheets are posted on storage unit doors or nearby
☐ Vaccine Storage Unit Digital Data Logger Sign-off Sheets are completed daily and DDL reports are printed weekly
☐ Vaccine Storage Unit Digital Data Logger Sign-off Sheets are initialed by person who documents temperatures
☐ Completed temperature logs are maintained for three years and made available to VPDIP upon request for review

Please refer to the VPDIP website for guidance on Temperature Monitoring and Excursions

INVENTORY MANAGEMENT

Inventory Maintenance:
☐ Physical vaccine inventory is reconciled in TennIIS daily
☐ Facility has adopted an inventory control system
☐ Accurate records, including packing slips and inventory management records, are maintained and made available upon request to VPDIP
☐ Vaccines that are drawn up and not used are disposed of correctly and recorded in TennIIS
☐ Facility stores diluent for vaccine appropriately
☐ Facility clearly labels diluents that are not packed with its vaccine so they can be easily identified
☐ Diluents are not placed in the freezer

Stock Rotation, Returns, and Transfers
☐ Vaccine stock is rotated monthly to assure that vaccines with the shortest expiration dates are used first
☐ If vaccine expires or spoils, it is:
  • Removed from storage unit
  • Reconciled appropriately in TennIIS
  • Returned to the vaccine manufacturer or wasted per VPDIP guidance
☐ If vaccine is due to expire within two weeks and will not be used, this facility will:
  • Notify VPDIP at VPDIP.Pandemic@tn.gov about vaccine
  • Request a transfer approval from VPDIP
☐ If facility needs to transfer or transport vaccine, CDC’s Packing Vaccines for Transport during Emergencies Job Aid is followed
☐ This facility does not return the following items:
  • Used syringes with or without needles
  • Syringes with vaccine drawn up and not used
  • Broken or damaged vaccine vials
  • Multi-dose vials that have already been withdrawn
☐ Spoiled, expired, or wasted vaccine are reported to VPDIP before placing a new vaccine order
Vaccine Ordering:
NOTE: While supplies are limited, TDH will continue to allocate doses directly to providers. Any orders submitted through VOMS will be rejected. VPDIP will communicate to all vaccinating providers when ordering is permitted.

☐ Orders are submitted in TennIIS and placed according to clinic-based eligibility data, assigned order frequency, vaccine usage, and current inventory in stock.
☐ A physical vaccine inventory is conducted before placing a vaccine order
☐ This facility places orders with sufficient inventory on hand to allow time for order processing delivery
☐ This facility confirms operation hours in TennIIS before submitting each order
☐ This facility reports any changes to the practice's hours to VPDIP to avoid receiving vaccine shipments when the clinic is closed or staff is not available

Receiving and Inspecting Vaccine Shipments:
☐ Staff is familiar with procedures for accepting vaccine shipments in TennIIS
☐ Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, and that the vaccines being delivered match those listed on the packing slip and order confirmation
☐ This facility assumes responsibility for all COVID-19 vaccine that is shipped to its site
☐ This facility never rejects a vaccine shipment
☐ Shipment discrepancies and vaccines exposed to out-of-range temperatures are reported to VPDIP at 800-404-3006 or Temperature.Health@tn.gov immediately
☐ Vaccines are stored immediately and appropriately upon delivery
☐ Vaccines are accepted in the TennIIS inventory upon receipt
# VACCINE STORAGE UNIT INFORMATION

<table>
<thead>
<tr>
<th>Unit Type</th>
<th>Unit Location</th>
<th>Brand</th>
<th>Model Number</th>
<th>Serial Number</th>
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<tbody>
<tr>
<td>Refrigerator (1)</td>
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<td>Refrigerator (2)</td>
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<td>Freezer (4)</td>
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Where are your digital data logger reports and temperature logs located?

If you have a manual defrost freezer, please provide a description of your plan for regular defrosting *:

* A defrost plan is required for providers with a manual defrost freezer. The plan should include 1) where you will transfer vaccines, 2) what equipment will be used to transfer vaccines, and 3) when/how often you will defrost your freezer.

VPDIP must be notified before transporting vaccines, and all temperature excursions that occur during transport must be reported to VPDIP.
### DIGITAL DATA LOGGER AND CALIBRATION INFORMATION

**Primary Data Loggers (must have one for each unit listed in previous section):**

<table>
<thead>
<tr>
<th>DDL Brand, Model # /Serial #</th>
<th>Calibration Date</th>
<th>Calibration Expiration Date</th>
<th>Low Alarm Setting</th>
<th>High Alarm Setting</th>
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**Primary Data Loggers (must have at least one readily available on-site):**

<table>
<thead>
<tr>
<th>Data Logger Model/Serial #</th>
<th>Calibration Date</th>
<th>Calibration Expiration Date</th>
<th>Low Alarm Setting</th>
<th>High Alarm Setting</th>
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Calibration Company: ___________________________ Phone Number: ______________________

Location of Certificates of Calibration: _________________________________________________
## USEFUL EMERGENCY NUMBERS

<table>
<thead>
<tr>
<th>Service</th>
<th>Name</th>
<th>Main Phone Number</th>
<th>Alternate Number</th>
<th>Email Address</th>
<th>Fax Number</th>
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<tbody>
<tr>
<td>Utility Company</td>
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<td>Building Maintenance</td>
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<td>Building Alarm Company</td>
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<tr>
<td>Refrigerator/Freezer Alarm Company</td>
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<tr>
<td>Refrigerator/Freezer Repair Company</td>
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<tr>
<td>Point of Contact for Vaccine Transport</td>
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</table>

<table>
<thead>
<tr>
<th>VPDIP Team</th>
<th>Main Phone Number</th>
<th>Alternate Number</th>
<th>Email Address</th>
<th>Fax Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Excursions</td>
<td>(800) 404-3006</td>
<td>615-741-7247</td>
<td><a href="mailto:Temperature.Health@tn.gov">Temperature.Health@tn.gov</a></td>
<td>(615) 401-6829</td>
</tr>
<tr>
<td>Vaccine Storage and Handling</td>
<td>(800) 404-3006</td>
<td>615-741-7247</td>
<td><a href="mailto:Vaccine.Storage@tn.gov">Vaccine.Storage@tn.gov</a></td>
<td></td>
</tr>
<tr>
<td>VOMS</td>
<td>(800) 404-3006</td>
<td>615-741-7247</td>
<td><a href="mailto:TennIIS.VOMS@tn.gov">TennIIS.VOMS@tn.gov</a></td>
<td></td>
</tr>
<tr>
<td>TennIIS Help Desk</td>
<td>(844) 206-9927</td>
<td></td>
<td><a href="mailto:TennIIS.Help@tn.gov">TennIIS.Help@tn.gov</a></td>
<td></td>
</tr>
</tbody>
</table>

* All times are in Central Time Zone. Unavailable on all [Tennessee State Holidays](#)
The following sections include space for information and necessary actions to take in the event of an emergency, such as unit malfunction, mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

<table>
<thead>
<tr>
<th>Role/Responsibility</th>
<th>Name</th>
<th>Phone Number</th>
<th>Email Address</th>
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</table>

Does the clinic have a generator? If so, where is it located?

If your clinic does not have a generator, and/or your vaccine storage unit fails, it may be necessary to transport vaccine to alternate storage locations.* Please identify two back-up locations:

<table>
<thead>
<tr>
<th>Alternate Vaccine Storage Location</th>
<th>Address and City</th>
<th>Point of Contact Name</th>
<th>POC Contact Information</th>
</tr>
</thead>
<tbody>
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</table>

* Alternate storage locations must have vaccine storage units and continuous temperature monitoring equipment that is in compliance with requirements outlined by VPDIP and the CDC Storage and Handling Toolkit

☐ I have confirmed that the point of contact for the alternate storage locations will accept my vaccines during an emergency situation.

Signature: ___________________________ Date: _______________________

Where is the location of your emergency packing supplies?
If you have a generator and no back-up locations, the generator should be tested quarterly and serviced once a year. In the section below, please record the last date that the generator was tested and serviced and sign and date each time this occurs during the year.

The REVMP does not need to be re-submitted each time the generator is tested or serviced, but it will be reviewed during routine and drop-in site visits:

### Quarterly Tests

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
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<td>Q1</td>
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<td>Q4</td>
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</table>

### Annual Service

Signature: ____________________________ Date: ____________________________
Complete the following information for emergency storage units that will be used by your facility for emergencies that do not require an alternate storage location.*

<table>
<thead>
<tr>
<th>Unit Type</th>
<th>Unit Location</th>
<th>Brand</th>
<th>Model Number</th>
<th>Serial Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator (1)</td>
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</table>

* Alternate storage locations must have vaccine storage units and continuous temperature monitoring equipment that is in compliance with requirements outlined by VPDIP and the CDC Storage and Handling Toolkit

Use the following guidance for safeguarding vaccines in the event of planned or unplanned power interruptions (e.g. power outages, severe weather, building maintenance/repairs, etc.):

**Before an Emergency:**
- Maintain emergency contact information for designated vaccine management personnel
- Place water bottles on the top shelf, in the door, and on the bottom of vaccine refrigerators, where vaccines cannot be stored to stabilize temperatures. Place frozen cold packs in standalone freezers for similar purposes.
- Identify alternate vaccine storage locations (e.g. a local hospital, a local health department, or another COVID-19 provider). Ensure the location has adequate space to accommodate vaccines and that their temperature monitoring equipment meets requirements.
- Update necessary contact information for alternate vaccine storage locations, including facility name, address, contact person, and telephone number.
- Stock emergency supplies as indicated in CDC’s Packing Vaccines for Transport during Emergencies Job Aid
- Label and keep accessible any necessary vaccine packing and transport supplies, copies of vaccine transport job aids, facility floor plans when available, and other related information
- Be familiar with back-up power sources for commercial, laboratory, and pharmacy-grade storage units

**During an Emergency:**
- Assess the situation. Do not open the vaccine storage unit.
- Determine the cause of the power failure and estimate the time it will take to restore power.
- Notify key vaccine management staff listed on the Emergency Plan as appropriate
- If the power outage is expected to be short-term, usually restored within 2 hours:
  - Record the time that the outage started, unit temperatures (current, minimum, and maximum) for each day, and the room temperature
  - Place a “DO NOT OPEN” sign on the storage unit(s) to conserve cold air mass
  - Monitor the temperature until power is restored
- If the outage is expected to be long-term, usually longer than 4 hours, consider moving vaccines to an alternative unit or facility. See details below, under Relocating Vaccine.

*NOTE: Temperatures in vaccine storage units tend to increase faster during power outages. As a result, clinics may need to monitor temperature more frequently and/or transport vaccines to an alternate location sooner.*
Relocating Vaccine:
If a power outage is expected to be long-term (e.g. not restored by the end of the day) or storage units are not working properly, prepare to relocate vaccines to alternate storage locations. If moving vaccines, a DDL must remain with the vaccine at all times.

Before transporting vaccines:
☐ Review CDC’s Packing Vaccines for Transport during Emergencies Job Aid
☐ Contact the alternate storage facility to verify that they can accept the vaccines
☐ If transport or relocation is not feasible (e.g. alternate location is not available or travel conditions are unsafe):
  ☐ Keep units closed and document the current, minimum, and maximum temperatures for each day
☐ Notify the VPDIP Team at 800-404-3006 or Temperature.Health@tn.gov

Packaging and transporting vaccines:
☐ Complete the Refrigerated Vaccine Transport Log and/or the Freezer Vaccine Transport Log
☐ Attach DDL to cooler
☐ Prepare cooler(s) for transport following CDC’s Packing Vaccines for Transport during Emergencies Job Aid
  ☐ Use frozen cold packs for frozen vaccines. Never use dry ice.
  ☐ Use conditioned (slightly defrosted) frozen packs for refrigerated vaccines. Placing refrigerated vaccine directly on frozen packs and packaging it without sufficient insulation may freeze and therefore, damage vaccine. If clinic does not have time to condition frozen packs, refrigerated cold packs or cold water bottles may be used.
☐ Package and prepare diluent
  ☐ Diluents stored in the refrigerator should be transported with refrigerated vaccines
  ☐ Diluents stored at room temperature should be transported at room temperature
  ☐ Diluents packaged with their vaccine should be transported with their vaccine
☐ Upon arrival at the alternate vaccine storage location, document total vaccine transport time, the current, minimum, and maximum temperatures in the transport cooler(s), and the current, minimum, and maximum temperatures in the alternate storage unit(s).

After Power is Restored:
☐ Verify storage units are functioning properly and temperatures are within range before attempting to move any vaccine
☐ Follow the same transportation procedures and transfer vaccine back to its original storage unit
☐ Vaccine kept at the proper temperature during the power outage, whether transported or not, may be used
☐ For any vaccine not stored at proper temperature:
  ☐ Segregate it in the storage unit
  ☐ Mark it “Do Not Use Until Further Notice”
  ☐ Contact the VPDIP Team at 800-404-3006 to report the excursion
☐ Never return vaccine to the vaccine distributor without authorization from VPDIP
Acknowledgement and Signature Log

Please sign and date this acknowledgement and signature log when you update practice-specific information.

By signing this log, facility staff are acknowledging that they have reviewed, understand, and agree to the key duties assigned to them as vaccine management personnel for this facility.

Updates and comments to changes made in Routine and Emergency Vaccine Management Plans:

**CMO:**
Name: __________________________________________________________________________________________________________________________
Signature: _______________________________________________________________________  Date: ______________________________________

**PRIMARY Vaccine COORDINATOR:**
Name: __________________________________________________________________________________________________________________________
Signature: _______________________________________________________________________  Date: ______________________________________

**BACK-UP Vaccine COORDINATOR:**
Name: __________________________________________________________________________________________________________________________
Signature: _______________________________________________________________________  Date: ______________________________________

**CEO/CFO:**
Name: __________________________________________________________________________________________________________________________
Signature: _______________________________________________________________________  Date: ______________________________________

**Pharmacist (if applicable):**
Name: __________________________________________________________________________________________________________________________
Signature: _______________________________________________________________________  Date: ______________________________________

Name: ___________________________________________________________________________  Date: ________________________________
Signature: _______________________________________________________________________  Date: ______________________________________
**COVID-19 Vaccine**  
Refrigerated Vaccine Transport Log

**Instructions:** Complete this log when transporting vaccines to an alternate or back-up refrigerator.

**Date:** ________________________________

**Provider Name:** ___________________________  COVID/VFC PIN: ___________________________

**Transferred To:** ___________________________  COVID/VFC PIN: ___________________________

**Vaccines Transferred Due To:**  
- ☐ Power Outage  
- ☐ Excess Supply  
- ☐ Short Dated  
- ☐ Unit Malfunction  
- ☐ Building Maintenance  
- ☐ Other: ___________________________

---

**Vaccine Inventory Information – may also attach most recent reconciliation report from TennIIS.**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Lot Number</th>
<th>Number of Doses</th>
<th>Expiration Date</th>
<th>Vaccine Previously Transported? (Yes/No)</th>
<th>Comments</th>
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**Temperature Monitoring Information**

- Temperature of vaccine in refrigerator prior to transfer: ___________________________  
  Celsius/Fahrenheit: ___________________________  
  Time: ___________________________

- Temperature of vaccine in cooler before departure: ___________________________  
  Celsius/Fahrenheit: ___________________________  
  Time: ___________________________

- Temperature of vaccine in cooler upon arrival: ___________________________  
  Celsius/Fahrenheit: ___________________________  
  Time: ___________________________

- Temperature of back-up refrigerator: ___________________________  
  Celsius/Fahrenheit: ___________________________  
  Time: ___________________________

Contact the VFC Program (800-404-3006) if temperatures during transport exceed recommended ranges.

**Total Transport Time:** ___________________________ Min/Hr
Moderna COVID-19 Vaccine

Vaccine Administration
Moderna COVID-19 Vaccine
Vaccine Preparation and Administration Summary

» General Information
Vaccine: Moderna COVID-19 Vaccine
Two multidose vial presentations:
- Maximum of 11 doses per vial
- Maximum of 15 doses per vial
Dosage: 0.5 mL
Do NOT mix with a diluent.

» Age Indications
18 years of age and older

» Schedule
2-dose series separated by 1 month (28 days). A series started with Moderna COVID-19 Vaccine should be completed with this product.

» Administration
Intramuscular (IM) injection in the deltoid muscle

» Thawing Frozen Vaccine
- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature:
  - Refrigerator: Between 2°C and 8°C (36°F and 46°F). Unpunctured vials may be stored in the refrigerator for up to 30 days.
  - Room temperature: Between 8°C and 25°C (46°F and 77°F). Unpunctured vials may be held at room temperature for up to 24 hours.
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
  - In the refrigerator: Up to 3 hours
  - Room temperature: Up to 1 hour and 30 minutes
- Do NOT refreeze thawed vaccine.
- Use vials in the refrigerator before removing vials from the freezer.
- Use CDC’s beyond-use date labels for this vaccine to track storage time at refrigerated temperatures.

» Expiration Date
To determine the expiration date, scan the QR code located on the vial or carton. The QR code will bring up a website; then choose the lookup option, enter the lot number, and the expiration date will be displayed. Another option is to access the website directly: http://www.modernatx.com/covid19vaccine-eua. CDC’s expiration date tracking tool (https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf) can facilitate documenting expiration dates.

» Prepare and Administer the Vaccine

Assess recipient status:
- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*

Vaccine must be thawed before using. If removing the vial from the refrigerator, let it stand at room temperature for 15 minutes.

Unpunctured vials: Check the expiration date. Never use expired vaccine.
Punctured vials: Check the beyond-use time. Never use vaccine after the beyond-use time.

With the vial upright, gently swirl the vaccine. Do NOT shake. If the vial is shaken, contact the manufacturer.
Note: Gently swirl the vaccine before withdrawing subsequent doses.

Examine the vaccine. It should be white to off-white in color and may contain white or translucent particles. Do not use if liquid contains other particulate matter or is discolored.

Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.

Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.

*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.
Prepare and Administer the Vaccine (continued)

Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.

Withdraw 0.5 mL of vaccine into the syringe. Ensure the prepared syringe is not cold to the touch.

- Discard vial when there is not enough vaccine to obtain a complete dose.
- Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.5 mL.

Once you can no longer withdraw a complete dose from a vaccine vial, dispose of the vial (with any remaining vaccine) as medical waste according to your local and state regulations. Contact your jurisdiction’s immunization program (https://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html) for guidance.

Note the date and time the vial was first punctured. Keep the vaccine between 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard any unused vaccine after 12 hours.

Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.

Ensure staff has the correct PPE before administering vaccine and implement policies for the use of face coverings for vaccine recipients (if tolerated).

Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.

Observe recipients after vaccination for an immediate adverse reaction:

- 30 minutes: Persons with a:
  - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
  - Contraindication to Janssen COVID-19 Vaccine who receive Moderna COVID-19 Vaccine
  - History of anaphylaxis due to any cause

- 15 minutes: All other persons

*It is not necessary to change needles between drawing vaccine from a vial and injecting it into a recipient unless the needle has been damaged or contaminated.

Scheduling Doses

<table>
<thead>
<tr>
<th>Vaccination History†§</th>
<th>And</th>
<th>Then</th>
<th>Next Dose Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 doses</td>
<td></td>
<td>Give dose 1 today</td>
<td>Give dose 2 at least 28 days after dose 1 ‡</td>
</tr>
<tr>
<td>1 dose (Moderna COVID-19 Vaccine)</td>
<td></td>
<td>Give dose 2 today</td>
<td>Series complete; no additional doses needed</td>
</tr>
<tr>
<td></td>
<td>It has been at least 28 days since dose 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>It has not been at least 28 days since dose 1</td>
<td>No dose today</td>
<td>Give dose 2 at least 28 days after dose 1 ‡</td>
</tr>
<tr>
<td>2 doses (Moderna COVID-19 Vaccine) at least 28 days apart‡</td>
<td></td>
<td>Series complete; no additional doses needed</td>
<td></td>
</tr>
<tr>
<td>2 doses (1 product unknown) at least 28 days apart§</td>
<td></td>
<td>Series complete; no additional doses needed</td>
<td></td>
</tr>
</tbody>
</table>

†COVID-19 vaccines and other vaccines may be administered at the same visit, as well as within 14 days of each other. When deciding whether to administer COVID-19 vaccines and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient’s risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

§Every effort should be made to determine which vaccine product was received as the first dose. In exceptional situations in which the vaccine given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at least 28 days after the first dose.

‡Administer the second dose as close to the recommended interval (28 days) as possible. If the second dose is not administered within 42 days of the first dose, the series does not need to be restarted. Doses inadvertently administered less than 28 days apart do not need to be repeated.
Contraindications and Precautions

Contraindications:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see Table 1 for a list of ingredients in COVID-19 vaccine products)

Note: Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).

Precautions:

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of an immediate allergic reaction* to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
  - This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
- People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote).
- Moderate to severe acute illness

For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at [www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](http://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html).

Management of Anaphylaxis

Be prepared to manage medical emergencies.

- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.


Document the Vaccination

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (i.e., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.

Document each recipient’s vaccine administration information in the:

- Medical record
  - Vaccine and the date it was administered
  - Manufacturer and lot number
  - Vaccination site and route
  - Name and title of the person administering the vaccine

- Personal vaccination record card (shot card):
  - Date of vaccination
  - Product name/manufacturer
  - Lot number
  - Name/location of the administering clinic or healthcare professional
  - Give to the vaccine recipient.

- Immunization information system (IIS) or “registry”:
  - Report the vaccination to the appropriate state/local IIS.

*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

†Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project [https://www.cdc.gov/vaccinesafety/ensuring-safety/monitoring/cisa/index.html](https://www.cdc.gov/vaccinesafety/ensuring-safety/monitoring/cisa/index.html). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.
Reporting Adverse Events
Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults or children
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety reporting requirements per the Food and Drug Administration’s conditions for use of an authorized vaccine throughout the duration of the EUA

Adverse events should be reported even if the cause is uncertain. Healthcare professionals are also encouraged to report any clinically significant AEs that occur after vaccine administration. Submit reports to [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

For additional information, see the vaccine manufacturer’s product information at [www.modernatx.com/covid19vaccine-eua/](http://www.modernatx.com/covid19vaccine-eua/).

For additional information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors, see [www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A](http://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A).

Table 1: Ingredients included in COVID-19 vaccines
The following is a list of ingredients for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines reported in the prescribing information for each vaccine.

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech (mRNA)</th>
<th>Moderna (mRNA)</th>
<th>Janssen (viral vector)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active ingredient</strong></td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein</td>
</tr>
<tr>
<td><strong>Inactive ingredients</strong></td>
<td>2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide</td>
<td>PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol</td>
<td>Polysorbate-80</td>
</tr>
<tr>
<td></td>
<td>1,2-distearyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearyl-sn-glycero-3-phosphocholine</td>
<td>2-hydroxypropyl-β-cyclodextrin</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
<td>Cholesterol</td>
<td>Citric acid monohydrate</td>
</tr>
<tr>
<td></td>
<td>(4-hydroxybutyl)lazanediyli(bis(hexane-6,1-diyli)bis(2-hexyldecanoate)</td>
<td>SM-102: heptadecane-9-yl 8-[(2-hydroxyethyl)(6-oxo-6-(undecyloxy) hexyl) amino) octanoate</td>
<td>Trisodium citrate dihydrate</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>Tromethamine</td>
<td>Sodium chloride</td>
</tr>
<tr>
<td></td>
<td>Monobasic potassium phosphate</td>
<td>Tromethamine hydrochloride</td>
<td>Ethanol</td>
</tr>
<tr>
<td></td>
<td>Potassium chloride</td>
<td>Acetic acid</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>Sucrose</td>
<td></td>
</tr>
</tbody>
</table>

None of the vaccines contain eggs, gelatin, latex, or preservatives

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called “pegylation” to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients of vaccines and medications can be found in the package insert, [CDC’s vaccine excipient summary](https://www.cdc.gov/vaccines) and the National Institutes of Health [DailyMed database](https://www.dailymed.nlm.nih.gov) can also be used as resources.
Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose
To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure
Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

- Has not completed a COVID-19 vaccination series, regardless of brand. If 2 doses of an mRNA vaccine have been administered or a single dose of Janssen vaccine has been administered, no additional doses are recommended.
- If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at an interval of least 28 days (but preferably before 42 days).
- If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.

For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines

Moderna COVID-19 vaccine may be coadministered with other vaccines - on the same day, as well as within 14 days of each other.

Defer vaccination with Moderna COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.

Screen for contraindications and precautions.

Contraindications:
- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see Table 1 in this document for a list of vaccine components)

Note: Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote). Prior to administration of Janssen COVID-19 Vaccine, inform women 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group. Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.

Precautions:
- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- History of an immediate allergic reaction of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
  - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polyethylene glycol (PEG) or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
  - People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote).

Moderate to severe acute illness

*Administer the second dose as close as possible to the recommended interval (28 days). If the second dose is not administered within 42 days of the first dose, the series does not need to be restarted. Doses inadvertently administered less than 28 days apart do not need to be repeated.

When deciding whether to coadminister COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient’s risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

Consider consultation with an allergist-immunologist to help determine if a patient with a contraindication to an mRNA vaccine can safely receive the Janssen COVID-19 vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

Educational materials are available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/Update.html
Provisional COVID-19 Vaccine
Standing Orders for Administering Vaccine

to Persons 18 Years of Age and Older

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 18 years of age:
    - Site: Deltoid muscle of arm.
  - 19 years of age and older: See chart above.
- Follow the manufacturer’s guidance for storing/handling punctured vaccine vials.
- Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer’s website at https://www.modernatx.com/
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - 30 minutes: Persons with a:
      - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
      - Contraindication to Janssen COVID-19 Vaccine who receive Moderna COVID-19 Vaccine
      - History of anaphylaxis due to any cause
    - 15 minutes: All other persons
  - Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
  - Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.
  - For more information, please see:
    - CDC’s General Best Practice Guidelines for Immunization, “Preventing and Managing Adverse Reactions,” at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html
    - Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Adults in a Community Setting” at https://www.immunize.org/catg.d/p3082.pdf

<table>
<thead>
<tr>
<th>Sex and Weight of Patient</th>
<th>Needle Gauge</th>
<th>Needle Length</th>
<th>Injection Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female or male fewer than 130 lbs</td>
<td>22–25</td>
<td>½₈–1&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female or male 130–152 lbs</td>
<td>22–25</td>
<td>1&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 152–200 lbs</td>
<td>22–25</td>
<td>1–1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 152–260 lbs</td>
<td>22–25</td>
<td>1–1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 200+ lbs</td>
<td>22–25</td>
<td>1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 260+ lbs</td>
<td>22–25</td>
<td>1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
</tbody>
</table>

1 Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.
2 Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).
Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    » Vaccine administration errors (whether associated with an adverse event [AE] or not)
    » Serious AEs (irrespective of attribution to vaccination)
    » Multisystem inflammatory syndrome (MIS) in adults or children
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS:
  » Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

» Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the __________________________ effective ____________ until rescinded or until ____________.

Medical director (or other authorized practitioner)
________________________________________/______________________________________.

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders

» Table 1: Ingredients included in COVID-19 vaccines
The following is a list of ingredients for the Pfizer-BioNTech, Moderna, and Johnson & Johnson COVID-19 vaccines reported in the prescribing information for each vaccine.

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<tr>
<th>Description</th>
<th>Pfizer-BioNTech (mRNA)</th>
<th>Moderna (mRNA)</th>
<th>Janssen (viral vector)</th>
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</thead>
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<tr>
<td>Active ingredient</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein</td>
</tr>
<tr>
<td>Inactive ingredients</td>
<td>2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide</td>
<td>PEG2000-DMG: 1, N-dimyristoyl-rac-glycerol, methoxy polyethylene glycol</td>
<td>Polysorbate-80</td>
</tr>
<tr>
<td></td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>2-hydroxypropyl-β-cyclodextrin</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
<td>Cholesterol</td>
<td>Citric acid monohydrate</td>
</tr>
<tr>
<td></td>
<td>(4-hydroxybutyl)azanediylibis(hexane-6,1-diylibis(2-hexyldecanoate)</td>
<td>SM-102: heptadecane-9-yl 8-(2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino octanoate</td>
<td>Trisodium citrate dihydrate</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>Tromethamine</td>
<td>Sodium chloride</td>
</tr>
<tr>
<td></td>
<td>Monobasic potassium phosphate</td>
<td>Tromethamine hydrochloride</td>
<td>Ethanol</td>
</tr>
<tr>
<td></td>
<td>Potassium chloride</td>
<td>Acetic acid</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* None of the vaccines contain eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients for vaccines and medications can be found in the package insert, CDC’s vaccine excipient summary and the National Institutes of Health DailyMed database can also be used as resources.
FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA)
OF THE MODERNA COVID-19 VACCINE TO PREVENT
CORONAVIRUS DISEASE 2019 (COVID-19)
IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or
vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “What is an Emergency Use Authorization (EUA)?” section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?
Tell your vaccination provider about all of your medical conditions, including if you:

• have any allergies
• have a fever
• have a bleeding disorder or are on a blood thinner
• are immunocompromised or are on a medicine that affects your immune system
• are pregnant or plan to become pregnant
• are breastfeeding
• have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?
FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?
You should not get the Moderna COVID-19 Vaccine if you:

• had a severe allergic reaction after a previous dose of this vaccine
• had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.
**HOW IS THE MODERNA COVID-19 VACCINE GIVEN?**
The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second
dose of the same vaccine 1 month later to complete the vaccination series.

**HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?**
The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately
15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna
COVID-19 Vaccine.

**WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?**
In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent
COVID-19 following 2 doses given 1 month apart. The duration of protection against
COVID-19 is currently unknown.

**WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?**
There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe
allergic reaction. A severe allergic reaction would usually occur within a few minutes to
one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your
vaccination provider may ask you to stay at the place where you received your vaccine for
monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported in a clinical trial with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the
  same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and
  vomiting, and fever

  - Side effects that have been reported during post-authorization use of the Moderna
COVID-19 Vaccine include:

- Severe allergic reactions

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

**WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to [https://vaers.hhs.gov/reportevent.html](https://vaers.hhs.gov/reportevent.html). Please include “Moderna COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-6633762).

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

**WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?**

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

**ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?**

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.
CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

<table>
<thead>
<tr>
<th>Moderna COVID-19 Vaccine website</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="www.modernatx.com/covid19vaccine-eua">QR Code</a></td>
<td>1-866-MODERNA (1-866-663-3762)</td>
</tr>
</tbody>
</table>

HOW CAN I LEARN MORE?
- Ask the vaccination provider
WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction’s Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which
includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Moderna US, Inc.
Cambridge, MA 02139

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Patent(s): www.modernatx.com/patents Revised: Mar/26/2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.
Barcode Date: 04/2021
FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, MODERNA COVID-19 VACCINE, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS
Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccineeua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION
**Storage and Handling**
The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light.

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.

Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50ºC (-58ºF).

Vials may be stored refrigerated between 2º to 8ºC (36º to 46ºF) for up to 30 days prior to first use.

Vials may be stored between 8º to 25ºC (46º to 77ºF) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2º to 25ºC (36º to 77ºF). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

**Transportation of Thawed Vials at 2º to 8ºC (36º to 46ºF)**

If transport at -50º to -15ºC (-58º to 5ºF) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2º to 8ºC (36º to 46ºF) when shipped using shipping containers which have been qualified to maintain 2º to 8ºC (36º to 46ºF) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2º to 8ºC (36º to 46ºF), vials should not be refrozen and should be stored at 2º to 8ºC (36º to 46ºF) until use.

**Dosing and Schedule**
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID19 Vaccine to complete the vaccination series.
**Dose Preparation**

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

<table>
<thead>
<tr>
<th>Vial</th>
<th>Thaw in Refrigerator</th>
<th>Thaw at Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum 11-Dose Vial (range: 10-11 doses)</strong></td>
<td>Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.</td>
</tr>
<tr>
<td><strong>Maximum 15-Dose Vial (range: 13-15 doses)</strong></td>
<td>Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.</td>
</tr>
</tbody>
</table>

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
  - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
  - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
  - Each dose must contain 0.5 mL of vaccine.
  - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
  - Pierce the stopper at a different site each time.
• After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

**Administration**
Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent productrelated particulates. During the visual inspection,

• verify the final dosing volume of 0.5 mL.
• confirm there are no other particulates and that no discoloration is observed.
• do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

**CONTRAINdICATION**
Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine (see Full EUA Prescribing Information).

**WARNINGS**
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.


Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

**ADVERSE REACTIONS**
Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. (See Full EUA Prescribing Information)

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.
Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

**USE WITH OTHER VACCINES**
There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

**INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS**
As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua) to obtain the Fact Sheet) prior to the individual receiving each dose of the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

Provide the [v-safe](http://www.cdc.gov/vsafe) information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in [v-safe](http://www.cdc.gov/vsafe). [V-safe](http://www.cdc.gov/vsafe) is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. [V-safe](http://www.cdc.gov/vsafe) asks questions that help CDC monitor the safety of COVID-19 vaccines. [V-safe](http://www.cdc.gov/vsafe) also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID19 vaccination. For more information, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

**MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION**
In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):
1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
   - vaccine administration errors whether or not associated with an adverse event,
   - serious adverse events* (irrespective of attribution to vaccination),
   - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
   - cases of COVID-19 that result in hospitalization or death.

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html.
   For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words “Moderna COVID-19 Vaccine EUA” in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

   *Serious adverse events are defined as:
   - Death;
   - A life-threatening adverse event;
   - Inpatient hospitalization or prolongation of existing hospitalization;
   - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
   - A congenital anomaly/birth defect;
   - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

**OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.**
Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Revised: Mar/31/2021
### ADDITIONAL INFORMATION
For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

<table>
<thead>
<tr>
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<td><a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a></td>
<td>1-866-MODERNA (1-866-663-3762)</td>
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### AVAILABLE ALTERNATIVES
There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

### FEDERAL COVID-19 VACCINATION PROGRAM
This vaccine is being made available for emergency use exclusively through the CDC COVID19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

Revised: Mar/31/2021
AUTHORITY FOR ISSUANCE OF THE EUA
The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the Full EUA Prescribing Information.

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.


COUNTERMEASURES INJURY COMPENSATION PROGRAM
The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Moderna US, Inc.
Cambridge, MA 02139

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Patent(s): www.modernatx.com/patents
Revised: Mar/31/2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page
FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.
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<td>Maximum 11-Dose Vial</td>
<td>Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.</td>
</tr>
<tr>
<td>(range: 10-11 doses)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum 15-Dose Vial</td>
<td>Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.</td>
</tr>
<tr>
<td>(range: 13-15 doses)</td>
<td></td>
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- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
  - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
  - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
  - Each dose must contain 0.5 mL of vaccine.
  - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
  - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.
2.2 Administration
Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,
• verify the final dosing volume of 0.5 mL.
• confirm there are no other particulates and that no discoloration is observed.
• do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS
Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS
Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine [see Description (13)].

5 WARNINGS AND PRECAUTIONS
5.1 Management of Acute Allergic Reactions
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

5.2 Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.3 Limitations of Vaccine Effectiveness
The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the

REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID-19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male.
47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were other races, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

**Solicited Adverse Reactions**

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected in an electronic diary for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose are presented in Table 1 and Table 2, respectively.

**Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)**

<table>
<thead>
<tr>
<th></th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1 (N=11,406) n (%)</td>
<td>Dose 2 (N=10,985) n (%)</td>
</tr>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>9,908 (86.9)</td>
<td>9,873 (89.9)</td>
</tr>
<tr>
<td>Pain, Grade 3b</td>
<td>366 (3.2)</td>
<td>506 (4.6)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>1,322 (11.6)</td>
<td>1,775 (16.2)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness, Grade 3b</td>
<td>37 (0.3)</td>
<td>46 (0.4)</td>
</tr>
<tr>
<td>Swelling (hardness) ≥25 mm</td>
<td>767 (6.7)</td>
<td>1,389 (12.6)</td>
</tr>
<tr>
<td>Adverse Reaction</td>
<td>Moderna COVID-19 Vaccine</td>
<td>Placeboa</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>--------------------------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>Dose 1 (N=11,406) n (%)</td>
<td>Dose 2 (N=10,985) n (%)</td>
</tr>
<tr>
<td>Swelling (hardness), Grade 3c</td>
<td>62 (0.5)</td>
<td>182 (1.7)</td>
</tr>
<tr>
<td>Erythema (redness) ≥25 mm</td>
<td>344 (3.0)</td>
<td>982 (8.9)</td>
</tr>
<tr>
<td>Erythema (redness), Grade 3c</td>
<td>34 (0.3)</td>
<td>210 (1.9)</td>
</tr>
<tr>
<td><strong>Systemic Adverse Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>4,384 (38.4)</td>
<td>7,430 (67.6)</td>
</tr>
<tr>
<td>Fatigue, Grade 3d</td>
<td>120 (1.1)</td>
<td>1,174 (10.7)</td>
</tr>
<tr>
<td>Fatigue, Grade 4e</td>
<td>1 (&lt;0.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Headache</td>
<td>4,030 (35.3)</td>
<td>6,898 (62.8)</td>
</tr>
<tr>
<td>Headache, Grade 3f</td>
<td>219 (1.9)</td>
<td>553 (5.0)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>2,699 (23.7)</td>
<td>6,769 (61.6)</td>
</tr>
<tr>
<td>Myalgia, Grade 3d</td>
<td>73 (0.6)</td>
<td>1,113 (10.1)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>1,893 (16.6)</td>
<td>4,993 (45.5)</td>
</tr>
<tr>
<td>Arthralgia, Grade 3d</td>
<td>47 (0.4)</td>
<td>647 (5.9)</td>
</tr>
<tr>
<td>Arthralgia, Grade 4e</td>
<td>1 (&lt;0.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Chills</td>
<td>1,051 (9.2)</td>
<td>5,341 (48.6)</td>
</tr>
<tr>
<td>Chills, Grade 3g</td>
<td>17 (0.1)</td>
<td>164 (1.5)</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>1,068 (9.4)</td>
<td>2,348 (21.4)</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th></th>
<th>Moderna COVID-19 Vaccine</th>
<th></th>
<th>Placebo(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1 ((N=11,406))</td>
<td>Dose 2 ((N=10,985))</td>
<td>Dose 1 ((N=11,407))</td>
</tr>
<tr>
<td>Nausea/vomiting, Grade 3(^h)</td>
<td>6 (0.1)</td>
<td>10 (0.1)</td>
<td>8 (0.1)</td>
</tr>
<tr>
<td>Fever</td>
<td>105 (0.9)</td>
<td>1,908 (17.4)</td>
<td>37 (0.3)</td>
</tr>
<tr>
<td>Fever, Grade 3(^i)</td>
<td>10 (0.1)</td>
<td>184 (1.7)</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Fever, Grade 4(^j)</td>
<td>4 (0.1)</td>
<td>12 (0.1)</td>
<td>4 (0.1)</td>
</tr>
<tr>
<td>Use of antipyretic or pain medication</td>
<td>2,656 (23.3)</td>
<td>6,292 (57.3)</td>
<td>1,523 (13.4)</td>
</tr>
</tbody>
</table>

\(^a\) Placebo was a saline solution.

\(^h\) Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

\(^i\) Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

\(^j\) Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

\(^*\) 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).
Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

<table>
<thead>
<tr>
<th></th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1 (N=3,762) n (%)</td>
<td>Dose 2 (N=3,692) n (%)</td>
</tr>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>2,782 (74.0)</td>
<td>3,070 (83.2)</td>
</tr>
<tr>
<td>Pain, Grade 3(^b)</td>
<td>50 (1.3)</td>
<td>98 (2.7)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>231 (6.1)</td>
<td>315 (8.5)</td>
</tr>
<tr>
<td>Axillary swelling/(\text{tenderness, Grade 3}^{b})</td>
<td>12 (0.3)</td>
<td>21 (0.6)</td>
</tr>
<tr>
<td>Swelling (hardness) ≥25 mm</td>
<td>165 (4.4)</td>
<td>400 (10.8)</td>
</tr>
<tr>
<td>Swelling (hardness), Grade 3(^c)</td>
<td>20 (0.5)</td>
<td>72 (2.0)</td>
</tr>
<tr>
<td>Erythema (redness) ≥25 mm</td>
<td>86 (2.3)</td>
<td>275 (7.5)</td>
</tr>
<tr>
<td>Erythema (redness), Grade 3(^c)</td>
<td>8 (0.2)</td>
<td>77 (2.1)</td>
</tr>
<tr>
<td><strong>Systemic Adverse Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>1,251 (33.3)</td>
<td>2,152 (58.3)</td>
</tr>
<tr>
<td>Fatigue, Grade 3(^d)</td>
<td>30 (0.8)</td>
<td>254 (6.9)</td>
</tr>
<tr>
<td>Headache</td>
<td>921 (24.5)</td>
<td>1,704 (46.2)</td>
</tr>
<tr>
<td>Headache, Grade 3(^e)</td>
<td>52 (1.4)</td>
<td>106 (2.9)</td>
</tr>
</tbody>
</table>

Revised: Mar/31/2021
<table>
<thead>
<tr>
<th></th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1 (N=3,762)</td>
<td>Dose 2 (N=3,692)</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>742 (19.7)</td>
<td>1,739 (47.1)</td>
</tr>
<tr>
<td>Myalgia, Grade 3&lt;sup&gt;d&lt;/sup&gt;</td>
<td>17 (0.5)</td>
<td>205 (5.6)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>618 (16.4)</td>
<td>1,291 (35.0)</td>
</tr>
<tr>
<td>Arthralgia, Grade 3&lt;sup&gt;d&lt;/sup&gt;</td>
<td>13 (0.3)</td>
<td>123 (3.3)</td>
</tr>
<tr>
<td>Chills</td>
<td>202 (5.4)</td>
<td>1,141 (30.9)</td>
</tr>
<tr>
<td>Chills, Grade 3&lt;sup&gt;f&lt;/sup&gt;</td>
<td>7 (0.2)</td>
<td>27 (0.7)</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>194 (5.2)</td>
<td>437 (11.8)</td>
</tr>
<tr>
<td>Nausea/vomiting, Grade 3&lt;sup&gt;g&lt;/sup&gt;</td>
<td>4 (0.1)</td>
<td>10 (0.3)</td>
</tr>
<tr>
<td>Nausea/vomiting, Grade 4&lt;sup&gt;h&lt;/sup&gt;</td>
<td>0 (0)</td>
<td>1 (&lt;0.1)</td>
</tr>
<tr>
<td>Fever</td>
<td>10 (0.3)</td>
<td>370 (10.0)</td>
</tr>
<tr>
<td>Fever, Grade 3&lt;sup&gt;i&lt;/sup&gt;</td>
<td>1 (&lt;0.1)</td>
<td>18 (0.5)</td>
</tr>
<tr>
<td>Fever, Grade 4&lt;sup&gt;l&lt;/sup&gt;</td>
<td>0 (0)</td>
<td>1 (&lt;0.1)</td>
</tr>
<tr>
<td>Use of antipyretic or pain medication</td>
<td>673 (17.9)</td>
<td>1,546 (41.9)</td>
</tr>
</tbody>
</table>

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary). <sup>a</sup> Placebo was a saline solution.

<sup>b</sup> Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.  
<sup>c</sup> Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.  
<sup>d</sup> Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.  
<sup>e</sup> Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.  
<sup>f</sup> Grade 3 chills: Defined as prevents daily activity and requires medical intervention.  
<sup>g</sup> Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.  
<sup>h</sup> Grade 4 Fever: Defined as a high fever (>100°F) requiring medical intervention.  
<sup>i</sup> Grade 4 Nausea/vomiting: Defined as a severe reaction requiring medical intervention.  
<sup>j</sup> Grade 4 Arthralgia: Defined as a severe reaction requiring medical intervention.
Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.  
Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.  
Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 1 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than after Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

**Unsolicited Adverse Events**

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and 0.4% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy is insufficient to determine a causal relationship with the vaccine.
There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

**Serious Adverse Events**

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell’s palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

**8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS**

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of multisystem inflammatory syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;

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• A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
• A congenital anomaly/birth defect;
• An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

• Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
• If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll- free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

• Patient demographics (e.g., patient name, date of birth)
• Pertinent medical history
• Pertinent details regarding admission and course of illness
• Concomitant medications
• Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
• Pertinent laboratory and virology information
• Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
   a. Write “Moderna COVID-19 Vaccine EUA” as the first line
   b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:

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a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

<table>
<thead>
<tr>
<th>Email</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:ModernaPV@modernatx.com">ModernaPV@modernatx.com</a></td>
<td>1-866-599-1342</td>
<td>1-866-MODERNA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1-866-663-3762)</td>
</tr>
</tbody>
</table>

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866- MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically
recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age [see Clinical Trial Results and Supporting Data for EUA (18)]. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants [see Overall Safety Summary (6.1)].

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleosidemodified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18
mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

A Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older is ongoing in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set) included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were White, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per-Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at
least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

**Efficacy Against COVID-19**

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38°C), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

**Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set**

<table>
<thead>
<tr>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants (N)</strong></td>
<td><strong>COVID-19 Cases (n)</strong></td>
</tr>
<tr>
<td>14,134</td>
<td>11</td>
</tr>
</tbody>
</table>

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

The subgroup analyses of vaccine efficacy are presented in Table 4.
Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

<table>
<thead>
<tr>
<th>Age Subgroup (Years)</th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo</th>
<th>% Vaccine Efficacy (95% CI)†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Participants (N)</td>
<td>COVID-19 Cases (n)</td>
<td>Incidence Rate of COVID-19 per 1,000 Person Years</td>
</tr>
<tr>
<td>18 to &lt;65</td>
<td>10,551</td>
<td>7</td>
<td>2.875</td>
</tr>
<tr>
<td>≥65</td>
<td>3,583</td>
<td>4</td>
<td>4.595</td>
</tr>
</tbody>
</table>

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection Multiple-Dose Vials are supplied as follows:

NDC 80777-273-99 Carton of 10 multiple-dose vials, each vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL)
During storage, minimize exposure to room light.

Store frozen between -50° to -15°C (-58° to 5°F). Store in the original carton to protect from light.

Do not store on dry ice or below -50°C (-58°F). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

**Transportation of Thawed Vials at 2°C to 8°C (36°F to 46°F)**

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (36° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (36° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (36° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (36° to 46°F) until use.

**20 PATIENT COUNSELING INFORMATION**

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: [https://www.cdc.gov/vaccines/programs/iis/about.html](https://www.cdc.gov/vaccines/programs/iis/about.html).

**21 CONTACT INFORMATION**

Revised: Mar/31/2021
For general questions, send an email or call the telephone number provided below.

<table>
<thead>
<tr>
<th>Email</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:medinfo@modernatx.com">medinfo@modernatx.com</a></td>
<td>1-866-MODERNA</td>
</tr>
<tr>
<td></td>
<td>(1-866-663-3762)</td>
</tr>
</tbody>
</table>

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

Moderna US, Inc.
Cambridge, MA 02139

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Patent(s): [www.modernatx.com/patents](http://www.modernatx.com/patents)
Revised: Mar/31/2021
Moderna COVID-19 Vaccine

Vaccine Management
## Vaccine Ordering Management System (VOMS) Receiving

### 1) Select Create/View Orders
To receive an order, go back to the Main page. After clicking on the main page, you will see an "Orders/Transfers" tab. Click the tab. Once the tab expands, click Create/View Orders.

### 2) View Current Order/Transfer List
After selecting the Create/View Orders tab, a Current Order/Transfer List page will appear.

### 3) Arrow in select column
In the "Select" column under Inbound Orders, press the arrow next to the order number for the order that you want to view.

### 4) Verify/Receive Shipment
To receive the shipment, for each vaccine, you need to:
- Insert the quantity in the "Receipt Quantity"
- If needed, insert quantities in the "Rejected Quantity"
- If you need to reject a quantity, choose a "Reason for Rejecting" from the dropdown
- Upon reviewing the order details for accuracy, press "Receive" to confirm your order.

*After inserting receipt quantity, rejecting quantity (if applicable), and picking a reason for rejecting, be sure to check the Vaccine, Manufacturer, Lot number and Expiration Date before receiving the order.*
1) Select Organization and Facility
Upon logging into VOMS, you will press "Select Organization" from the "Main" drop down, pressing submit. Afterwards, go to "Select facility" and press continue.

2) Locate "Reconciliation" Tab
Under "Lot Numbers," you will see "Reconciliation." Press this to continue.

3) Reconciliation Page
After clicking "Reconciliation," this page should appear. Within this page, you are able to view the vaccines available within your facility. This includes their lot numbers, expiration, and quantity. After printing the reconciliation page, count and record your physical inventory of vaccine. Record the number underneath the "Physical Inventory" column. Once on the reconciliation page, some vaccines will appear highlighted in red or yellow. Yellow highlighted vaccines are expiring soon. Red highlighted vaccines have expired and need to be discarded of and reordered.
4) **Count and Record Inventory**
After printing the reconciliation page, count and record your physical inventory of vaccine. Record the number underneath the "Physical Inventory" column.

5) **Input Data**
Once you have physically recorded your vaccine count, go back to the reconciliation page and enter the quantity under "Physical Inventory." Don't forget to select a category and reason for the vaccines if the quantity on hand is different from the physical inventory.

6) **Submit Inventory**
Once you have completed the reconciliation page, it is now time to submit. Before submitting, check to make sure changes were successfully saved. If not, check for error messages.

*Make sure to click on "Submit Monthly Inventory," to submit.
*Don't forget to reconcile once a month, even if you do not order vaccine.
1) Using the Navigation Menu, click on the "Orders/Transfers" tab.

2) Click "Create/View Orders" to show the current Order/Transfer List.

3) Click on the "Create Transfer" button.

4) Select the organization/facility you wish to send the vaccine to from the dropdown list.

5) Find the vaccine and lot number on the list.

6) Enter the number of doses you wish to transfer. There is no need to enter in zeroes for blank categories. You must put in a transfer reason or it will not allow you to submit.

7) Click “Create Transfer.”
1) Using the Navigation Menu, click on the "Orders/Transfers" tab.

2) Click "Create/View Orders" to show the current Order/Transfer List.

3) Select the arrow next to the order you are receiving.

4) Enter the Receipt Quantity, Rejected Quantity (if applicable), and the Reason for Rejecting.

5) Click "Receive" and the inventory will be added.
An adverse event following immunization” is an adverse health problem or condition that happens after vaccination. It may be truly caused by the vaccine or an unrelated coincidence.

Per the COVID-19 Vaccination Program Provider Agreement, healthcare providers are required to report clinically important adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS). Healthcare providers are strongly encouraged to report vaccine administration errors.

VAERS is a national early warning system to detect possible safety problems in U.S. licensed vaccines.

Two Ways to Submit an Online Report to VAERS

Report Online to VAERS (Preferred)
Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and re-turned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.

URL for online form: https://vaers.hhs.gov/esub/index.jsp

Report using a Writable PDF Form
Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

URL for PDF form: https://vaers.hhs.gov/uploadFile/index.jsp

Information needed for reporting
• Patient information (age, date of birth, sex)
• Vaccine information (brand name, dosage)
• Date, time, location administered
• Date and time when adverse event(s) started
• Symptoms and outcome of adverse event(s)
• Medical tests and laboratory results (if applicable)

For additional information about VAERS, visit https://vaers.hhs.gov/index.html. Email info@VAERS.org or call 1-800-822-7967 for further assistance with reporting to VAERS.
Modern COVID-19 Vaccine

Vaccine TennIIS Information
Reminder/Recall

What is included in this guide?
1. How do you select the patient list you want to include in reminder/recall?
2. How do you review the patient reminder/recall list?
3. How do you generate the notifications to send to the patients?

What is reminder/recall?
Reminder/recall is a system that allows providers to notify patients about upcoming or past due vaccinations.
Notifications can be generated in the following formats:
- Generate a patient list
- Print letters
- Generate auto-dialer content
- Generate mail-merge
- Create custom postcards
- Send email
- Print address labels

When should reminder/recall be used?
- That decision is made by your clinic based on the size of your patient population. However often you choose to do it (weekly, monthly, etc.), it is helpful to include reminder/recall into your regular workflow.
- Reminder/recall can also be helpful to use when you have vaccine that is about to expire. This helps decrease wastage and ensures patients are up-to-date with vaccines.

Why do you care about reminder/recall?
- It can help prevent disease by improving the timeliness and completion of recommended immunizations.
- It can help your practice improve your coverage rates.
- Viewing a patient list pulled from reminder/recall in TennIIS can help you determine if your patient list is up-to-date.

Who is this Quick Reference Guide for?
- This guide is meant for providers who want to improve vaccination rates by reminding patients of upcoming or past due vaccines.

Reminder/Recall
How do you select the patient list you want to include in reminder/recall?

1. Click **Reminder/Recall** in the TennIIS navigation menu on the left side of the screen.

2. Click the **Reminder/Recall** link and the reminder/recall module will load on the screen.

3. Under the “**How do you want to run this Reminder/Recall**” section, select from the options on the page.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For all patients you own</strong></td>
<td>A patient is considered to be under your organization/facility's ownership if that is the last place where they received an administered vaccine in TennIIS. Schools, pharmacies, and local health departments cannot own patients in TennIIS.</td>
</tr>
<tr>
<td><strong>For all patients you have seen at your facility</strong></td>
<td>This pulls all of the patients that have received a record of an administered vaccine, a historical vaccine, or a demographic change from your organization/facility. This will generate a larger patient list than running by ownership.</td>
</tr>
<tr>
<td><strong>Include Inactive Patients (excluding deceased)</strong></td>
<td>If selected, patients flagged as inactive are included in the patient list, except for patients marked as deceased. If not selected, inactive patients are not included.</td>
</tr>
<tr>
<td><strong>Due Date Timeframe</strong></td>
<td>This determines which patients to include based on the Recommended Date column on the forecast.</td>
</tr>
</tbody>
</table>
How do you select the patient list you want to include in reminder/recall?

4. Under the “Who do you want to contact?” section, select from the options on the page.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Location</td>
<td>Filter patients by organization or facility.</td>
</tr>
<tr>
<td>Patient Age Range</td>
<td>Only one of these two options can be selected. Patient age range is the default.</td>
</tr>
<tr>
<td>Patient Birth Date</td>
<td>For Patient Age Range, enter the number of days, months, or years (and select which one from the drop-down lists) for the starting and ending age range. Note that you cannot enter a number that is zero or less. For Patient Birth Date, enter the starting birthdate in the From field and the ending birthdate in the Through field.</td>
</tr>
<tr>
<td>Patient Gender</td>
<td>Select one or more gender options using the drop-down list.</td>
</tr>
<tr>
<td>Exclude patients who were sent a notice in the last...</td>
<td>To exclude patients who were sent a reminder/recall notification in a specific timeframe, enter a number and then select days, weeks, months, or years from the drop-down list.</td>
</tr>
</tbody>
</table>

Advanced view options include physician, health plan, facility type, association, program, high risk category, state, county, region, zip code, appointment date, deferred vaccinations only, compromised vaccinations, and do not include confidential vaccinations. These allow you to apply more filters when selecting the patient list.
How do you select the patient list you want to include in reminder/recall?

5. Under the “Which vaccines would you like to include?” section, select from the options on the page, then click Generate Patient List.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select a series</td>
<td>Select a vaccine series from the drop-down menu. A list of vaccines that makes up the series appears in the box below the drop-down menu.</td>
</tr>
</tbody>
</table>
| I only want to see my patients who are... | Select a vaccination status for patients that applies to the selected vaccines:  
  - **Due for all selected vaccines** (default) - Reminder/recall returns a list of patients who are due for one or more of the selected vaccines.  
  - **One Dose Away** - Reminder/recall returns a list of patients who are one dose away from completing the required number of doses for the selected series.  
  - **One Visit to Complete the Series** - Reminder/recall returns a list of patients who are one visit away from completing the entire vaccine series, which could include multiple vaccines that could be completed in one visit. |

Congratulations, you have just generated a reminder/recall patient list!
Reminder/Recall

How do you review the patient reminder/recall list?

1. Clicking **Generate Patient List** takes you to the second step, reviewing the list of patients.

![Patient List Example]

2. You can remove categories of patients from the list by selecting one of the **Remove** options at the top.

3. The list of patients retrieved appears below the Remove options. To see more information about a patient, hover the mouse over the patient's name.

4. To **remove a patient** from the list, click the checkbox on the left side of the patient's name to remove the checkmark, or select a **Reason for Inactivation** (which will also deselect the patient from the list). Removed patients will appear greyed out.

   (If a reason for inactivation is selected, the patient is removed from the list and their Patient Status on the demographics page is changed to Inactive once you click **Submit**).

5. To **re-add a patient** to the list, click the checkbox (after which a checkmark appears).
To export the list of patients, click **Export Patient List** and follow the prompts.

When finished with the patient list, click **Submit** to save the changes. The next page is where you can select an action to use with the list.

**Congratulations, you have reviewed your reminder-recall patient list!**
How do you generate the notifications to send to patients?

1. After you click Submit on the patient list page, the *action page* opens. At the top of the page are icons with numbers next to them, showing how many total patients are included, along with how many mailing addresses, telephone numbers, cell phone numbers, and email addresses are available for the list of patients.

2. On the action page are *icons* that represent the different types of notifications to send to patients. Each icon is a link you can click to generate that type of file.
How do you generate the notifications to send to patients?

This action generates an HTML file that displays a detailed list of your patients, including their vaccination forecast.

This action generates a reminder/recall letter for each patient on the patient list.

This action generates an HTML file that can be used with any external auto-dialer application.

This action generates a reminder/recall postcard for each patient on the patient list, which can be printed on Avery 8387 postcards. You can define the dimensions of the postcard and the message content.

This action generates a PDF file that can be printed on Avery 5160 labels or similar.

This action saves your final patient reminder/recall list as a patient group (cohort) that you can use again for reminder/recall notifications. If the patient list represents a specific service population that you intend to send notifications to on a regular basis, saving the list as a cohort can save time and effort.

This action generates a text file that can be used with any external mail-merge application.

This action generates a reminder/recall email for each patient on the patient list.

Congratulations, you have generated notifications for your reminder/recall patient list!
Tennessee Immunization Information System (TennIIS)
Mass Immunizations Module Quick Reference Guide

Description of this guide:

This guide describes TennIIS functionality in the MASS IMMUNIZATIONS MODULE for all TennIIS users with the Mass Immunizations permission.

Included in this guide:

- **Before the Mass Immunization Event:**
  - Setting Lot Number Defaults
  - Adding/Updating Vaccinators
- **During the Mass Immunization Event:**
  - Searching for a Patient
  - Adding a New Patient
  - Adding Administered Vaccines
  - Viewing and Printing Patient Records

Please contact TennIIS.Training@tn.gov or 844-206-9927 with questions about this quick reference guide.
Before the Mass Immunization Event: Setting Lot Number Defaults

It is important to record the vaccine lot number whenever a vaccine is administered, as this information is critical in the event of a vaccine recall or report of an adverse event after vaccination.

Each facility will designate one or more individuals who will have "Default Vaccine Management" permission. These users will set the lot number for the vaccines that are being used during the mass immunization event by entering the lot number default(s) in their facility settings or personal settings.

Setting the default lot number(s) results in the lot number being automatically populated in the patient's TennIIS record when anyone administering vaccines during the mass immunization event records an administered vaccine in TennIIS. When the administered vaccine and lot number are added to the patient record, the vaccine dose is subtracted from the TennIIS inventory which maintains vaccine dose accountability and accurate inventory management.

1) **Select a Facility**
   
   Login to TennIIS and verify that the correct Organization and Facility are displayed.

   If the correct facility is not displayed, click “Select Facility” under the Main tab in the navigation menu and select the correct facility from the drop-down, then click the “Continue” button.

2) **Navigate to the Mass Immunizations Module**
   
   In the navigation menu, click “Select Application.”

   Select Mass Immunizations from the Application drop-down and click the “Submit” button.
3a) **Set Facility Default Lot Numbers**

Users with the “Default Vaccine Management” permission can set Default Lot Numbers for all users within a facility.

To set facility Default Lot Numbers, click “Facility” under the Settings tab in the navigation menu. Next click **Default Lot Numbers**. On the next screen, select the vaccine and lot number that will be used in the mass immunization event, click the arrow button to the right to add the vaccine, then click the Save button.

**Note:** Check that "Override Facility Settings" is NOT checked in the user's personal settings.

---

3b) **Set Personal Lot Defaults**

Personal Lot Defaults should only be used if the facility has **not** set lot defaults in the facility settings.

To set **Lot Defaults** for individual users, click “Personal” under the Settings tab in the navigation menu. On the Personal Settings screen, click **Lot Defaults** to expand the section.

Select the vaccine description for the vaccine that will be used in the mass immunization event from the drop-down list. Next click the link below the manufacturer field and select the lot number for the vaccine that will be used in the mass immunization event from the pop-up menu. Click the “Add” button.

---

Please contact [TennIIS.Training@tn.gov](mailto:TennIIS.Training@tn.gov) or 844-206-9927 with questions about this quick reference guide.
4) **Note:** If the lot number for the vaccine to be used in the mass vaccination event is not listed in the pop-up menu:

1. Make sure that the correct Vaccine Description was selected. The selected vaccine description must match the vaccine description in the TennIIS inventory.
2. Make sure the lot number is in the TennIIS inventory. Users with the Lot Number Manager Access permission can view the TennIIS inventory.
3. If the lot number for the vaccine to be used in the mass vaccination event is not listed, it will need to be added before the event. Contact TennIIS.VOMS@tn.gov or 615-741-7247 for assistance. Health Departments can contact their Regional Immunization Representative for assistance.

Please contact TennIIS.Training@tn.gov or 844-206-9927 with questions about this quick reference guide.
Before the Mass Immunization Event: Adding/Updating Vaccinators

The facility point of contact (POC) is responsible for managing the list of Physicians and Vaccinators for their facility. “Vaccinators” are individuals who administer vaccines to patients. Individuals added as a vaccinator will be listed in the drop-down menu on the Vaccination Detail screen in TennIIS and in the Vaccinator drop-down within the Mass Immunizations Module.

If a vaccinator is selected when an administered vaccine is added to a patient record, the vaccinator’s name will be displayed on the Vaccination Detail Screen in TennIIS. The Patient Detail Report lists the vaccinator’s name, and the report can be run for all vaccinators within a facility or limited to specific vaccinators.

Note: Adding or inactivating vaccinators is not the same as adding or inactivating TennIIS users.

1) **Select a facility**
   
   Login to TennIIS and verify that the correct Organization/Facility is displayed.

   If the correct facility is not displayed, click “Select Facility” under the Main tab in the navigation menu and select the correct facility from the drop-down, then click the “Continue” button.

2) **Navigate to Physicians & Vaccinators**
   
   In the navigation menu, click “Physicians & Vaccinators.”

   Click Search/Add.

3) **On the Physician/Vaccinator Maintenance screen, click the Search button to review the list of vaccinators.**

Please contact TennIIS.Training@tn.gov or 844-206-9927 with questions about this quick reference guide.
4) **Edit Existing Vaccinators**  
   To edit an existing vaccinator, click the Select button for that vaccinator.

5) **On the Physician/Vaccinator Maintenance [Detail] screen, click the Edit button at the bottom right, make the necessary changes and click the Save button.**

6) **Adding Vaccinators**  
   To add a vaccinator, click the Add button on the Physician/Vaccinator Maintenance screen.

7) **Enter the vaccinator’s information (required fields in red) and click the Save button**

Please contact TennIIS.Training@tn.gov or 844-206-9927 with questions about this quick reference guide.
During the Mass Immunization Event: Searching for a Patient

1) Select a facility
   Login to TennIIS and verify that the correct Organization/Facility is displayed.

   If the correct facility is not displayed, click “Select Facility” under the Main tab in the navigation menu and select the correct facility from the drop-down, then click the “Continue” button.

2) Navigate to the Mass Immunizations Module
   In the navigation menu, click “Select Application.”

   Select Mass Immunizations from the Application drop-down and click the “Submit” button.

3) Searching for a patient
   In the navigation menu, click “Search/Add” under the Patient tab.

   Enter the patient’s first and last name or initials and date of birth in the search fields and click the Search button.

4) Search results are displayed at the bottom of the next screen.

   If the patient has an existing immunization record in TennIIS, the patient's name will appear in the search results. Click the arrow button next to the patient’s name to select the patient.

   If the patient's name is not listed, the patient will need to be added as a new patient (see "Adding a New Patient" below).

Please contact TennIIS.Training@tn.gov or 844-206-9927 with questions about this quick reference guide.
5) Verify the patient’s demographic information. If the address listed at the top of the page is correct, check the box in the upper left corner to add that information to the fields below. If changes need to be made, enter the changes in the "Patient Edit" section. Fields in RED are required.

Adding the patient’s current phone number is crucial and necessary for recalling patients when they need additional doses or other vaccines.

During the Mass Immunization Event: Adding a New Patient

1) If the patient is not listed in the search results, click the “Add New Patient” button.

2) Add the patient’s demographic information. Required fields are red.

Adding the patient’s current phone number is crucial and necessary for recalling patients when they need additional doses or other vaccines.
During the Mass Immunization Event: Adding Administered Vaccines

1) From the Patient Edit (existing patients) or the Patient Add (new patients) screen, select a **Campaign** from the drop-down list (required).

Campaigns are set by TennIIS Program Administrators. If the campaign for your mass vaccination event is not listed, contact TennIIS.Training@tn.gov or 615-741-7247.

2) After selecting a Campaign, select a Tier group from the drop-down list (required).

Tier groups are set by TennIIS Program Administrators and may differ from those shown in this example. If the tier group for your mass vaccination event is not listed, contact TennIIS.Training@tn.gov or 615-741-7247.

3) After selecting a Campaign and Tier group, select the vaccinator (the individual who administered the vaccine) from the drop-down list (optional).

If a vaccinator is not selected when the vaccination is recorded in TennIIS, one can be added later using the Edit Record button on the Vaccination Detail screen.

The facility point of contact can add/update vaccinators for the facility.

Please contact TennIIS.Training@tn.gov or 844-206-9927 with questions about this quick reference guide.
4) Check the appropriate box for the vaccine and lot number being administered. Only the vaccines that were set up for the campaign and the lot number defaults in the facility/personal settings will appear in this list. In some cases there will be only one option shown.

Ensure that the correct vaccination date is the date shown in the Date column. If the date is not correct, enter the correct date in the Default Date box.

Click the Save button to record the vaccination or the Cancel button to start over.

If the lot number being administered is not listed, contact your facility's mass immunization event coordinator or TennIIS.Training@tn.gov.
### During the Mass Immunization Event: Viewing and Printing Patient Records

1) Immediately after adding a vaccine to a patient’s record and before searching for the next patient, you can print a copy of the patient’s complete TennIIS record.

To print a patient record for the previous patient, click the Reports tab in the navigation menu then click Patient Record.

2) Select “All Recorded Vaccinations (option 2)” and click the “Create Report” button.

3) The Patient Vaccination Record will open in a new window.

The patient’s complete TennIIS record will be displayed. Upcoming due dates and overdue dates for additional vaccinations are listed below the recorded vaccination dates.

Print the record using your internet browser’s print function or press “Ctrl + P.”

Sign or stamp the printed record with your facility information in case the patient or another provider have questions about the record.

Please contact TennIIS.Training@tn.gov or 844-206-9927 with questions about this quick reference guide.
In the event that TennIIS were to be offline due to technical difficulties, the below spreadsheet can be used to collect the required data elements for entry when back online.

<table>
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<th>Patient Last Name</th>
<th>Patient DOB (YYYYMMDD)</th>
<th>Patient Gender (M=Male; F=Female; O=Other; U=Unknown)</th>
<th>Patient Address Street</th>
<th>Patient Address City</th>
<th>Patient Address State</th>
<th>Patient Address Zip</th>
<th>Patient Race</th>
<th>Patient Ethnicity</th>
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<th>Administering Facility RXA-11</th>
<th>Vaccination Date (YYYYMMDD)</th>
<th>Vaccination CVX Code</th>
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To access:
- Right click on the image
- Select “Worksheet Option”
- Select Open
Moderna COVID-19 Vaccine

Healthcare
Educational
Information
What are COVID-19 Vaccines?

- There are many COVID-19 vaccines in development.
- Currently, there are two mRNA vaccines that have been approved for use in the United States. Both of these vaccines have shown that they can reduce the chance of getting COVID-19 by 95%.
- The two vaccines in use in the United States are the Moderna Vaccine and the Pfizer-BioNTech Vaccine.
- Both mRNA vaccines require two doses to provide protection against the virus.
- Early data show the vaccines are effective across all ages, races, and health conditions.

How do mRNA vaccines work?

- mRNA vaccines provide the body with a genetic “recipe” so the body can produce the “spike protein” that is found on the surface of the virus. The body sees the protein as foreign and makes antibodies to destroy it. If the body is later infected with the virus, the antibodies recognize the spike protein and destroy the virus before it can cause illness.
- COVID-19 mRNA vaccines are given in the upper arm muscle.

When will I be able to get a vaccine?

- While vaccine supply is limited, first priority will be to vaccinate hospital staff who have direct contact with patients or materials that are potential infectious as well as first responders with direct contact to the public (e.g., EMS and law enforcement). Eventually, anyone who wants a vaccine will be able to get a vaccine unless there is a medical contraindication.
- For more information regarding the phases of vaccine distribution in Tennessee, please visit https://covid19.tn.gov/covid-19-vaccines/vaccine-phases/.

Are COVID-19 vaccines safe?

- Yes! Vaccine safety is the first priority!
- These vaccines have already been given to tens of thousands of volunteers and have been shown to be safe and very effective at preventing them from getting sick with COVID-19.
- The vaccine will continue to be monitored to make sure any rare problems are found as soon as possible and studied to see if they were caused by the vaccine.
- While the possibility of a rare but serious adverse event cannot be ruled out, rare events could occur in <0.01% of people who receive a COVID-19 vaccine. The case fatality rate of COVID-19 in Tennessee is currently >1%, or approximately 100 times greater than the chance of the vaccine causing a serious event.
What happens if I don’t get the second dose of COVID-19 vaccine?

You likely won’t be protected against COVID-19. The first dose “primes” the immune system. The second dose creates the lasting protection.

What happens if I don’t get the second dose of vaccine on time?

You need to go get it as soon as possible, even if you are late.

I didn’t feel well after the first dose. Will I feel bad after the second?

Just as with the first dose, it is not uncommon to experience low-grade fever, fatigue, or headache after you receive the vaccine. These symptoms usually go away after a day or two. The symptoms of COVID-19 are often much worse and can be life-threatening. It’s important to get the second dose to protect yourself, your family and your community.

Where can I get the second dose?

The facility that gave you the first dose should give you your second dose. Contact them or your local health department.

Do I have to get the same vaccine as last time?

YES! There are currently TWO different vaccines available (Moderna and Pfizer-BioNTech). You MUST get the same brand you received the first time. If you do not know which one you received, the facility where you received your first dose can help you or you can contact your local health department.

Reminder: Check the vaccine card that was given to you when you received your first dose or check your phone to see if you took a picture of it.

Pfizer Vaccine is due 21 days after the first dose.

Moderna Vaccine is due 28 days after the first dose.
What is v-safe?

**V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC’s **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2 p.m. local time. To opt out, simply text “STOP” when **v-safe** sends you a text message. You can also start **v-safe** again by texting “START.”

How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You’ll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.*

*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data’s level of sensitivity.
How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the v-safe website using one of the two options below:

   Use your smartphone’s browser to go to vsafe.cdc.gov

   OR

   Aim your smartphone’s camera at this code

2. Read the instructions. Click Get Started.

3. Enter your name, mobile number, and other requested information. Click Register.

4. You will receive a text message with a verification code on your smartphone. Enter the code in v-safe and click Verify.

5. At the top of the screen, click Enter vaccine information.

6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click Next.

7. Review your vaccine information. If correct, click Submit. If not, click Go Back.

8. Congrats! You’re all set! If you complete your registration before 2 p.m. local time, v-safe will start your initial health check-in around 2 p.m. that day. If you register after 2 p.m., v-safe will start your initial health check-in immediately after you register—just follow the instructions.

   You will receive a reminder text message from v-safe when it’s time for the next check-in — around 2 p.m. local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a v-safe check-in text message on your smartphone, click the link when ready.

2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I’m interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- v-safe will automatically ask you to update your second dose information. Just follow the instructions.

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You’ll also get reminders if you need a second vaccine dose.

Sign up with your smartphone’s browser at vsafe.cdc.gov

OR

Aim your smartphone’s camera at this code

Learn more about v-safe www.cdc.gov/vsafe
Healthcare professionals who are knowledgeable about evidence-based immunization strategies and best practices are critical to implementing a successful vaccination program. They are key to ensuring that vaccination is as safe and effective as possible. Some healthcare professionals administering COVID-19 vaccine may have extensive experience with immunization practices, since they routinely administer recommended vaccines in their clinical practice. For others, administering COVID-19 vaccine may be their first clinical experience with vaccination. Below is a list of immunization training and educational materials, including basic and COVID-19-vaccine-specific information.

**Vaccine Storage and Handling**

Vaccine storage and handling practices are only as effective as the staff who implement them. Staff who are well-trained in general storage and handling principles and follow standard operating procedures for vaccine management are critical to ensuring vaccine supply potency and patient safety.

<table>
<thead>
<tr>
<th>Training Program / Reference Material</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><em>You Call the Shots: Vaccine Storage and Handling</em></td>
<td>An interactive, web-based immunization training course on storage and handling best practices and principles.</td>
</tr>
<tr>
<td>“Keys to Storing and Handling Your Vaccine Supply” video</td>
<td>This video is designed to decrease vaccine storage and handling errors by demonstrating recommended best practices and addressing frequently asked questions.</td>
</tr>
<tr>
<td><em>Vaccine Storage and Handling Toolkit</em></td>
<td>Comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.</td>
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<tr>
<td><em>Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum</em></td>
<td>The <em>Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum</em>, provides information, recommendations, and resources on storage and handling best practices to help safeguard the COVID-19 vaccine supply and ensure patients receive safe and effective vaccines.</td>
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<tr>
<td><em>Epidemiology and Prevention of Vaccine-Preventable Diseases</em></td>
<td>Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 5 is dedicated to vaccine storage and handling (updated 2020).</td>
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**Vaccine Administration**

Healthcare professionals who will administer vaccines should receive comprehensive, competency-based training in vaccine administration policies and procedures before administering vaccines. Staff’s vaccine administration knowledge and skills should be validated using a skills checklist and maintained using quality improvement processes.

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<tr>
<th>Training Program / Reference Material</th>
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<tbody>
<tr>
<td><em>You Call the Shots: Vaccine Administration</em></td>
<td>An interactive, web-based vaccine administration course that provides training using videos, job aids, and other resources.</td>
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<tr>
<td>Vaccine administration videos</td>
<td>Short, skill-based demonstration videos of vaccine administration activities, including injection techniques based on age and medication preparation.</td>
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<tr>
<td><em>Skills Checklist for Vaccine Administration</em></td>
<td>This checklist from the Immunization Action Coalition is a self-assessment tool for healthcare professionals who administer vaccines.</td>
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<tr>
<td><em>Epidemiology and Prevention of Vaccine-Preventable Diseases</em></td>
<td>Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 6 is dedicated to vaccine administration (updated 2020).</td>
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</table>
Communicating with Patients about Vaccines

Healthcare professionals play a key role in improving vaccine acceptance as they are in contact with patients throughout the office visit. By fostering a culture of immunization in the practice, both providers and patients can vaccinate with confidence.

<table>
<thead>
<tr>
<th>How Nurses and Medical Assistants Can Foster a Culture of Immunization in the Practice video</th>
<th>Research shows that healthcare professionals are patients’ most trusted source of information when it comes to vaccines. By highlighting key points before, during, and after a patient’s visit, this presentation will support vaccine conversations and reinforce best practices for improving vaccination coverage.</th>
</tr>
</thead>
<tbody>
<tr>
<td>“#HowIRecommend” vaccination video series</td>
<td>These videos explain the importance of vaccination, how to effectively address questions from patients about vaccine safety and effectiveness, and how clinicians routinely recommend same-day vaccination for their patients.</td>
</tr>
<tr>
<td>Provider Resources for COVID-19 Vaccine Conversations with Patients</td>
<td>Information for healthcare providers on how to talk to patients about COVID-19 vaccines, including giving strong recommendations, setting expectations about vaccine availability, and preparing to answer likely patient questions.</td>
</tr>
<tr>
<td>Epidemiology and Prevention of Vaccine-Preventable Diseases</td>
<td>Comprehensive information on routinely used vaccines and the diseases they prevent. Chapter 3, discusses essential strategies healthcare professionals can use when talking to patients about vaccines (updated 2020).</td>
</tr>
</tbody>
</table>

COVID-19 Vaccine Training and Clinical Materials

This suite of COVID-19 vaccine training programs and clinical materials for healthcare professionals include general and product-specific information. A variety of topics and formats are available. All are based on manufacturer’s guidance and vaccine recommendations made by the Advisory Committee on Immunization Practices (ACIP). These trainings and materials will be made available as each vaccine product is authorized by FDA.

| COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers | A web-based training course outlining best practices and principles for healthcare providers when preparing to administer COVID-19 vaccine. It is a high-level overview of the following topics with links to detailed information: vaccine development and safety, safety monitoring programs, Emergency Use Authorizations (EUAs), vaccine storage/handling, preparation, administration, PPE, scheduling, documentation, and reporting adverse events. Information on each vaccine product will be added as each is authorized by FDA. |
| COVID-19 Vaccine Webinar Series | These interactive, web-based training modules offer a real-world perspective on different issues around COVID-19 vaccines. Each webinar is approximately 15 minutes and offers CE. |
| Clinical materials | COVID-19 vaccine screening form for contraindications and precautions
Expiration date tracker
Reporting a temperature excursion
IIS off-line vaccine administration documentation tool
Guide to ancillary supplies kit (for staff helping providers order vaccine)
COVID-19 vaccine frequently asked clinical questions web page
Prevaccination screening form |
| Clinical Considerations | Interim Clinical Considerations Guidance
| Severe Allergic Reactions
| Vaccinating Special Populations |

| **Pfizer vaccine materials** | Online training module
| Vaccine preparation and administration summary
| Storage and handling summary
| Temperature log for ultra-cold freezer units, including online fillable PDF version
| Beyond use date tracker labels for refrigerator storage
| Standing orders template
| Storage labels for refrigerator
| Temperature logs for the refrigerator
| Infographic poster for vaccine preparation
| Checklist for vaccine delivery |

| **Moderna vaccine materials** | Online training module
| Vaccine preparation and administration summary
| Guidance for transporting vaccines
| Storage and handling summary
| Temperature log for freezer units
| Beyond use date tracker labels for refrigerator storage
| Standing orders template
| Storage labels for refrigerator
| Temperature logs for the refrigerator |

| **Janssen vaccine materials** | Online training module
| Vaccine preparation and administration summary
| Storage and handling summary
| Standing orders template
| Temperature logs for the refrigerator
| Guidance for transporting vaccines
| Storage labels for the refrigerator |
Moderna COVID-19 Vaccine

Appendix
COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>MI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of birth</th>
<th>Patient number (medical record or IIS record number)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Product Name/Manufacturer</th>
<th>Lot Number</th>
<th>Date</th>
<th>Healthcare Professional or Clinic Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; Dose COVID-19</td>
<td></td>
<td></td>
<td>/ /</td>
<td>mm dd yy</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; Dose COVID-19</td>
<td></td>
<td></td>
<td>/ /</td>
<td>mm dd yy</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td>/ /</td>
<td>mm dd yy</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td>/ /</td>
<td>mm dd yy</td>
</tr>
</tbody>
</table>
Reminder! Return for a second dose!

¡Recordatorio! ¡Regrese para la segunda dosis!

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Date / Fecha</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 vaccine</td>
<td></td>
</tr>
<tr>
<td>Vacuna contra el COVID-19</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mm dd yy</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Otra</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mm dd yy</td>
</tr>
</tbody>
</table>

Bring this vaccination record to every vaccination or medical visit. Check with your health care provider to make sure you are not missing any doses of routinely recommended vaccines.


You can report possible adverse reactions following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) at vaers.hhs.gov.

Lleve este registro de vacunación a cada cita médica o de vacunación. Consulte con su proveedor de atención médica para asegurarse de que no le falte ninguna dosis de las vacunas recomendadas.


Puede notificar las posibles reacciones adversas después de la vacunación contra el COVID-19 al Sistema de Notificación de Reacciones Adversas a las Vacunas (VAERS) en vaers.hhs.gov.
COVID-19 Pfizer BioNTech or Moderna Vaccination

PLEASE PRINT

Patient FIRST Name: ____________________________ LAST Name: ____________________________ MI: __________
Maiden Name (Optional): ____________________________
DOB: _______/_____/__________ Current Age: ________SEX: ☐ F ☐ M ☐ Other

Race: ☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaskan Native ☐ Other
☐ Native Hawaiian or Other Pacific Islander ☐ Unknown

Ethnicity: ☐ Hispanic or Latino ☐ Non-Hispanic or Latino ☐ Unknown

Address: ____________________________ City: ____________________________ State: ____________________________ Zip: ____________________________

Cell Phone: (______)__________ Alternate Phone: (______)__________

The following questions will help determine if there is any reason you should not receive a COVID immunization injection. Questions should be answered for the person who will be vaccinated.

1. Younger than 18 years old? ................................................................. ☐ Yes ☐ No
2. History of any immediate allergic reaction, of any severity, after a previous dose of mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG]) or polysorbate? ................................................................. ☐ Yes ☐ No
   Cause/Allergy: ____________________________
3. History of immediate allergic reaction of any severity to any substance? ................................................................. ☐ Yes ☐ No
   Cause/Allergy: ____________________________
4. Ever received a COVID-19 vaccine? ................................................................. ☐ Yes ☐ No
   Date: _______________ Manufacturer: ____________________________
5. Sick today, including symptomatic/asymptomatic infection with COVID-19? ................................................................. ☐ Yes ☐ No
6. Received passive antibody therapy for COVID-19 in the last 90 days? ................................................................. ☐ Yes ☐ No
7. Pregnant or breastfeeding? ................................................................. ☐ Yes ☐ No

Request for Administration of COVID-19 Vaccine for the above-named recipient: I acknowledge that I have received the Vaccine Information Statement or Emergency Use Authorization Information Sheet and the Tennessee Department of Health’s Notice of Privacy Practices. I have had an opportunity to ask questions regarding the vaccine and understand the risks and benefits. I am aware that, to provide protection against the virus that causes COVID-19, two doses of this same vaccine may be required. I acknowledge that I may receive a reminder for a second dose by text (if cell phone number provided, standard messaging rates may apply), phone call, or mail.

PATIENT/PARENT OR GUARDIAN/POWER OF ATTORNEY SIGNATURE: ____________________________ DATE: ________________

This consent is valid for 12 months from date signed.
## COVID-19 Pfizer BioNTech or Moderna Vaccination

### Vaccination Site [name, address]

<table>
<thead>
<tr>
<th>AREA FOR OFFICIAL USE ONLY</th>
<th>Nursing Immunization [INJECTION #1]</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Manufacturer: Pfizer</td>
<td>☐ Manufacturer: Moderna</td>
<td></td>
</tr>
<tr>
<td>Dose: 0.3 mL</td>
<td>Dose: 0.5 mL</td>
<td></td>
</tr>
<tr>
<td>Pfizer EUA Date: 12/2020</td>
<td>Moderna EUA Date: 12/2020</td>
<td></td>
</tr>
<tr>
<td>Route: IM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site Administered: □ Right Deltoid</td>
<td>□ Left Deltoid</td>
<td>□ [Other]</td>
</tr>
<tr>
<td>Lot Number: __________</td>
<td>Expiration Date: / /</td>
<td></td>
</tr>
<tr>
<td>Date Given: / /</td>
<td>Provider number ___. (Optional)</td>
<td></td>
</tr>
</tbody>
</table>

**Signature**

Signature indicates immunization given according to PHN Protocol

☐ Vaccine NOT given secondary to contraindication:

☐ Verbal Order obtained from ________________________________ to proceed with immunization per protocol; readback completed. Special Instructions:

PHN Signature:

### AREA FOR OFFICIAL USE ONLY

<table>
<thead>
<tr>
<th>Nursing Immunization [INJECTION #2]</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
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<td>☐ Manufacturer: Moderna</td>
</tr>
<tr>
<td>Dose: 0.3 mL</td>
<td>Dose: 0.5 mL</td>
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<tr>
<td>Pfizer EUA Date: 12/2020</td>
<td>Moderna EUA Date: 12/2020</td>
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<tr>
<td>Route: IM</td>
<td></td>
</tr>
<tr>
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<td>□ Left Deltoid</td>
</tr>
<tr>
<td>Lot Number: __________</td>
<td>Expiration Date: / /</td>
</tr>
<tr>
<td>Date Given: / /</td>
<td>Provider number ___. (Optional)</td>
</tr>
</tbody>
</table>

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PHN Signature:
Vacuna de Pfizer BioNTech o Moderna contra el COVID-19

FAVOR USAR LETRA DE MOLDE

<table>
<thead>
<tr>
<th>PRIMER nombre del paciente</th>
<th>APELLIDO:</th>
<th>INICIAL DEL SEGUNDO NOMBRE</th>
</tr>
</thead>
</table>

Apellido de soltera (opcional):

FECHA DE NACIMIENTO:   Edad actual:   Sexo: ☐ F ☐ M ☐ Otro

Raza: ☐ Blanca   ☐ Negra o afroamericana   ☐ Asiática   ☐ Indígena americana o natural de Alaska   ☐ Otra
☐ Natural de Hawái o de Islas del Pacífico   ☐ Desconocida

Etnia: ☐ Hispánica o latina   ☐ No hispánica ni latina   ☐ Desconocida

Dirección:

Ciudad:   Estado:   Código postal:

Celular: (       )   Teléfono alternativo: (       )

Las siguientes preguntas ayudarán a determinar si hay alguna razón por la que no debería recibir la vacuna inyectable contra el COVID. Responda a estas preguntas respecto a la persona que recibirá la vacuna.

Sí una pregunta no está clara, solicite explicación a un proveedor de salud.

1. ¿Tiene menos de 18 años de edad?………………………………………………………………… ☐ Sí  ☐ No

2. ¿Tiene antecedentes de reacciones alérgicas inmediatas de cualquier intensidad después de una dosis previa de la vacuna de ARNm contra el COVID-19 o cualquiera de sus componentes (incluso el PEG-polietilenglicol- o el polisorbato)?………………………………… ☐ Sí  ☐ No
   **Causa/Alergia:**
   
   __________________________________________________________

3. ¿Tiene antecedentes de reacciones alérgicas inmediatas de cualquier intensidad a alguna sustancia?……………………………………………………………………………………….. ☐ Sí  ☐ No
   **Causa/Alergia:**
   
   __________________________________________________________

4. ¿Le han puesto una vacuna contra el COVID-19 antes?…………………………………………… ☐ Sí  ☐ No
   **Fecha:** _______________________   **Fabricante:** ______________________

5. ¿Está enfermo hoy, por ejemplo, con infección sintomática/asintomática de COVID-19? ..... ☐ Sí  ☐ No

6. ¿Ha recibido terapia pasiva con anticuerpos contra el COVID-19 en los últimos 90 días?..... ☐ Sí  ☐ No

7. ¿Está embarazada o amamantando?...?………………………………………………………. ☐ Sí  ☐ No

Solicitud de administración de vacuna contra el COVID-19 para el receptor arriba mencionado: Reconozco que he recibido la declaración de datos de la vacuna o la hoja informativa de autorización para uso de emergencia y el aviso de prácticas de privacidad del Departamento de Salud de Tennessee. Tuve la oportunidad de hacer preguntas sobre la vacuna y entiendo los riesgos y beneficios. Estoy al tanto de que, para brindar protección contra el virus que causa el COVID-19, puede que se requieran dos dosis de esta misma vacuna. Reconozco que puede ser que reciba un recordatorio de la segunda dosis, vía texto (si doy mi número de celular, puede que apliquen cobros estándar de mensajería), por teléfono o correo.
Vacuna de Pfizer BioNTech o Moderna contra el COVID-19

FIRMA DEL PACIENTE/PADRE O TUTOR/PORTADOR DE PODER LEGAL: ____________________________FECHA:_________

Este consentimiento vale por 12 meses desde la fecha en que se firmó.

Departamento de Salud del Condado de [ingrese el condado]
Lugar del centro de vacunación [dirección]______________________________________________

<table>
<thead>
<tr>
<th>ÁREA SOLO PARA USO OFICIAL</th>
</tr>
</thead>
</table>

Documentación de vacuna por el enfermero [INYECCIÓN #1]

<table>
<thead>
<tr>
<th>Fabricante: Pfizer</th>
<th>Dosis: 0.3 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecha de autorización para uso de emergencia para Pfizer: 12/2020</td>
<td></td>
</tr>
<tr>
<td>Vía: IM</td>
<td></td>
</tr>
<tr>
<td>Punto de administración: ☐ Deltoides derecho ☐ Deltoides izquierdo ☐ [Otro]</td>
<td></td>
</tr>
<tr>
<td>Número de lote: __________</td>
<td>Fecha de vencimiento: / /</td>
</tr>
<tr>
<td>Fecha de administración: / /</td>
<td>Número del proveedor: ______ (Opcional)</td>
</tr>
<tr>
<td>Firma: ____________________________</td>
<td></td>
</tr>
</tbody>
</table>

La firma indica que la vacuna se administró según el protocolo de enfermería de salud pública

☐ Vacuna NO administrada debido a contraindicación:

☐ Orden verbal obtenida de______________________________ para proceder con la inmunización según protocolo; se hizo lectura de confirmación. Instrucciones especiales:

Firma del enfermero en salud pública:

<table>
<thead>
<tr>
<th>ÁREA SOLO PARA USO OFICIAL</th>
</tr>
</thead>
</table>

Documentación de vacuna por el enfermero [INYECCIÓN #2]

<table>
<thead>
<tr>
<th>Fabricante: Pfizer</th>
<th>Dosis: 0.3 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecha de autorización para uso de emergencia para Pfizer: 12/2020</td>
<td></td>
</tr>
<tr>
<td>Vía: IM</td>
<td></td>
</tr>
<tr>
<td>Punto de administración: ☐ Deltoides derecho ☐ Deltoides izquierdo ☐ [Otro]</td>
<td></td>
</tr>
<tr>
<td>Número de lote: __________</td>
<td>Fecha de vencimiento: / /</td>
</tr>
<tr>
<td>Fecha de administración: / /</td>
<td>Número del proveedor: ______ (Opcional)</td>
</tr>
<tr>
<td>Firma: ____________________________</td>
<td></td>
</tr>
</tbody>
</table>

La firma indica que la vacuna se administró según el protocolo de enfermería de salud pública

☐ Vacuna NO administrada debido a contraindicación:

☐ Orden verbal obtenida de______________________________ para proceder con la inmunización según protocolo; se hizo lectura de confirmación. Instrucciones especiales:

Firma del enfermero en salud pública