

*****INFORMATION ONLY*****



HOW TO PREPARE FOR YOUR UPCOMING SURVEY!

Follow these steps and your next survey will go much smoother!

1 CONFIRM acknowledgment of schedule letter

- Contact your surveyor (found in the schedule letter) via text, email, fax or phone.

2 FIND pre-survey documents

- Go to <https://www.tn.gov/hfc/division-of-licensure-and-regulation/certification/clinical-laboratory-improvement-amendments/forms-and-resources.html>
- Find the section “Pre-Survey Packet Forms”

3 COMPLETE pre-survey forms

Complete all 4 forms online or print them out and complete:

- CMS-209: Laboratory Personnel Form
- PH-3724: CLIA Laboratory Specialties Test Volumes
- PH-4150: Disclosure of Ownership and Control Interest Statement
- CMS-116: CLIA Application for Certification

4 PREPARE for the survey

Make available the records for the past two (2) years for the following documents:

- Policy and procedure manual
- Personnel records, current licenses, individual responsibilities, training/lab experience for the Director, Technical Supervisor, Technical Consultant and Testing Personnel
- Proficiency testing, quality control, calibration, and preventative maintenance plan
- Quality Assurance Plan
- Patient test logs, records, and reports
- Copy of the current director’s license and CLIA certificate

Also review Appendix C of the State Operations Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf

