Attn: Lab Director, Lab Supervisor, Lab Personnel

MICROBIOLOGY MEDIA

(Solid, Semi-solid, Liquid)

QUALITY CONTROL (QC) PER CLIA

§493.1256 (e)(1) The laboratory must check each batch, lot number and shipment of media, reagents, disks, stains, antisera and identification systems when prepared or opened for positive and negative reactivity. Streamline QC no longer meets CLIA requirements and each substrate must be tested for positive and negative reactivity.

§493.1256 (e)(4) Check each batch of media for sterility if sterility is required for testing. Document the physical characteristics of the media when compromised and report to manufacturer.

§493.1256 (e)(4)(ii) Check each batch of media for its ability to support growth and select or inhibit specific organisms or produce a biochemical response.

§493.1256 (e)(5) ALWAYS FOLLOW MANUFACTURER'S INSTRUCTIONS.

§493.1261 (b) For antimicrobial susceptibility tests the lab must check each batch, lot and shipment of antimicrobial agents using approved control organisms each day tests are performed. The lab's zone sizes must be within established limits before reporting patient results.

IF YOU WANT TO PERFORM LESS FREQUENT QC THAN CLIA REGULATIONS YOU MUST PERFORM IQCP.

TN Department of Health