Guidelines for Laboratories Establishing Daily Quality Control Equivalence for FilmArray Systems

TECHNICAL
::: NOTE

Purpose

The Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists (CAP) checklists include requirements that external controls are run daily for qualitative, unmodified, tests of moderate complexity cleared or approved by the FDA. Both CLIA and CAP regulations have allowances to limit daily quality control to internal or built-in controls, if the laboratory formally demonstrates the reliability of the internal control (e.g. The CAP 20 Day Daily QC Study).

This document provides guidelines to assist your laboratory in developing a protocol for establishing daily quality control equivalence for FilmArray Systems.

The Laboratory Director is ultimately responsible for ensuring that procedures meet the appropriate standards for CLIA and applicable laboratory accrediting agencies.

Materials

Please refer to the following documents for materials that may be needed for procedures: FLM1-PRT-0060 for RP, FLM1-PRT-0137 for BCID, FLM1-PRT-0151 for GI, and FLM1-PRT-0165 for ME.

Protocol Guidelines

- On each day of the study perform one test containing a single positive analyte (not pooled material) using qualified reference material.

  Note: The control material may be from the same source as material used during the Verification of Performance Specifications.

- Each target on the panel should be tested at least once over the course of the study.

- Laboratories with multiple systems should perform the 20 day study on one system and then perform comparison testing to confirm performance for all systems. The laboratory director is responsible for determining the extent of the comparison studies for the other instruments.

- Perform a 20 day study for each FilmArray panel.

- Record all test results. If an invalid result occurs (e.g. failed process control), retest the sample, but it is not necessary to restart the 20 day study.

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- In the event of an unexpected result (false positive or false negative result) repeat the test. If the unexpected result is reproduced on the second attempt, contact the FilmArray Technical Support team at 801-736-6354 option 5 or by email at support@biofiredx.com.

Acceptance Criteria

- As per CLIA regulations, the acceptance criteria for the 20 day study are ultimately at the discretion of the laboratory director.
- We recommend that a single false positive or false negative result that is resolved upon a retest is acceptable.

Technical Support Contact Information

BioFire is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the FilmArray Technical Support team for assistance.

BioFire Technical Support
Email: support@biofiredx.com
Phone: +1-801-736-6354, select Option 5 and then Option 1

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