MLS Laboratory Update: MDH-PHL discontinues offering confirmatory testing for *Cryptosporidium* by BioFire® FilmArray® Gastrointestinal (GI) Panel

MAY 2, 2023

Purpose of this Message:

This message is to inform clinical labs that the MDH-PHL will no longer be offering confirmatory testing for suspicious false positives for *Cryptosporidium* on the BioFire® FilmArray® Gastrointestinal (GI) Panel starting June 1st, 2023.

Action Item:

- MDH will be no longer be accepting specimens for confirmation after being positive by BioFire® FilmArray®, since bioMerieux has provided a software solution for this problem.
- For those laboratories using the BioFire® FilmArray® Gastrointestinal (GI) Panel:
    - Review the Field Corrective Action (FCA) sent to customers on 4/25/2023 from bioMérieux to update the BIOFIRE GI Pouch Module Software, along with the link for the instructions: eIFU - BioFire Diagnostics, LLC (https://www.biofiredx.qarad.eifu.online/ITI/all?keycode=ITIFA20GI21).
    - Once the pouch module software has been updated, bioMerieux requests that users complete the webform located at Acknowledgement of Advisory Notice Receipt Form (GI FCA 5747 - AOR) - BioFire Diagnostics (https://www.biofiredx.com/gisoftware-5747/).
    - If you have any questions or concerns regarding installation, please contact the BIOFIRE Technical Support team directly at biofiresupport@biomerieux.com.

Background:

In June 2022, MDH-PHL notified MLS laboratories about an increase in false positive test results of *Cryptosporidium spp.* by BioFire due to software issues with the BioFire FilmArray Gastrointestinal (GI) panel (MLS Laboratory Update: Possible performance issues with BioFire FilmArray Gastrointestinal (GI) panel for Cryptosporidium spp., June 2022

(https://www.health.state.mn.us/diseases/idlab/mls/LabAlerts/220614biofiregipanelforcrypto.pdf). While bioMérieux was developing a software update to address the misinterpretation issue, the CDC recommended that clinical laboratory partners communicate with their public health laboratories for alternative testing options in cases where only the Crypt 2 assay is positive. Since November 2022, MDH-PHL has been offering CLIA-validated Direct Fluorescent Antibody (DFA) assay testing using the MeriFluor *Cryptosporidium*/*Giardia* test kit (Meridian Bioscience) to identify *Cryptosporidium* species. With the update to the interpretation software, this confirmatory testing is no longer necessary.

Questions: Please contact Jisun Haan at 651-201-5041, jisun.haan@state.mn.us

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