DEPARTMENT OF HEALTH

MLS Laboratory Update: MDH-PHL is offering confirmatory testing for *Cryptosporidium* on probable false positive specimens by BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel

NOVEMBER 22, 2022

Purpose of this Message:

This message is to inform clinical labs of false positive *Cryptosporidium* results on the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel caused by a non-specific amplification generated in the Crypt 2 assay, and that MDH-PHL is offering confirmatory testing.

Action Item:

For those laboratories using the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel:

- MDH recommends confirmatory testing on *Cryptosporidium*-positive specimens when only the Crypt 2 assay is positive.
    - MDH-PHL is offering confirmatory testing on specimens with a BIOFIRE® GI Panel result of *Cryptosporidium* detected that may be due to an erroneous software interpretation.
    - Review the interpretation for Crypt 1 and Crypt 2 assays for all *Cryptosporidium*-positive specimens and send stool specimens to MDH for confirmatory testing when **only the Crypt 2 assay is positive**.

Specimen Submission Information:

- Please submit stool specimens by filling in the “Parasitology” section on the submission form for the confirmation testing.
    - Source: Stool
    - Test Requested: Parasite ID/confirmation (CrypID) and leave the comment “only Cryp2 was positive on BioFire assay” in the comment section.
    - Shipping condition: Store stool specimens in transport media (Cary Blair, EcoFix, Enteric Plue, Formalin, TotalFix, Zn-PVA, unpreserved stool are accepted) and ship at refrigeration or ambient temperature.
    - Turnaround time: 1-3 business days

- If other reportable pathogens are co-detected (i.e, Salmonella, Campylobacter) along with a probable false positive *Cryptosporidium*, they need to be sent to MDH-PHL as well by filling "Reportable Disease" section on the submission form, as usual.

Background:

MDH-PHL alerted MLS laboratories about an increase in false positive test results of *Cryptosporidium* by BioFire in June of this year. (MLS Laboratory Update: Possible performance issues with BioFire FilmArray Gastrointestinal (GI) panel for Cryptosporidium spp., June 2022 (state.mn.us) bioMérieux has been investigating specimens obtained from the CDC in collaboration with the Association of Public Health Laboratories (APHL) and other state public health labs to identify the cause of false positive results. On November 15, 2022, bioMérieux notified customers of a previously unknown non-specific product that is being generated by the Crypt 2 assay that is erroneously interpreted as "positive" by the software.

Currently, bioMérieux is developing a software update to resolve the mis-interpretation issue, but the timeline for implementing the update will be contingent upon regulatory agency review. In the meantime, bioMérieux and CDC encourage clinical laboratory partners to communicate with local public health laboratories for alternative testing options for cases when only the Crypt 2 assay is positive. If clinical labs suspect a discordant result and need confirmatory testing, MDH-PHL can perform CLIA-validated Direct Fluorescent Antibody (DFA) assay testing using the Meridian Bioscience MeriFluor Cryptosporidium/Giardia test kit to identify *Cryptosporidium* species.

More information: bioMérieux client letter https://www.aphl.org/Materials/FS/bioMerieux-DX-REG-122060-01-CSN-2022-167-0-GI-FP-Crypt-US-Letter.pdf

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

Thank you for your attention to this important issue.

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