

Accession Number: A41539	ECRI Priority: High	Published: 11/20/2023
Channel: Devices	FDA: Not Specified	Last Updated: 11/20/2023
Maine Molecular Quality Controls—FilmArray BCID2 Control Panel M416: May Yield <i>Candida tropicalis</i> "Not Detected" Results When Testing BIOFIRE Blood Culture Identification 2 Panels		

Product Identifier(s)

[Consumable]

Product	Maine Molecular Quality Controls Inc Part No.
MMQCI FilmArray BCID2 Control Panels	M416

Manufacturer(s)

Maine Molecular Quality Controls Inc , 23 Mill Brook Rd, Saco, ME 04072, United States

Problem

In a November 1, 2023, Customer Bulletin letter submitted by an ECRI member hospital, Maine Molecular Quality Controls (MMQCI) states that the above panels, when used with the BIOFIRE BCID2 Panel, may yield *Candida tropicalis* "Not Detected" results. FilmArray BCID2 Negative Control included in the FilmArray BCID2 Control Panel M416 is not affected by the problem.

MMQCI also states that bioMerieux determined that there has been a small, systematic increase in melting temperatures observed across the BIOFIRE BCID2 Panel because of years of BIOFIRE panel and instrument manufacturing process improvements. As a result, in some portion of test runs using the FilmArray BCID2 Positive Control, the *C. tropicalis* is amplified but reported as "Not Detected" because the melting temperature (T_m) of the assay amplicon falling outside the acceptable limit assigned to the assay for calling positive results. The design of the synthetic external quality control material in the MMQCI Panel results in a *C. tropicalis* amplicon with a higher T_m than that observed for cultured isolates and clinical specimens. The *C. tropicalis* in patient samples is currently being detected correctly, and the M416 positive control is performing as expected.

Action Needed

Identify any affected product in your inventory. If you have any affected product in your inventory, verify that you have received the November 1, 2023, Customer Bulletin letter from MMQCI. Until the investigation is completed, MMQCI will temporarily provide a single-plex *C. tropicalis* control that results in a T_m within range of the assay. This control will be available at no charge. This product, *Candida tropicalis* Positive Control M417-1, is intended for in vitro analytical testing and is provided for research use only. If a "Not Detected" result is reported for *C. tropicalis* when testing the FilmArray BCID2 positive control, contact MMQCI to request a *Candida tropicalis* Positive Control M417-1 kit free of charge. Notify all relevant personnel at your facility of the information in the letter.

For Further Information:

Maine Molecular Quality Controls

Tel.: (207) 885-1072

E-mail: info@mmqci.com

Website: [Click here](#)

UMDNS Term(s)

IVD Test Reagent/Kits, Microbiology, Bacteria, Blood Culture Media [19493]

Geographic Region(s)

Europe, U.S.

Suggested Distribution

Clinical Laboratory/Pathology, Materials Management

Comment

- For information on a related action, see [Alert A41418](#).
- This alert is a living document and may be updated when ECRI receives additional information.