**Planned Deviation Documentation**

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| Site(s): | Shady Grove Medical Center and White Oak Medical Center | | | |
| Procedure: | BioFire FilmArray Blood Culture Identification 2 (BCID2) Panel | | | |
| Reason for Deviation: | **Medical Device Correction: FSCA 5788**  “Potential for *Candida tropicalis* ‘Not Detected’ results when testing the MMQCI FilmArray BCID2 Control Panel M416 with the BIOFIRE Blood Culture Identification 2 (BCID2) Panel”  BioMerieux has received reports of *C. tropicalis* ‘Not Detected’ results when testing the BIOFIRE Blood Culture Identification 2 (BCID2) Panel (part number: RFIT-ASY-0147) with Maine Molecular Quality Controls, Inc (MMQCI) FilmArray BCID2 Control Panel M416.  There is no impact on the detection of Candida tropicalis nucleic acid from patient samples and there is no identification that the BIOFIRE BCID2 Panel is functioning out of specification with clinical specimens.  Corrective Action: If the positive QC (M416), which includes all 43 targets within the BCID2 panel, fails to detect the *Candida tropicalis* target (e.g: results are “not detected”), QC testing should be repeated with the alternate positive QC - specific for *Candida tropicalis* (Maine Molecular Quality Controls, Candida tropicalis Positive Control M417-1).  Candida tropicalis patient results will be “held” or “hidden” from patient samples until the C. tropicalis QC material is within acceptable limits. | | | |
| Medical Director or Designee: | Dr. Nicolas Cacciabeve / Dr. Vittal Ponraj | | Date: 12/12/23 | |
| Supervisor: | Hollie Genser / Zanetta Morrow | | Date:12/12/23 | |
| Deviation Start Date: | 12/12/23 | | Deviation End Date: | |
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| Testing Personnel Signatures | Start Deviation Signatures |  | End Deviation Signatures |  |
| Printed Name / Tech Code | Signature | Date | Signature | Date |
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| *See Documentation in MTS* |  |  |  |  |
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