STRECK

Executive Summary

Streck has developed FDA-cleared external positive controls for the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel that are designed to closely resemble a patient sample in terms of appearance, composition and performance. Containing intact red blood cells and bacteria as well as culture media, MDx-Chex™ for BCID2 will verify the full range of the instrument, effects of PCR inhibitors and preanalytical variables. These features offer increased compliance with CAP and CLSI guidelines when compared to controls currently available on the market.

The following table displays the differences between the Streck control versus currently available controls.

Benefits of MDx-Chex for BCID2 over other available controls

	Streck	Competitor A	Competitor Z
Preanalytical Variables			
Sample tracking (via barcode)◆	Yes	No	No
Controls technician sample handling	Yes	No	No†
Instrument Variables			
Lysis			
Contains non-infectious intact organisms	Yes	No	Yes
Contains human RBCs and WBCs	Yes	No	No
Lyses all panel organisms	Yes	No	Yes*
Nucleic Acid Isolation and Purification	Yes	No	No
Patient-like sample matrix	Yes	No	No
PCR Inhibitors			
RBCs (i.e., hemoglobin)	Yes	No	No
WBCs (i.e., interleukin, human genomic DNA)	Yes	No	No
Culture media chemicals	Yes	No	No
PCR Amplification Specificity			
All targets present	Yes	Yes	Yes*
Off target (human gDNA) present	Yes	No	No
Detection			
All DNA targets	Yes❖	Yes	Yes*

† Requires pooling of multiple components, not part of patient sample testing workflow
* If all panel organisms are pooled
◆ Barcode allows the control lot number, expiration date and level to be captured in the software
❖ Streck control will contain all DNA targets for the new BIOFIRE BCID2 panel available now