Quality Control Materials for use with BD MAX System

Vircell MDR-TB Panel Validation Report

This report summarizes the results of the validation of the **AmpliRun® TOTAL MDR-TB Verification & Control Panel** for use with the **BD Max™ MDR-TB assay**.

AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL (SPUTUM)

Cat. No. MBTC027

Inactivated *Mycobacterium tuberculosis* (MTB) cells formulated to mimic human sputum specimen and intended to control sample processing, analysis and detection of *Mycobacterium tuberculosis* (TB) nucleic acids and genetic markers for drug resistant using the product as an external run control. MBTC027 panel is a 5-member panel; 1 sensitive, 2 RIF strains harboring rpoB mutations (S531L) and (H526D) that confers rifampicin resistance and 2 INH strains harboring a katG mutation (S315T) and inhA mutation (C15T) that confers isoniazid resistance.

Panel Member and Expected BD Max™ MDR-TB Assay Results:

Vircell Panel Members	Expected BD MAX result
VIRCELL TOTAL MTB CONTROL (SPUTUM)	MTB detected, RIF/INH Resistance NOT detected
VIRCELL TOTAL MTB RIF RESISTANT (531) CONTROL (SPUTUM)	MTB detected, RIF Resistance Detected, INH Resistance NOT Detected
VIRCELL TOTAL MTB RIF RESISTANT (526) CONTROL (SPUTUM)	MTB detected, RIF Resistance Detected, INH Resistance NOT Detected
VIRCELL TOTAL MTB INH RESISTANT (katG) CONTROL (SPUTUM)	MTB detected, RIF Resistance NOT Detected, INH Resistance Detected
VIRCELL TOTAL MTB INH RESISTANT (inhA) CONTROL (SPUTUM)	MTB detected, RIF Resistance NOT Detected, INH Resistance Detected

Summary of Execution and Study Design

Tested three unique batches of AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL and all five strains in each batch. Tested 12 replicates total across three panel batches per strain. Performed test with two MAX operators assigned to two MAX platforms. Tested two different BD MAX MDR-TB assay reagents across both BD MAX platforms.
Location: BD Life Sciences. 54 Loveton Circle. Sparks, MD 21225. USA

Results Summary and Data Analysis

The Percent Positive Agreement (PPA) was determined as follows:
100 x TP/(TP+FN) where TP=True Positive as defined by Vircell identification and FN=False Negative defined as MAX result not matching AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL strain identification.

Vircell Strain/Batch	MAX Lot 1 (x 2 users)			MAX Lot 2 (x 2 users)			Total N	PPA
	1	2	3	1	2	3		
1	2	2	2	2	2	2	12	12/12=100%
2	2	2	2	2	2	2	12	12/12=100%
3	2	2	2	2	2	2	12	12/12=100%
4	2	2	2	2	2	2	12	12/12=100%
5	2	2	2	2	2	2	12	12/12=100%

The PPA for each of the 5 strains in the AmpliRun® TOTAL MDR-TB Verification & Control Panel is 100% with BD Max MDR-TB assay.

The **BD MAX™ System** for molecular diagnostics is the next generation platform which fully automates cell lysis, nucleic acid extraction, PCR set-up, amplification and detection.

vircell MICROBIOLOGISTS

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