Reproducibility of bioMérieux VITEK MS for Identification of Bacteria and Yeasts

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ABSTRACT

Background: VITEK® MS* is a bacterial and fungal identification system which uses the matrix-assisted laser desorption / ionization time of flight (MALDI-TOF) mass spectrometry method. Results are provided within minutes and must be accurate and reproducible.

Methods: In this study, two technologists at three different laboratories tested 10 blind-coded samples (R1 – R10) in duplicate on each of 5 days on the VITEK MS. For each day of testing, samples were positioned on the disposable slide in sequential order by sample number, and randomly positioned. Samples included isolates of Gram-positive and Gram-negative aerobic bacteria and yeasts. Three different lots of slides (VITEK MS-DS), α-cyano-4-hydroxycinnamic acid matrix (VITEK MS-CHCA) and formic acid (VITEK MS-FA) were used during testing. Each site collected 20 results for each reproducibility organism, for a total of 60 results per strain. **Results:** Results ranged from 98.3% (59/60) - 100% (60/60), with combined agreement at 99.7% (598/600).

Conclusions: This study showed the VITEK MS to be an accurate and reproducible method for organism identification.

*The VITEK MS has not been cleared for clinical use by the United States FDA

INTRODUCTION

The bioMérieux VITEK MS is a microbial identification system utilizing MALDI-TOF MS to identify bacteria and yeasts from culture. VITEK MS provides an identification based on the dynamics of ions projected by laser shots and high voltage acceleration into a vacuum flight tube. The resulting spectrum of mass distribution is interpreted according to a knowledge base and proprietary algorithm developed by bioMérieux.

The study objective was to evaluate microorganism identification reproducibility by testing a panel of representative microorganisms over 5 days on three systems at three different sites.

MATERIAL AND METHODS

System reproducibility was determined by testing 10 blind-coded organisms on each of 5 days, with two runs per day and two replicates of each sample per run. Two technologists at three sites performed the reproducibility testing. The panel of reproducibility organisms included Gram-positive and Gram-negative bacteria and yeast isolates (Table 1). Identification of the reproducibility organisms was confirmed by sequencing (16S for bacteria and 26S for yeasts).

18-72 h TSAB for bacteria and SDA for yeasts) at 35-37C → VITEK MS-DS target

Bacteria → Spot, add 1 µl VITEK MS-CHCA, dry, load

Yeasts → Spot, add 0.5 µl VITEK MS--FA, dry; add 1 µl VITEK MS-CHCA, dry, load

Figure 1: Sample Preparation

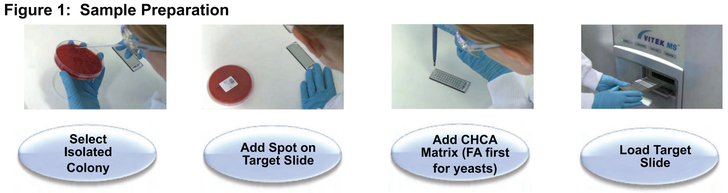
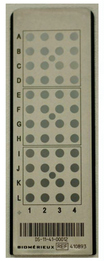


Table 1: Organisms

#	Species
R1	*Enterobacter aerogenes*
R2	*Escherichia coli*
R3	*Klebsiella pneumoniae*
R4	*Proteus mirabilis*
R5	*Pseudomonas aeruginosa*
R6	*Staphylococcus aureus*
R7	*Streptococcus agalactiae*
R8	*Klebsiella oxytoca*
R9	*Candida albicans*
R10	*Candida glabrata*

Figure 2: Disposable Slide (VITEK MS-DS)

- **Barcoded for traceability and easy use**
- **Three acquisition groups per slide**
  - ✓ 16 samples per group
- **Calibration spot for each acquisition group**
  - ✓ Verifies correct operation (tuning, alignment, etc.)
- **No cleaning required**



Each day of testing, samples were positioned on the VITEK MS-DS in sequential order by sample number (e.g., R1, R1, R2, R2, etc.) by one technologist, and tested a second time in random order by a second technologist (Table 2). Three different lots of VITEK MS-DS, VITEK MS-CHCA and VITEK MS-FA were alternated throughout testing (Table 3.

Table 2: Randomization of Target Positions

	1	2	3	4
A	R2	R3, R2	R1	R8
B	R5	R2	R9	R3
C	R9	R4	R10	R1
D	R7, R7	R1, R7	R9, R6, R1	R6, R5, R5
E	R3, R10, R9	R5, R8, R3	R10, R3, R3	R4, R6, R6
F	R3, R4, R2	R9, R1	R8, R7	R5, R7
G	R8, R8	R2, R10, R10	R6, R4, R4	R7, R4, R9
H	R4, R10, R5	R2, R5, R1	R5, R10, R8, R6	R7, R1, R6, R8
I	R5, R2, R6	R6, R9, R7	R1, R8	R8, R3
J	R10, R9	R9, R1	R6, R2	R4, R7
K	R4, R4	R2, R3	R9, R10	R8, R5
L	R7, R2	R3	R10	R1

Table 3: VITEK MS Reagents

Day	Sample #s	Run #1	Run #2
1	R1-R10	Technologist 1 – 2 replicates, lot 1	Technologist 2 – 2 replicates, lot 2
2	R1-R10	Technologist 2 – 2 replicates, lot 3	Technologist 1 – 2 replicates, lot 1
3	R1-R10	Technologist 1 – 2 replicates, lot 2	Technologist 2 – 2 replicates, lot 3
4	R1-R10	Technologist 2 – 2 replicates, lot 1	Technologist 1 – 2 replicates, lot 2
5	R1-R10	Technologist 1 – 2 replicates, lot 3	Technologist 2 – 2 replicates, lot 1

*Lots 1, 2 & 3 were unique lots of VITEK MS-CHCA, -FA and -DS

RESULTS

Results were viewed using Myla software and displayed as good identification, low discrimination (one or more identification choices) or no identification

Table 4: Results by Individual Organism and All Organisms Combined

Sample	Species	Day					Total (X%)
		1	2	3	4	5	
R1	*E. aerogenes*	12-Dec	12-Dec	12-Dec	12-Dec	12-Dec	60/60 (100.0%)
R2	*E. coli*	12-Dec	12-Dec	12-Dec	12-Dec	12-Dec	60/60 (100.0%)
R3	*K. pneumoniae*	12-Dec	12-Dec	12-Dec	12-Dec	12-Dec	60/60 (100.0%)
R4	*P. mirabilis*	12-Dec	12-Dec	12-Dec	12-Dec	12-Dec	60/60 (100.0%)
R5	*P. aeruginosa*	12-Dec	12-Dec	12-Dec	12-Dec	12-Dec	60/60 (100.0%)
R6	*S. aureus*	12-Dec	12-Dec	12-Dec	12-Dec	12-Dec	60/60 (100.0%)
R7	*S. agalactiae*	12-Dec	12-Dec	12-Dec	12-Dec	12-Dec	60/60 (100.0%)
R8	*K. oxytoca*	12-Dec	12-Dec	12-Dec	12-Dec	12-Dec	60/60 (100.0%)
R9	*C. albicans*	12-Dec	12-Dec	12-Nov	12-Dec	12-Dec	59/60 (98.3%)
R10	*C. glabrata*	12-Dec	12-Dec	12-Nov	12-Dec	12-Dec	59/60 (98.3%)
	Total	**120/120**	**120/120**	**118/120**	**120/120**	**120/120**	**598/600 (99.7%)**

One replicate of sample R9, *Candida albicans*, at one site on day-3 of testing, and one replicate of sample R10, *Candida glabrata*, at another site on day-3 of testing, gave a result of No ID from Myla due to no identification. All other results showed a good identification.

CONCLUSION

This study showed the VITEK MS to be an accurate and reproducible method for organism identification with a very high overall agreement rate of 99.7%.