Paper # **C-022**

A Retrospective Examination of Mycobacteria Recovery Rates from the VersaTREK® Automated Microbial Detection System and the MGIT® 960

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ABSTRACT

Background: A split clinical specimen side by side evaluation does not exist comparing the performance of the VersaTREK (VT) System versus the BACTEC® MGIT 960 (MGIT) for the detection of mycobacteria. Therefore, a retrospective analysis of mycobacterial data for 12 consecutive months and comparative cost analysis was performed at Rhode Island Hospital (RIH).
Methods: A retrospective analysis compared VT performance to the previous MGIT system for the same calendar months. Parameters assessed for each system included; total number of mycobacteria cultures tested, percent positivity rates, recovery rates, time to detection range comparisons (TTD) and smear results for *Mycobacteria tuberculosis* (*Mtb*) and *Mycobacterium avium* complex (MAC), additional mycobacterial species recovered, specimen types yielding positive *Mtb* cultures, and cost analysis.
Results: Total number of mycobacterial cultures tested using the VT and MGIT system were 3,651 and 2,999, respectively. Overall, mycobacterial positivity rates were equivalent; 3.0% for both VT and MGIT. In the timeframe studied, VT recovered more *Mycobacterium avium* complex (MAC) and mycobacteria other than tuberculosis (MOTT) compared to MGIT including; *M. marinum (4), M. lentiflavum (1),* SAV group (2), *M. chelonae (9)* and *M. nebraskense (2).* VT recovered 26 *Mycobacteria tuberculosis* (*Mtb*) isolates from 12 patients and 54 MAC isolates from 33 patients from a variety of specimen sites, including tissue. MGIT recovered 20 *Mtb* isolates from 6 patients and 45 MAC isolates from 27 patients all from respiratory sites with the exception of one urine. VT TTD (days) for *Mtb* and MAC per patient versus MGIT was 16.7, 11.6, and 13.1, 15.8 respectively. Additionally, VT demonstrated a 21% cost savings for RIH compared to MGIT.
Conclusions: While not a split sample side by side evaluation, the retrospective data allows interpretation. VT was equivalent to MGIT when accessing total mycobacteria positivity rates for specimens submitted. This was in the context of decreased *Mtb* reported from other sites in the state at the time of VT implementation. Interestingly, the VT system detected a great diversity of atypical mycobacteria as well as *Mtb* from multiple specimen types compared to MGIT increasing the probability of overall recovery. Additional benefits of the VT system are the simplicity of one medium and instrument for all sample types, including blood. While costs vary between healthcare settings, hospitals converting to VT should recognize an overall cost savings.

INTRODUCTION

Publications comparing the performance of the VersaTREK Automated Microbial Detection System (VT) (TREK Diagnostic Systems, Cleveland, Ohio, USA) to the MGIT 960 (MGIT) (Becton Dickenson, Sparks, Maryland, USA) do not exist. Therefore, a retrospective analysis was performed to evaluate total mycobacteria recovery rates per system, mycobacterial species recovered, time to detection comparisons (TTD) and cost analysis.

The retrospective study was performed at Rhode Island Hospital, a 719 bed teaching facility that converted to VersaTREK from MGIT. The same calendar months were assessed during the evaluation to rule out potential outliers.

Two main differentiators exist between the VersaTREK and MGIT systems. First, VersaTREK's technology detects pressure changes within the headspace of the VersaTREK mycobacteria bottle. Because Mycobacteria are typically oxygen consumers, the VersaTREK monitors a decrease in pressure because of microbial gas consumption. Conversely, MGIT media contains an oxygen quenched fluorochrome that fluoresces when free oxygen is utilized during bacterial growth. Secondly, the VersaTREK system is able to detect mycobacteria from any specimen type including blood and urine. The MGIT system is not able to detect mycobacteria from blood or urine mycobacteria samples; a separate system is required.

METHODS

Rhode Island Hospital conducted a retrospective analysis comparing VT mycobacteria performance to the previous MGIT system for 12 months. Parameters assessed for each system included; total number of mycobacteria cultures tested, percent positivity rates, *Mtb* recovery and number of isolates per patient, *Mtb* time detection comparisons (TTD) and smear results, MAC recovery and number of isolates per patient, MAC time detection comparisons (TTD) and smear results, additional mycobacteria species recovered, specimen types, and cost analysis. Contamination rates could not be obtained for the MGIT system and therefore, this parameter was not included in the evaluation. Media utilized for the VT system consisted of the VT Mycobacteria media; the MGIT tube was used with the MGIT system. The decontamination method used with the VT was Alpha-Tec; MycoPrep was used with the MGIT. Both decontamination methods use 3% NaOH with NALC.

Table 1. Total Number of Mycobacteria Cultures and Positivity Rates

	VersaTREK	MGIT
No. Cultures Tested	3,651	2,999
Positivity Rate	3.1%	2.7%
Mtb Recovery	26;12 patients	20;6 patients
Mtb TTD (days)	16.7	13.1
MAC Recovery	54;33 patients	45;27 patients
MAC TTD (days)	11.6	15.8

Table 2. *Mycobacteria* species Recovered Per System

	VersaTREK	MGIT
M. abscessus	√	√
M. chelonae	√	
M. duvalii		√
M. fortuitum	√	√
M. gordonae	√	√
M. lentiflavum	√	
M. marinum	√	
M. nebraskense	√	
M. species	√	√
M. terrae	√	
SAV Group	√	

RESULTS

Table 3. Positive and Negative Smear Results for *Mtb* for VT and MGIT by Patient

POSITIVE SMEAR DATA

VERSATREK				MGIT			
Patient Designation	No. of Isolates	TTD (Days)	Range	Patient Designation	No. of Isolates	TTD (Days)	Range
VT4	1	4.1		M3	4	20, 9, 9, 8	8-20
VT5	1	14.7		M5	1	6	
VT6	5	15.5, 22, 22, 18, 17.9	15.5-22				
VT8	1	12					
VT9	2	11.3, 12	11.3-12				

NEGATIVE SMEAR DATA

VERSATREK				MGIT			
Patient Designation	No. of Isolates	TTD (Days)	Range	Patient Designation	No. of Isolates	TTD (Days)	Range
VT1	3	15.7, 16, 13	13-16	M1	2	29, 18	18-29
VT2	1	38		M2	3	22, 18, 13	13-22
VT3	2	12, U*		M4	1	11	
VT4	2	26, 18	18-26	M5	1	8	
VT7	1	6.8		M6	8	16, 11, 16, 15, 14, 14, 19, 18	11-19
VT9	1	20					
VT10	2	30, 28	28-30				
VT11	2	38, 38.1	38-38.1				
VT12	2	20, 6.7	6.7-20				

*TTD unknown

Table 4. Positive and Negative Smear Results for MAC for VT and MGIT by Patient

POSITIVE SMEAR DATA

VERSATREK				MGIT			
Patient Designation	No. of Isolates	TTD (Days)	Range	Patient Designation	No. of Isolates	TTD (Days)	Range
VT1	1	2.5		M5	2	5, 4	4-5
VT2	1	10		M7	1	17	
VT8	3	10, 14, 7.9	7.9-14	M10	1	7	
VT9	1	4.6		M21	1	3	
VT14	3	5.5, 10, 6.1	5.5-10	M22	1	4	
VT25	3	4.8, 6.8, 6	4.8-6.8	M24	2	13, 13	
VT26	1	10.4					

NEGATIVE SMEAR DATA

VERSATREK				MGIT			
Patient Designation	No. of Isolates	TTD (Days)	Range	Patient Designation	No. of Isolates	TTD (Days)	Range
VT3	2	22, 8.9	8.9-22	M1	2	21, 46	21-46
VT4	1	8.9		M2	1	11	
VT5	1	8		M3	1	50	
VT6	1	15		M4	1	12	
VT7	1	11		M6	1	35	
VT10	1	14.8		M7	2	35, 11	11-35
VT11	1	14		M8	1	23	
VT12	1	16		M9	1	7	
VT13	1	7.5		M11	2	10, 11	
VT14	1	12		M12	1	15	
VT15	2	8.5, 8	8-8.5	M13	5	11, 13, 19, 7, 13	7-19
VT16	1	6.5		M14	1	42	
VT17	4	12, 11, 7.4, 18	7.4-18	M15	1	32	
VT18	1	24		M16	1	18	
VT19	1	15.1		M17	6	10, 16, 22, 15, 15, 19	10-22
VT20	2	5.7, 12	5.7-12	M18	1	9	
VT21	3	12, 11.3, 20	11.3-20	M19	1	14	
VT22	3	36, 12, 16	12-36	M20	2	9, 9	
VT23	1	9.6		M22	1	9	
VT24	1	30		M23	1	44	
VT26	1	9.8		M25	2	6, 2	2-6
VT27	3	10.1, 7.6, 6.6	6.6-10.1	M26	1	7	
VT28	2	12, 12		M27	1	6	
VT29	1	26					
VT30	1	16					
VT31	1	10.9					
VT32	1	18.9					
VT33	1	12					

RESULTS

1. Table 1 displays a summary of the retrospective data analyzed. Parameters include; total number of mycobacteria cultures tested per each system and positivity rates.
2. Positivity rates for mycobacteria were equivalent for VT (≤0.4% difference) compared to MGIT. Total positivity rates for VT compared to MGIT were 3.1% and 2.7%, respectively.
3. Mycobacteria species recovered in the VT and MGIT systems are shown in Table 2. VT recovered more mycobacteria other than *Mtb* (MOTT) and MAC compared to MGIT including; *M. marinum (4), M. lentiflavum (1),* SAV group (2), *M. chelonae (9)* and *M. nebraskense (2).*
4. VT recovered 26 *Mycobacteria tuberculosis* (*Mtb*) isolates from 12 patients and 54 MAC isolates from 33 patients. MGIT recovered 20 *Mtb* isolates from 6 patients and 45 MAC isolates from 27 patients.
5. VT overall average TTD (days) for *Mtb* and MAC per patient versus MGIT was 16.7, 11.6, and 13.1, 15.8 respectively. The overall average included both smear positive and smear negative results. Data was arranged into separate smear positive and smear negative results and TTD ranges between and amongst the samples was assessed (Table 3 and 4). Due to the large variability in TTD of strains within the same patient samples and the small number of data points, the overall TTD range for each organism provides the best assessment of system detection time performance in this analysis.
6. Table 3 displays the time to detection range for smear positive and smear negative *Mtb* for each system.
   - VT smear positive TTD range for *Mtb* was 4.1 – 22 days; 6-20 days for MGIT
   - VT smear negative TTD range for *Mtb* was 6.7 – 38 days; 8-29 days for MGIT
7. Table 4 displays the time to detection range for smear positive and smear negative MAC for each system.
   - VT smear positive TTD range for MAC was 2.5 - 14 days; 3-17 days for MGIT
   - VT smear negative TTD range for MAC was 5.7 – 36 days; 2 - 50 days for MGIT
8. A cost analysis performed at RIH demonstrated a 21% cost savings when converting to VT from MGIT.

DISCUSSION AND CONCLUSION

According to the World Health Organization it was estimated that 1.7 million deaths occurred in 2006 as a result of *Mycobacteria tuberculosis* (*Mtb*) infection[1]. In addition, over one-third of the world's population is infected with *Mtb*[2]. With the rise of MDR-TB and XDR-TB, rapid detection of *Mtb* as well as other Mycobacteria isolates is critical for effective patient management and treatment. Currently, three liquid systems are cleared by the FDA for mycobacteria testing; VT (TREK), MGIT (Becton Dickenson), and BacT/ALERT (bioMeriéux). Because a split sample side by side comparison does not exist for the VT and MGIT systems, a retrospective analysis of the two systems was performed comparing the same calendar months. A retrospective study allows for interpretation of instrument performance as well as identification of obvious benefits or discrepancies between the two systems.

In this analysis, VT was found to be equivalent to MGIT for total mycobacteria positivity rates for specimens submitted within a 12 month period. Interestingly, the VT system detected a greater diversity of atypical mycobacteria compared to MGIT as well as from a greater variety of specimen types. These groups of mycobacteria are seen in an increasing number of infections in the U.S. compared to the incidence of *M. tuberculosis.*

One of the disadvantages of a retrospective study is in the analysis of TTD. Samples can vary greatly in the amount of bioburden between samples from the same patient, and individual strain rate of growth can also vary greatly. In the study there were differences in times to detection observed for smear positive and negative samples, even from the same patient (Table 3 and 4) and large TTD ranges for the two systems for positive and negative smears. In addition, the number of patients in the study, especially for *Mtb* was very low. Thus, one large variation in TTD will skew the data. Because of this variation, only a side-by-side comparison of the same sample can determine any TTD advantages of one system compared to another.

The VT system offers additional benefits such as the simplicity of one medium and instrument for all sample types, including processed blood samples and urine. Additionally, the VT system offers easy-to-use windows-based software and for laboratories performing susceptibilities, both high and low level antibiotic susceptibility testing for *Mtb* are offered in the same kit. While costs will vary between healthcare settings, hospitals converting to VT should recognize an overall cost savings. In evaluating RIH the cost savings realized from converting to VT from MGIT was approximately 21%

REFERENCES

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