Clinical evaluation of IMMY MycoDDR™ Digestion/Decontamination Reagents for the Recovery of Mycobacterium

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INTRODUCTION

Tuberculosis (TB) is a serious disease that affects a significant portion of the world’s population and is one of the leading causes of death in developing countries. Proper digestion and decontamination of patient samples is a critical step in facilitating the diagnosis of TB. This study aimed to accelerate positive detection of mycobacteria through comparison of digestion and decontamination sample processing reagents. Of the 159 specimens, 10 tested positive for mycobacterium. Of the 10 positive samples processed using the MycoDDR™ (3.0% NaOH) system, positive results were obtained in equal or less time than the paired samples processed by the Alpha-Tec (3.0% NaOH) system. These data show that the use of IMMY’s MycoDDR™ system provides positive results approximately 1 day earlier on average than processing of samples with the NAC-PAC™ Red system (mean numbers of days to positive culture results: MycoDDR™: 8.4 days vs. NAC-PAC™ Red: 9.6 days). The remaining 2 positive samples were detected after processing with the MycoDDR™ system in an average of 26.6 days and remained negative in the paired samples using the Alpha-Tec system. Additionally, the MycoDDR™ system produced these results using less neutralization buffer to achieve the optimal pH than the NAC-PAC™ Red system.

ABSTRACT

Tuberculosis (TB) is a serious disease that affects a significant portion of the world’s population and is one of the leading causes of death in developing countries. Proper digestion and decontamination of patient samples is a critical step in facilitating the diagnosis of TB. This study aimed to accelerate positive detection of mycobacteria through comparison of digestion and decontamination sample processing reagents. Of the 159 specimens, 10 tested positive for mycobacterium. Of the 10 positive samples processed using the MycoDDR™ (3.0% NaOH) system, positive results were obtained in equal or less time than the paired samples processed by the Alpha-Tec (3.0% NaOH) system. These data show that the use of IMMY’s MycoDDR™ system provides positive results approximately 1 day earlier on average than processing of samples with the NAC-PAC™ Red system (mean numbers of days to positive culture results: MycoDDR™: 8.4 days vs. NAC-PAC™ Red: 9.6 days). The remaining 2 positive samples were detected after processing with the MycoDDR™ system in an average of 26.6 days and remained negative in the paired samples using the Alpha-Tec system. Additionally, the MycoDDR™ system produced these results using less neutralization buffer to achieve the optimal pH than the NAC-PAC™ Red system.

RESULTS

1) Positive Results are Obtained in Less Time and Without False Negatives with the MycoDDR™ Sample Processing System

(a) In 8 of the 10 positive samples processed using the MycoDDR™ (3.0% NaOH) system, positive results were observed in equal or less time than processing of samples using the Alpha-Tec system. Positive results were observed in an average of 8.4 days for the MycoDDR™ system compared to 9.6 days for the Alpha-Tec system.

(b) The MycoDDR™ (3.0% NaOH) system showed a 20% false negative rate. The remaining 2 positive samples were detected after processing with the MycoDDR™ (3.0% NaOH) system in an average of 26.6 days and remained negative in the paired samples using the Alpha-Tec system. The 143 samples were confirmed positive for MTB using molecular-based testing.

2) The MycoDDR™ Sampling Processing System Uses Less Neutralization Buffer to Achieve Optimal pH

(a) The MycoDDR™ (3.0% NaOH) system used approximately 50% less neutralization buffer compared to the Alpha-Tec (3.0% NaOH) system, resulting in reduced handling time and cost-effective processing.

(b) The initial pH of 5 mL simulated samples was recorded and then each sample was processed separately using the NAC-PAC™ Red System (grey), the MycoDDR™ system (blue), and the Alpha-Tec NAC-PAC™ Red system. The results showed that the MycoDDR™ system delivered greater clarity and quality than the Alpha-Tec NAC-PAC™ system.

3) The MycoDDR™ Sampling Processing System Provides True Positive Results Faster than the Alpha-Tec NAC-PAC™ Red System

(a) Of the 10 positive samples processed using the MycoDDR™ (3.0% NaOH) system, positive results were observed in equal or less time than processing of samples using the MycoDDR™ reagent set or the Alpha-Tec NAC-PAC™ Red system.

(b) The NAC-PAC™ Red (3.0% NaOH) system showed a 20% false negative rate. The remaining 2 positive samples were detected after processing with the MycoDDR™ (3.0% NaOH) system in an average of 26.6 days and remained negative in the paired samples using the Alpha-Tec system. The 143 samples were confirmed positive for MTB using molecular-based testing.

OBSERVATIONS & CONCLUSIONS

1. When acid fast bacilli smear and fluorochrome staining was performed on the paired processed samples, the MycoDDR™ reagent set delivered greater clarity and quality than the Alpha-Tec NAC-PAC™ system.

2. The ability to visualize neutralization in bloody samples was facilitated with the blue pH indicator provided in the MycoDDR™ reagent set.

3. The use of approximately 50% less neutralization buffer on average, with the use of the MycoDDR™ reagent set ultimate-ly results in a substantial cost savings.

In conclusion, this study demonstrates that the MycoDDR™ (3.0% NaOH) system is superior to the Alpha-Tec NAC-PAC™ Red (3.0% NaOH) system for the digestion and decontamination of patient samples for quicker positive detection of mycobacterium at a substantial cost savings.

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