Increased Detection of Bacterial and Fungal Pathogens in Culture Negative Specimens Using Universal Microbe Detection Assay Compared to Routine 16S and 28S Analyses in a Diagnostic Laboratory

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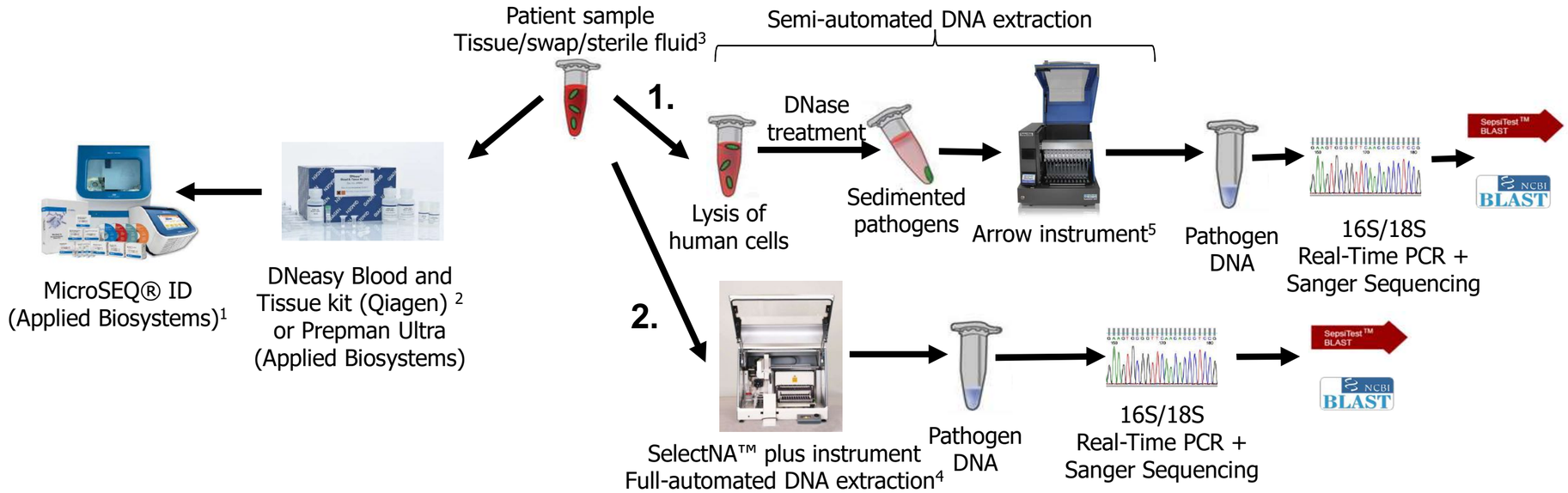
Background

Culturing is the gold standard for identifying bacterial and fungal pathogens. However, some pathogens are difficult to culture due to slow growth, strict growth requirements or previous antibiotic treatment. At our Department of Clinical Microbiology in a tertiary referral hospital, 16S and 28S analyses were implemented 6 years ago improving diagnostics, but the majority of the samples analysed are negative. The broad-range Universal Microbe Detection (UMD) SelectNA™ assay (Molzym, Germany) is based on the MolYsis™ technology where human DNA is removed prior to extraction. It has been demonstrated to have an increased detection rate compared to culture. We, therefore, wanted to evaluate the UMD assay for identification of bacteria and fungi in culture negative specimens and compare to the routine analyses in the Department. Recently, a new version of the assay, MicroDx™, with a full-automatic DNA extraction instrument was released by Molzym and we also tested this.



Method

Study 1 - UMD

81 culture negative samples (tissues, fluids and swaps) from patients suspected of having an infection were processed with both the UMD SelectNA™ kit (Molzym, Germany) and with our routine 16S and 28S analyses.

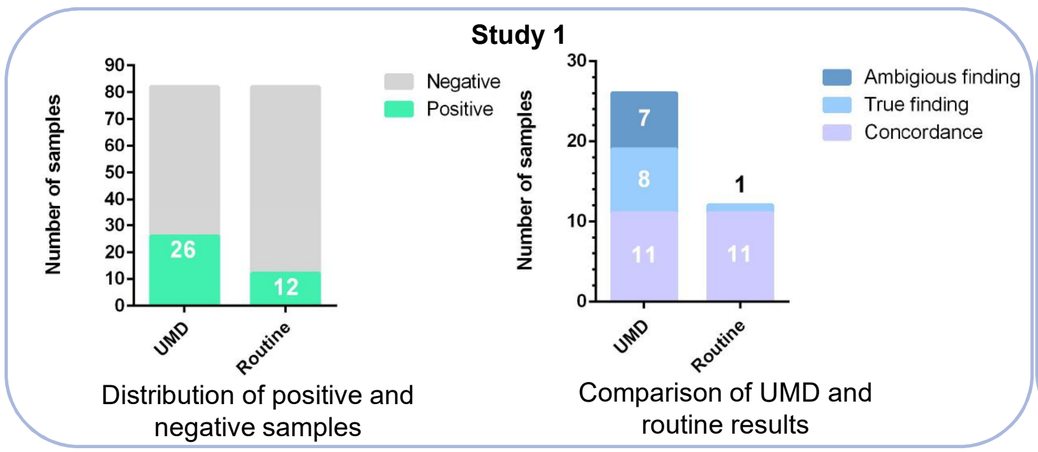
Study 2 - MicroDx

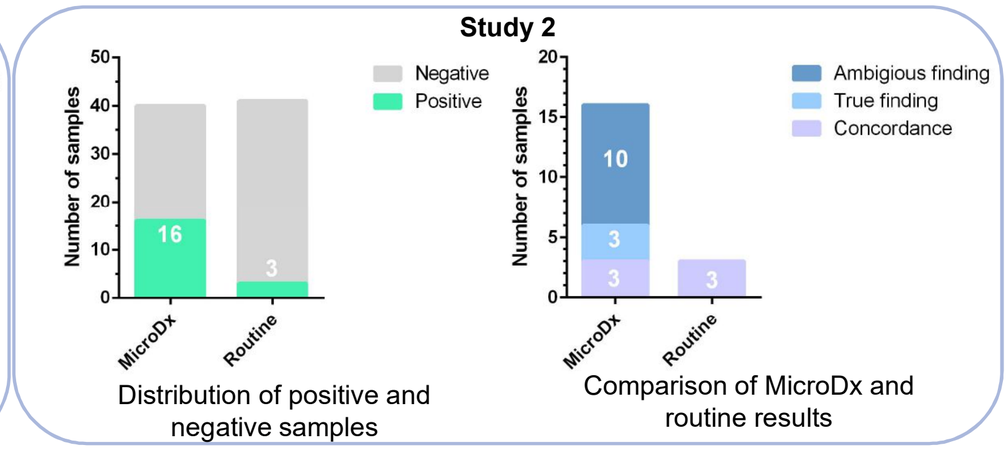
41 culture negative samples (tissues, fluids and swaps) from patients suspected of having an infection were processed with both the MicroDx™ (Molzym, Germany) and with out routine 16S and 28S analysis.

In both studies, the results of the two methods were compared to each other and to other findings from the patient, both molecular and culture. The results were divided into the three groups; 1) *concordance* between the methods 2) *true findings*: other findings from the patient confirmed the result, 3) *ambiguous findings:* the results were not confirmed by other findings

Results

Both the UMD SelectNA and the MicroDx assay demonstrated a higher positivity rate and identified more true findings than the routine analyses. Additionally, the UMD and the MicroDx identified bacterial and fungal species in samples where the results were not confirmed by other findings (ambiguous findings). Some of the identified species were possible pathogens according to literature, and others were most likely contaminants introduced during sampling or handling.





Conclusion

The UMD SelectNA and the MicroDx assay was found to be more sensitive than our routine 16S and 28S analyses for detecting relevant bacteria and fungi in culture negative clinical specimens. The assays also found bacterial and fungal species that could be the cause of the infection, but could also be a contaminant introduced somewhere in the sampling or handling of the specimen. Therefore, the increased sensitivity of the assays necessitates a thorough clinical evaluation of the patient's history in order to assess the relevance of the finding.

Pictures: 1,www.thermofisher.com 2, www.qiagen.com 3, www.bionity.com, 4 MicroDx Manual from Molzym, 5www.isogen-lifescience.com

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