

Order RD000-063-943



Patient: Jane Doe DOB: 01/01/1902 Gender: Female Provider: Albert C Domm
Practice: Lifetime Sciences Test

Account

4037 Rural Plains Circle,

Suite 150

Franklin, TN, 37064

 Specimen:
 Midstream Urine

 Identifier:
 SP000-063-922

 Collected:
 06/02/2022 02:17pm

 Received:
 06/02/2022 02:28pm

 Reported:
 06/03/2022 10:21am

Targets Not Detected					
Target	Туре	Result	Estimated Microbial Load		
Atopobium vaginae	Bacteria	Not Detected	Not Detected		
BVAB2	Bacteria	Not Detected	Not Detected		
Bacteroides fragilis	Bacteria	Not Detected	Not Detected		
Chlamydia trachomatis	Bacteria	Not Detected	Not Detected		
Enterococcus faecalis	Bacteria	Not Detected	Not Detected		
Escherichia coli	Bacteria	Not Detected	Not Detected		
Gardnerella vaginalis	Bacteria	Not Detected	Not Detected		
Haemophilus ducreyi	Bacteria	Not Detected	Not Detected		
Lactobacillus crispatus	Bacteria	Not Detected	Not Detected		
Lactobacillus gasseri	Bacteria	Not Detected	Not Detected		
Lactobacillus iners	Bacteria	Not Detected	Not Detected		
Lactobacillus jensenii	Bacteria	Not Detected	Not Detected		
Megasphaera 1	Bacteria	Not Detected	Not Detected		
Megasphaera 2	Bacteria	Not Detected	Not Detected		
Mobiluncus curtsii	Bacteria	Not Detected	Not Detected		
Mobiluncus mulieris	Bacteria	Not Detected	Not Detected		
Mycoplasma genitalium	Bacteria	Not Detected	Not Detected		
Mycoplasma hominis	Bacteria	Not Detected	Not Detected		
Neisseria gonorrhoeae	Bacteria	Not Detected	Not Detected		
Prevotella bivia	Bacteria	Not Detected	Not Detected		
Staphylococcus aureus	Bacteria	Not Detected	Not Detected		
Streptococcus agalactiae	Bacteria	Not Detected	Not Detected		
Treponema pallidum	Bacteria	Not Detected	Not Detected		
Ureaplasma urealyticum	Bacteria	Not Detected	Not Detected		
Candida albicans	Fungi	Not Detected	Not Detected		
Candida dubliniensis	Fungi	Not Detected	Not Detected		
Candida glabrata	Fungi	Not Detected	Not Detected		
Candida krusei	Fungi	Not Detected	Not Detected		
Candida lusitaniae	Fungi	Not Detected	Not Detected		
Candida parapsilosis	Fungi	Not Detected	Not Detected		
Candida tropicalis	Fungi	Not Detected	Not Detected		
Trichomonas vaginalis	Protozoan	Not Detected	Not Detected		







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Targets Not Detected (continued)				
Target	Туре	Result	Estimated Microbial Load	
Herpes Simplex 1	Viral	Not Detected	Not Detected	
Herpes Simplex 2	Viral	Not Detected	Not Detected	

Methodology

Total nucleic acid extraction is performed using DNA MagMax MVPII Kits, which are validated by their manufacturer to yield isolated nucleic acids of sufficient quantity and quality from the relevant sample types. Presence of either pathogenic nucleic acids and/or genetic markers documented to confer resistance to antimicrobial compounds was determined by conducting RT-PCR reactions with primers designed to target species-specific (or marker-specific) genomic regions. RT-PCR reactions were either conducted in single-reaction wells, or through OpenArray methodologies. Bacterial and fungal targets may be reported semi-quantitatively with microbial load estimates calculated based on Crt comparisons with controls of known concentrations. All sample runs contain a minimum of one negative extraction control (NEC), one negative template control (NTC), and one positive control of known pathogenic/ABX marker composition (PTC). All RT-PCR reactions are conducted using TaqMan chemistry from Thermo Fisher. Nucleic acid-based pathogen detection is performed on the QuantStudio 12K platform. This platform was designed by Applied Biosystems, Inc. and utilizes quantitative real-time PCR in conjunction with fluorescently-labelled nucleic acid probes. A DETECTED result signifies that amplification of genus, species, or marker-specific (dependent on the analyte) genetic markers was observed, based on validated detection metrics.

Disclaimer and Limitations

Nucleic acid-based pathogen detection (PD) is a laboratory-developed test (LDT) and as such, is not cleared by the FDA. Pathogen and antimicrobial marker screening at Lifetime Sciences does not screen for the presence of all pathogens documented to cause infections in the referenced tissues, nor every genetic markers documented to confer antimicrobial resistance. There may also be pathogens and resistance markers present that are not screened for nor previously documented. Nucleic acid-based pathogen detection analysis is intended to aid physicians in identifying underlying pathogens within a patient sample to help advise on possible treatment avenues. It should not be used in the contexts of diagnosis or supplant physician recommendations. These results should be interpreted along with clinical presentations and/or other laboratory results. These results and their clinical interpretations may not be accurate if the patient information/sample supplied is incomplete or inaccurate. If these results do not match clinical presentations, additional testing is recommended. The LDTs reported here were developed and had its performance metrics determined by Lifetime Sciences. Lifetime Sciences is certified under the Clinical Laboratory Improvements Act (CLIA) to perform high-complexity clinical laboratory testing. For other questions/concerns, please contact Lifetime Sciences.