Precision Microbio

Vaginitis PCR Lab Report

CLINIC INFORMATION	PATIENT INFORMATION		SPECIMEN INFORMATION	
Provider:	**Name:**	Yvette Jones	**Date Collected:**	9/7/2019
Dr. Smith	**DOB:**	11/2/1965	**Date Received by Lab:**	9/7/2019
	Gender:	Female	**Run Date:**	9/7/2019
			Date Reported:	9/7/2019
			Source:	SWAB

Controls

Patient Extraction Control $_1$	**PASS**
Endogenous Positive Control $_1$	**PASS**
Pathogen Positive Control $_2$	**PASS**
Pathogen Negative Control $_3$	**PASS**

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity

(2) Positive control is synthetic inactive pathogen.

(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.
Assay cutoff is represneted by CFU (bacteria), PFU (viruses) or Copy Number (DNA).

Test Performed	Lab Result (Qualitative)	
Vaginitis Pathogens		
A. vaginae	Not detected	
C. trachomatis	Not detected	
G. vaginalis	Not detected	
H. ducreyi	Not detected	
HSV-1	Not detected	
HSV-2	Not detected	
N. gonorrhoeae	Not detected	
T. pallidum	Not detected	
T. vaginalis	Not detected	
C. albicans	Detected - MEDIUM	
C. parapsilosis	Not detected	
C. krusei	Not detected	
C. lusitaniae	Not detected	
C. glabrata	Not detected	
C. dubliniensis	Not detected	
C. tropicalis	Not detected	
P. bivia	Not detected	
L. gasseri	Detected - LOW	
L. crispatus	Not detected	
L. iners	Not detected	
M. mulieris	Not detected	

Technician:

*This test detects the presence of pathogen and must be evaluated with clinical symptoms to/ diagnose disease. All test established and validated by Laboratory and not FDA approved.
Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.
Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed,r esulting in a false positive.
In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.

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Endogenous Positive Control $_1$	**PASS**	(2) Positive control is synthetic inactive pathogen.
Pathogen Positive Control $_2$	**PASS**	(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template
Pathogen Negative Control $_3$	**PASS**	(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff. Assay cutoff is represneted by CFU (bacteria), PFU (viruses) or Copy Number (DNA).

Test Performed	Lab Result (Qualitative)	
Vaginitis Pathogens		
M. curtisii	Not detected	
L. jensenii	Not detected	
BVAB-2	Not detected	
Megasphaera Type 2	Not detected	
Megasphaera Type 1	Not detected	
B. fragilis	Not detected	
E. faecalis	Not detected	
E. coli	Detected - MEDIUM	
M. genitalium	Not detected	
M. hominis	Not detected	
S. aureus	Not detected	
S. agalactiae (GBS)	Not detected	
U. urealyticum	Detected - MEDIUM	

Technician: David Ray

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Lab Director: Dr. Lab