

Name TEST PATIENT		Req Form # 2411131	Collected 01/05/2023	Client Test Client
Gender Female	Date of Birth 01/01/2000	Accession # 2411131	Received 01/06/2023	Address 111 First Street, Anywhere USA 12345
Patient ID 1284564	Race Unknown	Specimen Type Vaginal Swab	Report Date 01/06/2023	Ordering Provider John Smith, MD
Ordered Test(s):		Complete Vaginosis Panel + Antibiotic Resistance (AST) Complete Sexually Transmitted Infections (STI) Panel		
Disclosed Antibiotic(s):		None Disclosed		

Detected Vaginosis Pathogens:	Candida albicans (2x10 ⁶ Orgs/mL) , Gardnerella vaginalis (1.1x10 ⁸ Orgs/mL) , Prevotella bivia (1.6x10 ⁷ Orgs/mL)
Detected STI Pathogens:	None Detected

Specimen Validity			
Control Name	Measured Value	Reference Value	Evaluation
RNAse P	323470 cp/mL	> 10000 cp/mL	Valid

Comments
Antibiotic susceptibility testing is currently available only for Aerobic Vaginosis pathogens

Real Time PCR Pathogen Results					
Bacterial Vaginosis	Organisms/mL **	Cutoff	Protozoa	Organisms/mL **	Cutoff
Atopobium vaginae	Not Detected	1 x 10 ⁵	Trichomonas vaginalis	Not Detected	1 x 10 ⁴
Bacteroides fragilis	Not Detected	1 x 10 ⁵	Mycoplasmataceae	Organisms/mL **	Cutoff
BVAB2	Not Detected	1 x 10 ⁵	Mycoplasma genitalium	Not Detected	1 x 10 ⁴
Gardnerella vaginalis	1.1x10⁸	1 x 10⁶	Mycoplasma hominis	Not Detected	1 x 10 ⁴
Megasphaera 1	Not Detected	1 x 10 ⁵	Ureaplasma urealyticum	Not Detected	1 x 10 ⁴
Megasphaera 2	Not Detected	1 x 10 ⁵	STI Bacteria	Organisms/mL **	Cutoff
Mobiluncus curtisii	Not Detected	1 x 10 ⁵	Chlamydia trachomatis	Not Detected	1 x 10 ⁴
Mobiluncus mulieris	Not Detected	1 x 10 ⁵	Neisseria gonorrhoeae	Not Detected	1 x 10 ⁴
Prevotella bivia	1.6x10⁷	1 x 10⁵	STI Virus	Organisms/mL **	Cutoff
Lactobacilli	Organisms/mL **	LOD ‡	Herpes Simplex Virus	Not Detected	1 x 10 ⁴
Lactobacillus crispatus	Not Detected	1 x 10 ⁵	Aerobic Vaginosis	Organisms/mL **	Cutoff
Lactobacillus gasseri	Not Detected	1 x 10 ⁵	Enterococcus faecalis	Not Detected	1 x 10 ⁵
Lactobacillus iners	9.2x10 ⁷	1 x 10 ⁵	Escherichia coli	Not Detected	1 x 10 ⁵
Lactobacillus jensenii	Not Detected	1 x 10 ⁵	Staphylococcus aureus	Not Detected	1 x 10 ⁵
			Streptococcus agalactiae (group B)	Not Detected	1 x 10 ⁵
			Fungal Vaginosis	Organisms/mL **	Cutoff
			Candida albicans	2x10⁶	1 x 10⁵
			Candida dubliniensis	Not Detected	1 x 10 ⁵
			Candida glabrata	Not Detected	1 x 10 ⁵
			Candida krusei	Not Detected	1 x 10 ⁵
			Candida lusitaniae	Not Detected	1 x 10 ⁵
			Candida parapsilosis	Not Detected	1 x 10 ⁵
			Candida tropicalis	Not Detected	1 x 10 ⁵

** Organisms/mL (Orgs/mL) are based on the calculation of target genes detected. One genome equivalent is theoretically equal to one organism.

‡ LOD is the Limit of Detection.

Disclaimer: This assay is designed to detect unique viral/microbial genes. A Negative result does not preclude the possibility of infection since the adequacy of sample collection

and/or low viral/microbial burden may result in the presence of nucleic acids below the analytical sensitivity of this test method. Test results should be used along with other clinical and laboratory data in making the diagnosis. This test was developed and its performance characteristics determined and validated by Real Diagnostics. The FDA has not approved or cleared this test. However, FDA clearance or approval is not currently required for clinical use. The results are intended to be used only for clinical diagnosis.

Questions including Clinical Consultation on Results: Email lab@realdxlabs.com