

Certificate of Analysis

Product Description: AccuTrak™ TV/MG Verification Panel
 Material Number: 2400-0246
 Batch Number: 10671601
 Storage Temperature: 2° – 8°C
 Expiration Date: 30 JUN 2025

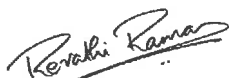
Contents: Contains cultured *Trichomonas vaginalis* (strain C-1: NIH) and *Mycoplasma genitalium* (strain G37) microorganisms that are diluted in a viral transport media.

QC Testing: Digital PCR (dCPR) using BioRad QX200™ Droplet Digital™ PCR System and primer/probe design targeting the negative regulation of protein localization to nucleolus gene region for *Trichomonas vaginalis* and rpoA gene for *Mycoplasma genitalium*. Qualitative testing used Abbott Alinity m STI assay for testing TV and MG.

Member	Nominal Concentration (copies/mL)	dPCR Result (copies/mL)	Abbott Alinity m STI Assay Result
<i>T. vaginalis</i> High – Member 1	1.00E+05	TV: 1.10E+05	TV Detected MG Not Detected
<i>T. vaginalis</i> Med – Member 2	1.00E+04	Not Tested, 1:10 Dilution of Member 1	TV Detected MG Not Detected
<i>T. vaginalis</i> Low – Member 3	1.00E+03	Not Tested, 1:10 Dilution of Member 2	TV Detected MG Not Detected
<i>M. genitalium</i> High – Member 4	1.00E+05	MG: 1.04E+05	TV Not Detected MG Detected
<i>M. genitalium</i> Med – Member 5	1.00E+04	Not Tested, 1:10 Dilution of Member 4	TV Not Detected MG Detected
<i>M. genitalium</i> Low – Member 6	1.00E+03	Not Tested, 1:10 Dilution of Member 5	TV Not Detected MG Detected
TV/MG High – Member 7	1.00E+05	TV: 1.07E+05 MG: 1.09E+05	TV Detected MG Detected
TV/MG Med – Member 8	1.00E+04	Not Tested, 1:10 Dilution of Member 7	TV Detected MG Detected
TV/MG Low – Member 9	1.00E+03	Not Tested, 1:10 Dilution of Member 8	TV Detected MG Detected

Safety Precautions: Preparation contains cultured microorganisms that are infectious. Use the Center for Disease Control recommended universal precautions.

Approval:



11 JUL 2023

Prepared By

Date



14 JUL 2023

QA Verified By

Date