

Certificate of Analysis

Product Description: AccuTrak™ CT/NG Verification Panel

Material Number: 2400-0245

Batch Number: 10670731

Expiration Date: 23JUN2025

Storage Temperature: 2 – 8 °C

Contents: Contains cultured *C. trachomatis* (Serovar L2 (LGV II)) and *Neisseria gonorrhoeae* (Strain 19424) that are diluted in a viral transport media.

QC testing: Digital PCR (dPCR) using BioRad QX200™ Droplet Digital™ PCR System and primer/probe design as per Whiley and Sloots, Pathology. 2005 Oct;37(5):364-70 targeting the porA pseudogene for *N. gonorrhoeae* and the major outer membrane protein gene (MOMP) for *C. trachomatis*. Qualitative testing used Cepheid® Xpert® CT/NG Assay run on the GeneXpert® instrument.

Member	Nominal Concentration (copies/mL)	dPCR Result (copies/mL)	Cepheid Xpert Result
<i>C. trachomatis</i> High – Member 1	1.00E+05	9.18E+04	CT Detected NG Not Detected
<i>C. trachomatis</i> Med – Member 2	1.00E+04	Not Tested, 1:10 Dilution of Member 1	CT Detected NG Not Detected
<i>C. trachomatis</i> Low – Member 3	1.00E+03	Not Tested, 1:10 Dilution of Member 2	CT Detected NG Not Detected
<i>N. gonorrhoeae</i> High – Member 4	1.00E+05	9.97E+04	CT Not Detected NG Detected
<i>N. gonorrhoeae</i> Med – Member 5	1.00E+04	Not Tested, 1:10 Dilution of Member 4	CT Not Detected NG Detected
<i>N. gonorrhoeae</i> Low – Member 6	1.00E+03	Not Tested, 1:10 Dilution of Member 5	CT Not Detected NG Detected
CT/NG High – Member 7	1.00E+05	9.85E+04	CT Detected NG Detected
CT/NG Med – Member 8	1.00E+04	Not Tested, 1:10 Dilution of Member 7	CT Detected NG Detected
CT/NG Low – Member 9	1.00E+03	Not Tested, 1:10 Dilution of Member 8	CT Detected NG Detected

Safety Precautions: Pathogenic organisms have been inactivated by heat. However, use Universal Precautions when handling this material.

Approval:


12 JUL 2023

 Prepared By Date


17 JUL 2023

 QA Verified By Date