

AccuTrak™ CT/NG Verification Panel (2400-0245)

INTENDED USE

The AccuTrak™ CT/NG Verification Panel (2400-0245) is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot CT/NG test methods. The panel contains different concentrations of positive reference material to enable evaluation of test performance at multiple points across the assay range; it is designed to support CT/NG multiplex test verification at installation. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product is a 9-member AccuTrak™ CT/NG Verification Panel (2400-0245). Panel members consist of cultured organisms for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* diluted to various concentrations in a patient-like matrix. The product is formulated in transport media that consists of Tris-buffered saline, with added glycerol, anti-microbial agents and human proteins. This material must go through extraction, similar to the patient sample.

Material Number: 2400-0245, 1 vial per member
9 members, 1.2 mL per vial

STORAGE

This product should be stored at 2 - 8 °C during regular use. It may also be initially stored at -20 °C, but subsequently maintain thawed material at 2 - 8 °C. Do not expose to multiple freeze thaw cycles. Each vial can be used multiple times up until the date of expiry.

INTERPRETATION OF RESULTS

Levels of reactivity for the AccuTrak™ CT/NG panel members may vary with different types of tests and different test kit lots, but positive reference materials are expected to give positive results. This product contains targeted formulations of either 100,000, 10,000, or 1,000 copies/mL for panel members as measured using reverse transcription digital PCR.

LIMITATIONS

AccuTrak™ CT/NG Verification Panel (2400-0245) is offered for research use only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC SeraCare Life Sciences does not claim that others can duplicate test results exactly. AccuTrak™ CT/NG Verification Panel must not be substituted for the control reagents provided with manufactured test kits. Test procedures and interpretation of results provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. AccuTrak™ materials are not calibrators and should not be used for assay calibration. Performance characteristics for AccuTrak™ CT/NG Verification Panel have been established only for amplified nucleic acid tests. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

PRECAUTIONS

Use Centers for Disease Control (CDC) recommended universal precautions for handling AccuTrak™ CT/NG materials and human specimens¹. Do not pipette by mouth; do not smoke, eat or drink in areas where specimens are being handled. Clean any spillage by immediately wiping with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

EXPECTED RESULTS

Table 1 lists target concentrations for each member of the AccuTrak™ CT/NG Verification Panel:

Table 1: Concentrations per Member

Member	Target Copies/mL*
<i>C. trachomatis</i> High – Member 1	100,000
<i>C. trachomatis</i> Med – Member 2	10,000
<i>C. trachomatis</i> Low – Member 3	1,000
<i>N. gonorrhoeae</i> High – Member 4	100,000
<i>N. gonorrhoeae</i> Med – Member 5	10,000
<i>N. gonorrhoeae</i> Low – Member 6	1,000
CT/NG High – Member 7	100,000
CT/NG Med – Member 8	10,000
CT/NG Low – Member 9	1,000

*Formulated based on digital PCR quantitation

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REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

**For assistance, contact LGC SeraCare at
508.244.6400.**

The package insert for this panel can be found at
www.seracare.com.

A printed copy of the package insert or data sheet may
be requested by email at CDx-Info@LGCGroup.com or
by phone at 508.244.6400.