

AccuTrak™ TV/MG Verification Panel (2400-0246)

INTENDED USE

The AccuTrak™ TV/MG Verification Panel (2400-0246) is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot *Trichomoniasis vaginalis* (C-1:NIH) and *Mycoplasma genitalium* (MG37) test methods. Characterized samples and comprehensive data are provided for comparative analysis. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product is a 9-member AccuTrak™ TV/MG Verification Panel (2400-0246). Panel members represent serial bleeds from a single donor during the development and progression of a *Trichomoniasis vaginalis* and/or *Mycoplasma genitalium* infection. Panel members consist of cultured organisms diluted with patient-like matrix (SCII buffer).

Material Number: 2400-0246, 1 vial per member
9 members, 1.2 mL per vial

STORAGE

Panel members should be stored refrigerated at 2-8 °C or colder. LGC SeraCare recommends that the panel members be divided into smaller aliquots to avoid multiple freeze-thaw cycles, if appropriate. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

INTERPRETATION OF RESULTS

The package insert for AccuTrak™ TV/MG Verification Panel (2400-0246) is available at www.seracare.com. The package insert lists results for panel members generated using commercially available screening, monitoring, and confirmatory test methods. Tests were performed at LGC SeraCare or at recognized reference laboratories (RL) by individuals who routinely use these procedures. Information regarding specific test methods is available on the data sheet. Package inserts are updated when new data are available.

LIMITATIONS

The AccuTrak™ TV/MG Verification Panel (2400-0246) 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.

PRECAUTIONS

These materials have not been treated and should be considered biohazardous. Follow Universal Precautions¹. All panel members were found positive by tests for *Trichomoniasis vaginalis* (C-1:NIH) and *Mycoplasma genitalium* (MG37). This does not ensure the absence of other human pathogens.

Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

These materials should be disposed of in a manner that will inactivate pathogenic agents.

EXPECTED RESULTS

Lists results for panel members generated using commercially available test kits.

Member	Nominal Concentration (copies/mL)
<i>T. vaginalis</i> High – Member 1	1.00E+05
<i>T. vaginalis</i> Med – Member 2	1.00E+04
<i>T. vaginalis</i> Low – Member 3	1.00E+03
<i>M. genitalium</i> High – Member 4	1.00E+05
<i>M. genitalium</i> Med – Member 5	1.00E+04
<i>M. genitalium</i> Low – Member 6	1.00E+03
TV/MG High – Member 7	1.00E+05
TV/MG Med – Member 8	1.00E+04
TV/MG Low – Member 9	1.00E+03

REFERENCES

- 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.