STI Evaluation Panel 01

STIEP01-B

FOR RESEARCH USE ONLY, NOT FOR USE IN DIAGNOSTIC PROCEDURES

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⚠ The following instructions must be read before using this product

Intended Use

Qnostics' Sexually Transmitted Infection (STI) Evaluation Panels are for research use only and intended to help laboratories develop their molecular assay procedures for the identification of pathogens associated with sexually transmitted infections including; *Trichomonas vaginalis, Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma urealyticum, Gardnerella vaginalis, Chlamydia trachomatis* (LGV), *Chlamydia trachomatis* (Swedish strain) and *Neisseria gonorrhoeae*.

The Panels can be used to support laboratory staff training and to assess assay performance in the molecular assays from extraction phase through amplification to detection.

Principles of the Panel

The Panel is manufactured to ISO standard 13485 compliant systems. The samples were produced by making serial dilutions of whole pathogen derived from clinical isolates into either transport medium or male human urine (Urine), which has been screened and found to be below the limit of detection for the pathogens listed in Table 1.

Samples are representative of clinical human swab or urine-based specimens and are traceable to an internal reference preparation in line with the requirements of ISO 17511.

The Panels are suitable for use with a wide range of commercial and in-house molecular methods. They can also be used to support the training and monitoring of new operators in line with laboratories quality management requirements.

Product Description and Performance Characteristics

The Panel consists of 10 x 4ml samples, 9 positive and 1 negative (see Table 1). The Panels are provided as liquid-frozen in a 'single–use' tube format and must be extracted immediately after thawing. The target concentrations of the Panel have been designed to cover the dynamic range of most molecular assays and are consistent within each lot and across batches.

Table 1: Panel Components and Characteristics

Sample Code	Sample Description	Matrix	Number of vials
STIEP01-S01	*Chlamydia trachomatis* (LGV)*	Transport media	1
STIEP01-S02	*Trichomonas vaginalis*	Simulated swab	1
STIEP01-S03	*Mycoplasma genitalium*	Simulated swab	1
STIEP01-S04	*Ureaplasma urealyticum*	Simulated swab	1
STIEP01-S05	*Mycoplasma hominis*	Simulated swab	1
STIEP01-S06	*Gardnerella vaginalis*	Simulated swab	1
STIEP01-S07	*Neisseria gonorrhoeae*	Urine	1
STIEP01-S08	*Chlamydia trachomatis* (LGV)*	Urine	1
STIEP01-S09	*Chlamydia trachomatis* (SW)	Urine	1
STIEP01-S10	Negative	Simulated swab	1

*** Clinical isolates in which the primary STI pathogen is *Chlamydia trachomatis with a* low-level of *Mycoplasma hominis which may not be detected by all molecular STI assays.***

IMPORTANT NOTE: The Panel members have an assigned positive or negative status for the targets as listed in Table 1. The Qnostics' reference assay, used for the qualification of the Panel generates a qualitative result correctly with a greater than 95% confidence interval, see Limitations.

Warnings and Precautions

The Panel contains whole pathogen and must only be handled by trained laboratory personnel and in accordance with Good Laboratory Practices, which must include the use of personal protective equipment (PPE). All residual materials must be treated as potentially hazardous and disposed of accordingly. This must be carried out according to the established procedures of the laboratory and in accordance with national and international regulations.

Do not pipette by mouth. Do not eat, drink or smoke when handling the samples or within laboratory spaces. Observe the expiration date for the Panels.

Hazard and Precautionary Statements: H303, H333, P202, P270, P280, P314

Additional Equipment Required but not Provided

The following equipment is not included:

- Personal Protective Equipment (PPE) - e.g. lab coat and gloves
- Biological safety cabinet
- Nucleic acid extraction kit used in accordance with the manufacturers' instructions
- Molecular Amplification assay specific for targets and, where appropriate, used in accordance with the manufacturers' instructions
- Bench vortex
- Micro-centrifuge (12-14,000 RPM)
- Calibrated pipettes and sterile barrier filter tips

Procedure

- The Panel must be thawed at room temperature.
- Vortex briefly and spin down at 12,000 RPM for 30 seconds before opening the sample tube.
- The samples must then be treated in the same manner to that required by the laboratory for routine specimens, in the normal molecular procedure being assessed.

IMPORTANT NOTICE: Each panel member is intended for 'single use' ONLY. After thawing and testing any surplus material must be disposed of according to laboratory procedures.

For technical queries please contact info@qnostics.com

Storage

The Panel must be stored within the recommended temperature range of -20/-80°C.

The re-freezing and repeated thawing or off label storage of the Panel is not recommended and may lead to variability in the results obtained.

Limitations

The Panel **must not** be used as a substitute for assay process controls and / or calibrators (Standards) provided by the manufacturer of the molecular assay.

This product is not an absolute reference material. The laboratory needs to establish its own target results using the Panel for their particular molecular assay system.

These products are labelled as Research Use Only and **cannot be used** as an *in vitro* diagnostic device for the management of human disease.

References

World Health Organisation (WHO). Laboratory Biosafety Manual, 3rd ed. 2004 ISBN 92 4 154650 6 (LC/NLM classification: QY 25).

Centers for Disease Control (CDC). Recommendations for the prevention of HIV transmission in healthcare settings. MMWR 1987; 36, Supplement no. 2S.

Centers for Disease Control (CDC). Update: Universal guidelines for the prevention of transmission of human immunodeficiency virus, hepatitis B virus and other blood borne pathogens in health-care settings. MMWR; 37:377-388

Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to healthcare and public-safety workers. MMWR 1989; 38(S6):1-36.

Symbols

Symbols used in the labelling of this product comply with BS EN ISO 15223-1 Medical Devices – 'Symbols to be used with medical device labels, labelling and information to be supplied'.

REF	Product Code		Single use only
	Temperature limitations	Σ	Contains sufficient for "N" tests
LOT	Batch code		Attention, consult instructions for use
	Expiry date (last day of month)		Biohazard
RUO	Research Use Only		Manufacturer

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