

INTRODUCTION

INTENDED USE

The InPouch® TV is a self-contained media system for the recovery and detection of *T. vaginalis* from female vaginal samples or male urethra/urine samples. The proprietary medium is selective for the transport and growth of *T. vaginalis*, while inhibiting the growth of other microorganisms, which can interfere with a reliable diagnosis.

EXPLANATION

Human trichomoniasis is a sexually transmitted infection (STI) caused by the flagellated protozoan, *Trichomonas vaginalis*. It is recognized as one of the most prevalent sexually transmitted infections world-wide, in both males and females.^{1,2} The CDC estimates five million new cases occur in the U.S. annually.

PRINCIPLES OF THE PRODUCT

The pouch is designed for user-friendly and convenient early microscopic detection by culture confirmation of *T. vaginalis*.^{3,4} The pouch consists of a high-barrier, oxygen-resistant, plastic with two V-shaped-chambers connected by a narrow passage that, together, provide a variety of benefits. The pouch allows users to easily inoculate a specimen, immediately observe (wet mount) the specimen, store and/or transport (optional) before transfer to the lab for incubation and recording.

REAGENTS

The InPouch® medium contains the following: peptones, maltose and other sugars, amino acids, salts and antimicrobial agents in a phosphate buffered saline base. An unopened pouch should contain a clear, amber liquid.

SPECIFICITY/SENSITIVITY

For cultivation of *T. vaginalis* only.

Clinical Specificity: 100%⁵; Clinical Sensitivity: 81-94%.^{5,6}

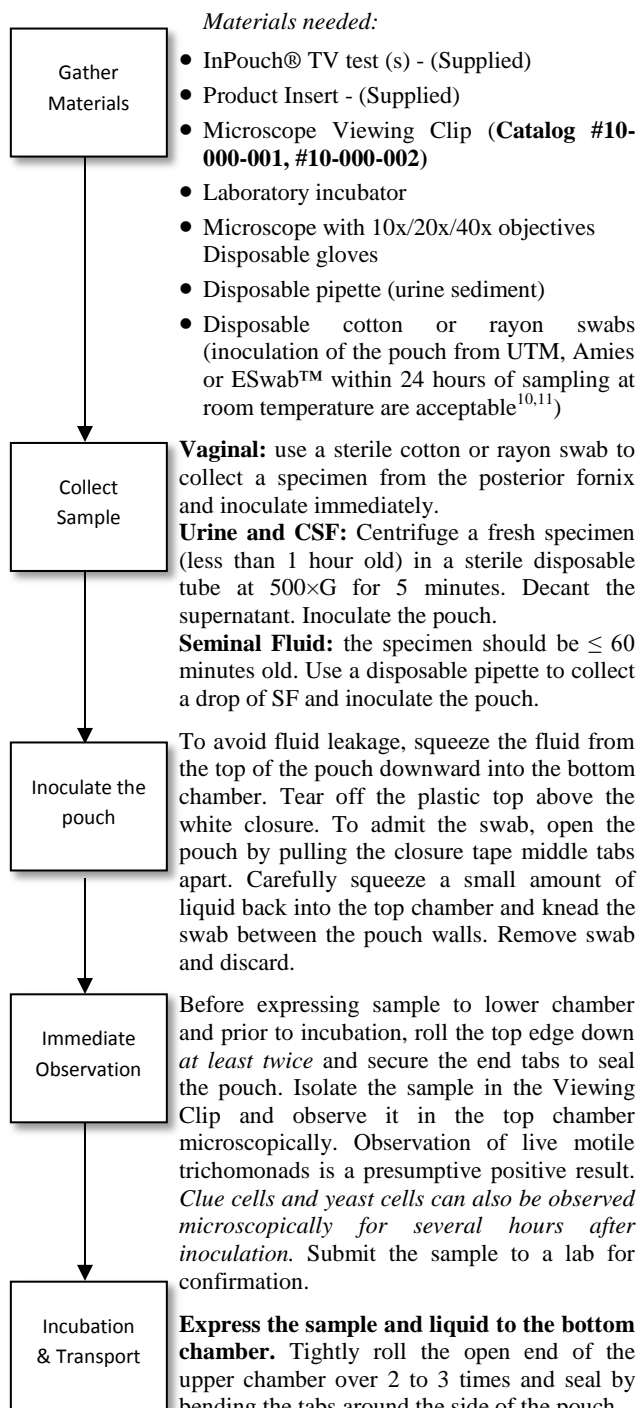
HANDLING

Handle all inoculated tests in accordance to CDC-NIH recommendation for BSL-2 organisms.

STORAGE & SHELF LIFE

- Store uninoculated pouches at room temperature (18°C-25°C) horizontally and away from direct sunlight.
- **Never refrigerate or freeze the product.**
- InPouch® products expire 12 months from the date of manufacture.

USING THE TEST



NOTE: Fill in the patient information and place patient label over the blue Biomed label, not on the viewing chamber.

Incubate the pouch vertically at 37° C for up to 7 days.⁸ The pouch is designed for safe transport.⁹ Inoculated tests should be transported within 48 hours after inoculation and maintained at 18° - 37°C.⁷

READING THE RESULTS

MICROSCOPIC EVALUATION

To search for the presence of trichomonads, place a Viewing Clip horizontally over the lower chamber of the pouch and close (the Viewing Clip is optional). Place the pouch on the microscope stage under low power (100x) to look for trichomonads. Use a higher power (200x - 400x) if necessary for confirmation.

Observation of 1 or more live, *T. vaginalis* cells is all that is required for a presumptive positive result. Continue incubation and microscopic observation daily for 5 working days before a negative result is reported.⁸

READING TIPS

- * Trichomonads gravitate to the bottom and side edges of the pouch chamber.
- * Verify that your field of focus is in the liquid and not the textured plastic film layer of the pouch.

ADDITIONAL PRODUCT NOTES

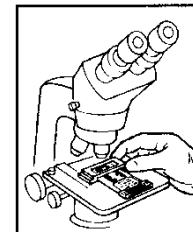
1. NEVER refrigerate or freeze the pouch.
2. Complete each label with the patient information.

DISPOSAL & SAFETY

Because inoculated pouches potentially contain live, infectious organisms, the pouch must be autoclaved at 121° C for 20 minutes or by other means appropriate for sterilization and disposal of BSL-2 organisms.

The InPouch® growth medium suppresses but may not entirely eliminate yeast and bacterial growth. Any build-up of gas from bacterial growth can be vented by opening the pouches inside a BSL-2 rated biological safety cabinet.

WARNING: This product contains chemicals known to the State of California to cause cancer, birth defects and other reproductive harm.



QUALITY CONTROL

The InPouch® TV product is for presumptive human *T. vaginalis* identification only. The InPouch® TV product is manufactured in accordance with controlled procedures at Biomed Diagnostics. Each lot undergoes an initial QC performance testing prior to release for customer use. Additional performance testing is repeated throughout the marked shelf-life of each lot to ensure absolute reliability.

The following is recommended for customers who choose to complete independent QC testing of the InPouch® TV product:

1. Obtain a sample of viable *T. vaginalis* organisms in the range of 2.0×10^6 live cells/mL.
2. Inoculate three (3) InPouch® tests with 1-12 drops (20 – 40 µL) of the live culture using a sterile glass Pasteur pipette per the “Inoculate the InPouch®” step as described on this insert.
3. Incubate the inoculated InPouch® tests for 24 hours at 37°C. After incubation, re-suspend the sample by kneading the pouch. Examine each pouch microscopically (10x objective) and confirm that you have viable *T. vaginalis* organisms in the range of 2.0×10^3 to 2.0×10^6 live cells/mL. Incubate the pouches for an additional 24 hours if necessary to confirm the doubling time.

NOTES ON QUALITY

1. Menses does not interfere with the test.
2. There are no patient age limitations on specimens collected.

Trichomonas vaginalis LIVE CULTURE

Live cultures of *T. vaginalis* (clinical isolate) for research, training and QC purposes are available (N. American customers only). This live culture (positive control) can be purchased from Biomed Diagnostics (Catalog #11-035-001, #11-041-003) to obtain an active culture of *T. vaginalis*.

TECHNICAL NOTES

An Evaluation of *Trichomonas vaginalis* Culture Viability After 48 Hours at Room Temperature

Trichomonas vaginalis SJCR66 was incubated for 48 hours at 37°C in an InPouch® TV test pouch. A Neubauer hemocytometer was used to determine a final dilution of the culture to 7.75×10^4 cells/mL.

TECHNICAL NOTES, CONTINUED

Four pouches were then inoculated from this dilution of trichomonads. Pouch #1 was inoculated with 30 µL, Pouch #2 with 60 µL, Pouch #3 with 90 µL and Pouch #4 with 120 µL.

The pouch densities were:

Pouch #1 2.3×10^3 cells/mL Pouch #3 6.9×10^3 cells/mL
Pouch #2 4.6×10^3 cells/mL Pouch #4 9.2×10^3 cells/mL

All four pouches were allowed to remain at room temperature for 48 hours before being placed into an incubator at 37°C for 24 hours. Each pouch was examined microscopically for viability after 24 hours. All were positive for motile trichomonads with Pouch #1 presenting the fewest and Pouch #4 the greatest numbers of organisms. This demonstrates that a specimen inoculated into the pouch containing viable trichomonads at 2.3×10^3 cells/mL would remain viable for a minimum of 48 hours if stored at room temperature.

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REFERENCES

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InPouch® TV

Trichomonas vaginalis Test

Catalog No. 11-031-001 10 Pack
Catalog No. 11-031-002 100 Pack

A SELECTIVE CULTURE SYSTEM FOR
THE DIAGNOSIS OF HUMAN

Trichomonas vaginalis

For *In Vitro* Diagnostic Use Only



BIOMED

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