

INTRODUCTION

INTENDED USE

The InPouch™ TV is a self-contained system for the 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 three million new cases occur in the U.S. annually.

PRINCIPLES OF THE PRODUCT

The InPouch™ is designed for user-friendly and convenient early microscopic detection by culture confirmation of *T. vaginalis*.^{3, 4} The InPouch™ 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 InPouch™ allows users to easily inoculate a specimen, immediately observe (wet mount) the specimen, store and/or transport (optional) before transfer to the lab for incubating 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 InPouch™ should contain a clear, amber liquid.

SPECIFICITY/SENSITIVITY

For cultivation of *T. vaginalis* only.

Clinical Specificity: 100%.⁵ Clinical sensitivity 81 – 94%.^{5, 6}

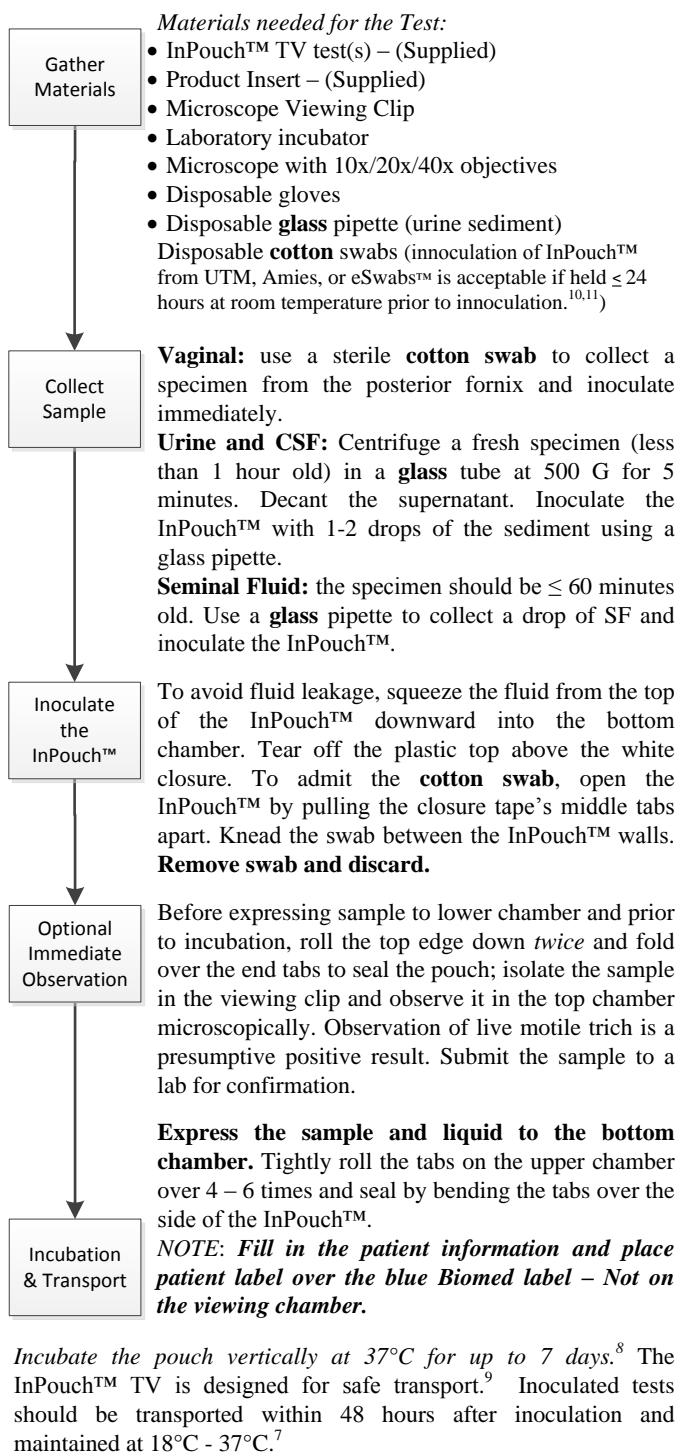
HANDLING

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

STORAGE & SHELF LIFE

- Store uninoculated InPouch™ tests at room temp. (18°-25°C) horizontally and away from direct sunlight.
- **Never refrigerate/freeze** the InPouch™.
- InPouch™ tests expire 12 months from the date of manufacture.

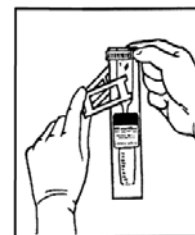
USING THE TEST



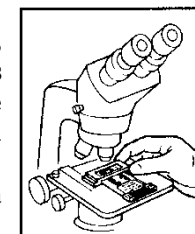
READING THE RESULTS

MICROSCOPIC EVALUATION

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



Observation of 1 or more live, motile *T. vaginalis* is all that is required for a presumptive positive result. Continue incubation and microscopic observation daily for 5 days over a 7 day period 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 specimen.
2. Complete each label with the patient information

DISPOSAL & SAFETY

Since InPouch™ TV has potential for containing live, infectious materials, the InPouch™ TV must be destroyed by autoclaving at 121°C for 20 minutes or other suitable means for sterilization and disposal of BSL-2 organisms.

The InPouch™ growth medium suppresses but does not eliminate yeast and bacterial growth. A 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 is for human *T. vaginalis* identification only. The InPouch™ TV test is manufactured in accordance with controlled procedures at Biomed Diagnostics. Each lot undergoes an initial QC performance testing prior to release for consumer 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:

1. Obtain a sample of viable *T. vaginalis* organisms in the range of 2.0×10^5 - 2.0×10^6 live cells/mL.
2. Inoculate three (3) InPouch™ TV tests with 1-2 drops (20-40µL) of the live culture using a sterile glass Pasteur pipette per the "Inoculate the InPouch™" step as described on this product insert.
3. Incubate the inoculated InPouch™ tests for 24 hours at 37°C. After incubation, resuspend 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 - 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 #11-2015) to maintain 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 /mL.

TECHNICAL NOTES, CONTINUED

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

The pouch densities were:

Pouch #1	2.3×10^3 /mL	Pouch #3	6.9×10^3 /mL
Pouch #2	4.6×10^3 /mL	Pouch #4	9.2×10^3 /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 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 InPouch™ TV with viable trichomonads with a minimum of 2.3×10^3 /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. 10-2010 10 Test Box
Catalog No. 10-2003 100 Test Box

A SELECTIVE CULTURE SYSTEM FOR
THE DIAGNOSIS OF HUMAN

Trichomonas vaginalis

For In Vitro Diagnostic Use Only



BIOMED

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