Introduction

Intended Use

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.

Description and Principle

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.

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 and Appearance

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. Final pH of media is 6.1 ± 0.05.

Precautions, Safety and Disposal

For *In Vitro* Diagnostic Use

Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing and gloves.

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

Once the pouch has been inoculated and resealed, re-open only in a biological safety cabinet. Because of the potential for containing infectious materials, the pouch must be destroyed by autoclaving at 121°C for 20 minutes.

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.

Storage

Store uninoculated pouches at 18-25°C horizontally and away from direct sunlight. Never refrigerate or freeze the product.

Shelf Life

InPouch products expire 12 months from the date of manufacture.

Procedure

Key notes regarding specimen collection:

Vaginal: Use a sterile cotton or rayon swab to collect a specimen from the posterior fornix and inoculate immediately.

Urine and CSF: Centrifuge a fresh specimen (less than 1 hour old) in a sterile disposable tube at 500 x *g* for 5 minutes. Decant the supernatant. Inoculate the pouch.

Seminal fluid: The specimen should be ≤60 minutes old. Use a disposable pipette to collect a drop of seminal fluid and inoculate the pouch.

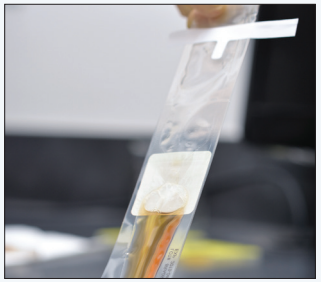
Materials required

- InPouch TV test(s)

Materials required but not provided

- Disposable pipette (urine sediment)
- Disposable cotton or rayon swabs (inoculation of the pouch from UTM, Amies or ESwab® within 24 hours of sampling at 18-25°C is acceptable[10,11])
- Viewing Clip (Catalog Nos. 10-000-001)
- Laboratory incubator capable of incubation at 37°C
- Microscope with 10x/20x/40x objectives

1- Prepare InPouch



To avoid fluid leakage, squeeze the fluid from the top of the pouch downward into the bottom chamber. Tear off the plastic top above the white closure.

2 - Inoculate Sample

To admit the swab, open the pouch by pulling the closure tape middle tabs apart. Carefully squeeze a small amount of liquid back into the top chamber and knead the swab between the pouch walls. Remove swab and discard.

3 - Integrate Sample

Before expressing sample to lower chamber and prior to incubation, roll the top edge down at least twice and secure the end tabs to seal the pouch. Isolate the sample in the Viewing Clip and observe it in the top chamber microscopically. Observation of live motile trichomonads is a presumptive positive result. Clue cells and yeast cells can also be observed microscopically for several hours after inoculation. Submit the sample to a lab for confirmation.

Incubation

Express the sample and liquid to the bottom chamber. Tightly roll the open end of the upper chamber over 2 to 3 times and seal by bending the tabs around the side of the pouch.

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]

Quality Control

This product has been tested and meets the CLSI (formerly NCCLS) Approved Standard for commercially prepared media (M22-A3). At the time of manufacture, quality control testing is performed on each lot of the InPouch TV. The ability of the media to support growth and demonstrate expected growth, selectivity and morphology is verified by lot.

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 x 10^6 live cells/mL.
2. Inoculate three (3) InPouch TV 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 x 10^3 to 2.0 x 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 Nos. 11-041-003) to obtain an active culture of *T. vaginalis*.

Reading The Results

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

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

Limitations

For cultivation of *T. vaginalis* only. The InPouch TV product is for presumptive human *T. vaginalis* identification only.

Performance Characteristics

Clinical Specificity: 100%; [5] Clinical Sensitivity: 81-94%.[5,6]

Technical Notes

An Evaluation of Trichomonas vaginalis Culture
Viability After 48 Hours at Room Temperature (18-25°C)

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

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 x 10^3 cells/mL
- Pouch #2 4.6 x 10^3 cells/mL
- Pouch #3 6.9 x 10^3 cells/mL
- Pouch #4 9.2 x 10^3 cells/mL

All four pouches were allowed to remain at room temperature for 48 hours before being placed into an incubator at 37ºC 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 x 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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Symbol glossary: biomeddiagnostics.com/l/symbol-glossary

Document Revision History

Rev. S -Replaced ® with ™.

Rev. T-No change.

Manufactured by:
Biomed Diagnostics, a DCN Dx brand
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biomeddiagnostics.com

100-001 IFU InPouch TV, Rev. T (09/2025)

BIO MED™
DIAGNOSTICS
A DCN DX BRAND

InPouch™ TV

A selective culture system for the diagnosis of

Human *Trichomonas vaginalis*

REF 11-031-001 Σ 10

REF 11-031-002 Σ 100

Not available in all countries; please inquire.
For *In Vitro* Diagnostic Use

CE IVD 18°C 25°C