

InPouch™ *Trichomonas vaginalis* (TV) Test

VALUE

High Throughput – Once the device is inoculated no other preparation is required saving time

Cost Savings – The InPouch™ TV reduces laboratory materials and medical waste

High Specificity – Selective for the growth of *Trichomonas vaginalis* by inhibiting the growth of yeast, mold, bacteria, and other commensal micro flora

BENEFITS

Convenient - Combines collection, culture, and observation into one device

Easy to use - Minimal lab procedures and equipment needed

Easy to store - One year shelf life at room temperature

Mobile - Compact and non-breakable package is ideal for off-site sampling or for point-of-care testing

Safe - Fully enclosed InPouch™ system prevents contamination and reduces exposure to collected samples

Functional - PCR compatible incubation and transport device

PRODUCT SPECIFICS

Storage - Room Temperature (18-25 °C)

Shelf Life - 12 months

Incubation - 48 hours at room temp, 37 °C if longer

Quantity Sold - 10 pack

PRODUCT BIO

BioMed's InPouch™ TV test is a microbiology sample collection, transport, and culture device that allows for simultaneous growth and observation of *Trichomonas vaginalis*, the parasite responsible for the sexually transmitted infection (STI) trichomoniasis. **By combining several procedures into a single device, BioMed's patented InPouch™ TV test saves time and money while reducing exposure to collected samples.**



The patented InPouch™ system consists of a high barrier, oxygen resistant, plastic pouch with two V-shaped chambers connected by a narrow passage. The innovative two-compartment system allows for direct preliminary observation of a

newly collected specimen in the upper chamber before expressing the contents into the lower chamber for culture and further observation when necessary. **Combining both growth and observation into one fully enclosed system removes the need to prepare wet mount slides increasing efficiency and throughput while decreasing the cost of laboratory materials and medical waste.**

In addition to the high throughput, cost saving, and secure design of the InPouch™ system, it is also designed to perform in austere environments with limited reliance on laboratory equipment, making the InPouch™ TV ideal for point-of-care testing or off-site sampling. This is possible because

the InPouch™ TV can be stored for up to a year at room temperature (18-25 °C) and can be incubated at this temperature for up to 48 hours (37°C is required for longer incubation periods).

Transport from off-site locations and point-of-care testing can be performed easily due to the flexible packaging and robust, integral design of the InPouch™ system.

As the first, most robust and economical IVD for clinical trichomoniasis, **the InPouch™ TV is known as The Gold Standard diagnostic for this STI.** The proprietary medium of the InPouch™ TV is selective for the transport and growth of *T. vaginalis* and increases specificity by inhibiting the growth of yeasts, mold, bacteria, and other commensal microflora. **The specially formulated media inhibits the potential for interference in obtaining accurate results.**

QUALITY CONTROL

Quality control testing is performed on each lot of InPouch™ TV tests prior to shipment in order to ensure viability, doubling time and sterility. **Quality control tests are repeated throughout the product shelf life** by BioMed Diagnostics confirming the ability of the InPouch™ TV to support the growth of *T. vaginalis* while maintaining specificity against other organisms.

BACKGROUND

Trichomonas vaginalis

Trichomonas vaginalis is a flagellated, parasitic protozoan, and the cause of the STI trichomoniasis in humans. ***T. vaginalis* is the most common pathogenic protozoan infection of humans in industrialized countries¹.** Infection rates are relatively the same between men and women and there are an estimated 7.4 million new cases each year^{1 2 3}.

Trichomoniasis can cause many complications in women, such as: preterm delivery, low birth

CORPORATE OVERVIEW

BioMed Diagnostics, Inc., a boutique biotech firm and an industry leader for the past 20 years, develops and produces *in vitro* diagnostic devices. BioMed's point of care ready tests provide accurate diagnostic tools to scientists and research professionals worldwide for the identification of bacteria, parasites and fungi. The company formed out of a mercy mission conducted by a group of physicians to Central America. There they discovered the need for robust diagnostic tools designed especially for use in austere environments. Their experience unleashed the inspiration for BioMed's innovative products that support medical professionals, veterinarians, research teams, and environmental and industry scientists.

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rate, infant mortality, and cervical cancer, but can also cause: pneumonia, bronchitis, and oral lesions in immunocompromised individuals^{1 2 3}. Symptoms in women usually appear 5-28 days after exposure while men are commonly asymptomatic. Whether symptomatic or asymptomatic, an infection in either males or females leads to an increased susceptibility to HIV transmission³.

Signs of infection in women usually consist of a frothy, yellow-green discharge, strong odor, inflammation, itching, and discomfort during intercourse or urination^{2 3}. Although trichomoniasis in men is often asymptomatic, when symptoms do occur, they usually consist of irritation inside the genitalia and is often accompanied by mild discharge, and slight burning after urination or ejaculation².

In the developing world, STIs and their complications rank among the top five disease categories for which adults seek treatment. According to WHO the presence of untreated *Trichomonas* infection increases the probability of acquisition and transmission of HIV by a factor of ten, even more for people in high-risk areas⁵.

INPOUCH™ TV DIRECTIONS

Specimen collection for culture should be taken from the posterior fornix of the vagina or from the male urethra. Male seminal fluid or urine can also be used as specimens.

To inoculate the upper chamber, tear along the notched area and pull the tabs to open the InPouch™, squeeze the top to close and fold the top edge down, roll twice and fold the wire tabs to prevent the InPouch™ from opening. Immediate specimen concentration can be observed under the microscope using the accompanying viewing clip. Only a few viable organisms are needed for detection; an inoculum containing 1 to 10 organisms is sufficient to result in a presumptive positive test.

For culture, express all liquid from the upper chamber into the lower chamber; use the edge of a straight hard surface, such as a workstation or table, for best results. Roll down the pouch until it reaches the top of the lower chamber then fold the wire tabs to lock the InPouch™ into position. Inoculated InPouch™ TV medium can be held up to 48 hours at room temperature (18°-25°C), but if held longer, incubation at 37°C is required. Specimens should be examined every 24 hours. *T. vaginalis* replicates within several hours after inoculation into the InPouch™ TV and can grow in the pouches for up to 5 days. However, after day 3 the organisms begin to die as the nutrients contained in the InPouch™ TV are exhausted. If no trichomonads are observed after 3 days and incubation at 37°C, the test is presumptive negative for *T. vaginalis*.

DETECTION

As the parasites multiply, white sediment along the sides and bottom of the chamber will become visible. *T. vaginalis* are oval shaped, flagellated, and measure slightly larger than a white blood cell⁴. Five flagella arise from the organism, four immediately extend out, while the fifth wraps backwards along the surface of the organism. A barb-like axostyle projection can be seen across from the four-flagella bundle⁴. If *T. vaginalis* organisms are present, they will be identifiable by their distinct features; characteristically the rolling, jerky motions exhibited by the protozoan.

An InPouch™ TV subculture medium is also available from Biomed Diagnostics Inc. as well as live viable cultures of *Trichomonas vaginalis* to be used as a positive control in diagnosing an infection.

REFERENCES

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