

INTRODUCTION

INTENDED USE

The InPouch™ TF is a self-contained system for the detection of *Tritrichomonas foetus* from bovine preputial or vaginal samples. The proprietary medium is selective for the transport and growth of *T. foetus*, while inhibiting the growth of other organisms which can interfere with a reliable diagnosis.

EXPLANATION

Bovine *Tritrichomoniasis* is a venereally transmitted protozoan parasite. The primary pathological manifestation of this infection is early embryonic death or abortion in impregnated cows. Cows show few other symptoms of infection, while bulls are asymptomatic.

PRINCIPALS OF THE PRODUCT

The InPouch™ TF is designed to facilitate and simplify the detection of *T. foetus* as the organism is infrequently be found in direct microscopic examination of clinical specimens and serological methods of diagnosis are not reliable. This device conveniently supports the following user needs in a single-exposure system:

1. Ease of inoculation
2. Proprietary medium selective for TF growth
3. Direct microscopic observation of the sample
4. Self-contained culture system
5. Direct microscopic observation of the culture
6. Incubatory capabilities
7. Safe transport and preservation of the specimen
8. PCR compatible

REAGENTS

The InPouch™ contains peptones, yeast extract, maltose and other nutrients, amino acids, salts, antifungal and antimicrobial agents in a phosphate buffered saline base constructed to isolate the positive detection of *T. foetus*.

SPECIFICITY

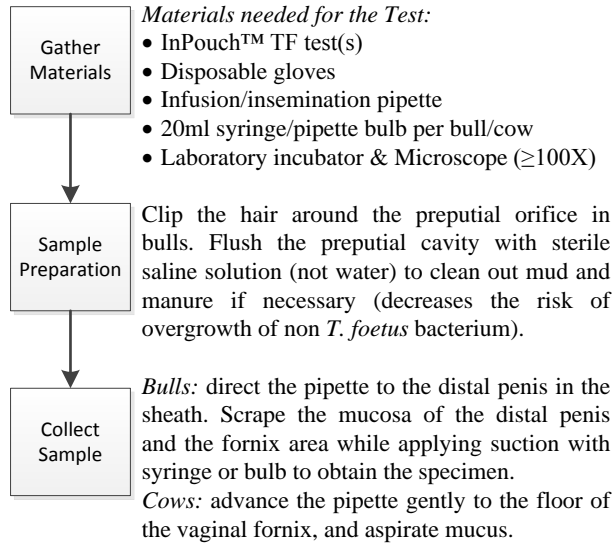
InPouch™ TF medium is known to be effective in culturing *T. foetus*, *T. suis*, *T. gallinae* and *P. hominis*.

STORAGE AND SHELF LIFE

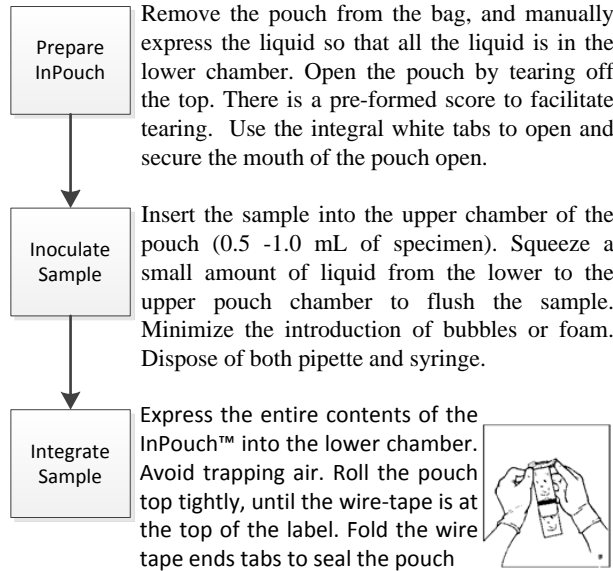
Do not **refrigerate or freeze** InPouch™ TF tests. Upon receipt, store at room temperature (18°C - 25°C) horizontally, away from direct sunlight. Do not use expired tests. Do not use an InPouch™ test if the liquid appears to be cloudy, leaky, dark brown or dried.

USING THE TEST

SAMPLE COLLECTION



INOCULATION



INCUBATION

Incubate the pouch vertically at 35°C - 37°C for up to 6 days. The InPouch™ TF is designed for safe transport, if needed. Inoculated InPouch™ TF tests should be transported within 48 hours after inoculation and maintained at 15°C - 37°C

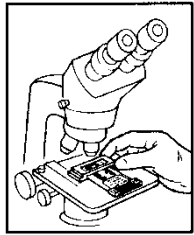
READING THE RESULTS

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 to 10 live, motile *T. foetus* is all that is required for a presumptive positive result. Continue incubation and **repeat the microscopic observation daily for six days before a negative result is reported.**



Field studies indicate that 98% of positive results will occur within 5 days; up to 2% of positive results may not be detected until the 6th day or incubation/observation.

READING TIPS

For immediate wet mount examination: Before expressing sample to lower chamber and prior to incubation, roll the top edge down *twice* and fold over the end tabs to seal the pouch; observe the sample in the top chamber microscopically.



**Tritrichomonas* 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.

*Do not mistake Brownian motion or small particles for evidence of *Tritrichomonas* activity. *T. foetus* are relatively large (9-20 µm) and highly motile.

ADDITIONAL PRODUCT NOTES

1. NEVER refrigerate or freeze the specimen.
2. Complete each label with the sample information
3. All specimens should be handled according to CDC-NIH recommendations for Biosafety Level 2 (BSL-2) organisms.

QUALITY CONTROL

The InPouch™ TF is manufactured in accordance with controlled procedures at BioMed. Each lot undergoes an initial QC performance testing prior to release for consumer use. Additional performance testing is repeated at specific intervals throughout the marked shelf-life of each lot to ensure absolute reliability of the product.

The following is recommended for customers who choose to complete independent QC testing of the InPouch™ TF:

1. Obtain a sample of viable *Tritrichomonas* organisms in the range 2.0×10^5 - 2.0×10^6 live cells/mL
2. Inoculate three (3) InPouch™ TF diagnostic tests with 1-2 drops of the live culture using a sterile glass Pasteur pipette (~20 – 40 ul) per the “Inoculation” steps discussed on the reverse side of this insert.
3. Incubate the inoculated InPouch™ TF diagnostic tests for 24 hours at 37°C

NOTES ON QUALITY

1. Too much fecal material can ruin the test by making the medium too cloudy for examination. When necessary, subculture the suspect InPouch™ tests into another InPouch™.
2. While differential staining can sometimes be of help in *Tritrichomonas* species identification based on the number of flagella, PCR testing is the only reliable means of definitive identification.
3. In bovine samples *P. hominis* or other non *T. foetus* protozoa are contaminants.

SAFETY

The InPouch™ TF is for veterinary protozoa identification and test results only.

Consult your local State Department of Agriculture regulations before use. Some states require that only certified veterinarians collect and read bovine TF cultures and/or submit samples for PCR testing.

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.

DISPOSAL

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

REFERENCES

BonDurant. Vet Clin North Am Food Anim Pract. 1997. 13(2):345-61

Thomas, *et al.* Agri-Practice. 1990. 11:13-17

Borchardt, *et al.* Veterinary Medicine. 1992. 11:104-112

Tritrichomonas foetus LIVE CULTURE

Live cultures of *T. foetus* (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 #11-1015**).

To maintain an active culture, inoculate a new pouch with one drop (approximately 40µl) of the actively growing culture and incubate at 37°C for 24 hours. They can then be moved to a 32°C incubator or to room temperature. Subculture every 3-4 days when the organisms reach a concentration of 1×10^5 /ml

InPouch™ TF

Tritrichomonas foetus Test

Catalog No. 11-1010

10 Test Kit

Catalog No. 11-1003

100 Test Kit

A SELECTIVE CULTURE SYSTEM
FOR THE DIAGNOSIS OF BOVINE
Tritrichomonas foetus

For Veterinary Use Only

For *In Vitro* Diagnostic Use Only



Manufactured by:

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