

INTENDED USE

The **Trichomonas Swab Verification Set** is recommended for use as an external quality control for molecular methods and DNA amplification systems.

SUMMARY & EXPLANATION

The **Trichomonas Swab Verification Set** contains a random set of swabs that contain quantitative positive whole cells of *Trichomonas vaginalis* (500 and 1,000 cfu's per swab) and negative swabs containing saline.

PRINCIPLES

Each swab is a simulated clinical specimen that can be tested for *Trichomonas vaginalis*. The **Trichomonas Swab** is intended to be processed according to the kit manufacturer's instructions for processing patient specimens.

PRODUCT DESCRIPTION

Each **Trichomonas Swab Verification Set** contains a randomly mixed set of 30 individually packaged swabs in a foil pouch coded with numbers 1-30. Included with each lot is an envelope containing decoded information on expected results. The stabilized cell mixtures include *Trichomonas vaginalis* or saline.

PRECAUTIONS

Trichomonas Swab Verification Sets are for In Vitro Diagnostic Use only and should be used by properly trained personnel. Take precautions for microbiological hazards. After use, all materials should be placed into an appropriate container for biohazardous material disposal.

STORAGE INSTRUCTIONS

The **Trichomonas Swab Verification Set** should be stored at 2-8°C in the original packaging. Do NOT freeze or overheat.

EVIDENCE OF DETERIORATION

Do not use this product if the expiration date has passed.

PROCEDURE

1. Open the foil pouch at the tear slit.
2. Remove the swab from the foil pouch and place the swab into a specimen collection tube. Rotate the swab to dislodge as much material as possible.
3. Follow the instrument manufacturer's recommended instructions for extraction.
4. Perform testing for *Trichomonas vaginalis* according to the manufacturer's recommended instructions and your laboratory's procedure for patient testing.
5. Record results and compare with the expected results.

****CAUTION: Interpret the results as soon as possible after completion of the test.**

EXPECTED RESULTS

Refer to lot specific decoded information included with each validation set for expected positive and negative results.

REFERENCES

This document is the Property of Microbiologics and is considered Confidential, Proprietary Information.

1. Rein MF. 1990. Trichomonas vaginalis. In: Principles and Practice of Infectious Diseases, 3rd ed. Mandell GL, RG Douglas, Jr, and JE Bennett (eds). New York: Churchill Livingstone Inc., pp.2115-2118.
2. World Health Organization, An overview of selected curable sexually transmitted diseases, pp. 2-27 in Global Program on AIDS, Geneva, Switzerland. World Health Organization, 1995.

Acknowledgements

BD Viper™ System is a registered trademark of BD Diagnostics

KEY OF SYMBOLS



Batch code



Catalogue number



Biological risk



Caution, refer to accompanying documents



In Vitro diagnostic medical device



Manufactured by (Manufacturer Name)



Temperature limitation



Use by (Expressed as: YYYY-MM-DD)