

USE

The **Tri-Valent™ Swab Validation Set** is recommended for use as an external quality control for probes and antigen/antibody detection kits.

SUMMARY & EXPLANATION

The **Tri-Valent™ Swab Validation Set** contains a random set of swabs that contain **positive** whole cells of *Trichomonas vaginalis*, *Gardnerella vaginalis*, *Candida albicans*, or **negative** whole cells of *Escherichia coli* or other negative samples.

PRINCIPLE

Each swab is a simulated clinical specimen that may be tested for *Trichomonas*, *Gardnerella*, and *Candida*. The **Tri-Valent™ Swab Validation Set** is intended to be processed according to the kit manufacturer's instructions for processing patient specimens.

PRODUCT DESCRIPTION

Each **Tri-Valent™ Swab Validation Set** contains a randomly mixed set of 22 individually packed swabs in a foil pouch coded with numbers 1 – 22. Included with each lot is an envelope containing decoded information on expected results. The following stabilized cell mixtures include:

- Trichomonas vaginalis*
- Gardnerella vaginalis*
- Candida albicans*
- Escherichia coli* or other Negative Sample

PRECAUTIONS

Tri-Valent™ Swab Validation Sets are For In Vitro Diagnostic Use only and should be used by properly trained personnel. Precautions should be taken against the dangers of microbiological hazards. After use, all materials should be placed into an appropriate container for biohazardous material disposal.

STORAGE INSTRUCTIONS

Tri-Valent™ Swab Validation Set should be stored at 2-8C 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 or elution buffer reagent supplied by the kit manufacturer. Rotate the swab to dislodge as much material as possible. If necessary, snap or cut the shaft of the swab to fit the tube.
3. Follow the kit manufacturer's recommended instructions for extraction or elution.











4. Perform testing for *Trichomonas*, *Gardnerella* and *Candida* according to the manufacturer's recommended instructions and your laboratory's procedure for patient testing.
5. Record results and compare with expected results.

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

REFERENCES

1. Briselden and Hillier. 1994. J. Clin. Microbiol. 32:148-152.
2. Camery, Unadkat, Yule, Rajakumar, and Lacey. 1988. J. Clin. Pathol. 41:806-808.
3. Garcia and Bruckner. 1997. Diagnostic Medical Parasitology. 3rd Ed. ASM, Washington, D.C.

KEY OF SYMBOLS

 LOT	Batch code	 REF	Catalogue number
	Biological risk		Caution, refer to accompanying documents
 IVD	In Vitro diagnostic medical device Name)		Manufactured by (Manufacturer
 CONTROL +	Positive control	 CONTROL -	Negative control
	Temperature limitation		Use by (Expressed as: CCYY-MM-DD)