

INSTRUCTIONS FOR USE

Tri-Valent Swab (Positive Control)

Catalog #: TVS-01

INTENDED USE

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

SUMMARY AND EXPLANATION

The **Tri-Valent Swab** contains whole cells of *Trichomonas vaginalis*, *Gardnerella vaginalis*, and *Candida albicans* for use in quality control.

PRINCIPLE

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

COMPOSITION

Each **Tri-Valent Swab** contains the following stabilized cell mixture:

- *Trichomonas vaginalis*
- *Gardnerella vaginalis*
- *Candida albicans*

PRODUCT DESCRIPTION

Each swab contains a stabilized cell mixture, sealed within a foil pouch that contains a desiccant to prevent adverse moisture accumulation.

WARNING AND PRECAUTIONS

Tri-Valent Swabs are for In Vitro Diagnostic Use only and should be used by properly trained personnel. Product is not intended for human, animal or pet consumption. 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. Refer to the SDS for more detailed information.

MATERIALS REQUIRED BUT NOT PROVIDED

Additional clinical microbiological equipment may be needed and is dependent on the test scheme selected. Please consult test kit instructions for additional details.

INSTRUCTIONS FOR USE

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.




















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

STORAGE AND EXPIRATION

Tri-Valent Swabs should be stored at 2°C to 8°C in the original packaging. Remove only the quantity required for immediate use. Do not freeze or overheat. Do not use this product if the expiration date has passed.

LIMITATIONS

This product may not be suitable for use with all kits and procedures.

KEY					
	Manufacturer		Keep Dry		Positive control
	Date of manufacture		Intended Use		Negative control
	Catalog Number		In vitro diagnostic		Biological risk
	Lot Number/Batch Code		Do not re-use		Caution
	Temp. Limit/Storage Temp.		Consult instructions for use		Contains sufficient for <n> tests
 	Expiration/Use-by-Date		Authorized representative in the European community		Total number of products in package

PRODUCT WARRANTY

This product is covered under warranty to meet the specifications and performance printed in product inserts, instructions and supportive literature. The warranty, expressed or implied, is limited when:

- the procedures employed in the laboratory are contrary to printed directions and instructions.
- the products are employed for applications other than the intended use cited.

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