

Cultura™ FLEX SWAB TRANSPORT SYSTEM

Sterile Flocked Collection Device with Specimen Transport Vial and Biohazard Bag

One of the routine procedures in the diagnosis of infections involves the collection of swab samples. This can be accomplished using the Merit Cultura™ Flex Swab which is a sterile flocked collection device. Merit's Cultura™ Flex Swabs have a plastic shaft and nylon fiber tips in a sterile peelable pouch.

INDICATIONS FOR USE

Merit Cultura™ Flex Swabs are sterile and intended for taking samples. The Molecular Transport Medium, (MTM), Vial contains a pathogen-inactivating nucleic acid-stabilization solution. It is intended for use with a collection swab. The patient sample is collected according to the US CDC and W.H.O. recommendations for collecting and testing human respiratory samples from either nasal or oral cavity. The transport vial can be processed using standard clinical laboratory operating procedures for molecular assay testing of specimens that potentially contain viral or bacterial infectious agents.

CONTRAINDICATIONS

None known

PRECAUTIONS

- Carefully follow the instructions for use.
- Do not use excessive force during sampling as the stick material is breakable.
- The fiber adhesion to the stick is validated for instantaneous sampling. Longer contact between the swab and the sampling area might cause the fiber to come out.
- If the swab is submitted to a chemical or physical sterilizing or micro-biostatic process, its intended functioning could be compromised.
- Product is sterile if package is unopened and undamaged.
- Product can not be reused or re-sterilized.
- Sterile gloves and protective clothing and eyewear should be worn when collecting and handling microbiology specimens.

STORAGE

Store product in a cool, dry place. Storage temperature for the vial with reagent is 5-25°C. Do not overheat or freeze prior to use.

NOTES

A slight yellowing of the tip may be noticed. This could be due to many factors: for example, the type of raw material used, the method by which the product was sterilized or the product's natural aging process. Because of this, product yellowing is not necessarily indicative of product deterioration. Swabs should not be used if (1) there is evidence of damage or contamination to the product, (2) the expiration date has passed, (3) the swab package is open or damaged, or (4) there are other signs of deterioration. The screw-capped transport tube with 2.5 mL of pathogen-inactivating nucleic acid-stabilization solution is ready for use and requires no further preparation. The transport product provides a simple solution used to inactivate virus and bacteria and stabilize the nucleic acids in the sample. Samples are stable at room temperature, allowing the collection of high-quality RNA/DNA required by downstream molecular assay testing and experiments. The stabilization solution contains a protein denaturant and surfactants that disrupt the viral capsid or envelope, cell walls and membranes rendering the microbe non-infectious. The denaturant, in addition to its pathogen inactivating properties, also stabilizes the nucleic acids (RNA and DNA) from the pathogen. Inactivated samples can be transported to the testing site at 5-25°C. Samples can be held at these temperature conditions or stored frozen (< -20°C) for archival purposes. It is recommended that each lab qualify sample storage conditions. The samples stored in this inactivating and nucleic acid-stabilization solution can be used for subsequent nucleic acid extraction and molecular assay testing. The inactivating solution nucleic acid stabilization solution abides by the Center for Disease Controls (CDC) guidelines for pathogen inactivation; it is not suitable for culture of infectious agents.

WARNINGS

- This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
- Do not re-sterilize unused swabs.
- Do not re-pack.
- Not suitable for any other application than intended use.
- The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
- Do not use if the swab is visibly damaged (i.e., if the swab tip or swab shaft is broken).
- Do not use excessive force, pressure or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft. The swab shaft features a molded breakpoint point designed for intentional breakage of the swab into a transport tube. When collecting swabs samples from patients, do not use excessive force, pressure or bending of the swab as this may result in accidental breakage of the swab shaft.
- Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
- To be handled by trained personnel only.
- It must be assumed that all specimens contain infectious micro-organisms; therefore all specimens must be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.

ADVERSE REACTIONS

None known

RX ONLY Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device, specific therapeutic or diagnostic procedure.

INSTRUCTIONS FOR USE

- Open the peel and extract the swab
- Collect the sample. During sampling, the swab end (tip) shall only come in contact with the suspected infection, so as to reduce contamination risks.
- After patient sampling, immediately place the tip of the swab into the tube containing the inactivating stabilization solution.
- Break the tip of the swab off inside of the vial, leaving the swab tip in the transport tube. Discard the stick and recap the transport tube containing the swab sample.
- After the stored sample's target RNA or DNA is extracted by commercial extraction kits, various gene detection and molecular assay tests can be performed.

Specimens collected for clinical investigations should be collected and handled following published manuals and guidelines.

Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. Shipping of specimens within medical institutions should comply with internal guidelines of the institution.

CAUTIONS

- In the laboratory, wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe biosafety recommendations when handling or analyzing patient samples.
- Condition, timing, and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
- Swabs must be used by skilled personnel only.
- Avoid swab contact with the exterior of the transport tube.
- The Inactivating Stabilization Solution is not suitable for culture of infectious agents.
- Check the package before using it. If damaged, do not use.
- The solution contains chemicals that are listed as being irritants. Wear appropriate personal protective equipment when handling. Do not expose solution to bleach.

WASTE DISPOSAL

Unused swabs may be considered as non hazardous waste and disposed of accordingly.

Dispose of used swabs as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.








WARNING

GeneSTAT MTM, like most lysis buffers and nucleic acid purification reagents, contains a form of guanidine. When bleach interacts with guanidine in the GeneSTAT MTM, there is a risk of exposure to harmful cyanide gas. Therefore appropriate caution should be used in laboratories that use bleach as part of their normal laboratory processes. GeneSTAT MTM should not be used with the Hologic Panther System due to a disinfecting step involving bleach that is specific to that testing platform.

REAGENT SPECIFICATIONS

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| Contents | |
| Chaotropic Salt | Surfactant |
| Chelating Agent | Buffer |
| Ethanol | Molecular Grade Water |

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| Product Type | GeneSTAT MTM |
| Pathogen-Inactivating and Nucleic Acid Stabilization Solution* | - Inactivates infectious agents - Stabilizes the nucleic acid integrity of the sample at ambient temperatures - 16.5x101mm self-standing screw cap tube - 2.5 mL fill *Suitable for Molecular Assays. Not suitable for culture of infectious agents. |

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|  | Single Use |  | Date of Manufacture |
|  | Do not use if package is damaged and consult instructions for use |  | Sterilized using Irradiation |
|  | Do not re-sterilize |  | In Vitro Diagnostic |
|  | Store at 5-25°C | | |



Cultura Swab and Biohazard Bag:
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1600 West Merit Parkway
South Jordan, Utah 84095

GeneSTAT MTM:
GeneSTAT Molecular Diagnostics, LLC
180 North 300 East, Suite 201
St George, Utah 84770

Made in U.S.A

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