

Cultura™ COLLECTION AND TRANSPORT SYSTEM

Sterile Flocked Collection Device with Transport Vial and Biohazard Specimen Bag

The Merit Cultura™ Collection and Transport System contains a sterile nylon-flocked collection swab with a plastic shaft, a vial with 3.0mL of Viral Transport Medium (VTM) and a resealable biohazard bag. The VTM consists of Hank's Balanced Salt Solution (HBSS) enriched with proteins and sugars with a neutral pH and pH indicator. The VTM contains antibiotics to inhibit overgrowth of bacteria, yeast and fungi, maintain cellular integrity and encourage preservation of viruses when properly stored and has been evaluated for transport of SARS-CoV-2. Prior to use, vials should be stored at 2-25°C. After collection, the transport tube containing the specimen can be stored for up to 120 hours at 2-25°C, which provides convenience for transportation to the laboratory and storage. Samples can be stored at -70°C for archival purposes.

INDICATIONS FOR USE

The Merit Cultura™ Collection and Transport System is intended for collection and transport to the analysis laboratory of clinical specimens for subsequent diagnostic/identification techniques.

CONTRAINDICATIONS

None known

LIMITATIONS

- The Cultura VTM is intended to be used with the swabs provided inside the kit. The use of medium, tubes, or swabs from any other source may compromise performance.
- PCR studies were performed in triplicate using the Cultura VTM and swabs with positive and negative SARS-CoV-2 controls to confirm nucleic acid detection.
- Testing has been performed in triplicate to show the suitability of the VTM for the preservation of nucleic acids (RNA and DNA) for downstream nucleic acid extraction and molecular assay testing and experiments when VTM and collection samples are stored per instructions provided.
- Although the VTM is formulated to encourage preservation of viruses, virus viability testing has not been performed.

Results obtained largely depend on proper and adequate specimen collection as well as the promptness with which the specimens are transported to the laboratory and analyzed.

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.
- Instructions 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.

CONTENTS

The Cultura™ Collection and Transport System is ready for use and requires no further preparation. The packaging includes:

- 1 Sterile Cultura Flex Swab with 100mm breakpoint
- 1 Vial with 3mL of Viral Transport Medium
- 1 Biohazard-labeled Specimen Bag

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 2-25°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.

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 VTM.
- Break the swab off into vial by aligning red-marked breakpoint with upper edge of vial and bend until swab breaks off at mark, leaving the swab tip in the transport tube. Discard the stick and recap the transport tube containing the swab sample.
- After collection, standard operating protocols for clinical specimen handling and preservation should be followed. The transport tube containing the swab with nucleic acids from the specimen can be stored for up to 120 hours at 2-25°C, which provides convenience for transportation to the laboratory and storage. It can be stored at -70°C for archival purposes.
- 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.
- Check the package before using it. If damaged, do not use.
- Vial container may become brittle at cold temperatures and may crack if dropped. Handle with care.









WASTE DISPOSAL

Unused swabs may be considered as non hazardous waste and disposed of accordingly. VTM must be disposed of in accordance with applicable regulations. 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.

REAGENTS

The VTM formulation includes proteins for virus stabilization, antibiotics and antimycotics to prevent overgrowth of bacterial and fungal flora and a buffer solution to maintain a neutral pH.

Component	Concentration
HBSS Solution	10 g/l
pH Indicator	< 1 g/l
FBS	20 g/l
Antibiotics	< 1 g/l

	Single Use		Date of Manufacture
	Do not use if package is damaged and consult instructions for use		Sterilized using Irradiation
	Do not re-sterilize		For In Vitro Diagnostic Use
	Storage Temperature, (2-25°C)		Use by Date



Made in U.S.A

Merit Medical
1600 West Merit Parkway
South Jordan, Utah 84095

406935003_002 ID 061020