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Instructions for Use

KSL Virus Specimen Collection Kit 4 Catalog No. 52018

Intended use

The KSL Virus Specimen Collection Kit 4 contains a sterile Viral Transport Media (VTM) filled tube and a sterile nasopharyngeal (NP) / oropharyngeal (OP) flocked-nylon swab. The VTM consists of Hank's Balanced Salt Solution (HBSS) and a pH color indicator. The antibiotics in the VTM inhibit growth of bacteria, yeast and fungi, maintain cellular integrity and encourage preservation of viruses. The kit is intended for collection and transport of clinical specimens to laboratories for analysis of microorganism infection and is specifically validated for SARS-CoV-2 detection.

While this transport media has not been reviewed by FDA, the collection device is available for use in the USA under the FDA guidance "Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" (July 2020). The VTM filled tube has completed the notification process to allow for sale within the United States. The VTM serves as a culture media for non-propagating transport. The device is to be used by trained and qualified professionals.

Kit contents

Description Component	Part No. Quantity		Main
KSL Activated Transport System 4	52010	Sterile Viral Transport Media (VTM) filled collection tube containing HBSS, Amphotericin B, Gentamicin and fetal bovine serum.	3 mL
Disposable Nasopharyngeal Swab	97-2012	Sterile nasopharyngeal (NP) / oropharyngeal (OP) flocked-nylon swab	1 each

Collection and handling of specimens

1. Ensure sterile gloves and protective clothing and eyewear are worn
2. Open plastic pouch and remove swab and collection tube
3. Peel open swab pouch and gently collect a nasopharyngeal (NP) or oropharyngeal (OP) sample
4. After sampling, immediately place the swab into the VTM tube and break the swab stick at the break point
5. Without touching the tube threads with your hands, re-attach the cap and tightly screw the cap into place
6. Appropriately identify the patient information on the tube prior to sending the tube to the laboratory for analysis
7. **After collection, standard operating protocols for clinical specimen handling and preservation should be followed. In order to achieve the best results for subsequent pathogen culture recovery the collection tube containing the specimen swabs should be stored at 2-8°C and shipped within 72 hours, which provides convenience for transportation to the laboratory and storage. Tubes containing specimen swabs can be stored at -70°C for archival purposes.**

Storage

The KSL Virus Specimen Collection Kit 4 should not be frozen prior to sample collection.

Shelf Life

Based upon stability studies, collection kits are stable for 1 year from date of manufacture when stored at 2° to 8°C. Collection kits may be stored at room temperature for 8 months.

Limitations

- The viral transport tube may be impacted by extreme temperatures and repeated freeze and thaw cycles
- The use of this product with any diagnostic test should be evaluated and tested by the end user
- This product is not a replacement for viral cell culture medium
- The product is sterile if the package is unopened and undamaged
- This product is not to be used if there are signs of damage, contamination, leakage, the swab package is open or other signs of deterioration are present
- Product cannot be reused or re-sterilized
- Sterile gloves and protective clothing and eyewear should be worn when collecting and handling microbiology specimens
- Specimen stability for this media was not validated for recovery of viral infectious particles using a culture-based assay

Performance Data

VTM tubes (Cat No. 52010) were tested using a commercial FDA EUA cleared RT-PCR assay using swabs (Cat No. 97-2012) from positive and expected negative SARS-CoV-2 viral material. In lieu of pulling swabs from PCR positive patients, clean swabs were placed into 5 vials of VTM from viral positive patients (oropharyngeal swab material) and the swabs were then transferred to clean KSL VTM tubes. Five oropharyngeal swabs were collected from expected negative patients and placed into clean KSL VTM tubes. KSL VTM tubes and swabs were also compared with competitor VTM and swabs using the same collection methods and specimens. All results were as expected. All previously positive VTM materials were positive with KSL and competitor VTM and swabs. All expected negative patient materials collected with KSL and competitor VTM and swabs were negative for SARS-CoV-2 RNA. A summary is shown below.

Sample ID	Tube / Swab	SARS-CoV-2 RT-PCR Result	Expected Result	Agree?
Pos 1	KSL	Positive	Positive	Yes
Pos 2	KSL	Positive	Positive	Yes
Pos 3	KSL	Positive	Positive	Yes
Pos 4	KSL	Positive	Positive	Yes
Pos 5	KSL	Positive	Positive	Yes
Pos 1	Other	Positive	Positive	Yes
Pos 2	Other	Positive	Positive	Yes
Pos 3	Other	Positive	Positive	Yes
Pos 4	Other	Positive	Positive	Yes
Pos 5	Other	Positive	Positive	Yes
Neg 1	KSL	Negative	Negative	Yes
Neg 2	KSL	Negative	Negative	Yes
Neg 3	KSL	Negative	Negative	Yes
Neg 4	KSL	Negative	Negative	Yes
Neg 5	KSL	Negative	Negative	Yes
Neg 1	Other	Negative	Negative	Yes
Neg 2	Other	Negative	Negative	Yes
Neg 3	Other	Negative	Negative	Yes
Neg 4	Other	Negative	Negative	Yes
Neg 5	Other	Negative	Negative	Yes

Quality Control

1. The collection kit has been validated by confirmation of positive and negative SARS-CoV-2 PCR results using a commercial FDA EUA cleared RT-PCR kit
2. Each lot of VTM tubes is tested for sterility prior to release for distribution

Symbol Key



Consult Instructions for Use



Manufacturer



Temperature Limit



Date of manufacture



Use by Date



Batch Code / Lot Number



Catalogue number / Part Number



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