VACUETTE®

greiner BIO-ONE

CE

VACUETTE® Virus Stabilization Tube

For In Vitro Diagnostic Use

EN

Intended Use

VACUETTE® Virus Stabilization Tubes are intended for the transport and storage of nasopharyngeal and oropharyngeal swab specimens. The product is to be used by healthcare professionals for SARS-CoV-2 testing only.

Product Description

VACUETTE® Virus Stabilization Tubes are made of PET with a pre-defined volume of a phosphate buffer saline solution at a pH of 7.4±0.2 to allow for the storage of the SARS-CoV-2 swab specimens for up to 72h at 4°C. The tubes are fitted with VACUETTE® Safety Caps. The tube interior is sterile. The product is single use only and can be used on a single patient only.

Precautions/Cautions

1. To be used only if universal transport media is not available.
2. Do not use tubes if foreign matter is present.
3. Do not use tubes after their expiration date.
4. Keep sterile tubes closed until use.
5. Do not pool the additive of different VACUETTE® Virus Stabilization Tubes.
6. Do not use the additive from VACUETTE® Virus Stabilization Tubes for premoistening or prewetting the applicator swab before collecting the sample or for rinsing or irrigating the sampling sites.
7. Do not ingest the additive in the tube.
8. Specimens for the detection of SARS-CoV-2 must be collected and handled using personal protective equipment against biological risk.
9. Handle all biological samples according to the policies and procedures of your facility.
10. Obtain appropriate medical attention in the case of any exposure to biological samples.
11. Ensure that after placing the specimen into the tube, that the cap is securely closed.
12. The tubes have a round bottom and are not self standing. Use of a sample rack is recommended.
13. The additive is transparent. Functionality of the product is not indicated by a color change.
14. Refer to the instructions for use of diagnostic assays for information on the correct sample material, correct storage and stability.
15. The user must validate the product when combining it with swabs, diagnostic kits or instruments before its use.

Storage

Storage guidelines for tubes before use
Store tubes at 4–25°C (40–77°F).
***NOTE**: Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the tube quality (i.e. drying out of liquid additives, coloring, etc.)*

Limitations

1. There is limited data available on test performance with specimens which have been frozen in any transport media; therefore, specimen stability should be validated if freezing is necessary. Please follow your facility protocol for this purpose.
2. The additive of the VACUETTE® Virus Stabilization Tube does not contain any RNase inhibitors.
3. The VACUETTE® Virus Stabilization Tube has a dimension of 13x100mm. The length of the inserted swab should not exceed 90mm.

Specimen Collection and Handling

The use of phosphate buffer saline (PBS) for stabilizing and transporting viruses is recommended by the U.S. Food and Drug Administration when universal transport media for viruses is not available. Please follow your institution´s policy regarding the correct sample collection and processing.
Remove the cap from the tube by twisting in an anti-clockwise direction. Insert swab and close the tubes by twisting in a clockwise direction until firmly closed.
Please ensure a correct transport of the sample in the tube according to international regulations, such as UN3373.

Disposal

1. The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed.
2. Disposable gloves and other personal protective equipment prevent the risk of infection.
3. Contaminated or filled tubes must be disposed of in suitable biohazard disposable containers, which can then be autoclaved and incinerated afterwards. Follow your facility's protocol.
4. Disposal should take place in an appropriate incineration facility or through autoclaving (steam sterilization).

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Label Information

	Manufacturer		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Catalogue number		*In vitro* diagnostic medical device
	Sterilized using irradiation		

References:

ISO / EN / ANSI/AAMI Standards
ISO 11137 “Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization”
CLSI M40-A2 Quality Control of Biological Transport Systems

FAQs on Diagnostic Testing for SARS-CoV-2. What if I do not have…? U.S. Food and Drug Administration. Accessed on April 6th, 2020. Available at: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2?utm_campaign=2020-03-21%20Mar%2021%20Update%3A%20New%20Information%20on%20Diagnostic%20Testing%20for%20SARS-CoV-2&utm_medium=email&utm_source=Eloqua#troubleobtainingviraltransport

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