InGenuityD

BioGenex Viral Transport Media (BGX-VTM)

Instructions for Use (IFU)

1. Intended Use

THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. FOR TRANSPORT OF SPECIMENS ONLY. NOT TO BE TAKEN INTERNALLY. INSTRUCTIONS MUST BE CAREFULLY FOLLOWED.

BioGenex Viral Transport Medium (BGX-VTM) contains a viral transport medium (Non-Propagating Transport Medium) intended to be inoculated with nasopharyngeal (NP) or oropharyngeal (OP) synthetic fiber swab specimens, transported appropriately to the laboratory and analyzed with qRT-PCR assays for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes COVID-19 disease in humans.

2. Description and Principle

BGX-VTM is a transport system to collect and transport viruses in an active form to the laboratory for isolation. It is designed to maintain the viability and the virulence of the viral sample. BGX-VTM is made of Sterile Hanks Balanced Salt Solution with calcium and magnesium ions. It contains a protective protein, antibiotics to control microbial & fungal contamination and buffers to control the pH. Phenol red is used as a pH indicator (Centers for Disease Control and Prevention; SOP#: DSR-052-05).[1]

The synthetic fiber swab has a short ultra-flexible plastic shaft that is designed for the patient comfort. This plastic shaft is attached with soft fiber strands that results in efficient collection and release of particulate matter. It yields significantly more sample which helps in maximizing the sensitivity of serological and molecular detection assays. This swab has a molded breakpoint which allows the swab to be broken into the tube.

3. Specimen types recommended

- A nasopharyngeal (NP) specimen collected by a healthcare provider; or
- An oropharyngeal (OP) specimen collected by a healthcare provider

4. Components and specification

a) 3 mL BGX-VTM in a screw capped self-standing sterile DNase/RNase free vials –50 units

b) Sterile Nasopharyngeal swab with breakpoint – 50 units

c) Sterile Oropharyngeal swab with breakpoint – 50 units

COMPONENT	FDA Status	VOLUME OF VTM PER VIAL/QTY	DIMENSIONS	WORKING VOLUME/QTY
Sterile VTM vial	Not Applicable	3 mL per vial x 50	H: 8.5 cm (capped Height) W: 1.5 cm	10 mL
Nasopharyngeal Swab (Shenzhen Cleanmo Technology Co., Ltd.)	Regulation Number: 880.6025	1 swab per unit	15.0 cm with break point	50 units
Oropharyngeal Swab (Shenzhen Cleanmo Technology Co., Ltd.)	Registered Establishment Number: 3016701575	1 swab per unit	15.5 cm with break point	50 units

5. Specimen Collection Procedure

IMPORTANT: Please ensure that a lab operator and trained authorized personnel read these Instructions for Use for BGX-VTM. Specimen should be collected according to the healthcare institutional guidelines.

A. Collection of Samples

For a complete diagnostic analysis of viral diseases, it is important that the infectivity of the viruses is preserved after sample collection. Stability of samples is enhanced by cooling; therefore, samples should be kept at 2-8°C after collection. The probability of a successful isolation is increased when the samples are processed immediately after collection. Viral load is maximized if the samples are collected immediately after the onset of clinical symptoms and before the administration of antiviral medications.

B. Directions:

1) Cut and open the pouch to remove the swab.
2) Specimen can be collected with the swab in accordance with healthcare institutional guidelines.
3) Break the swab near the break point or cut the swab with scissor and insert into the tube containing viral transport medium and close the cap tightly.
4) Label the sample correctly with the name of the patient and time and date of collection.
5) Transport the samples immediately to the laboratory for processing.

C. Transportation of the Samples:

Samples should be transported to the laboratory as soon as possible. Samples can be refrigerated at 2-8°C after collection or can be transported at 2-8°C on ice packs within 48 hours. If a long delay is expected in transit and processing, samples should be transported on dry ice and should be frozen at -70°C.[3]

6. Quality Control

BGX-VTM has been tested and meets the CLSI Approved Standard for commercially prepared media (M22-A3). At the time of manufacture, quality control testing is performed on each lot of BGX-VTM for verification of sterility.

Sterility Performance Testing: 1 mL of VTM is aseptically plated onto sheep Blood Agar and incubated for 48 hrs at 37°C ± 2°C and monitored for bacterial/ fungal growth.

Results / Acceptance Criteria: No bacterial/ fungal growth was observed after 48hrs at 37°C. The BGX-VTM appears clear pink/orange colored. Post-production pH of the media is 7.3 ± 0.2 at 25°C.

7. Performance evaluation & Stability Study

Performance evaluation was carried out for the BGX-VTM by detection of SARS-CoV-2 from positive and negative samples collected and stored in BGX-VTM for 24, 48 and 72 hours at 2-8°C. RNA was isolated using commercially available RNA extraction kit and detection of SARS-CoV-2 was carried out by qRT-PCR using AllPlex (Seegene) one step RT-PCR Kit on Qiagen Rotor-Gene Q5Plex HRM (Software Version 2.3.1.49). The assay results demonstrate consistent amplification with low cycle threshold value of the N1 gene. Testing of replicates demonstrate the consistency in the performance of the media across all the samples at different incubation time. This indicates that BioGenex manufactured BGX-VTM does not negatively interfere with RNA extraction and the qRT-PCR detection of SARS CoV-2 (See Fig. 1).

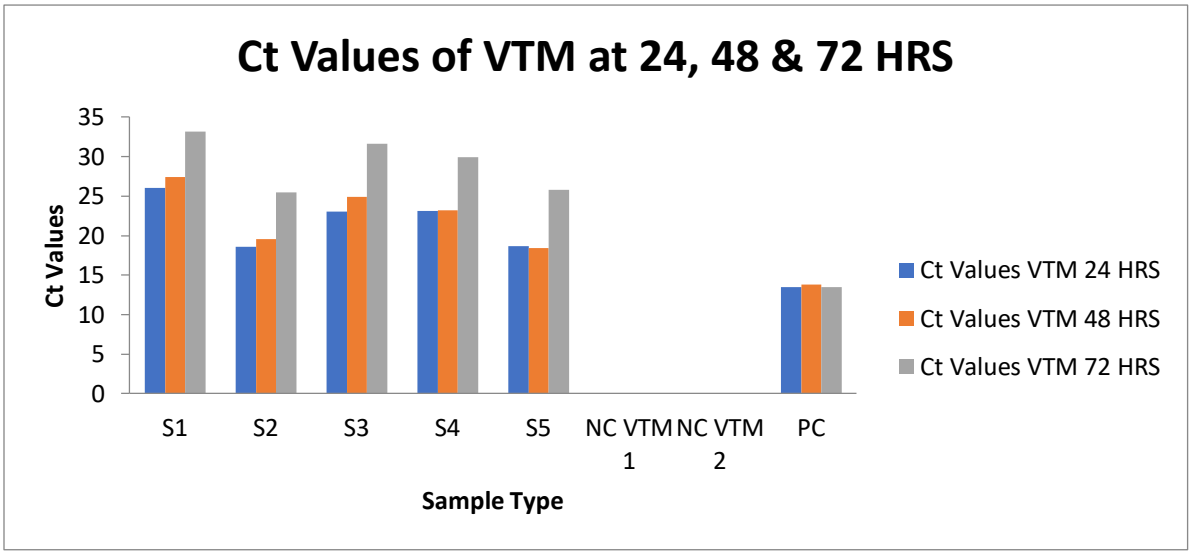


Figure 1. Amplification of N1 fragment of SARS CoV-2: Ct values of RT-PCR for positive samples (S1-S5) and PC (positive control). No amplification was observed for NC VTM (Negative control, VTM only).

8. Precautions:

1) Isolation of viruses will largely depend on proper specimen collection, timing of sample collection and processing of samples.
2) Specimen collection should be done in the acute phase of illness.
3) Do not use the product if
   a) there is change in the color of the medium,
   b) there is evidence of leakage,
   c) there are other signs of deterioration.
4) It is recommended to refer to standard procedures and published protocols for sample collection and processing.
5) Use before expiry date given on the product label.

9. Storage and Shelf Life

Do not freeze the BGX-VTM. Upon receipt, store at 2-8°C, and keep away from direct light exposure. After receipt or removal from refrigerated temperature (2-8°C), the BGX-VTM can be stored at room temperature (18-25°C) for up to 30 days without deterioration of performance, but not past the expiration date on the tube. The product label reflects the expiry date for product stored at 2–8°C.

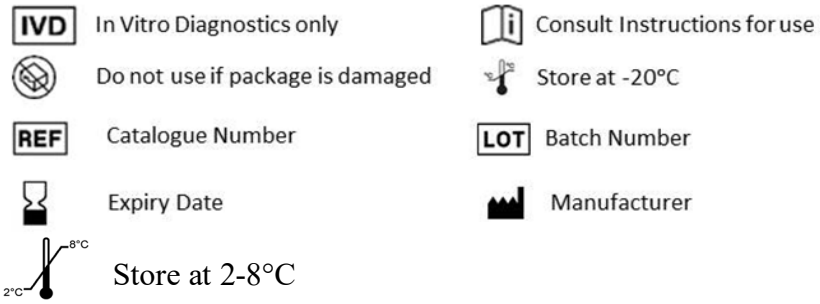
10. Risks

I. Performance of the BGX-VTM may be impacted by extreme temperature conditions.
II. The use of BGX-VTM, for uses other than described here shall be evaluated by the end user.
III. The use of swabs with wooden or calcium alginate components has not been tested with the BGX-VTM and should not be used.
IV. The use of this product with any diagnostic test should be evaluated and tested by the end user.
V. This product is not a replacement for viral cell culture medium.

11. References

1. https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf.
2. www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
3. FAQs on Viral Transport Media During COVID-19: www.fda.gov/medical-devices/coronaviruscovid-19-and-medical-devices/faqs-viraltransport-media-during-covid-19

Index Symbol



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