ARX Sciences Viral Transport Medium

The ARX VTM Transport System 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 ARX VTM Transport System has completed the notification process.

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INTENDED USE

ARX Sciences Viral Transport Medium is intended for the transport of clinical specimens containing upper respiratory viruses from collection sites for measurement of viral particles in the samples using molecular and antigen assays.

SUMMARY AND EXPLANATION

The US Centers for Disease Control and Prevention(CDC) recommends the use of viral transport media to collect and store respiratory disease specimens (1). ARX Sciences Transport Medium is manufactured and validated in the accordance with the CDC's standard operating procedure, which was created in response to COVID-19 (2).

PRINCIPLE

ARX Sciences Transport Medium maintains organism viability for up to 72 hours at 2-8°C. Antibiotics and fungicides present in the medium inhibit bacterial and fungal growth without the degrading viruses and other respiratory disease-causing agents.

REAGENTS

Fetal Bovine Serum
50 mg/mL Gentamicin
250 mg/mL Amphotericin B (Fungizone)
Prepared in Hanks Balanced Salt Solution
Precautions: *For In Vitro Diagnostic Use.*

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WARNINGS AND PRECAUTIONS: *For In Vitro Diagnostic Use.*

Follow standard precautions And handle using proper personal protective equipment and safe laboratory procedures. Do not ingest the medium. Not suitable for any other application than the intended use. Avoid multiple freeze-thaw cycles.

For use only by qualified healthcare workers for point-of-care testing covered by clinical laboratory's CLIA certification for high-complexity testing.

Not for home use, including at-home testing or specimen collection.

This device is to be used by trained and qualified professionals.

STORAGE: Ready to use. Store between 2°-25°C. This allows flexibility in transport temperature ranges - room temperature or refrigerated.

PRODUCT DETERIORATION:

Do not use if visual signs of deterioration (e.g., evaporation) are observed. Check expiration date before use. Product has a 18 month expiration date stored at 2°-25°C from time of manufacturing.

QUALITY CONTROL

ARX Sciences Transport Medium is tested for pH(USP<791>), conductivity (USP<644>), and sterility. Sterility is assessed by applying the solution to the surface of sheep blood agar plates and incubating for 48 hours at 37° C ± 2°C. The plate is checked for growth daily. Functional testing should be performed by user to determine efficacy.

PROCEDURE

Collect the specimen following the CDC Influenza Specimen Collection guidelines (3), then place the swab into ARX Sciences Viral Transport Medium. Store the specimen at 2-8°C for up to 72 hours after collection. Specimens can be stored at –70°C or below if there is a delay in testing or shipping (1)

PERFORMANCE

Viral particle recovery studies were performed using ARX Sciences Viral Transport Medium with SARS-CoV-2, Influenza A H3N2 Virus (Strain: Kansas/14/17), and Influenza B Virus (Strain: Alabama/2/17). The media was refrigerated (2-8°C) or incubated at (37°C) for 12 weeks before conducting the viral recovery studies. Culture Fluids were grown and frozen (-65°C or below) for experimental procedures. The culture fluids were thawed and combined with VTM either by direct spiking (1:10), or by swab transport using two separate swab manufacturers. As a control, the viruses were combined with PBS (Mock). Samples were taken from conditions at 0 and 72-hours post exposure, then frozen until testing was performed.

The infectivity testing was set up in 96-well plates, with serial dilutions of the samples loaded across the rows of the plate. Each sample was set up with 4 replicates (n=4). VeroE6 and MDCK cells were added to the wells to evaluate viral infectivity of SARS-CoV-2 and Influenza, respectively. Cytopathic effects (CPE) were visually observed over the 7-day assay to determine the outcome of the experimental conditions. The Reed and Muench calculator was used to determine the TCID50/mL titer of each sample.

SARS-CoV-2 samples were extracted within a Biosafety Cabinet (BSC) in a BSL-3 laboratory using the Purelink Viral RNA/DNA Kit. PCR assays were set up targeting the Envelope/Membrane Protein. Influenza A and B virus samples were extracted using the Qiagen Viral RNA Kit. Influenza A PCR assays were set up targeting the Matrix Protein 2 (M2) gene-segment 7. Influenza B PCR assays were set up targeting the Matrix 1 (M1) gene.

Table 1. ARX Sciences Viral Transport Medium (VTM) stored refrigerated or at room temperature maintained viral RNA stability at 2°-25°C for 72 hours.

PCR (Ct)	Virus Type	0 hrs.	SD	72 hrs.	SD
	SARS-CoV-2	21.90	1.09	22.55	0.60
	Influenza A	26.82	0.30	27.40	0.20
	Influenza B	21.81	0.17	23.31	0.08

REFERENCES

1. Interim guidelines for collecting, handling, and testing clinical specimens for COVID-19. US Centers for Disease Control and Prevention. Updated November 3, 2020. [Accessed November 16, 2020]

2. Preparation of viral transport medium. [PDF] US Center for Disease Control and Prevention. (2020) [Accessed November 16, 2020]

3. Influenza specimen collection. [PDF] US Center for Disease Control and Prevention. (2020) [Accessed November 16, 2020]

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