CE

SafeShield™-VLTM

Viral Lysis Transport Medium

INTENDED USE

SafeShield™-VLTM is intended for the collection, inactivation and transport of clinical specimens containing viruses and bacteria from the collection site to the testing laboratory. It is ideally suited for molecular testing of microbial RNA and DNA employing amplification tests.

SUMMARY AND PRINCIPLE

SafeShield™ -VLTM contains chaotropic agent and surfactant which interferes with the hydrogen bonds and intramolecular interactions of macromolecules. It solubilizes the proteins resulting in disintegration of cellular structures of the micro-organisms and also denatures DNase and RNase enzymes. The chelating agent sequester divalent cations which inactivates the nuclease enzymes and protects the nucleic acids released, and the buffering system also serves to protect them. This medium maintains the integrity of the nucleic acids for molecular testing. The lysing property of the Viral Lysis Transport Medium lyses the micro-organisms and renders them non infectious offering protection to the users. The inactivation and lysis of the micro-organisms is achieved within 30 minutes of introduction to the medium.

FORMULATION*

SafeShield™ -VLTM contains chaotropic agent (1 - 5 M), surfactant (0.1 - 0.5%) and chelating agent (0.01 - 0.05 mM), nuclease-free water,qs. The pH is adjusted to 6.7± 0.3 at 25 °C.

* Adjusted to suit performance parameter.

REF	203220250050
Σ	50 Tests

Important Note: Ten pairs of plastic hand gloves are provided with the kit, to be used while handling as the kit contains guanidine thiocyanate which is corrosive and can cause skin corrosion. Use of latex hand gloves is not recommended, however if used, should be doubly gloved using plastic gloves in addition.

STORAGE AND STABILITY

Store at 15°C - 25°C. Do not freeze or incubate. Keep the reagents away from direct sunlight. The shelf life of the reagents is as per the expiry date mentioned on the reagent vial labels. Do not use beyond expiry date.

ADDITIONAL MATERIAL REQUIRED

Standard microbiological supplies and equipment such as loops, incinerators, incubators, centrifuge, Pasteur pipettes, molecular testing kits, serological and biological reagents etc.

SPECIMEN COLLECTION AND PREPARATION

Once a swab specimen is collected it should be placed immediately into the **SafeShield™-VLTM** tube. Transport the specimen to the laboratory as soon as possible, to maintain optimum specimen viability. It is recommended to refrigerate the specimen during transit at 2°C-8°C to ensure best recovery. The specimen should ideally be tested at the earliest, ideally before 7 days post collection. If there is a long delay before processing, specimens should be frozen at -70°C or transported on dry ice, to prevent loss of integrity of nucleic acids. All specimens should be processed as soon as they are received in the laboratory. Specimens for viral and bacterial investigation should be collected and handled following the standard guidelines.

PROCEDURE

Proper collection of the specimen increases the probability of successful isolation and identification of the infectious organisms. Specimens should be collected a soon as possible after the clinical onset of disease. Highest viral titers are present during the acute illness

1. Peel open the sealed pouch pack and remove swab from the pouch.
2. Collect the specimen without breaking the swab.
3. Aseptically remove the cap from the tube.
4. Insert the swab into the vial containing the medium.
5. Break the swab shaft by bending the swab against the rim of the tube at the breakpoint.
6. Replace the cap and secure the lid, tightly.
7. Record the patient's information on the label.
8. Ship the specimen tube at 2°C-8°C in icebox to the laboratory for analysis.

QUALITY CONTROL

All lots of **SafeShield™-VLTM** are tested for microbial contamination, pH and the ability to inactivate microorganisms.

Appearance: Faint blue color clear solution. **Final pH at 25 °C:** 6.7 ± 0.3 **Volume:** 1.5 mL

INTERPRETATION OF RESULTS

Accuracy of results depends on proper specimen collection, transportation time and temperature as well as specimen handling in the testing laboratory.

LIMITATIONS

1. Condition, timing and volume of specimen collected are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
2. Repeated freezing and thawing of specimens may reduce the recovery of nucleic acids.
3. Dacron, rayon or nylon flocked swabs are recommended.
4. Calcium alginate or cotton swabs, as well as wooden stick swab, should not be used.

PRECAUTIONS

1. This product is for *in vitro* Diagnostic use only and to be used by trained and qualified professionals.
2. Read the instructions carefully before performing the test.
3. All laboratory specimens should be considered infectious and handled according to standard precautions.
4. Follow State, Local and Institutional guidelines for handling and disposal of Biohazard waste.
5. Do not ingest, inhale, or allow to come into contact with skin.
6. Do not pre-moisten the applicator before use.
7. Do not re-sterilize the swab. Also, do not use if the swab is damaged or broken.
8. Do not use if the medium is contaminated.
9. All specimens should be shipped in compliance with all the Local, State and hospital guidelines.

WARNINGS

Safeshield™-VLTM contains guanidine thiocyanate which is corrosive to metals, causes skin corrosion and serious eye damage.

- Recommended Personal Protective Equipment includes Dust mask type N95, Eye shields and thick durable Nitrile or Plastic Gloves .
- If on skin: Gently wash with plenty of water.
- If skin irritation or rash occurs: Get medical advice/attention.

Kindly note that this transport media should not be used in a testing platform that uses bleach or in laboratories that use bleach as a part of their routine decontamination and disposal process. When the bleach interacts with guanidine thiocynate it produces the hazardous cyanide gas.

REFERENCES

(1). Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, Wayne, Pa. (2). Anderson, N.L., *et. al,* Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C. (3). Jorgensen., *et. al,* Manual of Clinical Microbiology, American Society for Microbiology, Washington, D.C. Tille, P., *et. al,* Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.(4).Clyde, W.A., *et. al,* 1984. Cumitech 19; Laboratory Diagnosis of Chlamydial and Mycoplasmal Infections, Coordinating ed., W.L. Drew. American Society for Microbiology, Washington D.C. (5). Isenberg, H.D. Clinical Microbiology Procedures Handbook, Vol. I, II & III. American Society for Microbiology, Washington, D.C. (6). Murray, P.R., E. J. Baron, J. H. Jorgensen, M. A. Pfaller, and R. H. Yolken. 2003. Manual of Clinical microbiology. 8th ed. ASM, Washington, D.C. (7). Isenberg, H. D., 2004. Clinical microbiology procedures handbook, 2nd ed. ASM, Washington, DC. (6).P. Chomczynski and N. Sacchi,"The single-step method of RNA isolation by acid guanidinium thiocyanate-phenolchloroform extraction: twenty-something years on," Nature Protocols, Vol. 1, No. 2, pp. 581–585, 2006.(9). J. Sambrook and D. Russel, Molecular Cloning: A Laboratory Manual, Vol. 3, Cold Spring Harbor Laboratory Press, New York, NY, USA, 3rd edition, 2001. (10). K. Kojima and S. Ozawa, "Method for isolating and purifying nucleic acids," United State patent US 2002/0192667 A1, December 2002. (11). Data on File: Microxpress®, A division of Tulip Diagnostics (P) Ltd.

Symbol keys

Temperature Limit	Manufacturer	LOT Batch Code	EC REP Authorised Representative	Contains sufficient for <n> tests	IVD *In vitro* Diagnostic Medical Device
REF Catalogue Number	Consult Instructions for use	Use-by Date	This way up	STERILE A	Sterilized by aseptic processing techniques

Microxpress®
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0820/VER-01

Evaluation of SafeShield™ -VLTM (Viral Lysis Transport Medium) as a Lysis Buffer For specimen lysis and inactivation in VLTM.

Objective:

- To evaluate the lysing property of **SafeShield™ – VLTM (Viral Lysis Transport Medium)** on clinical samples collected in the **Microxpress® Viral Transport Medium**.
- To evaluate the sample lysis and inactivation property of **SafeShield™ –VLTM**.
- To evaluate if **SafeShield™ –VLTM** is an ideal viral sample collection, inactivation, transport and storage medium.

Background:

- One of the major requirements when handling microorganisms is for the safe collection and transport of the specimens to the testing centres.
- Viral Lysis Transport Medium is intended for the collection, inactivation and transport of clinical specimens containing viruses and bacteria from the collection site to the testing laboratory. It is ideally suited for molecular testing of microbial RNA and DNA employing amplification tests.
- The lysing property of the **SafeShield™ – VLTM (Viral Lysis Transport Medium)** lyses the microorganisms and renders them non-infectious offering protection to the users.
- The medium contains chaotropic agent and surfactant which interferes with the hydrogen bonds and intramolecular interactions of macromolecules. It solubilizes the proteins resulting in disintegration of cellular structures, and also denatures DNase and RNase enzymes maintaining the integrity of nucleic acids for molecular testing.
- The inactivation and lysis of the microorganisms is achieved within 30 minutes of introduction to the medium.

Materials:

Materials used for the quality assessment were prepared in accordance with the standard operating procedures and documented via batch history records.

Material	Make	Batch Number
Microxpress® Viral Transport Medium	**Microxpress®**	9152065
SafeShield™-VLTM (Viral Lysis Transport Medium)	**Microxpress®**	9402001

Equipments:

The following equipments were used to generate test result at **Microxpress®**

Equipment	Equipment No.	Calibrated On	Calibration Due Date
Micropipette	457	14/06/2020	13/06/2021
Laminar air flow	723	06/01/2020	05/07/2020
PCR Machine : Rotor-Gene Q (Qiagen)	QC/REF#I-257	01/06/2020	01/05/2021
RNA Extraction Kit : EX-RNA Spintube (Tulip Diagnostics)	-	-	-
PCR Kit: New Coronavirus Detection Kit (Perkin Elmer)	-	-	-

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Study Method:

- Required number of tubes of **SafeShield™-VLTM (Viral Lysis Transport Medium)** were selected.
- The tubes required for evaluation were brought to room temperature before testing.
- Each tube was examined for evidence of contamination such as cloudiness.
- Known positive and negative samples in VTM were brought to room temperature before testing.

Sample Description	Target Identification	Number of tubes inoculated
Throat and Nasal swabs (S1, S2)	Viral E, RdRp and Human RNase P	2
Negative Control (Water S3)		1

- RNA extraction was performed on all the positive and negative samples with standard extraction kit (Spin Column Method).
- In a modified protocol, **SafeShield™-VLTM (Viral Lysis Transport Medium)** was used as a lysis buffer in RNA extraction. Rest of the protocol remained same.

Results:

Physical parameters and pH:

SafeShield™-VLTM (Viral Lysis Transport Medium)

Test	Expected	Observed Results
Media Appearance	Faint blue clear solution	Complies
pH at 25 ± 2 °C	6.40 - 7.00	6.73
Volume	1.5 - 1.6 mL	Complies

Results and Interpretation:

Modified Method: SafeShield™-VLTM (Viral Lysis Transport Medium) used as Lysis Buffer

Samples	E	RdRp	RNase P
S1	26.99	29.27	24.12
S2	27.96	31.08	25.45
S3	Not Detected	Not Detected	Not Detected

Standard Method: Samples extracted with Spin Column Method

Samples	E	RdRp	RNase P
S1	27.41	29.78	25.43
S2	22.74	31.19	25.71
S3	Not Detected	Not Detected	Not Detected

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Conclusion:

- Inferred from the Ct values, the target gene was successfully detected in molecular testing with negligible Ct difference between the Standard and modified protocol.
- **SafeShield™ - VLTM (Viral Lysis Transport Medium)** decontaminates the specimen wherein it kills the bacteria and stabilizes and preserves the released nucleic acids.
- The **SafeShield™ - VLTM (Viral Lysis Transport Medium)** ensures for the safe collection and transport of the samples from the site of collection to the testing center.

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