आई सी एम आर - राष्ट्रीय प्रजनन स्वास्थ्य
अनुसंधान संस्थान
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

ICMR - National Institute for Research in Reproductive Health
Department of Health Research, Ministry of Health and Family Welfare, Government of India

01.10.2020

PERFORMANCE EVALUATION REPORT FOR VIRAL LYSIS TRANSPORT MEDIUM (VLTM) AND SWABS

• Name of the kit	VDx Viral Lysis Transport Medium Kit
• Name of the manufacturer	Vanguard Diagnostics Pvt. Ltd.
• Batch numbers	• VLTM200903
• Kit components	• 3 ml VLTM in 10 ml tubes (50 nos) • Sterile Oro-pharyngeal & Naso-pharyngeal swabs (50 nos each)
• Methodology	• Collect throat & nasal swabs from ten healthy individuals in ten tubes as per sample collection SOP. • Spike ten VLTM tubes with 100 µl of SARS-CoV-2 positive sample of Ct value in the range of 20-25. • Store all the tubes at 4°C for 8-12 hrs. • Extract RNA from all 20 samples using viral RNA extraction kit routinely used for detection of SARS-CoV-2 samples. • Test for SARS CoV-2 target genes by real time PCR along with human RNAseP or any other human housekeeping gene as an internal control (IC) to assess overall efficiency and consistency of extracted RNA.

जहांगीर मेरवानजी पथ, परेल, मुम्बई - ४०० ०१२, भारत
Jehangir Merwanji Street, Parel, Mumbai - 400 012, India

Tel: +91-22-24192000 / 24132111 / 12 | Fax: +91-22-24139412
Website: www.nirrh.res.in | Email: dir@nirrh.res.in, ao@nirrh.res.in

- Results

    1. Viral target amplification was observed in 10 VLTM tubes spiked with the virus.

    2. Amplification of internal control was noted in 20 tubes containing swabs.

- Conclusions:

    - Concordance among spiked positive samples: 100%
    - Concordance among negative samples: 100%
    - Samples showing amplification in internal control: 100%
    - Performance: Satisfactory

Disclaimers

1. ICMR's validation process does not approve / disapprove the kit design
2. ICMR's validation process does not certify user friendliness of the kit / assay
3. Validation of a kit by ICMR is not an assurance that the kit specifications would be included in the tendering process

- Note: This report is exclusively for VLTM Kit and Swabs
  Lot No. VLTM200903
  Manufactured by Vanguard Diagnostics Pvt. Ltd.
  The company shall not use or publish information or report for advertising or promotional purposes.

Evaluation Done on 01.10.2020

Evaluation Done by Dr. Dhanashree Jagtap

Signature of Director

Dr. Smita Mahale

BIOASSAY LABORATORY

Translational Health Science and Technology Institute, Faridabad

VALIDATION REPORT

Report No.: BL-VAL-008	**Date:** 28 Sep 2020

Validation Report of Viral Lysis Transport Medium (VLTM) by VANGUARD DIAGNOSTICS

Report prepared by Sign & Date	Report reviewed by Sign & Date	Report approved by Sign & Date
28sep2020	28 Sep 2020	29 SEP 2020

BIOASSAY LABORATORY

Translational Health Science and Technology Institute, Faridabad

VALIDATION REPORT

Report No.: BL-VAL-008	**Date:** 28 Sep 2020

Objective: To validate Viral Lysis Transport Medium (VLTM) manufactured by VANGUARD Diagnostics

Details of Materials used:

For RT PCR test: VLTM200901 (Expiry date: 08/2021) and VLTM200902 (Expiry date: 08/2021)
For Plaque assay: VLTM200901(Expiry date: 08/2021)
Control VTM: Microxpress Viral Transport Medium by Tulip Diagnostics (P) Ltd (Ref: 203220190050 Lot: 9152096, Expiry date: Jul, 2021)
RT-PCR kit: 2019-nCoV CDC Probe and Primer kit for SARS-CoV-2 (Lot: 143764)
RNA Isolation: QiAmp Viral RNA mini kit (Lot: 166024854, Expiry date: 30 Mar 2022)

Summary: VANGUARD Diagnostics has manufactured VLTM and has requested the Bioassay laboratory to validate two lots of VLTM for inactivation of SARS-CoV-2 and for detection of SARS-CoV-2 viral RNA by RT-PCR.

RT PCR Test:

100 µl of three different quantities of SARS CoV-2 (10^5 PFU, 10^4 PFU and 10^3 PFU) was added in respective VLTM tubes in triplicates. Routinely used Microxpress VTM tubes were used as controls. VLTM and microxpress VTM tubes without virus was used as negative control. 140 µl of medium containing virus was taken for RNA isolation by QiAmp Viral RNA mini kit as per the manufacturer's instructions. RNA was eluted in 50 µl of elution buffer and 5 µl of RNA used as template for RT PCR to detect SARS-CoV-2 RNA.

Plaque assay:

Plaque assay was setup in Vero E6 monolayer. Ten-fold serial dilution of virus stock was performed with VLTM followed by estimating virus titer by plaque assay procedure. Routine media with virus was used as positive control.

Quality controls:

Microxpress VTM used as Positive Control VLTM and microxpress VTM tubes without virus was used as negative control

28Sep2020	28 Sep 2020	29Sep2020
Test report prepared by Sign & Date	**Test report reviewed by Sign & Date**	**Test report approved by Sign & Date**

VALIDATION REPORT

Report No.: BL-VAL-008	**Date:** 28 Sep 2020

Results:

Plaque assay results:

SARS-CoV-2 diluted with VLTM completely inactivated the virus and produced no plaques.

RT PCR results:

S No	SARS CoV-2 isolate	2019-nCoV CDC Probe and Primer kit for SARS-CoV-2		
		Microxpress Viral Transport Medium	VLTM (Lot no: 200901)	VLTM (Lot no: 200902)
1	(10^5 pfu/100 µl)	17.65	16.51	16.75
2		17.44	16.57	16.46
3		17.52	16.52	16.43
4	(10^4 pfu/100 µl)	21.52	20.12	20.18
5		20.76	19.78	20.09
6		20.61	20.02	19.91
7	(10^3 pfu/100 µl)	24.72	23.61	23.56
8		24.07	23.27	23.21
9		24.37	23.24	23.42
10	Negative Control	0.00	0.00	0.00

Conclusion:

1. VLTM (Lot no VLTM200901) inactivates infectious SARS-CoV-2.
2. RT PCR results of VLTM (Lot no VLTM200901 and VLTM200902) were concordant with routine commercial VTM and found satisfactory

References:

1. Instruction manual for VLTM by Vanguard Diagnostics
2. Instructions for Use. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

28Sep2020	28 Sep 2020	29Sep 2020
Report prepared by Sign & Date	**Report reviewed by Sign & Date**	**Report approved by Sign & Date**