



01.10.2020

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

- Name of the kit V Dx 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.

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- 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



VALIDATION REPORT

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



VALIDATION REPORT

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

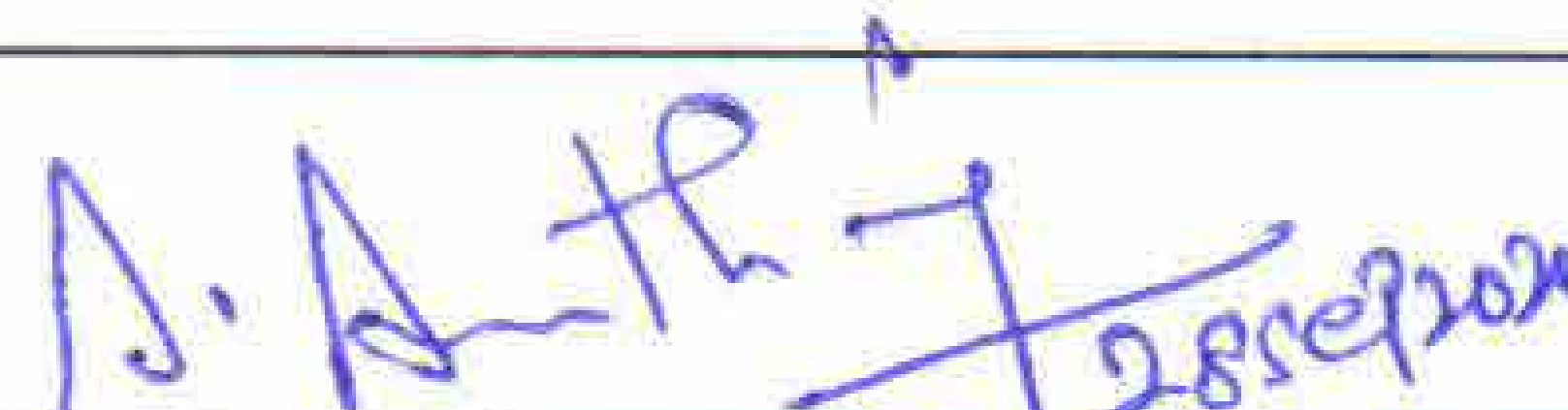


100 µl of three different quantities of SARS CoV-2 (10^5 PFU, 10^4 PFU and 10^3 PFU) was added in respective VLTM tubes in triplicates. Routinely used Microxpress VTM tubes were used as controls. VLTM and microxpress VTM tubes without virus was used as negative control. 140 µl of medium containing virus 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

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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
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Results:

Plaque assay results:

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

RT PCR results:


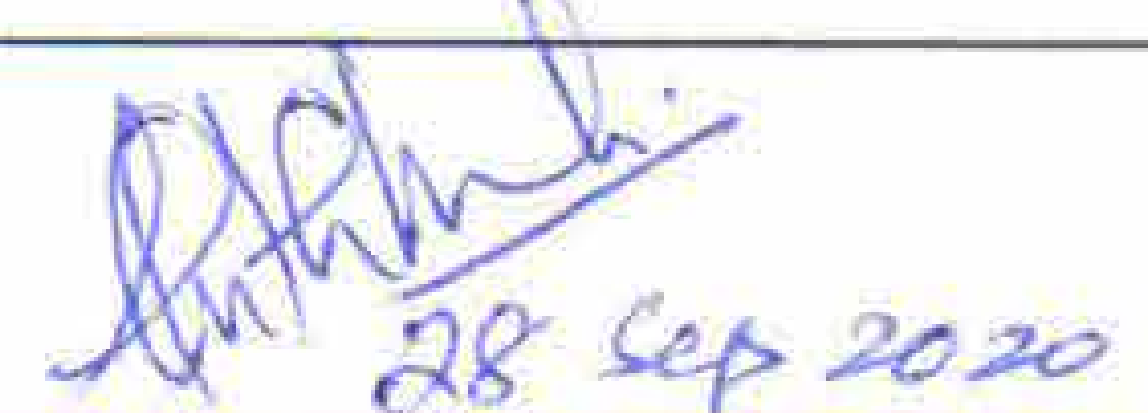
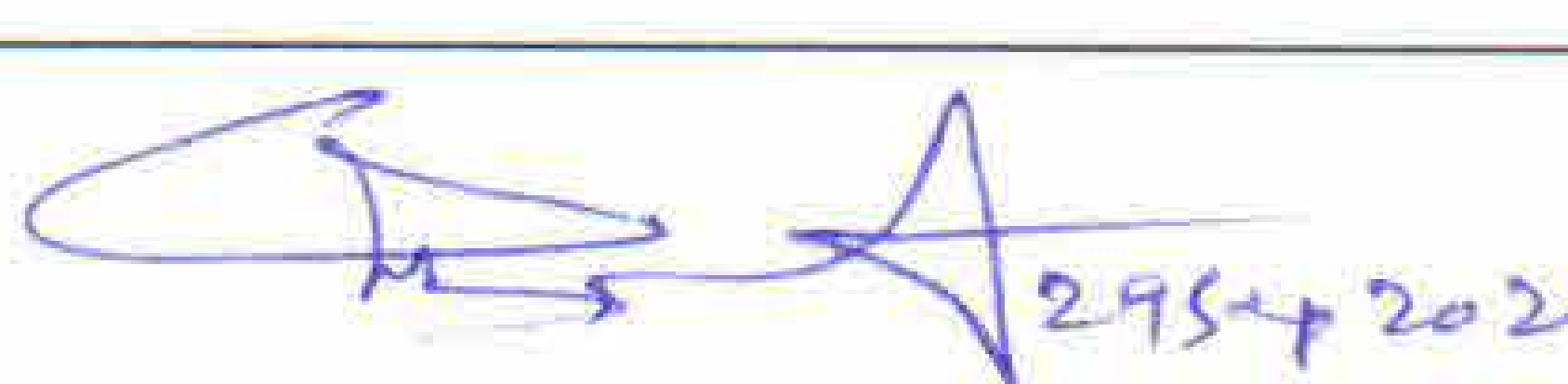
S No	SARS CoV-2 isolate	2019-nCoV CDC Probe and Primer kit for SARS-CoV-2		
		Microexpress Viral Transport Medium	VLTM (Lot no: 200901)	VLTM (Lot no: 200902)
1	(10 ⁵ pfu/100 µl)	17.65	16.51	16.75
2		17.44	16.57	16.46
3		17.52	16.52	16.43
4	(10 ⁴ pfu/100 µl)	21.52	20.12	20.18
5		20.76	19.78	20.09
6		20.61	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

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