आई सी एम आर – राष्ट्रीय विषाणु विज्ञान संस्थान
भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
I C M R - NATIONAL INSTITUTE OF VIROLOGY
Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare, Govt. of India
20 - ए. डा. आंबेडकर मार्ग, पोस्ट बॉक्स संख्या 11, पुणे - 411 001, भारत. 20-A. Dr. Ambedkar Road, Post Box No. 11, Pune 411 001, India.
Tel. : NIV Camp +91-020-26127301, 26006290, Fax : 26122669, 26126643 / NIV Pashan +91-020-26006390 Fax : No. 25871895 / 25870640
E-mail : director.niv@icmr.gov.in Website : www.niv.co.in

No: Inf/COVID-19/Evaluation/2020-1607 4 Oct 2021

To,
Molbio Diagnostics Private Limited
Plot No. L-46, Phase II D,
Verna Industrial Estate, Verna,
Goa - 403 722, India

Sub: Performance evaluation report of Truenat Influenza A/B kit Version-03

Sir,
We have evaluated Truenat Influenza A/B kit Version-03 (REF 601200020) RT PCR kit manufactured by Molbio Diagnostics Private Limited. Detailed report is attached for your information.

Thank you.

Prof. Priya Abraham
Director

ICMR- National Institute of Virology, Pune

PERFORMANCE EVALUATION REPORT FOR RT-PCR DIAGNOSTIC KIT

• Name of the Kit	Truenat Influenza A/B kit Version-03
• Name of the manufacture	Molbio Diagnostics Pvt. Ltd
• Catalog and batch no	REF 601200020, batch no AB006, AB007
• Date of Expiry	2022-09
• Application	Truenat Influenza A/B is a chip-based real time duplex RT-PCR assay intended for the detection of Influenza A and Influenza B virus in human throat and nasal swab specimen. RT-PCR test is based on Taqman chemistry.
• Kit components	Truenat Influenza A/B is a disposable, chip based duplex RT-PCR test with freeze dried RT-PCR reagents in micro-tube. Individually sealed pouches containing a Truenat Influenza A/B micro PCR chip, Microtube with freeze dried RT-PCR reagents and DNase & RNase free pipette tip.
• Method	RNA was extracted using MagMax RNA extraction kit as per kit protocol. The samples were tested simultaneously with gold standard (WHO/CDC protocol for Influenza A and Influenza B) and Truenat Influenza A/B kit. The gold standard assay was performed on Applied Biosystems 7500 Fast Real Time PCR System. Truenat Influenza A/B assay was performed as per kit protocol on Truelab Quattro real time quantitative micro PCR analyzer. Two different lots of Truenat Influenza A/B kit (REF 601200020, batch no AB006, AB007) were evaluated for sensitivity and specificity against the gold standard. Respiratory clinical samples well stored at -80 °C were used for evaluation.
• Sample Panel o Positive samples o Negative samples	42 Influenza A (H1N1: 19, H3N2: 23) and 40 Influenza B 77* Influenza negatives *A total 6 samples showed invalid results hence removed from the final analysis.
• Results interpretation	Result interpretation of Truenat Influenza A/B assay was carried out as per kit protocol. At the end of the test run, result is displayed on machine screen as Influenza A 'DETECTED' or Influenza B 'DETECTED' for positive result or 'NOT DETECTED' for negative result. For test validity, internal positive control (IPC) is also checked and depending on IPC detection validity of test run is counted. The validity of the test run is also displayed as 'VALID' or 'INVALID'. IPC validates the test run from samples to result. The result screen also display the viral load as 'HIGH', 'MEDIUM' or 'LOW' or 'VERY LOW' with ct values.

We have also calculated individual virus target sensitivity and specificity.

Sensitivity and specificity of the Truenat Influenza A/B kit for Influenza A virus

		Gold standard (WHO/CDC Protocol)		
		Positive	Negative	Total
Truenat Influenza A/B kit	Positive	42	24	66
	Negative	0	87	87
	Total	42	111	153

	Estimate (%)	CI 95%
Sensitivity	100	91.62 - 100
Specificity	78.38	69.84 - 85.02

Sensitivity and specificity of the Truenat Influenza A/B kit for Influenza B virus

		Gold standard (WHO/CDC Protocol)		
		Positive	Negative	Total
Truenat Influenza A/B kit	Positive	40	0	40
	Negative	0	113	113
	Total	40	113	153

	Estimate (%)	CI 95%
Sensitivity	100	91.24 - 100
Specificity	100	96.71 - 100

- Conclusions: **NOT SATISFACTORY**

ICMR guideline was followed for kit performance evaluation.

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.

This evaluation report is exclusively for Truenat Influenza A/B kit (REF 601200020) Version-03 manufactured by Molbio Diagnostics Pvt Ltd.

(Sensitivity and specificity have been assessed in controlled lab setting using the kits of the batch no. (AB006, AB007) provided by the manufacturer)

Dr. ML Choudhary
Scientist D, Influenza Group

Dr. VA Potdar
Scientist D, Influenza Group Leader

Dr. Priya Abraham
Director