



icmr
INDIAN COUNCIL OF
MEDICAL RESEARCH
Serving the nation since 1911

NIV
NATIONAL INSTITUTE
OF VIROLOGY

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/2020-200

16th June 2020

Ms. Tulip Diagnostics [P] Ltd

Subject: Performance Evaluation Report of Perkin Elmer Nucleic acid extraction kit (Lot No. 0920200402 manufactured by Suzhou Sym-Bio Lifescience Co. Ltd.

Sir

We have evaluated Perkin Elmer Nucleic acid extraction kit (Lot No. 0920200402 manufactured by Suzhou Sym-Bio Lifescience Co. Ltd. The report is attached for your information.

Yours sincerely


Prof. Priya Abraham

Director

विश्व स्वास्थ्य संघटन

उभरते वायरल संक्रमणों का सहयोग केन्द्र

राष्ट्रीय शीतज्वर केन्द्र

पोलिओ, खसरा एवं रुबेला के लिए रेफरल प्रयोगशाला



WORLD HEALTH ORGANIZATION

Collaborating Centre for Emerging Viral Infections

National Influenza Centre

Referral Lab for Polio, Measles and Rubella

Evaluation report for RNA extraction kit

Objective: To evaluate the performance of RNA extraction kit using a panel of SARS-CoV-2 positive and negative samples.

Name of the Kit: Perkin Elmer Nucleic acid extraction kit (Lot No. 0920200402) manufactured by Suzhou Sym-Bio Lifescience Co. Ltd., China

Kit components: lysis/binding buffer, magnetic beads, Wash buffer A, Wash Buffer B, Elution buffer

Sample Panel: Fifteen SARS-CoV-2 positive samples and five SARS-CoV-2 negative samples

Methodology: RNA was extracted from the SARS-CoV-2 positive samples and SARS-CoV-2 negative samples according to the manufacturer's instructions and subjected to SARS-CoV-2 screening and confirmatory assay targeting E, ORF-1b and RdRp genes and RNaseP internal control as per ICMR-NIV SARS-CoV-2 RT-qPCR protocol.

Results:

Among the SARS-CoV-2 positive samples, fourteen samples showed positive result. RNA from negative samples showed negative result. RNaseP (housekeeping gene) amplification was seen in RNA extracted from 20 samples.

Conclusion:

The performance of Perkin Elmer Nucleic acid extraction kit (Lot No. 0920200402) manufactured by Suzhou Sym-Bio Lifescience Co. Ltd. was SATISFACTORY since 93% of the positive samples showed concordant results.

Note:

This evaluation report is exclusively for Perkin Elmer Nucleic acid extraction kit (Lot No. 0920200402) manufactured by Suzhou Sym-Bio Lifescience Co. Ltd. *The company shall not publish or use information related to this evaluation without prior written consent from ICMR-NIV.


Prof. Priya Abraham

Director

ICMR-NIV

For kit evaluation team

Dr. K. S. Lole



Dr. K. Alagarasu



Dr. V. A. Potdar

