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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- 486

25<sup>th</sup> May 2021

Ms. Suparshva Swabs(1)

Subject: Performance Evaluation Report of TULIPS Nylon Flocked Nesopharyngeal Swabs with Breakpoint (Batch No. NF-055A) manufactured by Suparshva Swabs(1).

Sir

We have evaluated TULIPS Nylon Flocked Nesopharyngeal Swabs with Breakpoint (Batch No. NF-055A) manufactured by Suparshva Swabs(1). 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

**PERFORMANCE EVALUATION REPORT FOR SWABS**

- Name of the kit TULIPS Nylon Flocked Nesopharyngeal Swabs with Breakpoint
- Name of the manufacturer Suparshva Swabs(I)
- Batch number NF-055A
- Kit components Sterile Nylon Flocked Nesopharyngeal Swabs with breakpoint.
- Methodology Throat and nasal swabs were collected separately from ten healthy individuals each and swabs were transferred into virus transport medium (HiMedia VTM) tubes. Another set of ten VTM tubes (HiMedia) with nasal and oral swabs (five tubes for each type of swab) were spiked with 100 µl of a strong SARS-CoV-2 positive sample. All tubes were kept at 4°C for 12 hrs. RNA was extracted from all tubes and tested for viral targets (E, ORF1b, and RdRp genes) and human Actin gene (internal control) as per ICMR-NIV protocol.
- Results
  1. Viral target amplification was observed in all VTM tubes spiked with the virus
  2. Amplification of internal control was noted in all tubes containing swabs collected from healthy individuals
  3. Swabbed individuals did not report any discomfort or irritation during or after swabbing
- Conclusions:
  - Percentage concordance among spiked positive samples: 100%
  - Percentage concordance among negative samples: 100%
  - Percentage of samples showing amplification in internal control: 100%
  - Performance: **SATISFACTORY**

**Disclaimers**

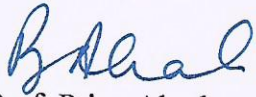
1. ICMR's validation process does not approve/ disapprove the kit design
2. ICMR's validation process does not certify user friendliness of the kit / assay
3. Validation of a kit by ICMR is not an assurance that the kit specifications would be included in the tendering process

**ICMR-National Institute of Virology**

Note: This report is exclusively for TULIPS Nylon Flocked Nasopharyngeal Swabs with Breakpoint (Batch No. NF-055A) manufactured by Suparshva Swabs(l).

The company shall not use or publish information or report for advertising or promotional purposes

Evaluation Done on 22-05-2021



Prof. Priya Abraham

Director

ICMR-NIV

For kit evaluation team

Dr. K. S. Lole



Dr. K. Alagarasu



Dr. V. A. Potdar

