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भारतीय आयुर्विज्ञान अनुसंधान परिषद  
स्वास्थ्य अनुसंधान विभाग  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

**I C M R - NATIONAL INSTITUTE OF VIROLOGY**

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No: Inf/Covid-19/Evaluation/2021- 489

29<sup>th</sup> May 2021

Ms. Pathkits Healthcare Pvt. Ltd.

Subject: Performance Evaluation Report of BeSure Flocked Nasopharyngeal swabs Code-  
PKSW001 and Oropharyngeal swabs Product Code-PKSW002 manufactured by Pathkits  
Healthcare Pvt. Ltd.

Sir

We have evaluated BeSure Flocked Nasopharyngeal swabs Code-PKSW001 (Batch No.-  
NP/05/21-01) and Oropharyngeal swabs Product Code-PKSW002 (Batch No.- OP/05/21-01)  
manufactured by Pathkits Healthcare Pvt. 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

**PERFORMANCE EVALUATION REPORT FOR SWABS**

- Name of the kit  
BeSure Flocked swabs  
1. Nasopharyngeal swabs Product Code-  
PKSW001  
2. Oropharyngeal swabs Product Code-  
PKSW002
- Name of the manufacturer  
Pathkits Healthcare Pvt. Ltd.
- Batch number  
Nasopharyngeal swab-NP/05/21-01  
Oropharyngeal swab - OP/05/21-01
- Date of manufacture  
May 2021
- Expiry Date  
April 2023
- Kit components  
Sterile Nylon Nasopharyngeal swab  
Sterile Nylon Flocked Throat swab
- Methodology  
Nasal and throat swabs were collected from ten healthy individuals and swabs were transferred into virus transport medium (HiMedia VTM) tubes. Another set of ten VTM tubes (HiMedia) with swabs 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 and ORF1b genes) and human actin gene (internal control) using ICMR-NIV RT-qPCR assay
- 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**

## ICMR-National Institute of Virology

### 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 BeSure Flocked swabs

1. Nasopharyngeal swabs Product Code-PKSW001 (Batch No.- NP/05/21-01)
  2. Oropharyngeal swabs Product Code-PKSW002 (Batch No.- OP/05/21-01)
- manufactured by Pathkits Healthcare Pvt. Ltd.

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

Evaluation Done on 29-05-2021



Prof. Priya Abraham

Director


ICMR-NIV

For kit evaluation team

Dr. K. S. Lole



Dr. K. Alagarasu



Dr. V. A. Potdar

