

PK Magnetic VIRAL RNA EXTRACTION KIT VALIDATION (PATHKITS)

NAME OF THE VALIDATION CENTRE: PGIMER, CHANDIGARH

PERFORMANCE EVALUATION REPORT FOR VALIDATION OF PK MAGNETIC VIRAL RNA EXTRACTION KIT

- Name of the kit PK Magnetic Viral RNA Extraction Kit
- Name of Manufacturer Pathkits Healthcare Pvt. Ltd. Guargaon-122015
- Number of Reactions 100
- Kit components
 - Micro Centrifugal Tubes 100 nos.
 - Lysis cum binding buffer 50 mL
 - Magnetic beads 05 mL
 - Buffer 1 50 mL
 - Wash Buffer (concentrate) 10 mL
 - Elution buffer 06 mL
 - Carrier RNA Solubilized 01 mL
- Lot No. EXT/001/03/21-01
- Expiry Date FEB 2023
- Sample Panel
 - Positive samples 40 SARS-CoV-2 positive samples with equal representations of high ct values 27 to 32 (n=14), medium ct values 23 to 26 positive samples (n=13) and low ct values <23 (n=13)
 - Negative samples 10 SARS-CoV-2 negative samples.
- Methodology Forty (40) SARS-CoV-2 positive samples (with equal representations of samples with high, medium and low ct values) and ten (10) SARS-CoV-2 negative samples were selected and RNA was extracted according to the manufacturer's instructions. All forty SARS-CoV-2 positive and ten SARS-CoV-2 negative samples were tested for E, N, RdRp and RNP genes.
- Results
 1. All the positive samples with low (n=13) and medium (n=13) ct values, showed amplification for the E and RdRp/ORF genes whereas, only two out of 14 high ct value samples did not show amplification for the E and RdRp/ORF genes.
 2. All the 10 negative samples were negative for the E and RdRp/ORF genes.
 3. Amplification of Internal Control (RNP) was seen in all the negative samples.

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4. Amplification of internal control (RNP) was seen in more than 95% samples.

- Conclusions:
 - Percentage concordance among positive and negative samples: **95% & 100%** respectively.
 - 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: Quality Assurance Report for the Magnetic Viral RNA Extraction Kit (100 tests), (Lot No.- EXT/001/03/21-01, Exp. Date- FEB, 2023), Manufactured by Pathkits Healthcare Pvt. Ltd., Gurgaon, 122015.

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

Evaluation Done on 20th April, 2021

Evaluation Done by *Ramandeep Kaur, Shubhankar Sircar & Dr. Manjari Baluni*

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