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**No: SARS-CoV-2/Rapid Antigen Test Kit evaluation/2020/KIPMR11**

**Evaluation report of Rapid Antigen Test using nasopharyngeal samples from COVID-19 suspected patients**

**Name of the Validation Centre:** King Institute of Preventive Medicine and Research, Chennai

**Name of the kit:** PATHKITS Simple COVID-19 Ag RAPID Test

**Country of Origin:** India

**Lot Nos.:** RK/CO/AG/11/20/01, RK/CO/AG/11/20/02, RK/CO/AG/11/20/03

**Recommended temperature of storage of kit:** 2 to 30 °C

**Details of kit components:** Test strips, Extraction buffer (2 x vials), nasal swabs, sample collection tubes, Instruction for use. 25 tests per pack

**Details of additional equipment required:** Timer, PPEs, disposal container, Real Time PCR is needed for validation purpose only

**Number of patients recruited:** 232

**Gold Standard used:** NIV Multiplex Single Tube SARS-CoV-2 RT PCR assay

**Methodology:**

A total of 232 samples, well characterized samples comprising of 151 RT PCR positives and 81 RT PCR negatives were taken for analysis.

These 232 Nasopharyngeal swab samples from 147 laboratory confirmed cases of COVID-19 (hospital inpatients) by RT-PCR and 85 patients from the out-patient department attending the healthcare centers with symptoms of SARS-CoV-2 infection and diagnosis was performed immediately as per the kit manufacturer's instructions.

All the 232 nasopharyngeal swab samples were put in VTM, validated by Real Time RT PCR using NIV Multiplex Single Tube SARS-CoV-2 RT PCR assay, which detects 3 targets such as E, RdRp and ORF of SARSCoV-2. Among the 232 samples, 151 samples were found to be COVID-19 positive and others negative. Among the positive samples, 55 samples were found to have early Ct values (Ct values between 14 to 20) for the target genes, 49 samples were

found to have early Ct values (Ct values between 14 to 20) for the target genes, 49 samples were found to have moderate Ct values *i.e.* 21 to 27 and 47 samples were found to have late Ct values between 28 to 32.

All the collected nasopharyngeal samples were subjected to the detection of SARS-CoV-2 antigen using the PATHKITS Simple COVID-19 Ag RAPID Test kit according to the manufacturer's instruction. Briefly, the swab was inserted into the 0.35 mL of extraction medium on extraction tube swirled well, squeezed the swab followed by closing of the tube was closed and incubation for 2 min. 90 µL of the test sample was added in the well of test strip and observed for appearance of colour in both control and test lines.

The evaluation of rapid antigen test and the real-time RT-PCR results were compared; considering real time RT-PCR as the gold standard test, the sensitivity and specificity of the rapid antigen test were calculated.

**Results:**

Rapid antigen test	NIV Multiplex Single Tube SARS-CoV-2 RT PCR assay (Gold standard)		Total
	Positive	Negative	
Positive	89	1	90
Negative	62	80	142
Total	151	81	232

**Sensitivity:** 58.94%

**Specificity:** 98.77%

**Positive Predictive Value:** 98.89%

**Negative Predictive Value:** 56.34%

**Comments on the kit performance:** Sensitivity of the kit is observed to be low

**Comments on quality of kit packaging:** Packaging is good; 25 tests/kit

**Name and signature of the In-charge:**

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