



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

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 10/09/2020

VALIDATION OF SARS-COV2 DIAGNOSTIC COMMODITIES: ACCEPTANCE CRITERIA

Type of Kit	Acceptance Criteria
RT-PCR Kit	Sensitivity: 95% and above Specificity: 99% and above
RNA Extraction Kit	At least 95% concordance among positive At least 90% concordance among negative samples > 95 % samples showing amplification in internal control
VTM	100% concordance among spiked samples 100% samples showing amplification in internal control
Antibody Rapid Kit	Sensitivity: 90% and above Specificity: 99% and above
ELISA / CLIA Kit	IgM: Sensitivity- 90% and above Specificity- 99% and above IgG: Sensitivity- 90% and above Specificity- 95% and above

Note: The cut-offs have been decided after deliberation in ICMR Expert Group and with the Drug Controller General of India (DCGI).