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आईसीएमआर – राष्ट्रीय विषाणु विज्ञान संस्थान

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

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Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare, Govt. of India

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E-mail : director.niv@icmr.gov.in Website : www.niv.co.in

13th April 2020

Performance evaluation of rapid COVID-19 diagnostic test

Objectives:

- ❖ To determine the day of antibody detection against SARS- CoV-2
- ❖ To assess the performance of RDT for COVID-19 diagnosis

Kit:

Alpine Biomedicals Pvt. Ltd

(Lots: A10420 and A20420)

Address: Plot No-348, Sector-2, IGC, HSIIDC Saha,

Ambala, Haryana (India)-133104

Gaurav Garg

+91 9306252669

alpinebiomedicals@gmail.com

Sample selection:

Composition of positive panel (N=24):

RT-PCR is currently the only approved method for confirmation of COVID-19 infection, which detects for viral genomic molecules, which are present in body fluids in early phase of infection.

Clinical samples (Blood, plasma and serum) from qRT-PCR positive cases of different post infection day (POD) were selected.

Composition of negative panel (N=12):

Clinical specimens (Blood, plasma and serum) from qRT-PCR negative cases were taken as negative samples. Samples positive for other related and non-related viruses for assessing cross-reactivity:

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Results:

The day wise antibody positivity in COVID-19 patients

ID	POD	Apline Biomedicals RDT (Lot A10420)RDT		Apline Biomedicals RDT (Lot A20420)	
		IgM	IgG	IgM	IgG
DVG-C-KM02-S001	2	±	-	±	-
DVG-C-KM02-S002	2	-	-	-	-
DVG-C-KM02-S003	2	-	-	-	-
DVG-C-KM02-S004	3	-	-	-	-
DVG-C-KM02-S006	3	-	-	-	-
DVG-C-KM02-S007	3	±	-	±	-
DVG-C-KM02-S008	4	±	+	±	+
DVG-C-KM02-S009	4	-	-	-	-
DVG-C-KM02-S005	5	-	-	-	-
DVG-C-KM02-S010	5	+	-	+	-
DVG-C-KM02-S011	6	-	-	-	-
DVG-C-KM02-S012	7	+	±	±	+
DVG-C-KM02-S013	7	±	+	±	-
DVG-C-03-S021	7	+	-	+	-
DVG-C-03-S022	7	+	-	+	-
DVG-C-03-S023	10	±	-	±	-
DVG-C-KM02-S014	11	+	+	+	+
DVG-C-03-S015	11	+	+	+	+
DVG-C-03-S016	11	+	+	+	+
DVG-C-03-S017	11	+	+	+	+
DVG-C-03-S018	11	±	±	±	±
DVG-C-03-S019	11	±	±	±	±
DVG-C-03-S020	11	±	±	±	±
DVG-C-03-S024	13	+	-	+	-

±: Weak signal

Analysis of cross-reactivity: No cross reactivity was observed with the selected panel.

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Covid-19 qRT-PCR positive samples



Disclaimer:

1. This report is valid only for the lot/s submitted by the company/vendor.
2. ICMR- National Institute of Virology does not guarantee that the rapid antibody test kit will continue to meet the above-represented standards. Validation has been performed on one or few representative lots and it is the responsibility of the manufacturer to maintain kit quality of subsequent lots.
3. This report is generated for the above-mentioned product only, and cannot be extended to other related or non- related product.
4. This report does not endorsed procurement of the kits from the supplier mentioned.
5. This report may not be used by manufacturers or distributors for commercial or promotional purposes.

Yours sincerely,

Checked and Approved by

Dr. Gajanan N. Sapkal

Scientist- E, ICMR-NIV

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