

20.04.2020

Performance evaluation of commercial kits for detection of SARS-CoV-2 RNA by Real Time PCR

Validation by ICMR institutes

Till date, 33 real-time PCR kits have been validated by ICMR validation centres, and the following were found to be satisfactory.

S. No	Name of Company	Name of the Kit	*Batch number
1	Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005
2	MY LAB	Patho Detect	PP00005-C-032001
3	Seegene	Allplex 2019-nCoV assay	RP4520A01
4	SD Biosensor	nCoV Real-Time Detection kit	MNCO 0120004
5	KILPEST (BLACKBIO)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	COV-19/V2/2020/01
6	Huwel Lifesciences	Quantiplus CoV detection kit ver 2.0	QLCNV0620
7	BGI	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
8	ABI (Applied bio systems)	TaqMan 2019-nCoV Control Kit v1	47532-020720
9	Medsorce Ozone Biomedicals	COVID-19 RT-PCR kit	20200433
10	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID 19] Real-time PCR kit	01/2020 MFD: 04/2020
11	ADT Biotech Sdn Bhd, Malaysi2	LyteStar 2019 nCoV RT-PCR kit 1.0	nCoV-2003-06; nCoV-2004-02; nCoV-2004-03
12	OSANG Health Care	Gene Finder COVID-19	2003-R45-22
13	Cepheid	Xpert Xpress SARS-CoV-2	1000191996, 1000191998, 1000191999
14	Biogenomics (India)	BIO COVID ID/ COVID-19 qualitative PCR detection kit v. 2	BGL/IVD/COV/0420 /004
15	Meril Diagnostics	Meril COVID-19 One-step RT-PCR Kit	MRD091

*Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.

Real-time PCR kits which are US-FDA and/or CE-approved

The complete list of US-FDA and/or CE-approved SARS-CoV-2 real-time PCR kits is available at (<https://www.finddx.org/covid-19/pipeline/>). US-FDA and/or CE-IVD approved kits can be used directly after due marketing approval from DCGI.