

SARS-COV-2 MOLECULAR ASSAY EVALUATION: RESULTS

INFORMATION FROM WWW.FINDDX.ORG/COVID-19/SARSCOV2-EVAL-MOLECULAR/MOLECULAR-EVAL-RESULTS/
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FIND conducted independent evaluations at the [Hôpitaux Universitaires de Genève](https://www.hug.ch/), to verify the limit of detection (LOD) and the clinical performance (as reported by the manufacturers) of the following molecular test kits. The LOD analysis was performed using cultured viral stocks from a clinical isolate from Switzerland, and quantified using an E gene standard. The clinical performance analysis was conducted on extracted samples from individuals suspected to have COVID-19 that were tested using an in-house PCR protocol that was optimized based on the Tib Molbiol assay.

Data for the first tests evaluated are summarized below. More results will be added as they become available. Tests were selected for evaluation according to the [scoring criteria](#), but the order in which the evaluations were conducted does not reflect any endorsement or prioritization.

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Company	Gene target	Verified LOD (copies / reaction)	Avg Ct (lowest dilution 10/10)	Clinical sensitivity (50 positives)	Clinical specificity* (100 negatives)	Product No.	Product name	Lot No.	PCR platform	Supplier recommended Ct cut-off
Altona Diagnostics	E	1–10	35.45	92% (95%CI: 81, 97)	100% (95%CI: 96, 100)	821003/ 821005	RealStar® SARS-CoV-2 RT-PCR Kit 1.0	023567	BioRad CFX96 deep well	None; any signal can be considered positive
	S	1–10	35.99	92% (95%CI: 81, 97)	100% (95%CI: 96, 100)					
Atila BioSystems Inc.	ORF1ab	50–100	N/A	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	iAMP-COVID-100-RUO	Atila iAMP COVID-19 Detection (isothermal detection)	COVID20200320	BioRad CFX96 deep well	Any signal is considered positive (isothermal)
	N	1–10	N/A	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)					
BGI Health (HK) Co. Ltd	ORF1	1–10	32.43	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	MFG030010	Real-time Fluorescent RT-PCR kit for detection 2019-nCoV (CE-IVD)	6220200305	Roche LightCycler 480	≤38
bioMérieux	N	10–50	36.44	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	423720 (CE-IVD) 423717 (RUO)	ARGENE® SARS-COV-2 R-GENE® ^b	1007989610 1007947520	BioRad CFX96 deep well	Any signal considered as positive
	RdRP	10–50	32.44	96% ^a (95%CI: 87, 99)	100% (95%CI: 96, 100)					
Bioneer	E	10–50	35.85	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	SCV-2122	AccuPower® SARS-CoV-2 Real-Time RT-PCR Kit	200931E	BioRad CFX96 deep well	<38
	RdRP	10–50	36.18	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)					
Boditech Med. Inc	E	10–50	34.9	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	UFPK-4	ExAmplar COVID-19 real-time PCR kit (L)	WLQCB02L	BioRad CFX96 deep well	≤42
	RdRP	50–100	33.46	90% (95%CI: 79, 96)	100% (95%CI: 96, 100)					

* Further investigation needed to determine if apparent false positives are truly false positives or whether they are due to a false negative reference standard result.

^a The two false negative samples tested positive with the second PCR (PCR 2) that targets E gene of SARS, SARS-COV-2 and/or SARS-like coronaviruses.

^b Samples for both analytical and clinical analyses were from already-extracted specimen, therefore the methods varied from those recommended by the supplier as the internal control was not included.

For questions relating to the evaluation of molecular tests, please contact our **Emerging Threats team**

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CerTest Biotec	ORF1ab	10–50	35.16	98% (95%CI: 90, 100)	100% (95%CI: 96, 100)	VS-NC0112L VS-NC0212L	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	NC0212L-023	BioRad CFX96 deep well	<40
	N	1–10	35.46	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)					
DAAN Gene Co. Ltd	ORF1	1–10	38.76	100% (95%CI: 93, 100)	96%* (95%CI: 90, 98)	DA0930- DA0932	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)	2020007	Roche LightCycler 480	≤40
	N	1–10	36.97	100% (95%CI: 93, 100)	98%* (95%CI: 93, 99)					
EUROIMMUN	ORF1ab/N	1–10	37.88	100% (95%CI: 93, 100)	98%* (95%CI: 93, 99)	MP 2606-0425	EURORealTime SARS-CoV-2	I200320AL	Light Cyclor 480 II	Any signal considered positive
GeneFirst Limited	ORF1	1–10	35.45	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	MPA-COVID19	The Novel Coronavirus (2019-nCoV) Nucleic Acid Test Kit	00072	BioRad CFX96 deep well	≤37.0 positive; 37-40 indeterminate; >40 negative
	N	1–10	36.72	98% (95%CI: 90, 100)	100% (95%CI: 96, 100)					
KH Medical Co. Ltd	S	1–10	37.94	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	RV008	RADI COVID-19 Detection Kit	V008.200202	BioRad CFX96 deep well	≤40
	RdRP	10–50	36.74	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)					
Primerdesign Ltd	RdRP	1–10	36.7	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	Z-Path-COVID-19-CE	Coronavirus COVID-19 genesig® Real-Time PCR assay	JN-02780-0009	LightCycler 480	Any signal regarded as positive

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R-Biopharm AG	E	1–10	37.99	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	PG6815RU0	RIDA®GENE SARS-CoV-2 RUO	21120N	BioRad CFX96 deep well	None; any signal can be considered positive
SD Biosensor Inc.	E	1–10	37.43	100% (95%CI: 93, 100)	97%* (95%CI: 92, 99)	M-NCOV-01	STANDARD M nCoV Real-Time Detection Kit	MNC00120005	Roche LightCycler 480	≤41
	ORF1	1–10	36.99	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)					
Seegene Inc.	E	1–10	33.3	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	RP10244Y RP10243X	Allplex™ 2019-nCoV Assay	RP4520C24	BioRad CFX96	≤40
	N	1–10	36.74	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)					
	RdRP	1–10	34.73	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)					
Shanghai Kehua Bio-Engineering Co., Ltd	ORF1	1–10	30.39	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	KH-G-M-574-48	KHB Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR)	20037410	BioRad CFX96 deep well	More than two targets detected and curve is of S shape
	N	1–10	32.95	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)					
	E	1–10	31.72	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)					

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Tib Molbiol	E	1–10	33.34	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	53-0776-96 6754155001	ModularDx Kit SARS-CoV (COVID19) E-gene (Tib Molbiol) + LightCycler Multiplex RNA Virus Master (Roche)	48202019 48274100	Roche LightCycler 480	Define the cut-off 2–4 cycles higher than observed Cp value for 10 copies

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