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SARS-COV-2 MOLECULAR ASSAY EVALUATION: RESULTS

INFORMATION FROM WWW.FINDDX.ORG/COVID-19/SARSCOV2-EVAL-MOLECULAR/MOLECULAR-EVAL-RESULTS/
LAST UPDATED: 3 JULY 2020

FIND conducted independent evaluations at the University Hospitals of Geneva (HUG) to verify the limit of detection (LOD) – as reported by the manufacturers – and the clinical performance of the following manual molecular test kits. The LOD analysis was performed using cultured viral stocks from a clinical isolate from Switzerland that was 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 all the tests selected for the first round of the evaluations are summarized below (Table 1). Tests were selected for evaluation according to scoring criteria, but the order in which the evaluations were conducted does not reflect any endorsement or prioritization.

Additionally, a limited clinical performance evaluation of the Cepheid Xpert Xpress SARS-CoV-2 assay was also performed at the HUG. A second collaborating site, the Translational Health Science and Technology Institute (THSTI) conducted a similar limited clinical performance evaluation of the Molbio TrueNat SARS-CoV-2 assay. Results on the performance of these automated near-POC assays are shown in Table 2.

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TABLE 1: Results for 21 manual (open) molecular tests included in the round 1 evaluation

Company	Product name	Product number	Gene target	Verified LOD (copies / reaction)	Avg Ct (lowest dilution 10/10)	Clinical sensitivity (50 positives)	Clinical specificity* (100 negatives)	Lot No.	PCR platform**	Supplier recommended Ct cut-off
altona Diagnostics	RealStar® SARS-CoV-2 RT-PCR Kit 1.0	821003/ 821005	E	1–10	35.45	92% (95%CI: 81, 97)	100% (95%CI: 96, 100)	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.	Atila iAMP COVID-19 Detection (isothermal detection)	iAMP-COVID-100-RUO	ORF1ab	50–100	N/A	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	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)			
Beijing Wantai Biological Pharmacy Enterprise Co. Ltd	Wantai SARS-CoV-2 RT-PCR Kit	WS-1248	ORF1ab	1–10	36.20	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	nCoVP20200305	BioRad CFX96 deep well	≤40
			N	1–10	37.12	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)			
BGI Health (HK) Co. Ltd	Real-time Fluorescent RT-PCR kit for detection 2019-nCOV (CE-IVD)	MFG030010	ORF1	1–10	32.43	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	6220200305	Roche LightCycler 480	≤38
bioMérieux SA	ARGENE® SARS-COV-2 R-GENE® [b]	423720 (CE-IVD) 423717 (RUO)	N	10–50	36.44	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	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 Corporation	AccuPower® SARS-CoV-2 Real-Time RT-PCR Kit	SCV-2122	E	10–50	35.85	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	200931E	BioRad CFX96 deep well	<38
			RdRP	10–50	36.18	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)			

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Boditech Med. Inc.	ExAmplar COVID-19 real-time PCR kit (L)	UFPK-4	E	10–50	34.9	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	WLQCB02L	BioRad CFX96 deep well	≤42
			RdRP	50–100	33.46	90% (95%CI: 79, 96)	100% (95%CI: 96, 100)			
CerTest Biotec S.L.	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	VS-NC0112L VS-NC0212L	ORF1ab	10–50	35.16	98% (95%CI: 90, 100)	100% (95%CI, 96, 100)	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 of Sun Yat-Sen University	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)	DA0930-DA0932	ORF1	1–10	38.76	100% (95%CI: 93, 100)	96%* (95%CI: 90, 98)	2020007	Roche LightCycler 480	≤40
			N	1–10	36.97	100% (95%CI: 93, 100)	98%* (95%CI: 93, 99)			
EUROIMMUN AG	EURORealTime SARS-CoV-2 [c]	MP 2606-0425	ORF1ab/N	1–10	37.88	100% (95%CI: 93, 100)	98%* (95%CI: 93, 99)	I200320AL	Light Cycler 480 II	Any signal considered positive
GeneFirst Ltd	The Novel Coronavirus (2019-nCoV) Nucleic Acid Test Kit	MPA-COVID19	ORF1	1–10	35.45	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	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	RADI COVID-19 Detection Kit	RV008	S	1–10	37.94	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	V008.200202	BioRad CFX96 deep well	≤40
			RdRP	10–50	36.74	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)			

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PerkinElmer Inc.	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay [c,d]	SY580	N	1–10	39.43	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)	8220200303	BioRad CFX96 deep well	≤42
			ORF1	1–10	38.99	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)			
Primerdesign Ltd	Coronavirus COVID-19 genesig® Real-Time PCR assay [c]	Z-Path-COVID-19-CE	RdRP	1–10	36.7	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	JN-02780-0009	LightCycler 480	Any signal regarded as positive
R-Biopharm AG	RIDA®GENE SARS-CoV-2 RUO	PG6815RUO	E	1–10	37.99	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	21120N	BioRad CFX96 deep well	None; any signal can be considered positive
Sansure Biotech Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) [e]	S3102E	ORF1	10–50	35.16	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	2020007ZC	Thermofisher Quantstudio 5	≤40
			N	10–50	34.96	100% (95%CI: 93, 100)	95%* (95%CI: 89–98)			
SD Biosensor Inc.	STANDARD M nCoV Real-Time Detection Kit	M-NCOV-01	E	1–10	37.43	100% (95%CI: 93, 100)	97%* (95%CI: 92, 99)	MNC00120005	Roche LightCycler 480	≤41
			ORF1	1–10	36.99	100% (95%CI: 93, 100)	99%* (95%CI: 95, 100)			

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Seegene Inc.	Allplex™ 2019-nCoV Assay	RP10244Y RP10243X	E	1–10	33.3	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	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	KHB Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR)	KH-G-M-574-48	ORF1	1–10	30.39	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	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)			
ThermoFisher Scientific	TaqPath™ COVID-19 CE-IVD RT-PCR Kit [f]	A48067	ORF1ab; S protein; N protein	1–10	NA	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	2225262	Quantstudio 5	Not Applicable (Automated software interpretation)
Vela Diagnostics	ViroKey™ SARS-CoV-2 RT-PCR Test [c]	300682	RdRP	10–50	30.95	94% (95%CI: 84, 98)	100% (95%CI: 96, 100)	1000000597	BioRad CFX96 deep well	≤40
			ORF1	1–10	35.57	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)			

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

* Clinical specificity: Further investigation is needed to determine if apparent false positives are truly false positives or whether they are due to a false negative reference standard result
** PCR platform: All products were evaluated on a PCR platform recommended by the supplier, listed in this table. Each test can be performed on other PCR systems detailed in the product's instructions for use.

[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.
[c] 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 added to the master mix.
[d] Evaluation procedure varied from recommended protocol. In order to achieve the recommended sample input volume, a 2.5 fold dilution of the samples was used.
[e] Sansure claims a lower LOD of 6.4 cp/rxn, which has been independently verified.
[f] Evaluation procedure varied from recommended protocol, as source material was already-extracted RNA; extracted MS2 control was added directly to the master mix.

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TABLE 2: Results for 2 near-POC automated tests included in the round 1 evaluation

Company	Product name	Product number	Gene target	Clinical sensitivity (50 positives)	Clinical specificity* (100 negatives)	Comparator test
Cepheid Inc.	Xpert® Xpress SARS-CoV-2	XPRSARS-COV2-10	N2	100% (95%CI: 92,100)	99% * (95%CI: 95, 100)	Roche Cobas® SARS-CoV-2
			E	97.7% (95% CI: 88, 100)	100% (95%CI: 96, 100)	
Molbio Diagnostics Pvt Ltd	TrueNat SARS-CoV-2 [1]	601410020	E+RdRP [2]	98% (95% CI: 90.98)	96% * (95% CI: 90,98)	altona Diagnostics (n=86) /LabGun™ (n=64) and/or Seegene, Inc. (n=12) N = 51 positive N = 111 negative
		601420050				

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

[1] Note: evaluation performed at THSTI
[2] RdRP is only used as a reflex test; the results are for combined E+RdRP positives

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