

SARS-COV-2 MOLECULAR ASSAY EVALUATION: RESULTS

INFORMATION FROM WWW.FINDDX.ORG/COVID-19/SARSCOV2-EVAL-MOLECULAR/MOLECULAR-EVAL-RESULTS/
LAST UPDATED: 15 MAY 2020

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.



**INFORMATION FROM WWW.FINDDX.ORG/COVID-19/SARSCOV2-EVAL-MOLECULAR/MOLECULAR-EVAL-RESULTS/
LAST UPDATED: 15 MAY 2020**

| 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 |
| 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) | | | | | |
| 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) | | | | | |

* 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.



INFORMATION FROM WWW.FINDDX.ORG/COVID-19/SARSCOV2-EVAL-MOLECULAR/MOLECULAR-EVAL-RESULTS/
LAST UPDATED: 15 MAY 2020

| 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 |
|--------------------|-------------|----------------------------------|--------------------------------|-------------------------------------|---------------------------------------|--------------------|---|---------------|------------------------|---|
| 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 Cycler 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 |
| R-Biopharm AG | E | 1–10 | 37.99 | 100% (95%CI: 93, 100) | 100% (95%CI: 96, 100) | PG6815RUO | 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) | | | | | |

* 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.

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

Visit the COVID-19 diagnostics resource centre



INFORMATION FROM WWW.FINDDX.ORG/COVID-19/SARSCOV2-EVAL-MOLECULAR/MOLECULAR-EVAL-RESULTS/
LAST UPDATED: 15 MAY 2020

| 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 |
|--------------|-------------|----------------------------------|--------------------------------|-------------------------------------|---------------------------------------|--------------------------|--|----------------------|-----------------------|---|
| 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) | | | | | |
| 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 |

* 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.

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

Visit the COVID-19 diagnostics resource centre

