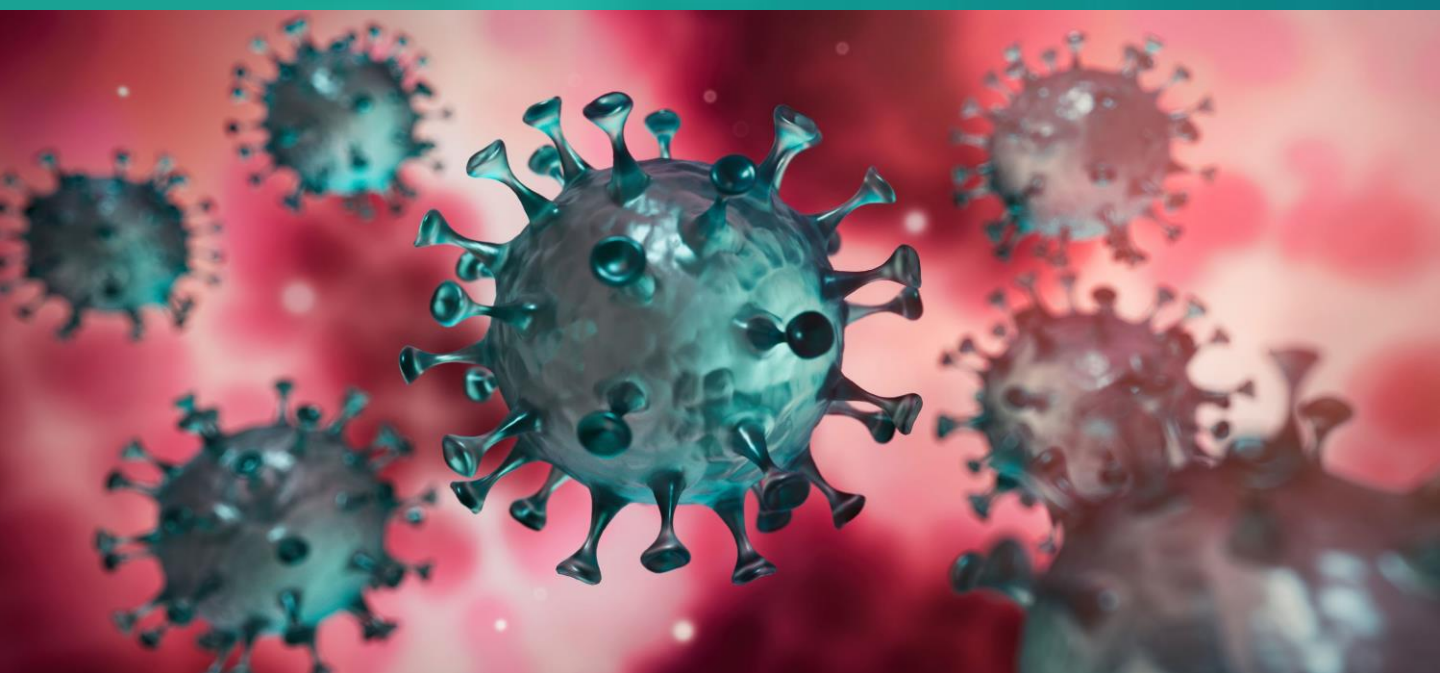


SARS-CoV-2 RT-PCR Detection Assay

CE IVD marked



A real-time reverse transcriptase (RT)-PCR assay developed using advanced bioinformatics to maximise performance.

KEY BENEFITS:

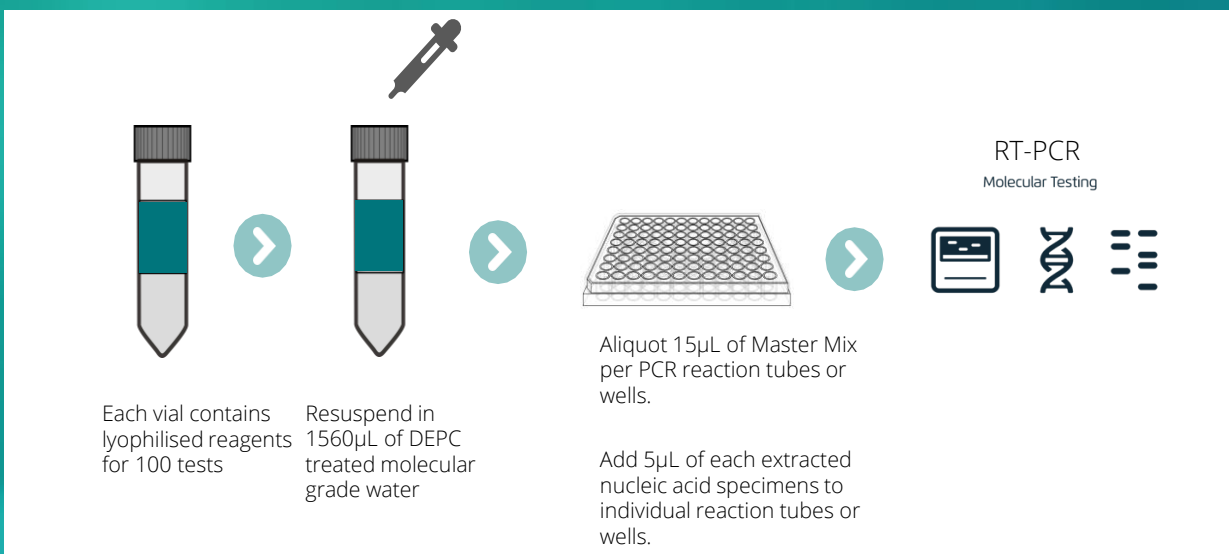
- | | |
|-----------------------------------|--|
| Specificity (<i>in silico</i>): | 100% coverage of all known SARS-CoV-2 sequences |
| Built-in QA: | Targets three SARS-CoV-2 specific loci - S gene, N gene and Orf1 region |
| Sensitivity: | Returns concise SARS-CoV-2 status with no 'indeterminant' result where SPC is positive |
| Versatility: | Runs on multiple platforms, for high and low throughput systems |
| Convenient: | One vial lyophilised reagents for ease of use, ease of shipping and longer shelf life |

Rapidly detects SARS-CoV-2 in a single test

Validated for use on:

- Qiagen Rotor-Gene Q
- Bio-Rad CFX96™ Dx
- Bio-Rad CFX96™ Deepwell
- Thermo Fisher QuantStudio™ 7 384 well
- Roche LightCycler® 480 II
- Thermo Fisher ABI™ 7500 Fast Dx

Simple workflow:



Kit includes:

- 1 x RT-PCR Master Mix (including enzyme)
- 1 x SARS-CoV-2 Primers
- 1 x Specimen Process Control Primers

Our SARS CoV-2 RT PCR Detection Assay is CE-IVD marked and has been submitted to the FDA for EUA authorisation and WHO for EUL authorisation.



Assay performance indicators

ATTRIBUTE	SPECIFICATION
Chemistry	TaqMan real-time
Specimen Type(s)	Nasopharyngeal, Oropharyngeal
Sample Input Volume	5µL
Specimen Process Control	Human RNase P
Analytical Sensitivity (Limit of Detection)	10 copies/reaction
Analytical Specificity	100% (<i>in silico</i>) 100% (wet testing)
Interfering Organisms	No interference (Testing at physiologically relevant concentrations of commensal and infections bacteria and viruses)
Interfering Substances	No interference (Testing at physiologically relevant concentrations)
Reproducibility	100% day-to-day, tech-to-tech, instrument-to-instrument, lot-to-lot
Throughput	94 specimens and 2 controls
Results Reporting	Qualitative
Results Readout	Positive/Negative/Invalid

SARS-CoV-2 (Orf1, S, N genes) FAM	RNase P (SPC) HEX	Data Interpretation
Positive	Positive/Negative	Positive for SARS-CoV-2 genomic RNA
Negative	Positive	Negative for SARS-CoV-2 genomic RNA
Negative	Negative	Invalid

Clinical performance evaluation

Evaluation Site	Pos./Neg.	PPA (Clinical Sensitivity) (95% CI)	NPA (Clinical Specificity) (95% CI)
Site 1	39/30	97.44% (86.52 – 99.94%)	100% (88.43 – 100%)
Site 2	52/92	100% (93.15 – 100%)	100% (96.07 – 100%)
Site 3	36/47	97.2% (85.47 – 99.93%)	100% (92.45 – 100%)
Site 4	26/24	100% (86.77 – 100%)	100% (85.75 – 100%)
Site 5	50/100	100% (92.89 – 100%)	100% (96.38 – 100%)
Totals	203/293	99.01% (96.49 – 99.88%)	100% (98.75 – 100%)

Extensive testing has been conducted on QuantuMDx' SARS-CoV-2 RT-PCR Detection Assay to understand both analytical and clinical performance specifications for a variety of nucleic acid extraction methods and real-time PCR instruments.

These studies were independently conducted at each site. All sites selected all the samples to be tested and QuantuMDx was not privy to the results until the study was completed and analysed by each site. The assay performed consistently across multiple sites and users.

Overall clinical performance was outstanding, with a positive percent agreement (PPA) of 99.01% and a negative percent agreement of 100%.

Key differentiators

Differentiator	Benefit
Master mix all inclusive of reagents	Ease of use Simple pipetting steps and Simple plate setup
Master mix supplied lyophilized	Increased stability for storage Ease of shipping (lower cost)
All SARS-CoV-2 targeted loci in a single channel	Ease of interpretation
RNase P	Specimen control to ensure that an adequate and appropriate specimen was collected Acts as a process control to ensure that extraction occurred appropriately and that all reagents are working appropriately
Validated manual and automated extraction methods	Ease of start-up Ease of internal validation
Multiple validated real-time platforms	Ease of start-up Ease of use

Our SARS-CoV-2 assay is available now, with stock ready for shipment.

FOR MORE INFORMATION:

Email: sales@quantumdx.com or ring: 44 (0) 870 803 1234

ABOUT QUANTUMDX GROUP:

QuantuMDx is a life science, tools and diagnostics company, headquartered in Newcastle upon Tyne, UK.