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Applied Biosystems™ TaqPath™ COVID-19 CE-IVD RT-PCR Kit

Riegardt Johnson
Field Application Scientist

TaqPath COVID-19 CE-IVD RT-PCR Kit

- Multiplex reverse transcriptase Real-Time PCR Kit for detection of SARS-CoV-2 RNA

- Compatible Instruments:
  - Applied Biosystems 7500
  - Applied Biosystems 7500 Fast
  - Applied Biosystems 7500 Fast Dx
  - *QuantStudio 5 Real-Time PCR System
    - 0.2ml variant

* Coming soon

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Features of the TaqPath COVID-19 CE-IVD RT-PCR Kit

Our highly-sensitive, real-time PCR solution enables your laboratory to run up to 94 specimens on a single plate in less than 2 hours

- A complete analysis to reporting solution for up to 94 specimens and genetic analysis using real-time PCR to diagnostic report generation in less than 2 hours.
  - In silico analysis suggest 100% coverage of available complete genomes for SARS-CoV-2 covered (April 10th 2020)
  - Assay targets ORF-1ab, spike (S) protein and nucleocapsid (N) protein regions were chosen with the goal to have high specificity and lower risk for mutation
  - COVID-19 Interpretive Software, which automatically converts genetic analysis data into reporting, to reduce interpretation errors

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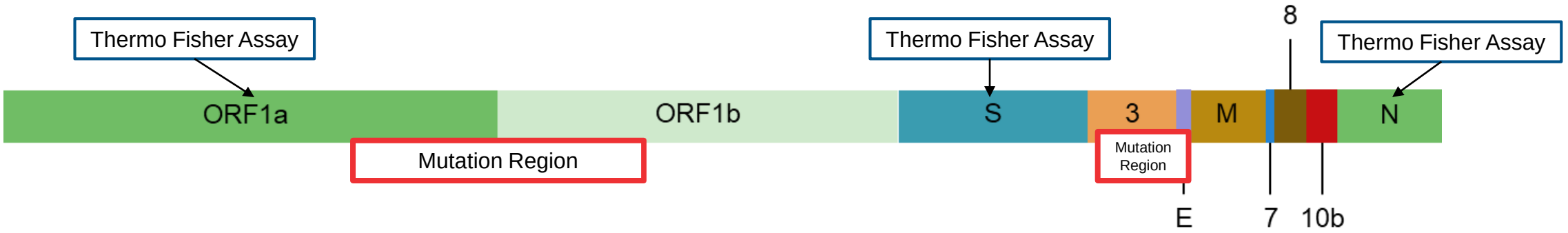
Superior Targeted Specificity

Our TaqPath COVID-19 CE-IVD RT-PCR Kit targets areas specific to the SARS-CoV-2 virus, reducing the risk of detecting other coronaviruses



- Applied Biosystems TaqPath COVID-19 assay targets areas specific to the SARS-CoV-2 virus, reducing the risk of detecting other coronaviruses
- Our assay targets regions of the SARS-CoV-2 virus outside of regions that are known for being mutation regions to reduce risk of loss of specificity
- Our assay covers 100% of available SARS-CoV-2 sequences available on April 10th , 2020

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Sample-to-Answer Workflow for TaqPath™ COVID-19 CE-IVD RT-PCR Kit

COVID-19

Same Day Turnaround Time

Service and support available throughout the entire process

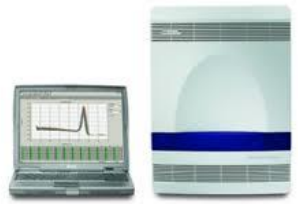
Sample collection

Sample Preparation*

Recommended product:
MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit, MagMAX™-96 Viral RNA Isolation Kit, or equivalent
(Manual or automated processing with KingFisher™ System)

Plate Setup**

Perform RT-PCR**



~115 min

Applied Biosystems™
7500 Fast Dx Real-Time PCR System
or 7500 Fast Real-Time PCR System
7500 Real-Time PCR System
***QuantStudio5 Real-Time PCR System

Transfer Data

SDS or EDS run file

Analysis and Reporting**

Applied Biosystems™
COVID-19 Interpretive Software

Please Note: Authorized laboratories using the TaqPath COVID-19 CE-IVD Kit will perform the TaqPath COVID-19 CE-IVD Kit as outlined in the Instructions for Use.
*Recommended as part of the TaqPath COVID-19 CE-IVD Kit Workflow
****Required*** as part of the TaqPath COVID-19 CE-IVD Kit Workflow
*** Coming soon

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Three Approved Sample Types

Approved specimen types* include:

- nasopharyngeal swabs,
- nasopharyngeal aspirate (nasal aspirate), and
- bronchoalveolar lavage (BAL)

*Further sample types undergoing testing and validation

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Guidelines for RNA extraction

- The quality of the sample preparation (purified RNA) may influence the quality of the qPCR test
- Laboratories shall only use the purification method they have selected
- Laboratories that do not have any selected method, may use the MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit, MagMAX™ Viral/Pathogen II, MagMAX™-96 Viral RNA Isolation Kit, or equivalent

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Extraction Workflow

- Prepare Work Area ~ 5 min
- Prepare 80% ETOH ~ 5 min
- Prepare Processing Plates ~ 5 min
- Sample Preparation ~ 20 min
- Sample Extraction on KingFisher System or Manual ~ 25 min
- Sample Storage

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Extraction

- TaqPath COVID-19 CE-IVD RT-PCR Kit has been tested and found compatible with many sample extraction methods
  - Subject to internal Laboratory testing
  - Provide highly pure viral RNA
  - Free from inhibitors
  - Nucleic Acid integrity maintained

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Guidelines for RNA extraction

- MS2 Phage Control provided in the kit must be used to verify the efficacy of the sample preparation and the absence of inhibitors in the RT-PCR reaction
- Use Nuclease-free Water (not DEPC-Treated) containing 10 µL MS2 Phage Control as the Negative Control.
  - The purified Negative Control is used as the Negative Control for RT-PCR.
- Add 10 µL of MS2 Phage Control to each sample well and to the Negative Control well just before lysis during RNA extraction.

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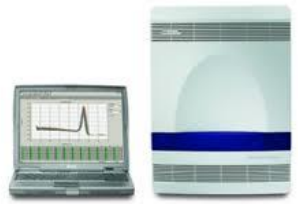

~115 min

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*Recommended as part of the TaqPath COVID-19 CE-IVD Kit Workflow
****Required*** as part of the TaqPath COVID-19 CE-IVD Kit Workflow
***Coming Soon

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What's in the Kit?

TaqPath COVID-19 CE-IVD RT-PCR Kit, 1000 Reactions (Cat. No. A48067)

Included in CE-IVD RT PCR	Description	Contains
TaqPath COVID-19 CE-IVD RT PCR Kit, 1000 reactions	COVID-19 Real-time PCR Assay Multiplex (Gene Orf-1ab, N Protein, S Protein, MS2)	1 tube (1,500µl)
	MS2 Phage Control	10 tubes (1ml)
	TaqPath COVID-19 Control IVT RNA Control	10 tubes (10µl (spec: 10^4 copies/µL)
	TaqPath COVID-19 Control Dilution Buffer for RNA Control	10 tubes (250µl)
	TaqPath™ 1-Step Multiplex Master Mix, (No ROX)	1 bottle (10 ml)

Gene	Dye	Quencher
ORF1ab	FAM	QSY
N Protein	VIC	QSY
S Protein	ABY	QSY
MS2 (Internal Positive Control)	JUN	QSY

CE IVD

For in vitro diagnostic use.

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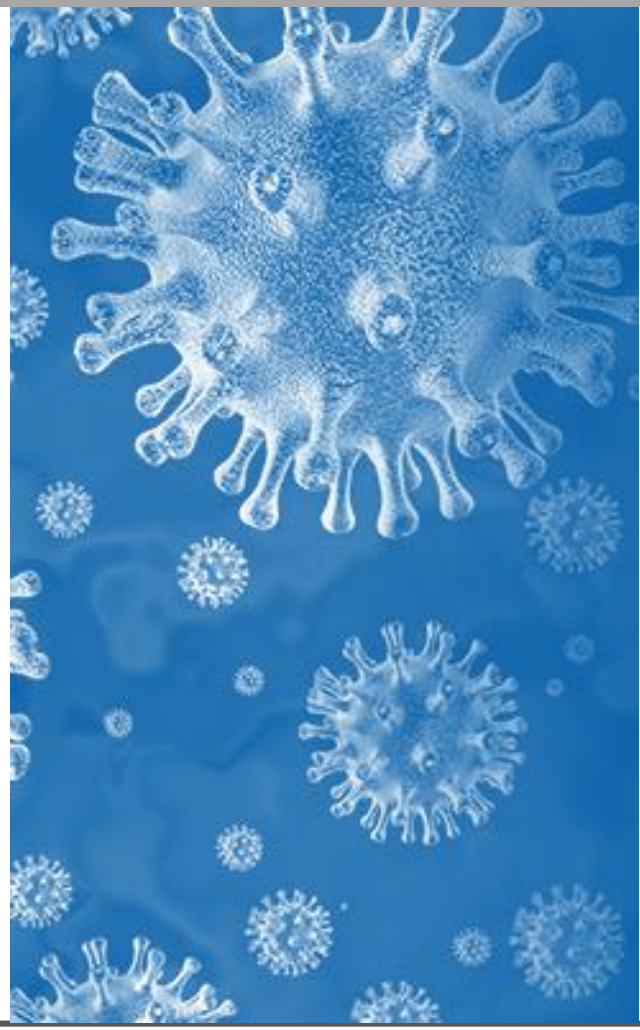
In summary, a highly specific multiplex assay for SARS-CoV-2 pathogen detection

As viruses mutate and spread, specificity to both the current virus and future mutations is absolutely necessary. Our multiplex assay provides laboratories with this certainty, and more…

- Highly sensitive and specific assay utilizing TaqMan technology, considered the gold standard for PCR.
- In silico analysis suggest 100% coverage of available complete genomes for SARS-CoV-2 covered (April 10th 2020)
- Our assay targets regions of the SARS-CoV-2 virus outside of regions that are known for being mutation regions to reduce risk of loss of specificity
- Multiplex kit available in 1000 reactions per kit to help maximize specimen throughput

Visit thermofisher.com/COVID19CEIVD for full intended use statement



Experiment Setup using TaqPath™ 1-Step Multiplex Master Mix (No ROX™)

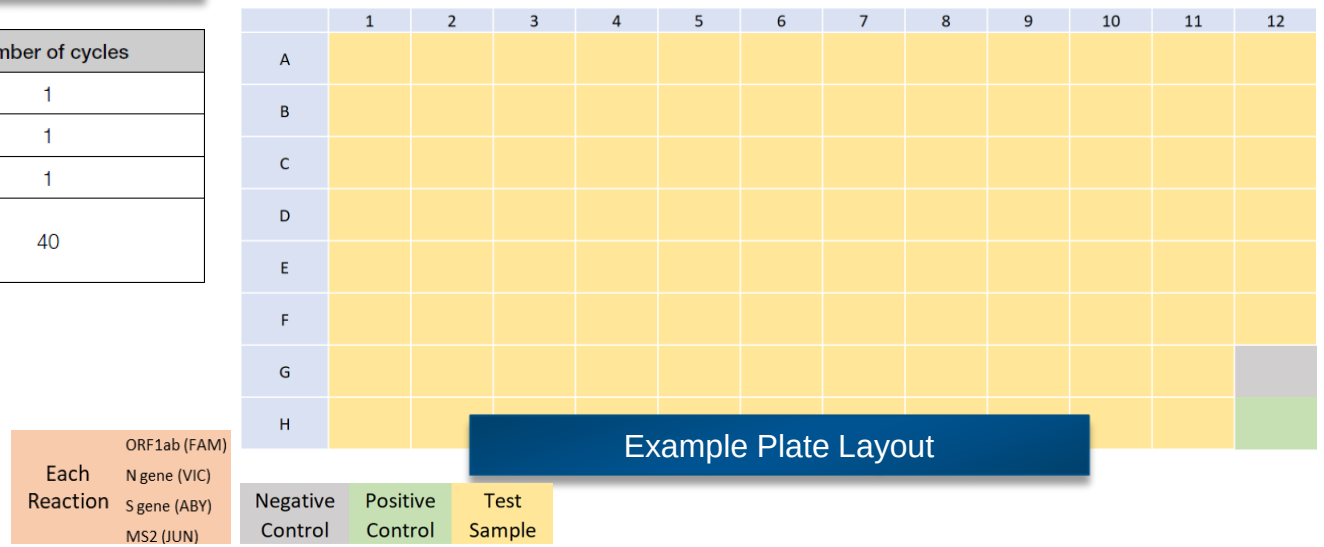
Sample Reaction Setup

Component	Volume per Sample or Control
TaqPath™ 1-Step Multiplex Master Mix (No ROX™) (4X)	6.25 µL
COVID-19 Real Time PCR Assay Multiplex	1.25 µL
Nuclease-free Water	12.50 µL
Total Reaction Mix volume	**20.0 µL**

Component	Volume per reaction		
	Sample reaction	Purified Positive Control (TaqPath™ COVID-19 Control)	Negative Control reaction
Reaction Mix	20.0 µL	20.0 µL	20.0 µL
Purified Sample nucleic acid	5.0 µL	–	–
Positive Control (TaqPath™ COVID-19 Control)[1]	–	2.0 µL	–
Nuclease-free Water	–	3.0 µL	–
Purified Negative Control	–	–	5.0 µL
Total volume	**25.0 µL**	**25.0 µL**	**25.0 µL**

Real-Time PCR Instrument Thermal Protocol

Step	Temperature	Time	Number of cycles
UNG incubation	25°C	2 minutes	1
Reverse transcription	53°C	10 minutes	1
Activation	95°C	2 minutes	1
Denaturation	95°C	3 seconds	40
Anneal / extension	60°C	30 seconds	



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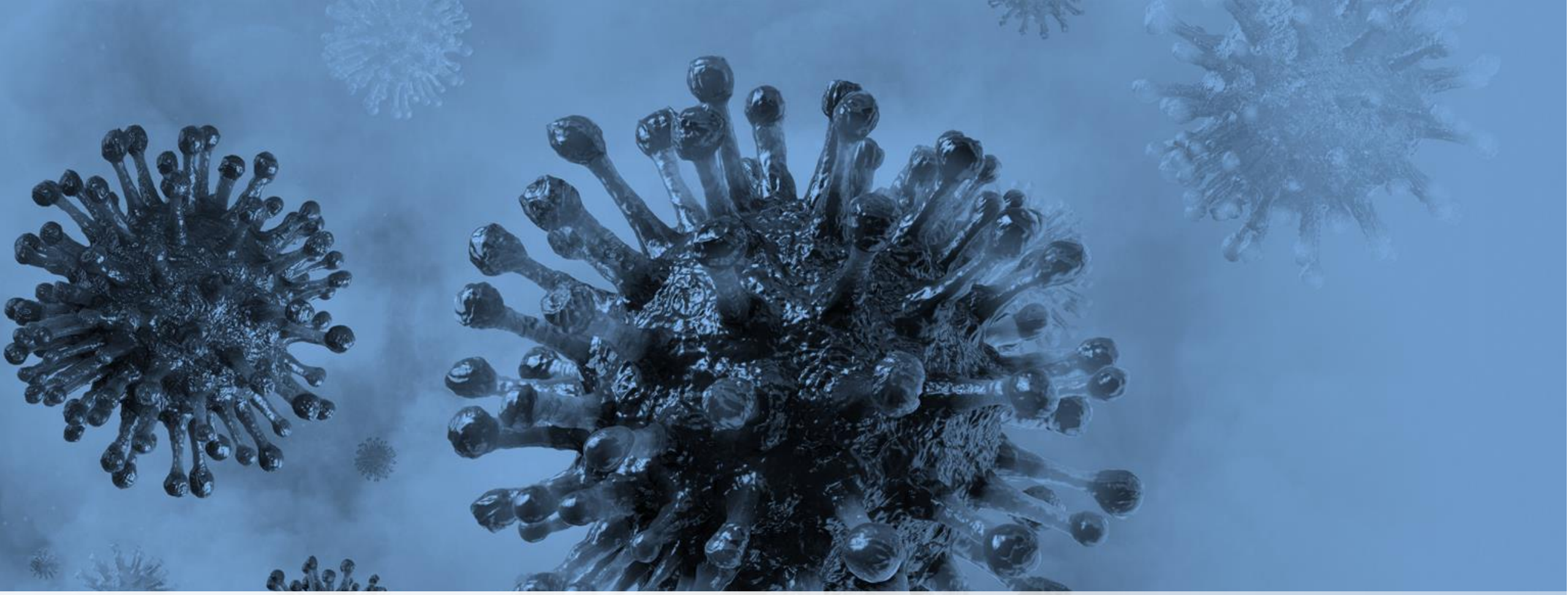

COVID-19 Interpretive Software

For in vitro diagnostic use.

NEW: Applied Biosystems COVID-19 Interpretative Software

The New **Applied Biosystems COVID-19 Interpretive Software** helps your lab decrease analysis and interpretation time, and eliminate subjective interpretation.

- Automatically interpret the data results from the TaqPath COVID-19 CE-IVD RT-PCR genetic analysis.
- Following Real-Time PCR run, the COVID19 Interpretive Software performs a QC check against all controls on the plate and alert user.
- Software generates interpretative report for each specimen.
- **COVID-19 Interpretive Software helps reduce time to diagnosis, along with risk of user error in translation or interpretation.**

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Software and Analysis Recommendations

Instruments	Instrument Software	Data Analysis Software
Applied Biosystems™ 7500 Fast Dx or 7500 Fast or 7500 Real-Time PCR Instrument	For 7500 Fast Dx use Software v1.4.1 For 7500 Fast use Software v2.3 or v1.5.1 For 7500 use Software v2.3 or v1.5.1	COVID-19 Interpretive Software v1.2
Applied Biosystems™ QuantStudio5 Real-time PCR Instrument	QuantStudio Design and Analysis Software FW v1.3.3 + DA v1.5.1	coming soon

ORF1ab	N gene	S gene	MS2	Status	Result	Action
NEG	NEG	NEG	NEG	Invalid	N/A	Repeat test. If the repeat result remains invalid, consider collecting a new specimen.
NEG	NEG	NEG	POS	Valid	SARS-CoV-2 Not Detected	Report results to healthcare provider. Consider testing for other viruses
Only one SARS-CoV-2 target = POS			POS or NEG	Valid	SARS-CoV-2 Inconclusive	Repeat test. If the repeat result remains inconclusive, contact CDC immediately for instructions for transfer of the specimen to CDC for additional testing and guidance.
Two or more SARS-CoV-2 targets = POS			POS or NEG	Valid	SARS-CoV-2 Detected	Report results to healthcare provider and CDC. Contact CDC immediately for instructions for transfer of the specimen to CDC for additional testing and guidance.

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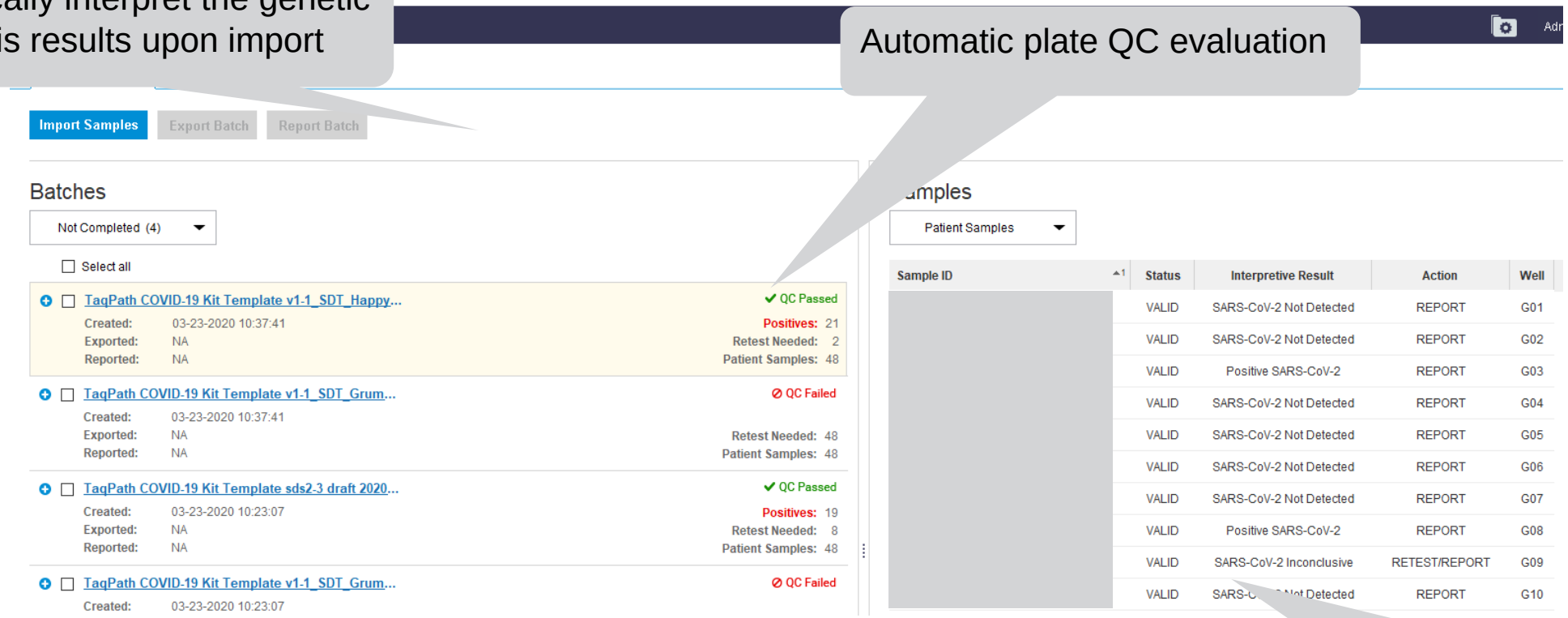
COVID-19 Interpretive Software Features & Benefits

Automatically interpret the genetic analysis results upon import

Automatic plate QC evaluation



View interpretation by samples

The Applied Biosystems COVID-19 Interpretive Software helps you to **decrease analysis and interpretation time and reduces risk of user interpretation error.**

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COVID-19 Interpretive Software Features & Benefits

Thermo Fisher Scientific
168 Third Avenue
Waltham, MA USA 02451

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TaqPath RT-PCR COVID-19 Kit Batch Report

Batch ID	**09Mar2020 BAL_Contrived Clinical Sample Plate 1**
Batch QC Status	**Pass**
Software Version	**COVID-19 Interpretive Software 1.1**
Date & Time of Report	**03-21-2020 20:52:25**

Quality Control Samples

Sample Name	Status	Interpretive Result	Action*
Neg Ctrl	VALID	NA	REPORT
Pos Ctrl	VALID	NA	REPORT

Patient Samples

Sample Name	Status	Interpretive Result	Action*
BAL2	VALID	SARS-CoV-2 Not Detected	REPORT
BAL3	VALID	SARS-CoV-2 Not Detected	REPORT
BAL5	VALID	SARS-CoV-2 Inconclusive	RETEST/REPORT
BAL6	INVALID	NA	RETEST
BAL6	INVALID	NA	RETEST
BAL8	INVALID	NA	RETEST

Generate a report for each plate

Build-in user access control

Export results for LIMS integration*

TaqPath RT-PCR COVID-19 Ki	Batch Export						
Software Version = COVID-19 Interpretive Software v1.1							
Date And Time of Export = 03/21/20 22:54:19							
Experiment Name = 09Mar2020 BAL_Contrived Clinical Sample Plate 1							
Instrument Software Version = sds7500fast							
Run End Date = Mon Mar 09 03:46:18 PDT 2020							
Run Operator = INSTR-ADMIN							
Run Start Date = Mon Mar 09 02:48:52 PDT 2020							
Batch Status = VALID							
Date And Time of Export	Batch ID	Sample Name	Well	Sample Type	Status	Interpretive Result	Action*
3/21/2020 22:54	09Mar2020 BAL_Contrived Clinical Sample Plate 1	BAL2	C01	Patient	VALID	SARS-CoV-2 Not Detected	REPORT
3/21/2020 22:54	09Mar2020 BAL_Contrived Clinical Sample Plate 1	BAL3	C04	Patient	VALID	SARS-CoV-2 Not Detected	REPORT
3/21/2020 22:54	09Mar2020 BAL_Contrived Clinical Sample Plate 1	BAL5	E04	Patient	VALID	SARS-CoV-2 Inconclusive	RETEST/REPORT
3/21/2020 22:54	09Mar2020 BAL_Contrived Clinical Sample Plate 1	BAL6	D04	Patient	INVALID	NA	RETEST
3/21/2020 22:54	09Mar2020 BAL_Contrived Clinical Sample Plate 1	BAL6	D10	Patient	INVALID	NA	RETEST
3/21/2020 22:54	09Mar2020 BAL_Contrived Clinical Sample Plate 1	BAL8	D09	Patient	INVALID	NA	RETEST

The Applied Biosystems COVID-19 Interpretive Software makes it easier for you to adopt our solution into your current environment

* Purchaser is responsible for any LIMS integration implementation.

Reagents required – not supplied

- For a list of required reagents not supplied, see instructions for use below

https://assets.thermofisher.com/TFS-Assets/LSG/manuals/MAN0019215_TaqPathCOVID-19_CE-IVD_RT-PCR%20Kit_IFU.pdf

Equipment	
Laboratory freezers • –30°C to –10°C • ≤ –70°C	MLS
Centrifuge, with a rotor for microplates	MLS
Microcentrifuge	MLS
Laboratory mixer, Vortex or equivalent	MLS
Single and multichannel adjustable pipettors (1.00 µL to 1,000.0 µL)	MLS
Cold block or ice	MLS

Item	Source
Nonstick, RNase-free microcentrifuge tubes (1.5 mL and 2.0 mL)	**thermofisher.com/plastics**
Sterilize aerosol barrier (filtered) pipette tips	**thermofisher.com/pipettetips**
Data analysis software	
Applied Biosystems™ COVID-19 Interpretive Software v1.1	See "Obtain the Applied Biosystems™ COVID-19 Interpretive Software" on page 17

Kits and reagents	
Nuclease-free Water (not DEPC-Treated)	MLS
Tubes, plates, and other consumables	
ABY™ Dye Spectral Calibration Plate for Multiplex qPCR, Fast 96-well	Contact us for specific part numbers, as these may vary depending on instrument model
JUN™ Dye Spectral Calibration Plate for Mutliplex qPCR, Fast 96-well	
MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL	
MicroAmp™ Clear Adhesive Film	
MicroAmp™ Optical Adhesive Film	
MicroAmp™ Adhesive Film Applicator	

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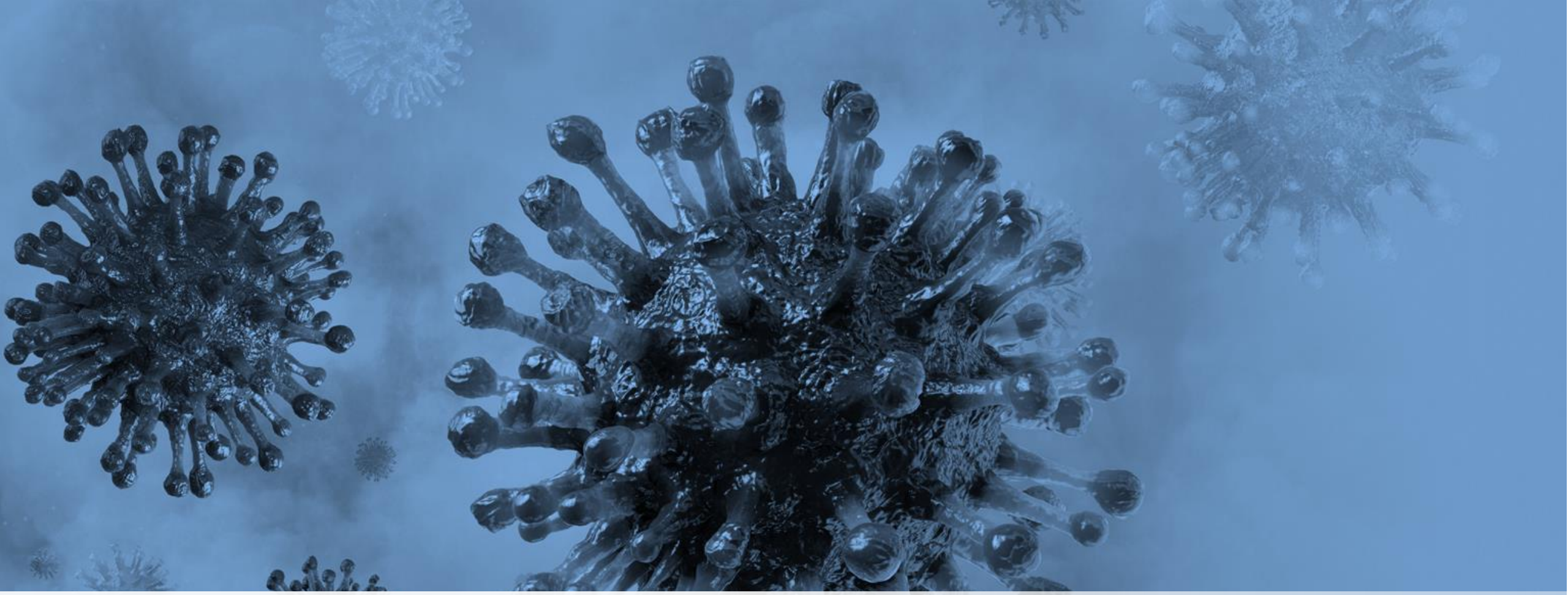

Performance Data: COVID-19 CE-IVD RT-PCR Kit

Limit of Detection (LoD) & Reactivity (Inclusivity)

The LoD study establisher the lowest SARS-CoV-2 viral concentration (Genomic Copy Equivalents of GCE) that can be detected by the TaqPath™ COVID-19 CE-IVD RT-PCR Kit in a particular specimen type at least 95% of the time. Banked Nasopharyngeal swab (NP) and Bronchoalveolar lavage (BAL) samples, obtained from U.S. patients in the years 2015-2019, were pooled, respectively, and spiked with purified SARS-CoV-2 RNA at several concentrations and processed through the TaqPath COVID-19 CE IVD RT PCR Kit workflow. A three phase approach was used to determine the LoD for each specimen type.

Table 4 LoD results

Specimen type	Limit of Detection (GCE/mL)	Limit of Detection (GCE/reaction)
Bronchoalveolar lavage	250 GCE/mL	10 GCE/reaction
Nasopharyngeal swab	250 GCE/mL	10 GCE/reaction

Reactivity (Inclusivity)

The assays were mapped to 185 complete SARS-CoV-2 genomes of human host in GenBank and GISAID databases as of March 5, 2020. Primer and probes sequences for SARS-CoV-2 ORF1ab, S gene, and N gene assays had 100% homology to all SARS-CoV-2 isolates analyzed, with one exception. EPI_ISL_407084 showed a mismatch at position 7 from the 5' end of the reverse primer (23 nt length) corresponding to 95.6% homology. The mismatch is located at the 5'end of the primer and does not affect the test performance.

Clinical Evaluation Study Outcomes

A clinical evaluation study was performed to evaluate the performance of the TaqPath RT-PCR COVID-19 Kit using nasopharyngeal swab (NP) and bronchoalveolar lavage (BAL) specimens.

A total of sixty (60) contrived positive specimens were tested:

- 30 contrived positive nasopharyngeal swab (NP) specimens
- 30 contrived positive bronchoalveolar lavage (BAL) specimens

Samples were contrived by spiking known concentrations of isolated SARS-CoV-2 RNA, relative to the product LoD, into matrices which were determined to be negative by the TaqPath RT-PCR COVID-19 Kit prior to spiking in the RNA.

In addition to the contrived positive specimen, sixty (60) negative specimens were tested:

- 30 negative nasopharyngeal swab (NP) specimens
- 30 negative samples bronchoalveolar lavage (BAL) specimens

Clinical evaluation study outcome

Table 6 BAL Clinical Evaluation Study

Final RNA Concentration in Sample	Interpretation
5X LoD	5/5 positive or detected
3X LoD	5/5 positive or detected
2X LoD	20/20 positive or detected
Negative	30/30 not detected

Table 7 NP Clinical Evaluation Study

Final RNA Concentration in Sample	Interpretation
5X LoD	5/5 positive or detected
3X LoD	5/5 positive or detected
2X LoD	20/20 positive or detected
Negative	30/30 not detected

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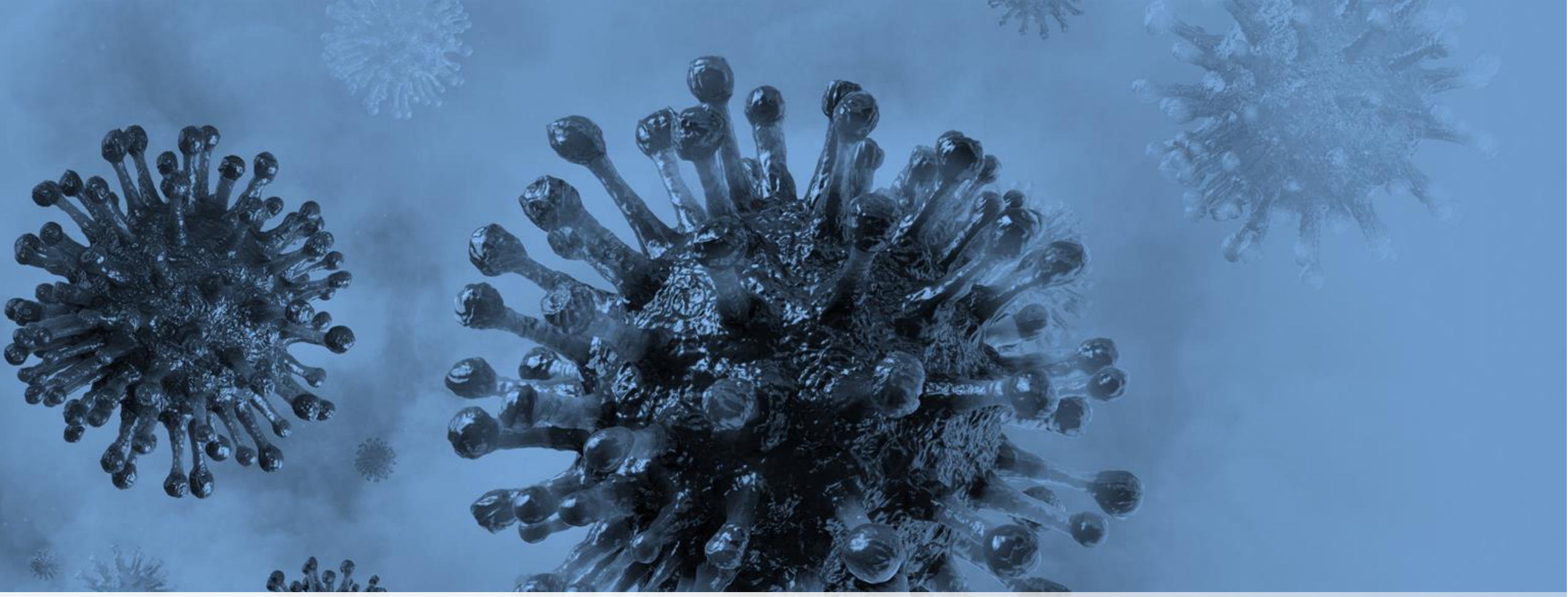

We would love to hear from you!

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Additional Resources and Material

- Further SARS-CoV-2 products:

https://www.thermofisher.com/za/en/home/clinical/clinical-genomics/pathogen-detection-solutions/coronavirus-2019-ncov.html

- TaqPath COVID-19 CE-IVD RT-PCR webpage:

https://www.thermofisher.com/za/en/home/clinical/clinical-genomics/pathogen-detection-solutions/coronavirus-2019-ncov/genetic-analysis/taqpath-rt-pcr-covid-19-kit.html

- qPCR Learning Centre:

https://www.thermofisher.com/za/en/home/life-science/pcr/real-time-pcr/real-time-pcr-learning-center.html

Our Africa Network & Contact Details

SA Headquarter for Africa

6 sites in SA , Offices in Kenya, Morocco and Ivory Coast

250+

Employees in Africa

50+

Engineers & Applications Specialists

If you would like any further information, please let us know!

Contact AfricaLeads@thermofisher.com

- Joanne Mizrachi – Sales Queries
  - joanne.bradfield@thermofisher.com
- Riegardt Johnson – Technical Queries
  - riegardt.johnson@thermofisher.com

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