molecular diagnostics

thermo a scientific b

applied biosystems

Solutions for your laboratory in response to the COVID-19 pandemic

Deploying molecular diagnostic tools and testing solutions in the global fight against COVID-19





From the leader in COVID-19 testing—solutions you can trust for the information you need

In a time when getting answers quickly is critical, we've responded with solutions to help keep the world moving forward. We deliver:

- Proven COVID-19 testing solutions for accurate, trusted results
- Reliable supply from a single source for uninterrupted testing
- Worldwide service and support to get, and keep, testing up and running

>50% COVID-19 testing Performed using technology from Thermo Fisher Scientific

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20M COVID-19 tests Manufacturing capability per week

Gold-standard technology qPCR-based testing solutions

Partnering with Thermo Fisher

Confidence and peace of mind for COVID-19 lab operations



End-to-end scalable testing solutions



Reliable innovation and supply chain



Global service and support



Accelerated COVID-19 testing innovations, launches, and access





Launched RUO assays

 Applied Biosystems[™] TaqMan[®] 2019-nCoV Assay Kit



 Applied Biosystems[™] TaqPath[™] COVID-19 Combo Kit



Expanded authorizations

- Applied Biosystems[™] TaqPath[™] COVID-19 Combo Kit EUA amendments:
 - Additional real-time PCR instruments
 - Additional workflow using Everlywell[™] Self-Collection Kit (nasal swab)
- Applied Biosystems[™] TaqPath[™] COVID-19 Combo Kit Advanced

Global expansion

Kits distributed in over 175 countries, including efforts for



Scaling production

humanitarian aid programs

• Ramped up to 20 million tests per week



New products and innovations

- Thermo Fisher Scientific[™] Amplitude[™] Solution (coming soon)*
- Applied Biosystems[™] TaqPath[™] COVID-19, Flu A, Flu B Combo Kit (coming soon)**
- Applied Biosystems[™] TaqPath[™] COVID-19 Pooling Kit (coming soon)**
- Applied Biosystems[™] TaqMan[®] SARS-CoV-2, Flu A, Flu B RT-PCR Assay (RUO)
- Applied Biosystems[™] TaqMan[®] SARS-CoV-2, Flu A/B, RSV RT-PCR Assay (RUO)
- Applied Biosystems[™] TaqCheck[™] SARS-CoV-2 Fast PCR Assay (RUO)

** The content provided herein may relate to products or workflows that have not been officially CE Marked, authorized by the US FDA or global health agencies, and is subject to change without notice; refer to current user manual for indications, warning and precautions.

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COVID-19 testing solutions: EUA-approved

TaqPath COVID-19 Combo Kit

Accessible workflow

- For use across 7 authorized Applied Biosystems real-time PCR instruments
- 6 authorized sample types

Reliable performance

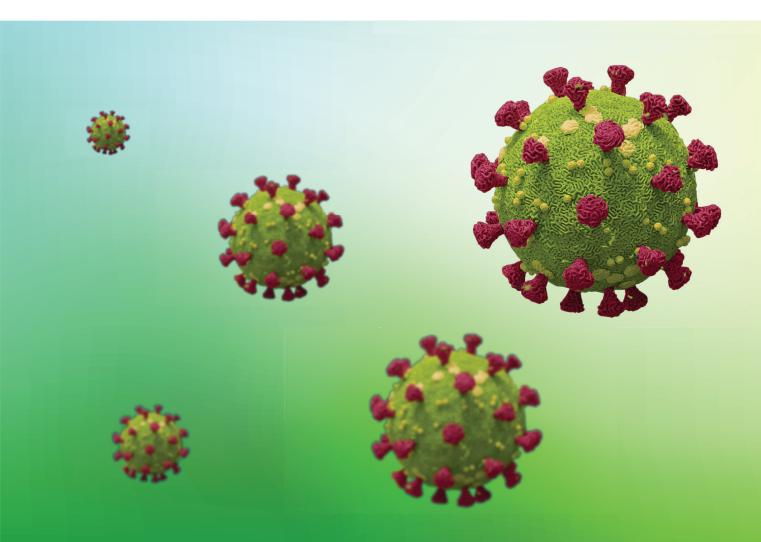
 Consistently high sensitivity and specificity to the SARS-CoV-2 virus

Fast turnaround time

• Complete workflow in <3 hours

thermofisher.com/covid19eua





COVID-19 testing solutions: coming soon

TaqPath COVID-19 Pooling Kit*

Exponentially increase testing capacity

- Add to existing testing menu using the same infrastructure
- Process pooled and single-source samples using the same kit
- Optimized pooling protocol maximizes sample throughput

Highly sensitive and specific

• 100% specificity to the SARS-CoV-2 virus

Simplified sample tracking and reporting

- Report is generated for each pool
- · Software tracks pooled samples and converts data

thermofisher.com/covid19pooling





Amplitude Solution**

- High throughput—analyze up to 8,000 samples per day
- Minimal resources—only 4 employees are required to operate
- Priority service partnership—helps reduce future downtime
- Single-source convenience—one supplier for all assays, consumables, and plastics
- Secured assay supply—up-front monthly delivery of a secured reagent supply over the first year

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COVID-19 testing solutions: coming soon (cont.)

TaqPath COVID-19, Flu A, Flu B Combo Kit*

Single test

- Detects and differentiates SARS-CoV-2, influenza A, and influenza B
- Helps diagnose and monitor the spread of COVID-19 and the flu

Highly sensitive and specific

- 100% homology to >99.9% of known SARS-CoV-2 genomes**
- Robust performance for detecting influenza A and B strains

End-to-end workflow

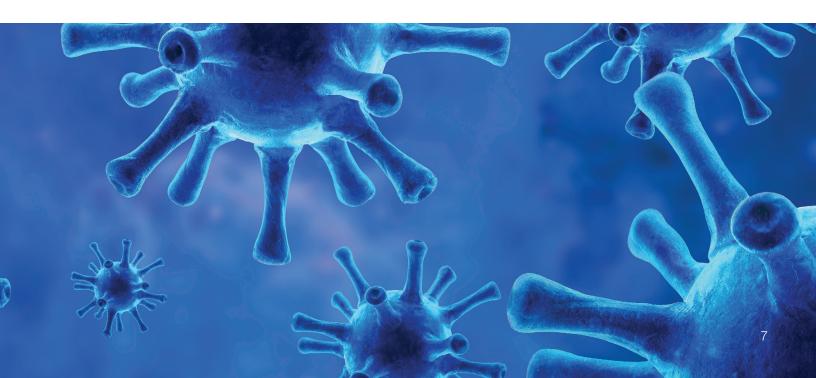
- Interpretive software to reduce risk of user interpretation error
- Complete workflow in approximately 3 hours

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** Those available as of September 8, 2020.

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SARS-CoV-2 testing services and support*

AB Platinum Plan

- 98% uptime guarantee**—get the total support that a pandemic demands
- Qualification service—documenting that your instruments are performing within manufacturing specifications
- Priority Technical Support⁺-365-day, 24/7 support, including weekends
- Rapid-response on-site support⁺⁺-guaranteed visit from field service engineer the next business day
- Field application scientist training—2-hour remote consultation
- Planned maintenance-included per requirements

thermofisher.com/abplatinum

- Comprehensive repair coverage—avoid extended downtime
- **Digital remote support**—on-demand tools and capabilities



* Services may not be available in your geographic region.

- ** Terms and conditions apply. For complete details, go to thermofisher.com/uptime.
- + Priority Technical Support is available in the English language only.
- ++ Rapid-response on-site support within the next business day is subject to regional availability.

RUO

SARS-CoV-2 surveillance testing

TaqCheck SARS-CoV-2 Fast PCR Assay

Enables widespread, high-frequency testing by reducing time, cost, and complexity

Fast

 Helps increase speed to results, enabling high-throughput testing

Cost-effective

• Minimizes infrastructure, supplies, reagents, and personnel costs across the workflow

Easy to use

• Simplifies workflow from raw saliva collection direct to PCR



thermofisher.com/taqcheck

For Research Use Only. Not for use in diagnostic procedures.

Which COVID-19 testing solution is right for you?

Thermo Fisher solution	Use case	Scalability	Primary testing populations	Stage of infection
TaqPath COVID-19 Combo Kit	Routine diagnostic testing	Multiples of 96- and 384-well systems	General patient testing	Symptomatic populations and surveillance testing
Amplitude Solution (coming soon)	High-throughput diagnostic testing with a secured supply of consumables	Up to 8,000 tests per day— not scalable	General patient testing, future screening applications	Symptomatic populations
TaqPath COVID-19, Flu A, Flu B Combo Kit (coming soon)	Diagnosis and differentiation of symptomatic patients during respiratory virus season	Multiples of 96-well systems	General patient testing	Symptomatic populations
TaqPath COVID-19 Pooling Kit (coming soon)	For improved efficiencies in testing of low-incidence populations	Multiples of 96- and 384-well systems	Students and staff at schools/universities, employee testing	Symptomatic populations and surveillance testing



Case studies from the United States



Case study: Enabling acute patient testing and surveillance in the state of Nevada

Actions

- 1. Thermo Fisher Scientific met with the Nevada governor's task force to accelerate deployment plan and identify 3 testing centers.
- 2. Supplied our FDA EUA COVID-19 workflow and redeployed instruments within the state.
- 3. Conducted state-wide instrument audit to identify deployable assets. Fast-tracked help with moving, installation, supplies, training, and validation.

Results

Starting point (March 30)

Testing 1,200 samples/week at University Medical Center (UMC) of Southern Nevada

Full implementation (mid-May 2020)

Achieved 140,000 tests per week for acute patient testing

Rapid lab transformation

- In <6 days, installed new and redeployed Applied Biosystems[™] 7500 Fast Dx systems and Thermo Scientific[™] KingFisher[™] purification systems
- Stood up first lab at UMC Southern Nevada within 9 days and reached 20,000 tests a week by mid-April

Testing is underway

- UMC expanded installed units and increased testing capacity to 70,000 samples per week
- Additional testing brought online in the Reno area by mid-May

Quick expansion

- Within 7 weeks, achieved 116x increased capacity
- Scaling to 210,000 samples per week to support surveillance testing

Rapidly scaled testing capacity to 140,000 samples/week in 7 weeks and expanding further for surveillance testing.





Case study: Helping Mako Medical implement COVID-19 testing for North Carolina and beyond

Mako Medical is a health care diagnostic laboratory in the USA that offers accurate testing and quick results.

Actions

- Thermo Fisher contacted the COO of Mako Medical to expand their menu into COVID-19 testing. Mako Medical is an experienced lab running >700 PGx tests using Applied Biosystems real-time PCR instruments and KingFisher purification systems.
- Added instruments they already use; plus, confidence from a strong, long-standing relationship with Thermo Fisher convinced Mako Medical to provide COVID-19 testing.
- 3. Thermo Fisher provided additional instrumentation and conducted remote support sessions with field application scientists to accelerate transition and ramp-up.

Results

Starting point (March 6)

Thermo Fisher proposes options to Mako Medical

Testing begins (March 20)

<2 weeks, Mako Medical is running COVID-19 tests

Full implementation (May 1) Mako Medical ramps up to 150,000 samples weekly

Efficiency was key to success

- Mako Medical obtained EUA in only 6 days
- Logistics team staffed entirely by US military veterans
- Built an 8,000 sq. ft. accessioning lab, and staffed it with 80 workers to overcome the potential bottleneck of a massive influx of COVID-19 samples
- Can accession 40 samples per minute and work 24/7 on COVID-19 sample accessioning

Increasing testing, extending reach

- May 1—running 150,000 COVID-19 tests per week using Applied Biosystems real-time PCR instruments and a KingFisher purification system
- Plan to increase to 200,000 tests per week with additional equipment
- Focused on expanding beyond North Carolina, contracting to test for other states

Working with us

- Mako Medical trusts Thermo Fisher expertise
- Will quickly adopt changes upon release—from protocol updates to product innovations

Within 2 weeks, we helped Mako Medical begin COVID-19 testing and quickly ramp up.





Case study: Enabling the Innovative Genomics Institute at UC Berkeley to begin testing for COVID-19

The Innovative Genomics Institute (IGI) is composed of diverse researchers at the University of California, Berkeley and the University of California, San Francisco. They believe in the potential of genome engineering to solve some of humanity's greatest problems.

Actions

- Partnered with IGI in the city of Berkeley to begin efforts to test first responders, the local homeless population, and the UC Berkeley campus community for COVID-19.
- 2. Supplied our FDA EUA COVID-19 workflow.
- IGI is using two 7500 Fast Dx Real-Time PCR Systems and one KingFisher purification system in their COVID-19 testing efforts.

Results

Starting point (March 15)

No experience with virology or clinical diagnostics

Full implementation (May 2020)

On target to meet goal of 5,000 samples/week

* Blueprint for a Pop-up SARS-CoV-2 Testing Lab Innovative Genomics Institute SARS-CoV-2 Testing Consortium, Dirk Hockemeyer, Fyodor Urnov, Ralph Green, Jennifer A. Doudna medRxiv

2020.04.11.20061424; doi: https://doi.org/10.1101/2020.04.11.20061424

Rapid lab transformation

- Previously, IGI conducted research solely in the genome engineering space
- IGI acquired CLIA certification within only a few weeks
- The stand-up laboratory is funded by philanthropy and staffed by 50 volunteers, including support from Thermo Fisher

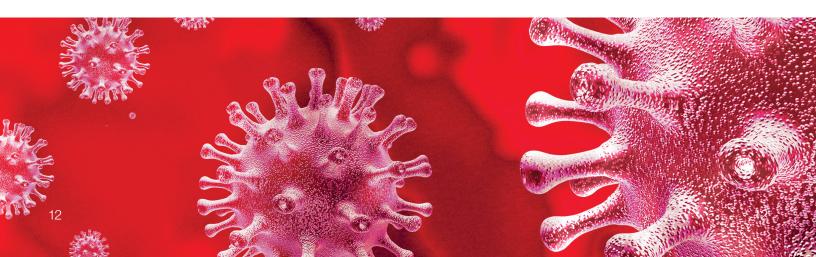
Testing is underway

- Convert 2,500 sq. ft. lab space dedicated to COVID-19 testing
- Using the 7500 Fast Dx Real-Time PCR System and a KingFisher purification system, with an automated workflow based on a Hamilton[™] liquid handler
- Method published in medRxiv*

Quick expansion

- In less than 2 months, IGI ramped up from testing 0 to 700 samples/week
- Offering testing services to surrounding cities/counties
- On target to reach their goal of 5,000 samples/week

Went from having no COVID-19 testing experience to being on target to meet goal of 5,000 samples/week in only 3 weeks.





Thermo Fisher Scientific is leading the response to the COVID-19 outbreak

Generating novel high-quality testing solutions at an accelerated pace to address urgent societal needs.

- Involved in more than 50% of global testing
- Proven COVID-19 testing solutions for accurate, trusted results
- Reliable supply from a single source for uninterrupted testing
- Worldwide service and support to get, and keep, testing up and running

And we're continuing to move forward—anticipating evolving testing needs and proactively developing innovative solutions to address future challenges.

Learn more about solutions you can trust for the information you need at **thermofisher.com/covid19**



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