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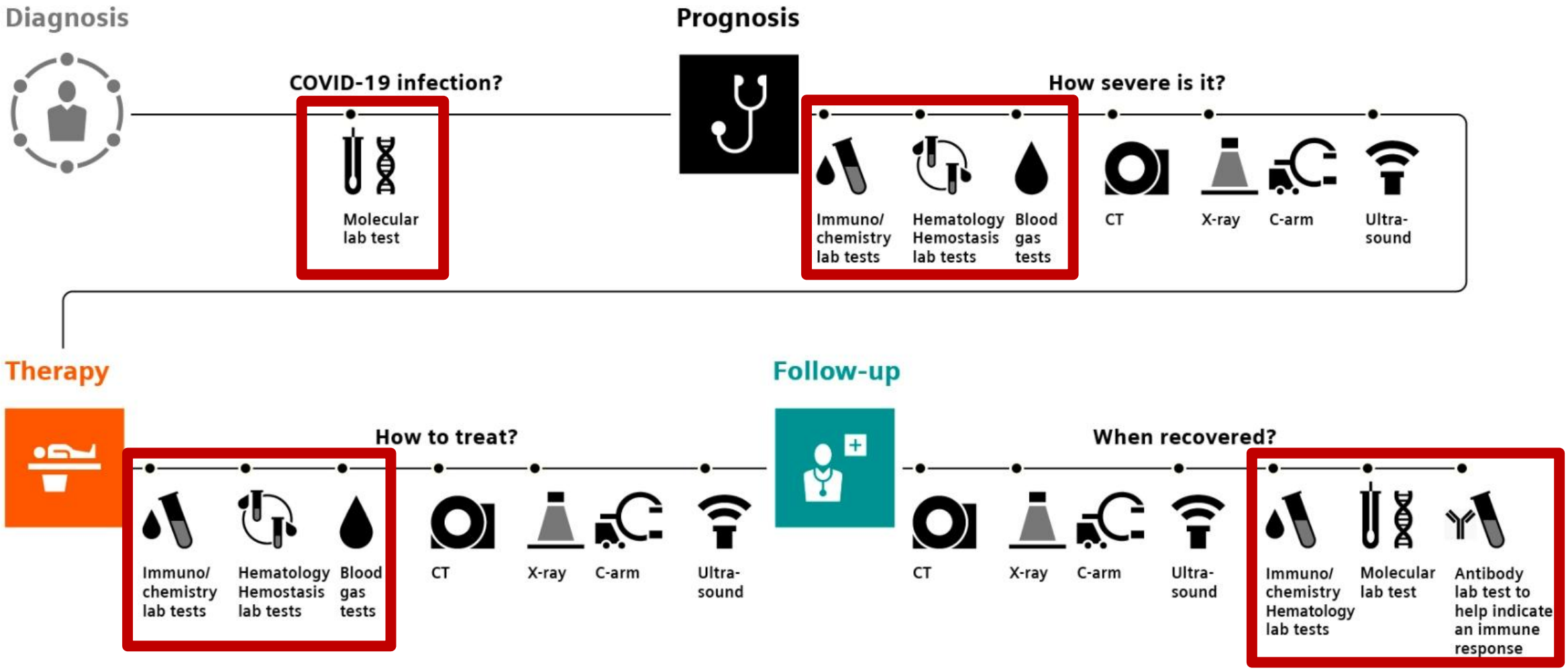
Adding another important tool in the fight against Covid-19

May 27, 2020

Siemens Healthineers plays a vital role across the COVID-19 patient pathway



This pathway is for illustration purposes only.

Providing quality testing for COVID-19 patients

Detection

Molecular SARS-CoV-2 Assay test kit

- CE-marked, FDA EUA approved, WHO EUL
- 100% positive agreement & 100% negative agreement[1]
- Planned ramp up to 2.5’ tests/month
- Complements and simultaneous with FTD Respiratory Pathogens 21[2] that identifies 21 different upper respiratory pathogens

Antibody testing at scale

Total Antibody Assay: IgG & IgM

- CE-marked, shipping worldwide
- High quality: 99,8% specificity, 100% sensitivity
- High throughput: Up to 440 tests/hour[3]
- Fast turn around time of 10 min[3]
- Available on 5 platforms spanning 20K systems worldwide, including largest IB in U.S.
- Production capacity of over 50‘ tests/month

Supporting COVID-19 patients

Providing critical lab tests COVID-19 patients

- Inflammation tests for escalated immune responses (IL-6)
- Coagulopathy tests (D-dimer)
- Tests to aid in managing high-risk patients

Blood Gas Monitoring

- New FDA-cleared RAPIDPoint 500e
- 5x scale of epoc® system for near-patient tests

1. In method comparison studies, FTD SARS-CoV-2 has shown Positive Percent Agreement: 100% (91.8-100, 95% CI) and Negative Percent Agreement: 100% (88.7-100, 95% CI) when tested in Copan eSwab nasopharyngeal and oropharyngeal swabs.
2. CE Marked in the EU and RUO in U.S.
3. For Atellica® Solution. Dependent on analyzer configuration and test mix. Product availability varies by country and is subject to local regulatory requirements..

Not all antibody tests are created equal

High quality, extensive reach and targeting the right protein are all essential to ensure we effectively manage the threat of COVID-19

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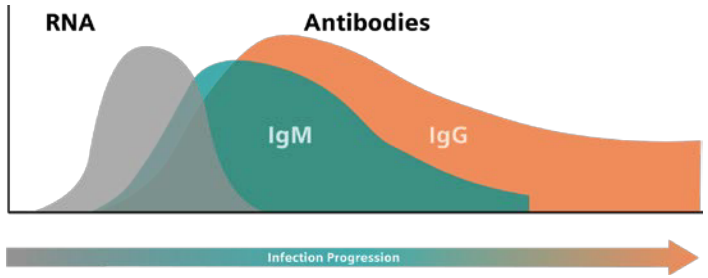
The SARS-CoV-2 Total Assay[1] is a highly sensitive and accurate antibody test

A total antibody test enables a clearer clinical picture over longer period of time.

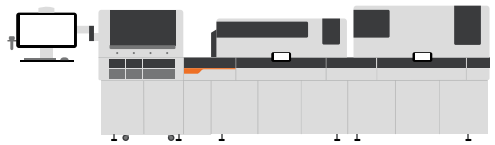


What is sensitivity and specificity?

A highly sensitive test should capture nearly all true positive results. A highly specific test should avoid nearly all false positive results.

100% sensitivity[2]

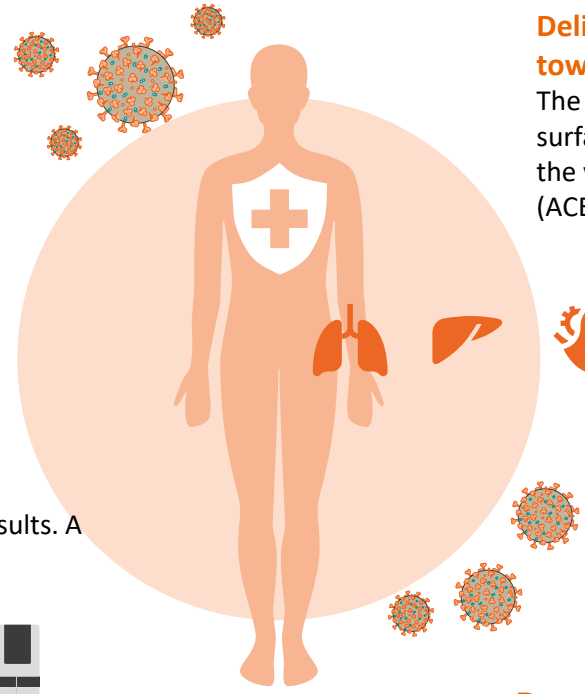
99.8% specificity[3]



Rapid

Identify SARS-CoV-2 antibodies in as little as 10 minutes.[5]

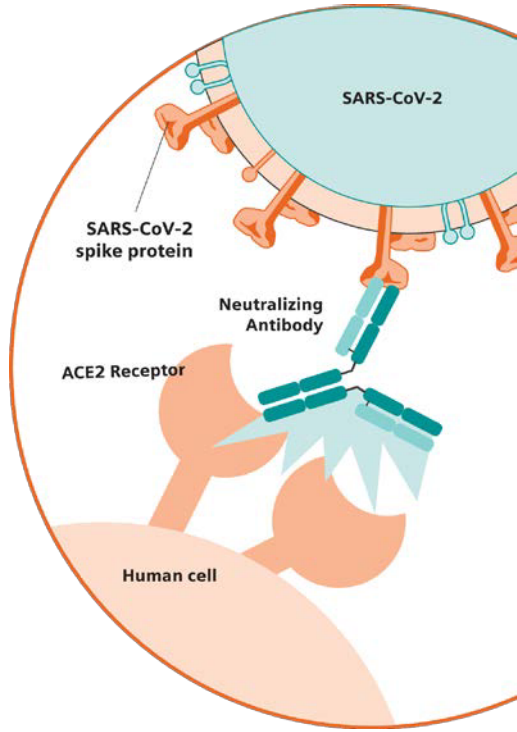
Total antibody blood tests, which run on laboratory analyzers, detect antibodies to SARS-CoV-2 (including IgG and IgM), that are used to identify those with an immune response that indicates recent infection or prior exposure.



Delivering long-term value as we look toward immunity and vaccination

The test detects antibodies to a key protein on the surface of the virus – a **spike protein**, which binds the virus to cells via a distinct human receptor (ACE2) found in lungs, heart, and multiple organs.

Studies indicate that certain (neutralizing) antibodies to the spike protein can **disarm SARS-CoV-2**, presumably by interfering with the ability of the virus to bind, penetrate and infect human cells.



Reaching millions of patients

~20,000

analyzers worldwide[4] with the largest installed base in the U.S.

50M/month

Production according to market demand as pandemic evolves

1. This test has not been reviewed by the FDA. In the U.S., use of this test is limited to laboratories that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high-complexity testing. Product availability may vary by country and is subject to regulatory requirements.
2. For samples collected ≥14 days after positive CR results.
3. Based on results for the ADVIA Centaur COV2T assay.
4. Installed base of ADVIA Centaur XP, ADVIA Centaur XPT, ADVIA Centaur CP, Atellica Solution, Dimension Vista and Dimension EXL analyzers.
5. Dependent on text mix and configuration using Atellica Solution.

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SARS-CoV-2 RT PCR detection test developed in record time

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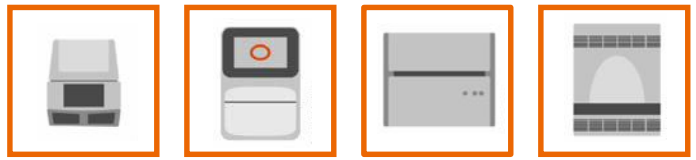
Detection

of infected individuals

Dual targeting

Evaluates two targets in one test tube, detecting two genes with less test preparation



Compatible with equipment widely used in laboratories worldwide

2-3 hours

Sample-to-answer time, including extraction and result generation

APRIL 24	MAY 5	MAY 21
CE-IVD	FDA EUA	WHO EUL

Supply chain expansion to produce

2.5M tests/mo.

dependent on demand

To make larger

Societal impact

100%

Positive agreement, negative agreement[1]

1. In method comparison studies, FTD SARS-CoV-2 has shown Positive Percent Agreement: 100% (91.8-100, 95% CI) and Negative Percent Agreement: 100% (88.7-100, 95% CI) when tested in Copan eSwab nasopharyngeal and oropharyngeal swabs.
2. Depending on the molecular system and lab resources employed.

Innovation and breadth of testing for COVID-19 patients

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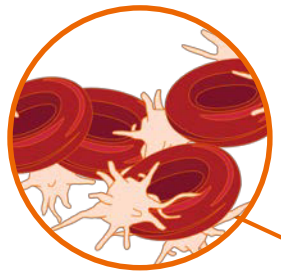
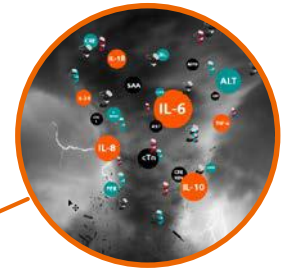
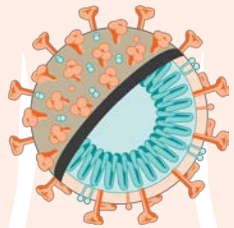
Manage patients with coagulopathies/thrombosis

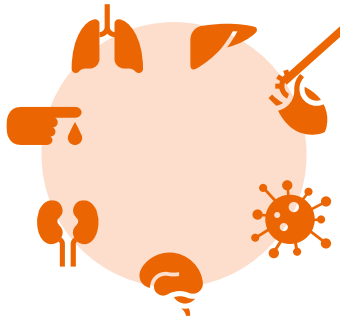


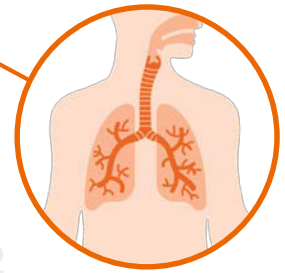


Predictive testing for inflammation to stay ahead of cytokine storm



High risk patients with pre-existing conditions





Manage patients with acute respiratory distress

Diagnosis | Monitoring | Recovery

1) AdvaMedDX, “A Policy Primer on Diagnostics,” June 2011.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