



QIArearch®

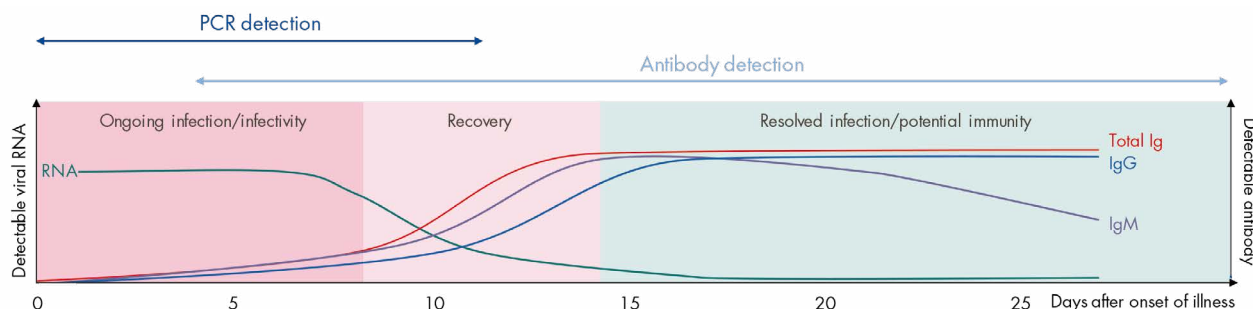
Anti-SARS-CoV-2 Total Test

The QIArearch Anti-SARS-CoV-2 Total Test is a scalable, digital assay to detect total SARS-CoV-2 antibodies (IgA, IgG, IgM), helping you identify possible past infection.

It lets you test up to eight patients at once for SARS-CoV-2 infection – with first positive results in just three minutes.

Expand the fight against COVID-19

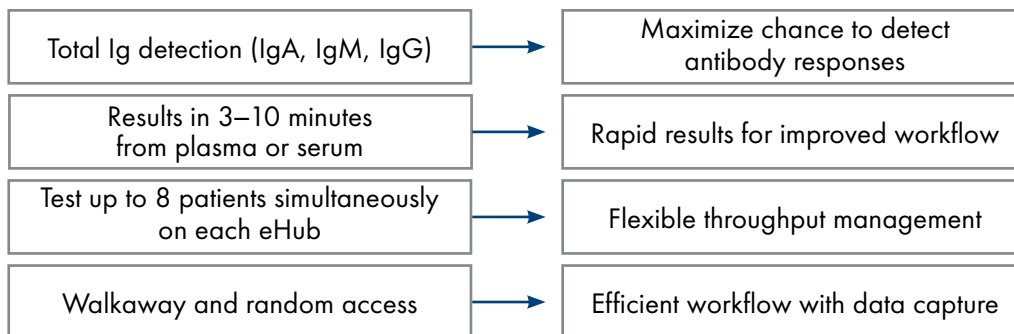
Accessible testing for past infection with SARS-CoV-2 is critical for infection control. Serology testing helps determine if a person may have been previously infected with the SARS-CoV-2 virus (1).



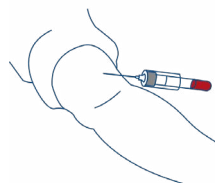
Access to SARS-CoV-2 serology made possible

The QIAreacH Anti-SARS-CoV-2 Total Test is an easy-to-use digital serology testing solution that provides trustworthy, rapid results.

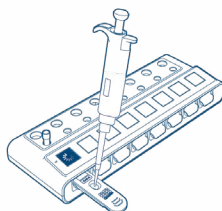
A smart solution



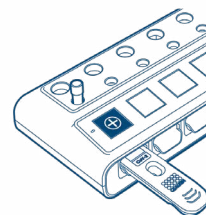
Minimal lab requirements



Draw patient sample using a plasma collection tube or standard serum tube



Process sample and transfer it to the QIAreacH eStick



The test will run automatically and display a result in 3–10 min

Figure 2. QIAreacH Anti-SARS-CoV-2 Total Test workflow

Trustworthy, reproducible results

The QIArearch Anti-SARS-CoV-2 Total Test uses nanoparticle fluorescence to provide qualitative detection of total antibodies to SARS-CoV-2 in human serum and plasma.

Table 1. Positive Percent Agreement/Sensitivity by days post-symptom onset (8).

Number of days after symptom onset	Number of samples tested	Number of QIArearch Anti-SARS-CoV-2 Total Test positive results	Positive percent agreement	95% confidence interval
0–7 days	3	2	66.67%	9.43–99.16%
8–14 days	13	12	92.31%	63.97–99.81%
≥15 days	49	47	95.92%	86.02–99.50%
All	65	61	93.85%	84.99–98.30%

Table 2. Negative Percent Agreement/Specificity (8).

Number of samples tested	Number of QIArearch Anti-SARS-CoV-2 Total Test negative results	Negative percent agreement	95% confidence interval
230	225	97.83%	95.00–99.29%

Portable testing that keeps you connected

The QIArearch Anti-SARS-CoV-2 Total Test provides fast testing on a digital portable device for ease of use, reliability and integrated data management. The test results are stored on the QIArearch eStick and displayed

on the QIArearch eHub. Optional connectivity allows for additional features including result printing or data export to LIS.

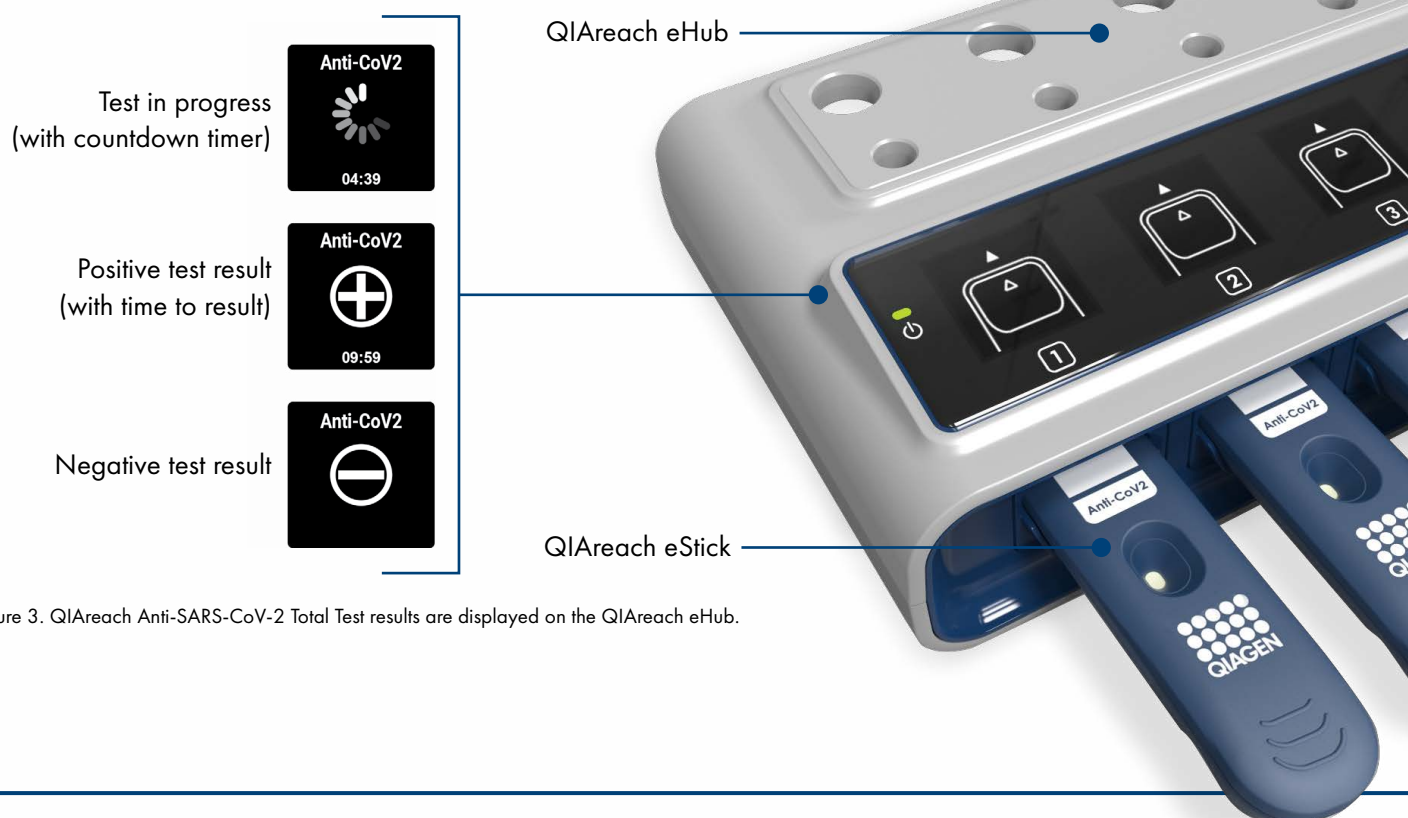


Figure 3. QIArearch Anti-SARS-CoV-2 Total Test results are displayed on the QIArearch eHub.

QIArearch Anti-SARS-CoV-2 Total Test

The QIArearch Anti-SARS-CoV-2 Total Test is part of a full suite of solutions from QIAGEN, your trusted partner in COVID-19 testing.



Ordering Information

Product	Contents	Cat. no.
QIArearch Anti-SARS-CoV-2 Total Test Kit	60 QIArearch eSticks, 60 QIArearch Processing Tubes, 3 x 10 ml QIArearch Diluent Buffer	645033
QIArearch eHub Device	QIArearch eHub, power adaptor, USB connector cable and service agreement	9003092

➔ Visit [QIAGEN.com/QIArearch-Antibody-Test](https://www.qiagen.com/QIArearch-Antibody-Test) to learn more

References

1. US CDC. Interim guidelines for COVID-19 antibody testing. www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html
2. Lou, B. et al. (2020) Serology characteristics of SARS-CoV-2 infection since the exposure and post symptoms onset. *Eur. Respir. J.* 2020 May 19:2000763. doi: 10.1183/13993003.00763-2020.
3. Zhao, J. et al. (2020) Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clin. Infect. Dis.* 2020 Mar 28. doi: 10.1093/cid/ciaa344.
4. Xiao, D.A.T. et al. (2020) Profile of specific antibodies to SARS-CoV-2: The first report. *J. Infect.* 81, 147-178.
5. Wölfel, R. et al. (2020) Virological assessment of hospitalized patients with COVID-2019. *Nature* 581, 465-469.
6. Tan, W. et al. (2020) Viral kinetics and antibody responses in patients with COVID-19. *medRxiv*. preprint doi: 10.1101/2020.03.24.20042382.
7. Ma, H., et al. (2020) Serum IgA, IgM, and IgG responses in COVID-19. *Cell. Mol. Immun.* 17, 773-775.
8. QIArearch Anti-SARS-CoV-2 Total Test Instructions for Use (Handbook). L1121905.

QIArearch Anti-SARS-CoV-2 Total testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C §263a, that meet requirements to perform moderate or high complexity tests.

- This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for detecting the presence of total antibodies to SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

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