



FIGHTING THE CORONAVIRUS DRIVES YOU.
DELIVERING HIGH-QUALITY ASSAYS DRIVES US.

Access SARS-CoV-2 IgG Assay



FIGHTING COVID-19 WITH SEROLOGY TESTING

Serology Testing and the Pandemic

Antibody testing could be a vital tool for determining who has already been infected and might have immunity to the coronavirus¹. Serology testing for SARS-CoV-2 is at increased demand in order to better quantify the number of cases of COVID-19, including individuals that may be asymptomatic or have recovered.²

Many individuals may benefit from serology testing as nearly 81% of infected people are asymptomatic or have mild to moderate symptoms.³

INDIVIDUALS WHO WILL BENEFIT FROM ACCESS SARS-CoV-2 IgG TESTING



**3.5
MILLION**

infections
globally¹



81%

of infected people
are asymptomatic/mild
to moderate²



14%

of infected people
show symptoms²



5%

of infected people
end up in the ICU²

The Access SARS-CoV-2 IgG Assay

By integrating high-quality antibody testing into their routine workflow, laboratories of all sizes can help identify front line healthcare providers, patients, and community populations who have potentially developed an immune response to the SARS-CoV-2 virus.

4,800 tests/day

Run up to 200 tests per hour
on the DxI 800 analyzer,
one of the highest throughput
analyzers in the market

99.8% specificity

100% sensitivity* and 99.8% specificity
validated against 1,395 negative broad
population-based samples

* >18 days between positive PCR & sample collection; for sensitivity analysis,
a total of 247 samples were collected from 192 individual patients

HIGH-QUALITY, ACCURATE AND RELIABLE RESULTS

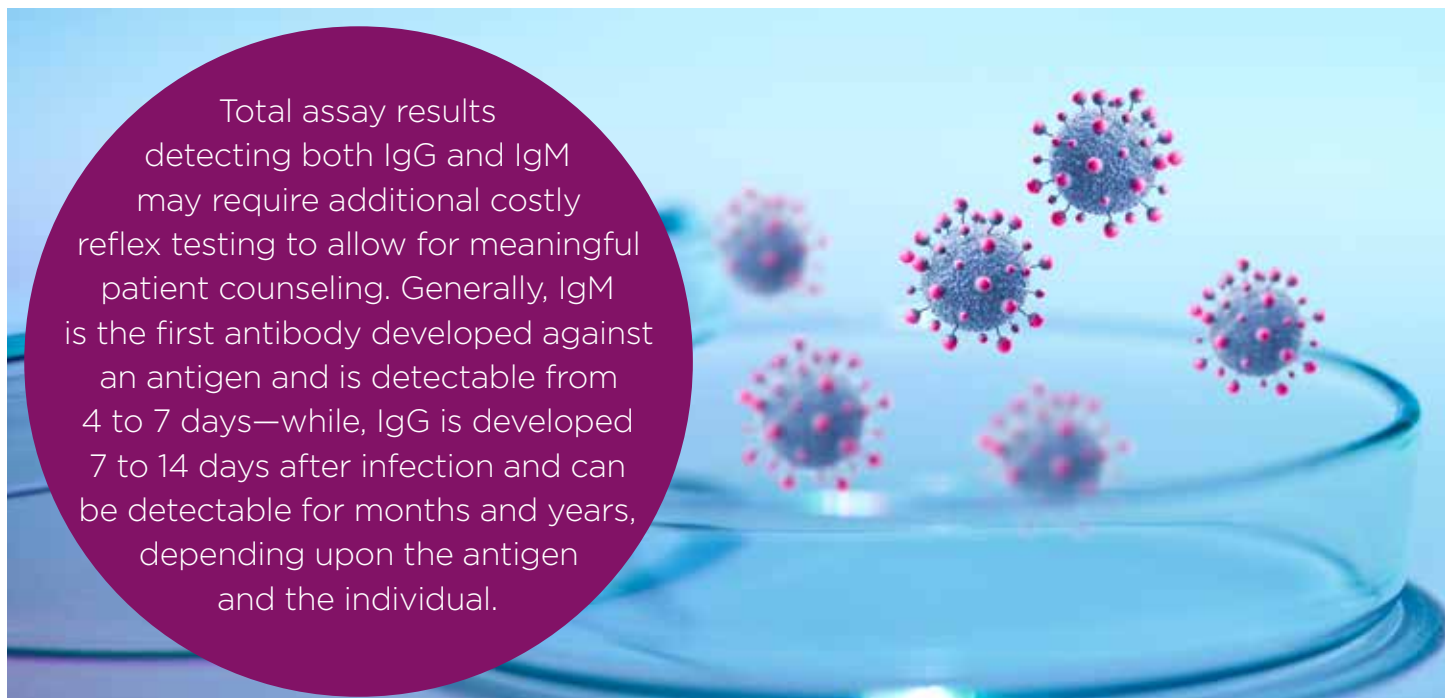
Generate accurate and reliable results that clinicians can trust for individualized patient care, with market-leading assay sensitivity and specificity

For clinicians, knowing whether a patient has developed IgG antibodies in response to SARS-CoV-2 is important. With this insight, clinicians can counsel the individual on prognosis, personalized care and immunity specific to their situation.

Tests without high accuracy could lead to large numbers of incorrect results, resulting in dangerous consequences.⁴

- The Access SARS-CoV-2 IgG assay has been validated against 1,400 negative broad population-based samples—significantly more than the number of samples required by the FDA for Emergency Use Authorization
- The Access SARS-CoV-2 IgG has 100% sensitivity and 99.8% specificity—one of the highest combined rates for SARS-CoV-2 antibody tests in the market.

However, since experience with SARS-CoV-2 is limited, the timing and characteristics of immunity are still uncertain.



Total assay results detecting both IgG and IgM may require additional costly reflex testing to allow for meaningful patient counseling. Generally, IgM is the first antibody developed against an antigen and is detectable from 4 to 7 days—while, IgG is developed 7 to 14 days after infection and can be detectable for months and years, depending upon the antigen and the individual.

IgM	IgG	SEROLOGY TESTING RESULT INTERPRETATION
—	—	No exposure to the virus, or could be consistent with very early active infection prior to IgM production
+	—	Acute infection; IgM develops within a few days of exposure in most individuals
+	+	There is a short window period—probably at around two weeks into infection—where both IgM and IgG are detectable
—	+	Pattern expected in those who have successfully cleared the virus and now may have a degree of immunity

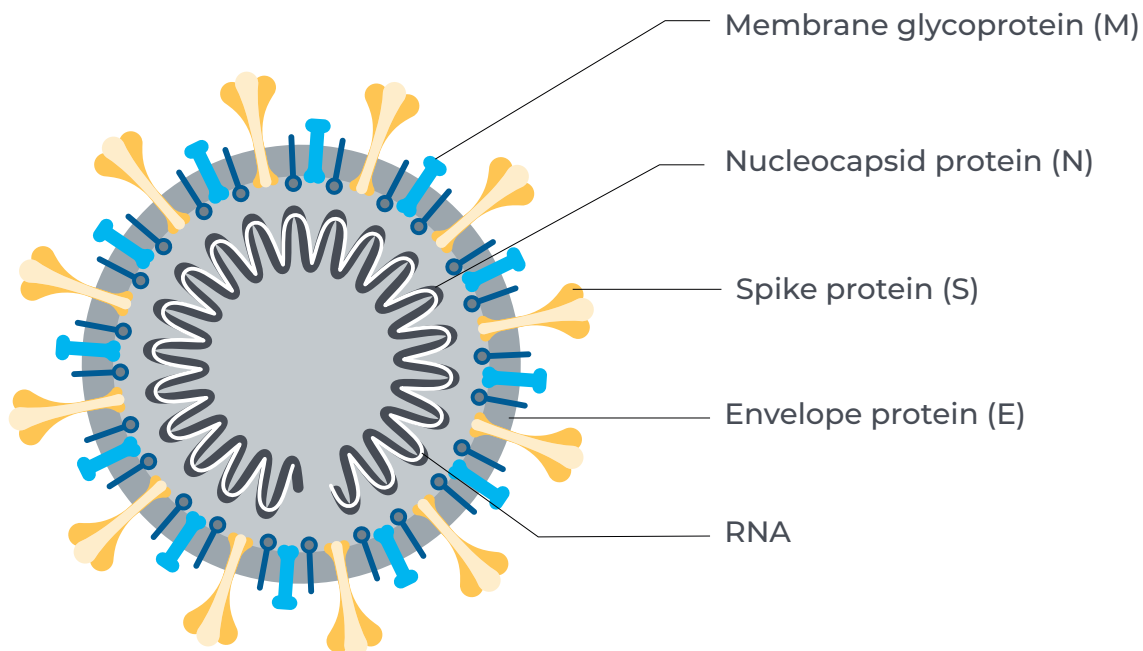
MEDICAL VALUE OF TARGETING THE SPIKE PROTEIN

Get high medical value by targeting antibodies against the SARS-CoV-2 Spike protein that may be more likely to confer immunity

- › To identify immunity against SARS-CoV-2, it is important to target the right antibodies
- › The Access SARS-CoV-2 IgG assay detects antibodies to the receptor-binding domain (RBD) of the spike protein, which may be important for immunity, based on laboratory studies
- › Studies have shown that antibodies against the RBD are neutralizing *in vitro*, indicating that they may be an effective measure of immunity when compared to antibodies against other SARS-CoV-2 viral proteins

Though the coronavirus uses many different proteins to replicate and invade cells, the spike protein is the major surface protein that it uses to bind to a receptor. After the spike protein binds to the human cell receptor, the viral membrane fuses with the human cell membrane, allowing the genome of the virus to enter human cells and begin infection.⁵

The coronavirus spike protein mediates entry into host cells by attaching to a receptor on respiratory cells called angiotensin-converting enzyme 2, or ACE2.⁶ Antibodies against it may promote neutralization of SARS-CoV-2.



A coronavirus contains four structural proteins, including spike (S), envelope (E), membrane (M) and nucleocapsid (N) proteins

Source: J Peiris, Y Guan & K Yuen, Severe acute respiratory syndrome, *Nature Medicine Supplement* 2004, 10 (12)

SEAMLESS INTEGRATION FOR IMPROVED LAB EFFICIENCY

Integrate the assay seamlessly into routine laboratory workflow without batching and extra maintenance

- › The Access SARS-CoV-2 IgG assay can be run in random access mode (RAM), **seamlessly integrating into current lab workflow without the need for batching or special maintenance**
- › The SARS-CoV-2 test throughput for Beckman Coulter is industry-leading, **at up to 200 tests per hour** depending on the analyzer used (for example, with Dxl 800, labs can run up to 4,800 tests/day)
- › **QC needs to be run only once every 24 hours** and calibration needs to be done only once every 28 days, or as required by individual laboratory procedure
- › The Access SARS-CoV-2 IgG assay has **200 tests per kit**, requiring less frequent ordering
- › **REMISOL Advance middleware** provides patient results from both diagnostic and serology tests on one screen for enhanced efficiency



GET HIGHER LAB EFFICIENCY WITH REMISOL ADVANCE

- › Integrate third-party systems like Cepheid's GeneXpert® Systems with Beckman Coulter immunoassay analyzers
- › REMISOL Advance middleware provides patient results from both diagnostic and serology tests on one screen, with built-in prompts
- › **Combining diagnostic and serology reporting makes it more efficient to generate reports about testing and results required by healthcare bodies**

Ordering information

Access SARS-CoV-2 IgG Reagent Kit, 200 tests/kit, 2 packs/kit, 100 t/pack	C58961
Access SARS-CoV-2 IgG Calibrators, CO-C1, 2 vials per kit, 2mL/vial	C58963
Access SARS-CoV-2 IgG QC, QC1-QC2, 2 levels, 3 vials/kit, 4mL/vial	C58964

For questions about reimbursement related to Beckman Coulter products please contact:
BECMedicalReimbursementHotline@beckman.com.

As manufacturers, we are prohibited from providing coding or billing recommendations or advice. Providers are responsible for determining appropriate coding selection/assignment for the services they perform. Further, as payer reimbursement policies vary, we strongly recommend providers consult with their own revenue cycle management teams, compliance teams, legal counsel, and payers to determine appropriate coding and billing practices based on provider-specific processes and practices. We cannot guarantee coverage or payment for any test.



For more information, please visit www.beckmancoulter.com/coronavirus

All Beckman Coulter products may not be available in your country or region at this time. Please contact your Beckman Coulter sales representative or distributor for more information.

REMISOL Advance is a trademark or registered trademark of Normand-Info SAS in the United States and other countries. Used under license.

Cepheid, GeneXpert, and Xpert are registered trademarks of Cepheid, its affiliates, or third parties.

References

1. Olson, J., 2020. *Minnesota Readies Antibody COVID-19 Response*. [online] Star Tribune. Available at: <https://m.startribune.com/minnesota-readies-antibody-covid-19-response/569595692/> [Accessed 6 May 2020].
2. Johns Hopkins Center for Health Security. 2020. *Global Progress On COVID-19 Serology-Based Testing*. [online] Available at: <https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html> [Accessed 6 May 2020].
3. Centers for Disease Control and Prevention. 2020. *Coronavirus Disease 2019 (COVID-19)*. [online] Available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html> [Accessed 6 May 2020].
4. Bonislowski, A. "False Positives Could Undermine Utility of SARS-CoV-2 Serology Testing." 360Dx, Apr 16, 2020. <https://www.360dx.com/infectious-disease/false-positives-could-undermine-utility-sars-cov-2-serology-testing>. Accessed on Apr 20, 2020
5. Saplakoglu Y. Coronavirus 'spike' protein just mapped, leading way to vaccine. LiveScience.com. <https://www.livescience.com/coronavirus-spike-protein-structure.html>. February 19, 2020. [Accessed May 1, 2020]
6. Pappas S. Scientists figure out how new coronavirus breaks into human cells. Live Science. March 11, 2020. <https://www.livescience.com/how-coronavirus-infects-cells.html>. [Accessed: May 1, 2020]
7. Ni L, Ye F, Cheng M et al. "Detection of SARS-CoV-2-specific humoral and cellular immunity in COVID-19 convalescent individuals." IMMUNI 4369. S1074-7613(20)30181-3. <https://doi.org/10.1016/j.immuni.2020.04.023>
8. Chen, X., Li, R., Pan, Z. et al. Human monoclonal antibodies block the binding of SARS-CoV-2 spike protein to angiotensin converting enzyme 2 receptor. *Cell Mol Immunol* (2020). <https://doi.org/10.1038/s41423-020-0426-7>

© 2020 Beckman Coulter, Inc. All rights reserved. Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

For Beckman Coulter's worldwide office locations and phone numbers, please visit

www.beckmancoulter.com/contact

BR-268865

