FAQs for the Rapid Antibody Test for SARS-CoV-2 IgG FOR USE WITH ABBOTT ARCHITECT.

Release Date: 4-24-2020

WHAT DOES THE TEST MEASURE ?

It measures detectable IgG antibody to SARS-CoV-2 (CoV-2 IgG)

IS THIS TEST NECESSARY FOR EVALUATION OF THE POPULATION ?

Dr Debra Birx, the coordinator of the White House coronavirus task force, has called this Antibody testing **"Critical"**. We agree.

WHAT IS THE SCIENCE BEHIND THIS TEST [i]

The SARS -CoV-2 IgG Test is a rapid assay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum or plasma as an aid in the diagnosis of primary and secondary SARS-COV-2 infections.

IS THE TEST ACCURATE?

Yes. The manufacturer [ii] states the following SARS-CoV-2 (CoV-2 IgG)
Results are best if specimens drawn on post day 14 from onset of symptoms.

Positive Percentage Agreement (PPA) by Days Post-Symptom Onset

Days Post-Symptom Onset	n	Positive	Negative	PPA (95% CI)
< 3	5	0	5	0.00%
3 - 7	10	5	5	50.00%
8 - 13	34	31	3	91.18%
≥ 14	73	73	0	95.07%,100.00%

In summary, if you test for the IgG antibody at 7 days, you will only have 50% positive agreement with usual symptoms, while if you test at over 14 days post onset of symptoms, you will essentially achieve over 95% positive correlation.

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The false positive rate is less than 1% ((181/182)-100) when tested with 182 pre covid-19 stored sample of convalescent serum from infection prior to the first date of identification of SARS-CoV-2 virus.

What is the expected Turn Around Time?

Currently we are sending the test to our reference lab, which results in a 3-5 days draw to result timeline. We are working on getting our own instrument, but the DOD, military, and large hospital systems with inpatient populations are first in line to receive rationed platforms and kits.

DOES THE TEST INFER IMMUNITY?

No positive or negative definitive statement can be made. The infection is just too new for the longitudinal studies needed to answer the question.

Perhaps Dr Harvey Fineberg, Chairman of the NAS committee put it best when he commented that the $64 question is **if the antibody level(s)equate(s) to resistance to getting ill again?".**

The Oxford chart below seems to indicate that immunity is achieved with the identification of the IgG antibody, but that has not been proven for this SARS-CoV-2 coronavirus we are now testing for. The chart only illustrates the normal antigenic stimulus to antigenic response for IgM and IgG antibody to a general antigenic challenge. For example, measles or mumps virus infections cause the body to make IgG antibodies that are protective for years and even decades, while for many coronaviruses, long term immunity is variable at best.

The current take home message on Immunity is that, to date (4-24-2020), there have been no longitudinal studies to demonstrate either partial or complete immunity to SARS-CoV-2 based upon the results of this test.

Demonstration of any long term immunity will take years of patient data to confirm or deny any relationship between test results and any possible immunity claims.

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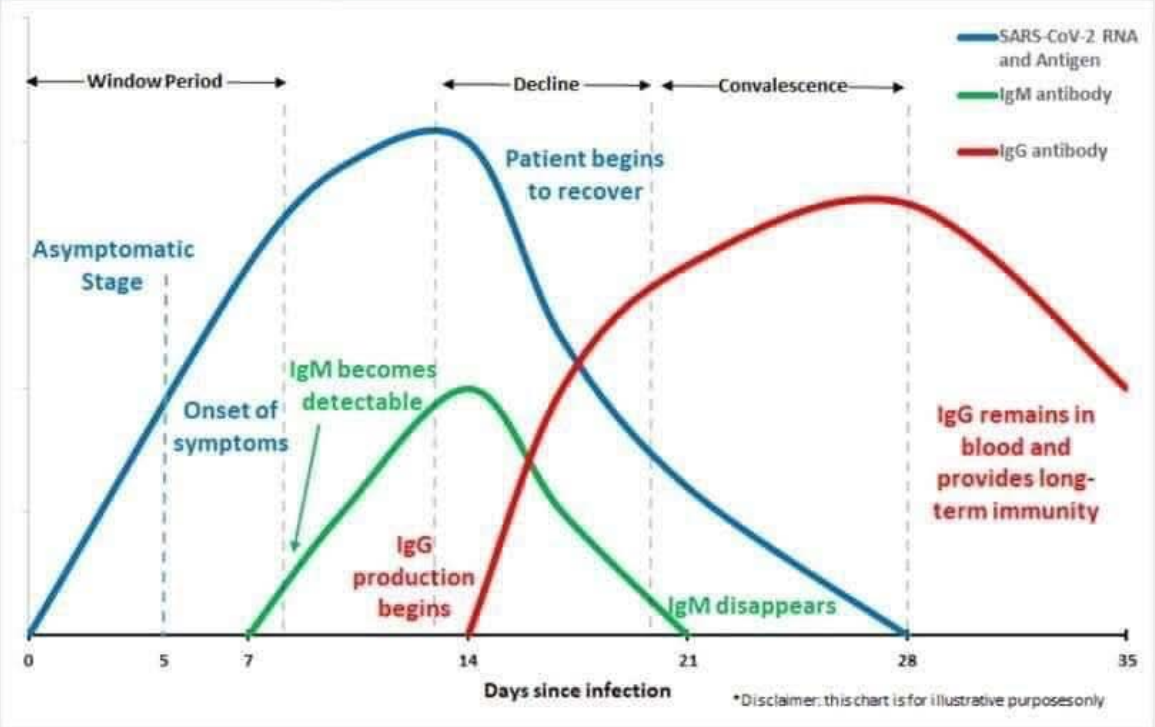
OXFORD CHART[iii]

Therefore, this COVID-19 Rapid Test should not be used until symptoms have been present for at least 3 days.



Test results			Clinical Significance
PCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patient is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. PCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the PCR result may be false-negative.

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Dr Anthony Fauci, a member of the of the White House coronavirus task force, has stated **"The test can help determine if someone is immune to the coronavirus and that's going to be important when you think about getting people back into the workplace"**

Has the test been reviewed by the FDA?.

No. This test has not been reviewed by the FDA. So the test report will include the following bullet points.

- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E."
- Not for the screening of donated blood.

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[ii] The SARS-CoV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma on the ARCHITECT i System .Abbott Laboratories

[iii] With credit to Trisha Greenhalgh, Prof of Primary Care, University of Oxford.