HATTIESBURG CLINIC

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During the week of April 20, 2020, Hattiesburg Clinic began validation of the SARS CoV-2 IgG antibody test on the Abbott Architect i2000 instrument. Abbott first made this test available as part of the U.S. Food and Drug Administration's notification without an Emergency Use Authorization (EUA) pathway that was outlined for COVID-19 diagnostic tests during the public health emergency; subsequent FDA authorization was received on April 26, 2020.

The test requires a single vial of blood from each patient, and the Abbott Architect i2000 can result up to 200 tests per hour. Per www.abbott.com, "An antibody is a protein that the body produces in the late stages of infection and may remain for up to months and possibly years after a person has recovered. Detecting these IgG antibodies will help determine if a person was previously infected with the virus that causes COVID-19."

At this time, it is not known for certain whether individuals infected with SARS-CoV-2 who subsequently recover will be protected, either fully or partially, from future infection with SARS-CoV-2 or how long protective immunity may last[1]. Recent published findings on patients admitted to the hospital with confirmed SARS-CoV-2 infection indicated that the median time to seroconversion was 11-14 days[2], which suggests that a significant portion of those infected do not produce antibodies to COVID-19 until 14 days after the infection. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. In addition, 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.

To date, Hattiesburg Clinic has performed 162 tests including those used for machine validation. The majority of the samples were obtained from healthcare workers who had no known prior diagnosis of COVID-19. Those healthcare workers included the doctors who evaluated patients at the Cough and Fever Clinic and all of the lab technicians who obtained swab samples from over 250 COVID-positive patients.

The results thus far are outlined in the table below:

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	Patients with RNA+ COVID (only pts >14d since sx onset)			Patients not known to have had COVID per RNA testing	
IgG + antibodies (titer ≥ 1.4)	n=		**21**	n=	**2**
	Average IgG titer		**6.1**	Avg IgG=	**2.4**
	Median IgG titer		**6.3**	Median IgG=	**2.4**
	Range of IgG titers		**3.6-7.7**	Range IgG=	**1.7-3.0**
	Days between symptom onset & IgG test	Avg	**31**		
		Median	**32**		
		Range	**16-39**		
	Days between RNA & IgG tests	Avg	**27**		
		Median	**28**		
		Range	**11-36**		
IgG - antibodies (titer <1.4)	n=		**3**	n=	**136**
	Average IgG titer		**1.0**	Avg IgG=	**0.1**
	Median IgG titer		**1.1**	Median IgG=	**0.0**
	Range of IgG titers		**0.8-1.2**	Range IgG=	**0.0-1.0**
	Days between symptom onset & IgG test	Avg	**29**		
		Median	**29**		
		Range	**25-34**		
	Days between RNA & IgG tests	Avg	**28**		
		Median	**27**		
		Range	**25-34**		

To summarize the data:

- Of the 24 COVID-positive patients who underwent antibody testing, 21 of them have developed IgG antibodies.
    - Average IgG titer in the group with antibodies was 6.1 in this group with a range of 3.6-7.7
    - Average IgG titer in the group without antibodies was 1.0 with a range of 0.8-1.2
- Of the 138 who did not have known COVID by RNA testing, only 2 of them have IgG antibodies.
    - Average IgG titer for the group without antibodies was 0.1 with a range of 0.0-1.0
    - Of these two patients, one of them has a medical condition that is known to cause false positive IgG testing results. The other patient has had loss of sense of smell for over 4 weeks, so it's possible she had COVID a month ago but did not undergo RNA testing. Their average IgG levels were 2.4 with a range of 1.7-3.0.

As we expand the sample size, we are certain to learn more about the relationship between the results of RNA testing and development of IgG antibodies, and some of these findings may be local to our area and different from what is being seen in other parts of the country. For now, there appear to be two points we can infer from our findings thus far, again noting that testing is still very early:

1. There do not appear to be significant amount of IgG antibody levels present in people who were not previously known to have had COVID, even in healthcare workers at Hattiesburg Clinic who have served on the front line at the Cough & Fever Clinic.
2. When used appropriately, Personal Protective Equipment (PPE) appears to be very effective in reducing the chance of developing COVID, assuming the development of IgG antibodies as a surrogate marker for having had COVID.

References:

[1]Patel, R, et al. mBio 11:e00722-20

[2]Zhao J, et al. Pre-print. 2019medRxiv 2020.03.02.20030189