

My valued patients and colleagues

More on antibody testing

You may have noticed that I have been spending a lot of time talking about antibody testing and the problems that I have seen with some of the tests currently being offered. You may also remember that I selected an antibody test that is semiquantitative because I believe a semiquantitative test provides the best information. Below is an example of the test results from the test I recommend. These are my actual test results - I am negative, which means I have not had COVID-19. Any number below 0.8 is negative, any number between 0.8 and 1.09 is borderline and any number over 1.09 is considered positive. This particular test is only an IgG test that checks for immunoglobulin G. Immunoglobulin G rises 10-14 days after exposure.

Procedure	Result	Abnormal	Range	Units
SEROLOGY - SENDOUT SARS-CoV-2 IgG	0.18		<0.80	Ratio
<p>No IgG antibodies to SARS-CoV-2 detected. Negative results may occur in patients collected too soon after infection, in immunosuppressed patients, and in some individuals infected with SARS-CoV-2. This test should not be used to exclude active or recent COVID-19.</p> <p>Interpretation: Ratio <0.8 Negative Ratio 0.8-1.09 Borderline Ratio >1.09 Positive</p> <p>Test methodology is the Euroimmun Anti-SARS-CoV-2 ELISA for the qualitative determination of IgG antibodies to SARS-CoV-2. The assay is designed to detect IgG antibodies to the S1 domain of the SARS-CoV-2 spike protein in patients with signs and symptoms of infection who are suspected of coronavirus disease (COVID-19) or in serum and plasma of subjects that may have been infected by SARS-CoV-2.</p> <p>This test is performed according to guidance of the U.S. Food and Drug Administration (FDA) for serologic testing for antibodies to SARS-CoV-2 described in policy FDA-2020-D-0987 section IV.D issued 3/16/2020. This test has not been reviewed by the FDA or cleared or approved by the FDA. 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. This assay is not for the screening of donated blood.</p> <p>Sonic Reference Laboratory, Inc. CLIA#45D2083658 3800 Quick Hill Rd, Building 3, Suite 101, Austin, TX 78728 Laboratory Director: Joseph H. Willman, M.D.</p>				

A semiquantitative test is different than little strips that light up “positive” or “negative”. I expressed concern about all the test kits coming from abroad that have not been validated. Evidently the FDA is

concerned as well because they are tightening the requirements for antibody testing for COVID-19 that must be met for a test to receive emergency use authorization (EUA). The policy, announced on May 4, requires developers to not only apply for Emergency Use Authorization under a tight time frame, but also provides specific performance thresholds for testing specificity and sensitivity.

The test sensitivity is the ability of a test to correctly identify those with the disease (true positive rate), whereas test specificity is the ability of the test to correctly identify those without the disease (true negative rate).

The FDA has noted that “unscrupulous actors” are marketing fraudulent test kits and “using the pandemic as an opportunity to take advantage of Americans’ anxiety”. Some test developers are falsely claiming their serological tests are approved or authorized. Other tests are being marketed incorrectly for “diagnostic use” or have performed poorly based on independent evaluation by the National Institutes of Health.

To date, there are only 12 antibody tests authorized for use under the EUA. Another 200 antibody tests are under review. I have heard of tests being offered for almost \$400 apiece. This is totally obscene and unnecessary, so be careful

Are we talking about masks again? Yes, Lone Ranger, we are!

In a previous newsletter, there was a discussion about N95 masks. It was noted that some public health officials stated that KN95 masks, which are made in China, were just as good as N95 masks. However, according to the Wall Street Journal, recent evidence uncovered by US regulators found that a significant number of N95 masks are falling short of acceptable standards. Sixty percent of 67 different types of imported masks allowed in more tiny particles than permitted. A mask falsely bearing an FDA logo filtered out as little as 35% of particles. Some masks labeled KN95, filtered less than 15% of particles. The KN95 and N95 masks are so named because they are supposed to filter out 95% of particles. Studies have found that millions of substandard masks have been imported from China and other countries.



KN95



50
pcs

Shipping Within 24 hours

Please note: handsome gentlemen on left is wearing the correct N95 mask with head straps while advertised KN95 mask has ear loops.

Here is a clue to test quality. The majority of poorly made masks used ear loops to secure the mask. All approved masks have headbands for a tighter fit, which is key to protection. This only applies to N95 masks. General surgical masks such as the one pictured below are not as effective because they allow particles in from the sides. However, they do decrease the number of particles expelled onto others near you from a cough or sneeze; they also keep you from touching your face.



Should schools re-open?

Several studies of COVID-19 hint that children are less likely to catch the novel coronavirus, and often do not transmit it to others. Using available data, some countries are allowing children back in school. Denmark sent children up to 11 years-old back on April 15 and Germany welcomed back older children on April 29. Some Israeli schools opened on May 3. Quebec and the Netherlands plan on reopening primary schools in May 11. Boy, this would be great news for children's education and parents' mental health if the US followed suit and reopened schools.

Iceland conducted mass screenings and found no infections in 848 children under age 10 without symptoms, compared to 1% in ages 10 and older. A US analysis of 150,000 infected people found just 1.7% were under age 18. Not all the data is so straight forward though. In Singapore, for example, there was a child who was not sick yet served as "virus" factory. In this example a 6-month-old without symptoms had the same virus levels as a sick adult.

Space and COVID-19

A US-Russian space crew landed safely a few weeks ago in Kazakhstan and, upon their return, took extra precautions due to the coronavirus pandemic. The recovery team and medical personnel assigned to help the crew out of the capsule and administer post-flight checks were under close observation for nearly a month and had received coronavirus tests. The Americans on board were driven from Baikonur to Kyzyl-Orda, a trip of 190 miles to board a flight to the US, quite a strenuous procedure if you have been weightless for months on the International Space Station. Interestingly, the crew returned to earth exactly 50 years after Apollo 13 astronauts splashed down in the Pacific Ocean after an oxygen tank explosion aborted the moon landing.



Crew of Apollo 13 left and 3 members of International Space Station right, two on outside are Americans who returned to earth recently.

Writing and Medicine

Emily Bronte caught a severe "cold" following the funeral service of her brother Branwell. Her respiratory symptoms continued, and she actually had tuberculosis. As her condition steadily worsened, she rejected medical help. Apparently felt similar to my patients, saying she would have "no poisoning

doctor" near her. As her condition continued to worsen, she was only able to whisper in gasps. She died shortly thereafter at age 29. At the time of her death, Ms. Bronte was so thin that her coffin was only 16 inches wide.

Her best-known work was Wuthering Heights published in 1847 under the name of Ellis Bell. Emily remains a mysterious figure. She did not seem to have any friends outside of the family. Her closest friend was her sister Anne (who wrote Agnes Grey and The Tenant of Wildfell Hall). You might also recognize the name of her other sister Charlotte who wrote Jane Eyre. Charlotte was the last of the Bronte sisters to die. During her pregnancy, Charlotte suffered from hyperemesis gravidarum, a complication of pregnancy which causes excessive nausea and vomiting.

I must admit I am not a reader of the Bronte sisters (not enough war, pillaging and blood), but my wife is an avid reader of classic literature, so this section is devoted to her.