# How Accurate is the Antibody Test?

On May 29, 2020, the FDA issued a letter to the manufacturer of the tests that BowTie Medical is using, HealGen Scientific. The letter was signed by Denise Hinton, Chief Scientist for the Food and Drug Administration ("FDA"). The letter can be viewed at the FDA's website. In that letter, our product was officially added to the FDA's list of products with Emergency Use Authorization ("EUA"). See quote below:

## Officially added to FDA list for Emergency Use List

*"Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization."*

Included in the letter were comments on the effectiveness and safety of the tests. See quotes below:

## Effectiveness of Tests

*"Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product."*

*"FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness."*

Independent testing was performed on our test kits prior to the FDA review. Below is a brief description of the testing process and the results.

## Independent Testing Data

Before the FDA makes any decision on a diagnostic test, the manufacturer is required to conduct an independent test. The most important question coming out an independent test is how accurately the test shows a true positive and true negative. These are referred to as Sensitivity (True Positive) and Specificity (True Negative). Although this sounds like a simple concept, there are several factors that go into the calculation of sensitivity and specificity.

As an example, because the human body typically does not begin to generate the IgG antibody until after 14 days, testing for its presence before 14 days of exposure will likely yield a negative (antibody absent). Performing the same test just 7 days later could yield a completely different outcome. This does not mean that the test is inaccurate. What it means is that the timing of when the test is performed can affect the outcome.

# How Accurate is the Antibody Test?

Independent tests performed on our test kits have yielded the following:

| Antibody | Sensitivity | Specificity |
|---|---|---|
| IgM | 100% | 100% |
| IgG* | 96.7% | 97.5% |

*IgG data is based on testing being performed during the "Convalescence Period", in other words later in the disease cycle when IgG is more likely to have been developed in the body.

As part of the FDA requirements for continued use of this testing process, BowTie is required to monitor the effectiveness of the tests being performed.

## Continued Testing

BowTie sends samples of its test kits to independent laboratories prior to their use for independent validation. In addition, we continue to conduct independent testing on the test outcomes from accredited medical and academic institutions. If you are tested, you may be contacted by BowTie Medical to voluntarily participate in a second test to assist with our validity testing.

We are required under the terms of the FDA's EUA to report any issues with our testing, in particular, any validation of "False Positives".

BowTie Medical is committed to providing high quality rapid antibody testing.

## Prevalence

An especially important and confusing concept related to the management of a pandemic is the issue of prevalence. Simply stated, prevalence is the % of any given population or community that has had the disease. Even as testing in the US continues to grow, we do not yet know what the prevalence of this disease is. Estimates seem to vary between 1% and 30%.

Understanding prevalence helps medical and government officials formulate more effective policy. By participating in antibody testing you are not only gaining an understanding of your own personal situation but more importantly, helping us better understand the prevalence of COVID 19 in our community.

## Questions

If you have additional questions about our testing process, please submit them to:

Info@BowTieMedical.com