

Antibody testing was correlated with PCR positive Covid patients from a hospital in Wuhan, China. Data is displayed in the figure below:

		IgM & IgG Rapid Test**		Total Number	
		+	-		
COVID-19 status*	+	37	7	44	COVID-19 positive patients
	-	14	169	183	COVID-19 negative patients
		51 patients tested positive	176 patients tested negative		

Sensitivity = 84.1%  
Specificity = 92.3%

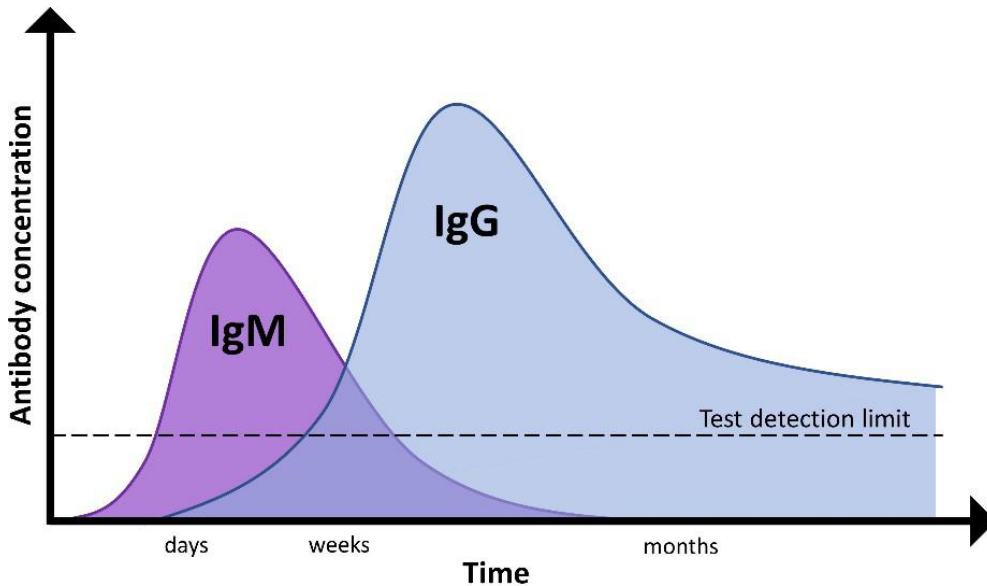
Figure 1. Sensitivity and specificity information when both IgM and IgG antibodies are measured. The sensitivity and specificity may change as we continue to test more samples.

\*Confirmed through other clinical methods (e.g., RT-PCR). \*\* Serum samples

Test Results			Clinical Significance
PCR*	IgM**	IgG**	
-	-	-	Patient does not have COVID-19
-	-	+	Patient may have had COVID-19 but the virus has cleared. Patient has likely gained immunity to COVID-19
-	+	-	Patient may have had COVID-19 but the virus has cleared. Patient has likely gained immunity to COVID-19
-	+	+	Patient has COVID-19 and is contagious (false-negative PCR results) or patient is in the recovery phase of COVID-19
+	-	-	Patient has COVID-19 and antibody levels are below the detection limit (see also Table 2 and Figure 3)
+	-	+	Patient may be in late or recurrent stage of infection
+	+	-	Patient is in the acute phase of COVID-19 and is contagious
+	+	+	Patient has COVID-19 and is contagious

\* PCR: Throat/nasal swab sample; Detects SARS-CoV-2 viral RNA. Viral load may reflect infectivity. False negatives can occur for various reasons, including improper sample collection technique.

\*\* IgM & IgG: Serum, plasma, and whole blood samples; Detects different antibody types to SARS-CoV-2 N-protein (Figure 3)



Schematic of IgM and IgG antibody profiles over time in response to infection. IgM antibodies are produced first followed by the IgG antibodies. The specific antibody profiles for COVID-19 infection across time are still being ascertained. Host immune responses and antibody binding characteristics will vary. Recently, the IgG levels of a subset of recovering COVID-19 patients have been reported to drop off quickly, which may lead to negative IgG rapid test results.

## Possible reasons for false negative or false positive results with the IgM/IgG rapid tests

Possible Reason	Explanation
Assay not performed properly	Please refer to our instruction manual. Running the test differently than what is outlined in the manual can result in inaccurate data.
Antibody level below detection limit	<ul style="list-style-type: none"> <li>IgM and IgG levels change over time, and their profiles in response to COVID-19 are still being ascertained (Figure 3). For example, a false negative result with the IgM rapid test may due to the IgM phase ending (as the IgG levels increase).</li> <li>Individual IgM and IgG responses will vary; we recommend that both IgM and IgG analyses are performed.</li> </ul>
Antibodies not present (false negative)	<p>This test detects antibodies to the wild-type Nucleocapsid Protein.</p> <ul style="list-style-type: none"> <li>The patient may not have generated antibodies against the SARS-CoV-2 protein used in the kit.</li> <li>SARS-CoV-2 virus is mutating. Patients may have antibodies to a mutated region Of the N-protein</li> </ul>
Antibody crossreactivity (false positive)	<p>This test detects antibodies to the SARS-CoV-2 Nucleocapsid Protein, but there are regions of this protein that are the same (homologous) as other virus' nucleocapsid proteins. Antibodies targeting these homologous regions in response to a different infection will result in a false positive result. However, the possibility of this is small.</p> <ul style="list-style-type: none"> <li>Previous infections will not have IgM antibodies and the IgG levels will be low.</li> <li>We tested 36 potentially interfering specimens (5 cases Of autoimmune disease related to anti-nuclear antibodies (ANA+), 6 cases of respiratory syncytial virus (RSV), 5 cases of influenza A virus, 6 cases of influenza B virus, 6 cases of hepatitis C virus (HCV) and 10 cases of hepatitis B virus (HBV) infected patients). None of them resulted in a false positive.</li> </ul>
Unknown cause	In vitro diagnostics tests are not accurate 100% Of the time. Sometimes the reasons for false results
Test not working properly	The test is working properly if the control line is present. Dunwoody Labs also performs quality