

Quantitative* COVID-19 (RBD) Antibody Testing Services

- Measure antibodies that bind the RBD of the virus - significantly associated with neutralization
- Accurately track levels over time with high-throughput CLIA laboratory testing
- Validated performance for a variety of sample types, including dried blood spots (DBS)

* Quantitative serum and plasma results reported, semi-quantitative dried blood spot results reported

SARS-CoV-2 (RBD) IgG Antibody Test Performance

The sensitivity of the SARS-COV-2 (RBD) IgG Antibody test was assessed by analyzing blood samples from 69 individuals with prior SARS-CoV-2 infections confirmed by PCR. As shown in the table below, the Positive Percent Agreement (PPA) was 100% for all samples acquired ≥ 15 days post onset of symptoms. For samples acquired earlier (0-14 days), the PPA decreased to 50% reflecting variable seroconversion rates among individuals. For individuals sampled >112 days post symptoms onset, the mean index value was lower than that observed at earlier time points; however, all samples remained positive (index >1.0).

The specificity of the SARS-COV-2 (RBD) IgG Antibody test was assessed by analyzing blood samples acquired pre-pandemic. Several populations were assessed including adults covering a range of demographic categories, chronic conditions, exposure to common infectious diseases and vaccination history and children who had been hospitalized for a variety of conditions. The Negative Percent Agreement (NPA) was 98.9% or greater for all groups (99.4% overall). Specificity of the assay was further tested with samples with confirmed levels of antibodies to other infectious agents (e.g., HIV-1, HCV, CVM, etc.), which yielded negative results for all tested.

Positive Percent Agreement (PPA)

Days after Symptoms Onset	ProterixBio SARS-CoV-2 (RBD) IgG Antibody Test				
	Total	Mean Index*	Positive	Negative	PPA
0 - 14 days	6	2.1	3	3	50%
15 - 28 days	9	10.5	9	0	100%
29 - 56 days	33	13.5	33	0	100%
57 - 112 days	14	25.1	14	0	100%
113 - 165 days	7	9.9	7	0	100%

*Average of sample index values from different individuals

Negative Percent Agreement (NPA)

Pre-2019, U.S. Population Groups	ProterixBio SARS-CoV-2 (RBD) IgG Antibody Test			
	Total	Positive	Negative	NPA
Children (<18 yrs)	100	0	100	100%
Adults (18-80 yrs)	127	0	127	100%
Adults w/ chronic respiratory disease (50-80 yrs)	282	3	279	98.9%

Quantitative Performance

The assay output is a numerical Index that is the ratio of the antibody concentration of the sample to that of a controlled calibrator level. For serum and plasma reporting the test Index calibrates to the First WHO International Standard NIBSC 20/136 material linearly across the assay range. The table below illustrates excellent precision across the measurement range. Additionally, the assay recovers to within 10% of expected for a range of samples spiked with the Standard. Samples above the assay range are diluted to achieve a reportable result.

Precision

Sample I.D.	N	Mean Index	Within Run		Day to Day	
			SD	CV%	SD	CV%
Sample A	80	16.65	1.23	7.1	0.60	3.6
Sample B	80	6.80	0.52	7.3	0.50	7.4
Sample C	80	3.39	0.17	4.7	0.28	8.2
Sample D	80	1.66	0.11	7.1	0.28	16.7
Sample E	80	0.54*	0.05	11.3	0.10	17.8

*Measured level is below the pos/neg cut-off (Index = 1) but above LoQ for the assay

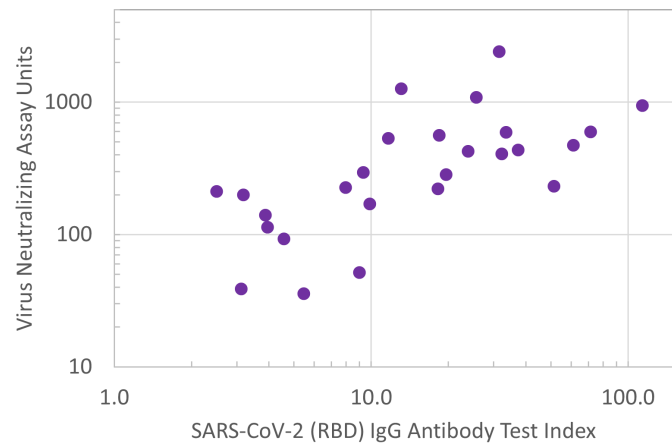
Linearity

Sample I.D.	Dilution	Observed Index	% CV	% Dev from Lin. Fit
Sample F (representative of multiple individual samples tested)	1	>ULIM		
	1:2	25.7	5.8	-5.9
	1:4	13.9	9.7	1.0
	1:8	6.7	6.9	-3.9
	1:16	3.5	3.0	-0.8
	1:32	1.9	5.3	2.3
	1:64	1.2	5.8	12.5

Neutralizing Activity

Seropositive samples (N=26), all >20 days post symptoms onset, were characterized with an independently validated neutralization assay, provided under CLIA, and the ProterixBio (RBD) SARS-CoV-2 IgG Antibody test.

The data are significantly associated with Spearman rank-order, correlation coefficient = 0.74 and p value < 0.001.

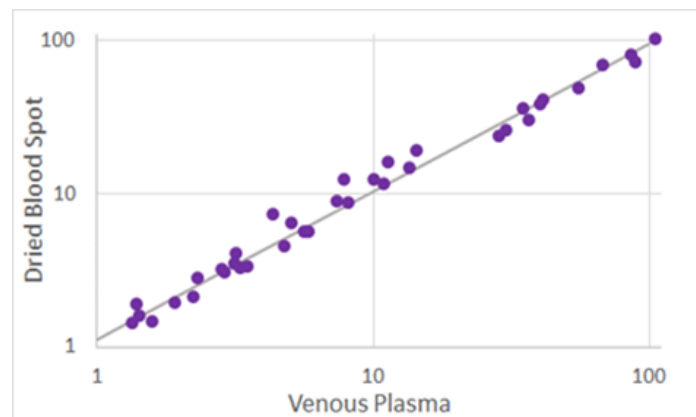


Dried Blood Spot / Finger Stick Performance

Spotted venous blood dried blood spots (DBS) compare to venous EDTA plasma (N=37).

Deming regression of ProterixBio SARS-CoV-2 (RBD) IgG Antibody test index values measured in both samples yielded a fit with slope = 0.97, p value < 1e-30, and a correlation coefficient = 0.99.

Additionally, finger stick derived DBS compare to spotted venous blood DBS (N=29) with Deming slope p value < 1e-20, and a correlation coefficient = 0.98.



References

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