Technical Bulletin

COVID-19 IgG/IgM, DBS

Self-Collection and Dried Blood Screening System for COVID-19 Awareness and Disease Management.

Performance Characteristics

• Within Run Precision

Within run precision was determined by testing dried blood replicates containing negative and positive COVID-19 IgG antibody. Each of the dried serum specimens was tested ten times:

Mean Antibody (OD)	Standard Deviation	Coefficient of Variation (%)
1.51	0.034	2.3
0.155	0.010	6.5

• Clinical Sensitivity and Specificity

Clinical sensitivity and specificity were determined by testing paired serum and dried blood specimens (DBS) samples containing variable levels of IgG/IgM antibodies and evaluated at a cut-off OD value determined by the background signal of negative controls:

N=38	DBS IgG/IgM POSITIVE	DBS IgG/IgM NEGATIVE
Serum IgG/IgM		
POSITIVE	38	0
NEGATIVE	0	38

• Test Interpretation

A sample that gives an OD value greater than the assay cut-off value 0.4 is interpreted as positive. A positive result from the assay only indicates the presence of COVID-19 related antibodies.

A sample that gives an OD value less or equal to the assay cut-off value of 0.4 is interpreted as negative. In this case, either the sample does not contain COVID-19 related antibodies or the sample was collected at an early stage of infection.

• Dried Serum Sample Stability

Dried blood specimens are stable for two weeks when stored at room temperature.

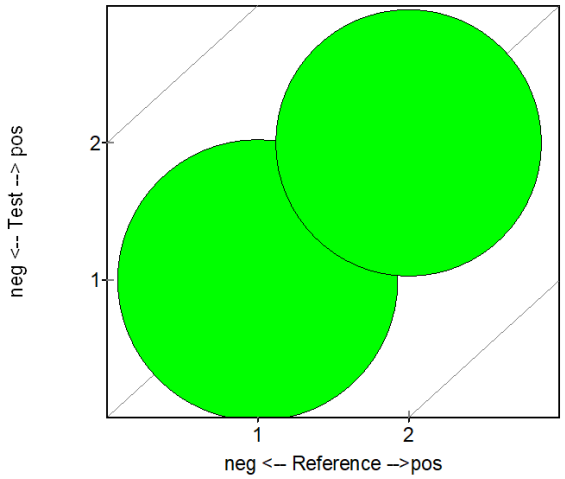
• Test Limitations

The COVID-19 screening test cannot detect an infection at early stages during the first 5 days after the incubation period, or if the novel coronavirus is present. The screening test is based on COVID-19 related antibodies detected approximately one week after the incubation period. Positive results confirm a recent exposure to the virus regardless of the severity of clinical symptoms, or may reveal likely immunity in apparently healthy individuals.

• Accuracy

Paired serum and dried blood specimens from individuals at different stages of coronavirus disease, including samples from apparently healthy individuals were tested. The presence of specific antibodies in the dried blood specimens versus serum (Reference) were statistically analyzed using the "score" method.

Agreement	100 %
Sensitivity	100 %
Specificity	100 %
Prevalence*	47 %
Negative Predictive Value	100 %
Positive Predictive Value	100 %
* Prevalence Estimated from Experimental Results	



• Sample Requirements

The Dried Blood COVID-19 Screening Test requires four (4) drops of blood placed onto a HemaSpot-SE® collection device. The device is then sealed and mailed to the laboratory for testing.

• Convenience and Simplicity

Simple instructions are provided to the health awareness participant for collection of a dried blood sample using a finger lancet. The Dried Blood COVID-19 Screening Test system requires three simple steps:

1. The collection screening kit is provided.
2. Participant applies blood sample onto HemaSpot-SE®.
3. Sample is sent to COREMEDICA in provided mailer.

CoreMedica

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For additional information, call

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