

Clinical Sample Study Report

Product Name:

QuickProfile™ COVID-19 IgG/IgM Test Card

Purpose:

To evaluate the performance of the QuickProfile™ COVID-19 IgG/IgM Test Card (Whole blood/Serum/Plasma) with clinical specimens.

Materials:

QuickProfile™ COVID-19 IgG/IgM Test Card, Lot: 20020110, Exp. Date: 8/31/2021

Three hundred and five (305) clinical specimens from healthy donors.

Seventy-four (74) confirmed positive COVID-19 specimens via RT-PCR and/or clinical diagnosis (including chest CT scan).

Method:

Each of the clinical specimens listed above were tested in duplicate using the QuickProfile™ COVID-19 IgG/IgM Test Card. The qualitative results obtained at 15 minutes for each specimen were compared retrospectively to known RT-PCR results or clinical diagnosis.

Test Procedure:

Refer to the package insert.

Results:

Table I. Seventy four specimens from COVID-19 confirmed patients.

Total Pos. Samples	Results of QuickProfile™ Test	Number of the results	Sensitivity
74	Both IgM and IgG Positive	62	Overall sensitivity = $(62+1+2) / 74 = 87.8\%$ IgM positive rate = $(62+1) / 74 = 85.1\%$ IgG positive rate = $(62 + 2) / 74 = 86.5\%$ PPV = true positive / (true positive + false positive) = $65/(65+3) = 95.6\%$
	IgM Positive, IgG Negative	1	
	IgM Negative, IgG Positive	2	
	Both IgM and IgG Negative	9	

Table II. Three hundred and five negative specimens from healthy donors.

Total Neg. Samples	Results of QuickProfile™ Test	Number of the results	Sensitivity
305	Both IgM and IgG Negative	302	Specificity of IgG = IgG negative/ total number of samples= 303 / 305 *100% =99.3%
	IgM Positive, IgG Negative	1	
	IgM Negative, IgG Positive	2	Specificity of IgM = IgM negative/ total number of samples= 304 / 305 *100% =99.7%
	Both IgM and IgG Positive	0	NPV = true negative / (true negative + false negative) = 302/(302+9) = 97.1%

Conclusion:

The results provided in this report indicates that the QuickProfile™ COVID-19 IgG/IgM Test Card provides a PPV of 95.6% and a NPV of 97.1%.

Discussion:

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Followup testing with a molecular diagnostic should be considered to rule out infection in these individuals.

As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.