

IVD rapid test for quantitative detection of SARS-CoV-2 antibody (Ab)

Sensitivity: 96.8% (90% for symptom onset with 0-4 days)

Specificity: 100%

Sample Type: Whole Blood, Plasma, Serum

Test Time: 10-15 minutes

COVID-19 Ultramicro

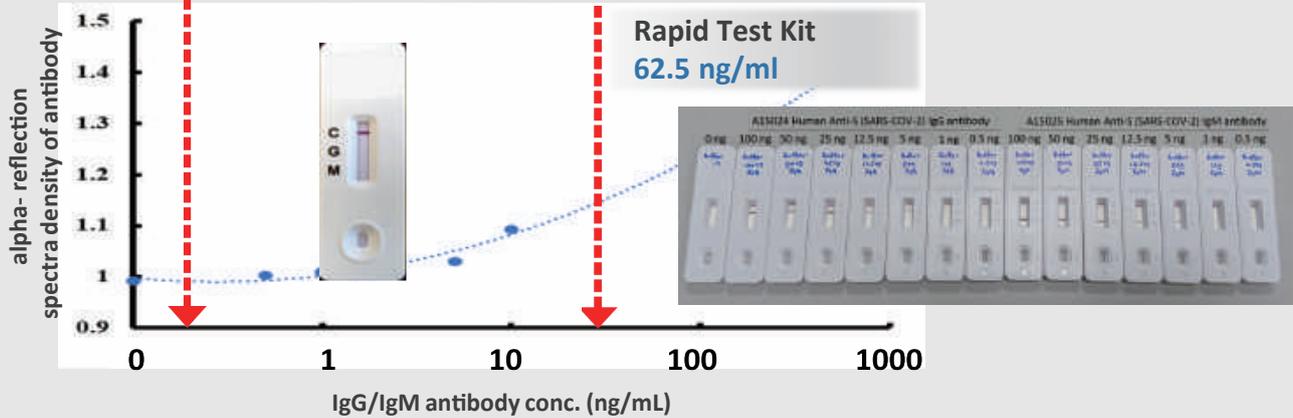
Quantitative IgG/IgM Antibody Rapid Test Platform



01 Limit of Detection

Higher sensitivity

The ONE InstantCare Quantitative Platform
0.362 ng/ml



02 Clinical Studies

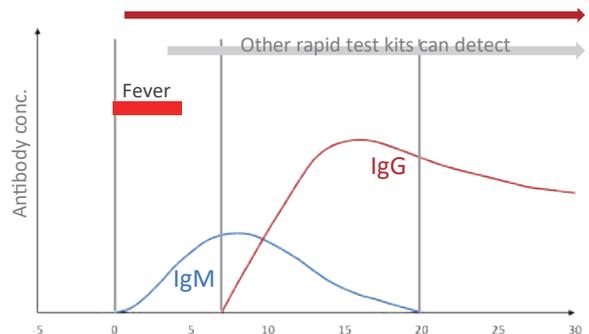
Earlier diagnosis

★ Sensitivity:

90% for symptom onset with 0-4 days
100% for symptom onset after 4 days

Detection by The ONE InstantCare COVID-19 Ultramicro Quantitative IgG/IgM Antibody Rapid Test Platform

Days after symptom appear	PCR Positive	IgG/IgM Positive	PPA
0-4	10	9	90%
5-8	2	2	100%
9-13	5	5	100%
≥14	15	15	100%



★ Clinical Studies Summary

			PCR Comparator*		Total
			Pos	Neg	
COVID-19 IgG/IgM Dual Detection Kit	Pos	IgG+/IgM+	14	0	36
		IgG+/IgM-	3	0	
		IgG-/IgM+	19	0	
	Neg	IgG-/IgM-	1	149	150
Total			37	149	186

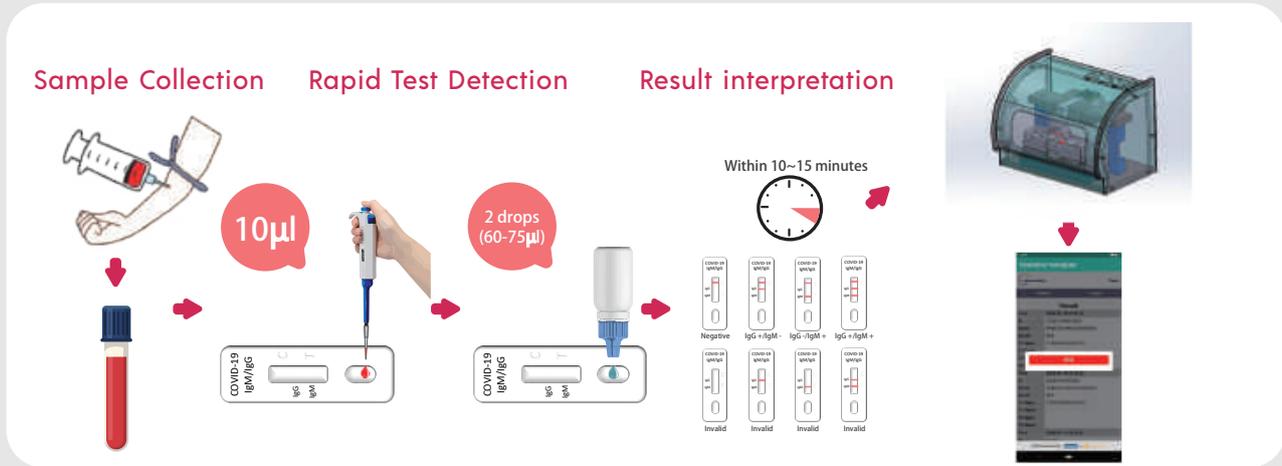
Sensitivity:

Positive Percent Agreement (PPA) = (IgM positive or IgG positive)/(PCR positive) = **97.30% (36/37)**

Specificity:

Negative Percent Agreement: (NPA) = (IgM negative and IgG negative)/(PCR negative) = **100% (149/149)**

03 Usage Steps



04 Components



- ★ COVID-19 (SARS-CoV-2) IgG/IgM Dual Detection Kit for detection of antibodies in serum, plasma or blood.
- ★ The ONE InstantCare Ultramicro Quantitative IgG/IgM Antibody Rapid Analyzer for capture of signal from rapid test kit.
- ★ Mobile operating system for data presentation and preservation at cloud database.

05 COVID-19 Total Solutions

COVID-19 Antigen Rapid Detection Platform



COVID-19 Nucleic acid Rapid Detection Platform



COVID-19 Antibody Rapid Detection Platform

