



Sample evaluation guide

GENEDIA W ONE COVID-19 IgM/IgG

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Sample evaluation guide



1. Kit storage and stability

- 1) The GENEDIA W COVID-19 Ag kit and kit components must be stored at 2~30°C (35.6~86°F) until the expiry date.
- 2) The test kit is stable for 18 months (while sealed in the original aluminum foil pouch) from the date of manufacture when stored at 2~30°C
- 3) Place all specimens, test devices, and assay diluent at room temperature prior to testing (15~30min).
- 4) Do not open the aluminum pouch until you are ready to perform a test. After the device pouch is opened, the test should be performed immediately. .

2. Limitations

- 1) GENEDIA W ONE COVID-19 IgM/IgG is designed for the primary screening of IgM and IgG antibodies against COVID-19. This kit can provide a fast and simple results but, do not completely exclude the possibilities of false positive or false negative results caused by various factors.
For confirmation, please make a final decision with clinical symptoms, other testing results, and doctor's assessment, collectively.
- 2) Positive rate of IgM is low in the early stage. But it begins to increases after 5 days of symptom onset, then subsequently decreases. Positive rate of IgG continuously maintain its rate.
- 3) So, Even if IgM and IgG are not detected at the same time, the result means positive.

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3. PRECAUTIONS AND WARNINGS

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date. Do not freeze the kit.
3. Do not use if the product seal or its packaging is compromised.
4. For professional in vitro diagnostic use only. Do not re-use the test device.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay. Wash hands thoroughly after finishing the tests.
6. Do not eat or smoke while handling specimens.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
8. Decontaminate and dispose of all specimens, in a biohazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations.

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4. Specimen collection

Specimen to be tested should be obtained and handled by standard methods for their collections. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

Factor	Sample	Instruction	
Specimen collection	Serum	Allow the blood to clot, then centrifuge to separate the serum.	
	Plasma	Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.	
	Whole blood	Venipuncture	Whole blood should be collected over heparin, citrate, or EDTA. Mix the blood by inversion and use it to the test. Whole blood samples should be tested immediately after sample collection
		Finger-prick	If fingertip blood is used to the test, prick the finger and collect the blood by a capillary tube And then, load the blood onto the sample well of the test device.
Specimen collection temperature	All	Room temperature(15~30°C)	
Specimen storage period	All	All specimens should be tested as soon as early they are prepared. Serum or plasma samples may be stored at 2~8°C for up to three days if the test cannot be performed immediately. The blood samples should attain room temperature prior to use	

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5. Preparation before use

Factor	Sample	Instruction		
Test temperature	All	Please test in room temperature(15~30°C). If the test kit is refrigerated(2~8°C), keep it at room temperature for 15~30 minutes prior to testing.		
Check the component condition		Verify if there is a sufficient extraction solution in the tube check the components of GENEDIA W ONE COVID-19 IgM/IgG .		
		Test device	Assay diluent	Capillary tube
				

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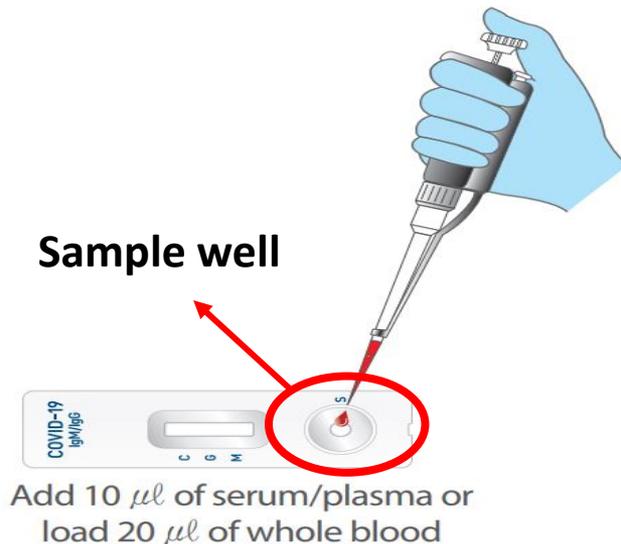
6. TEST PROCEDURE

Remove the test device from an aluminum pouch

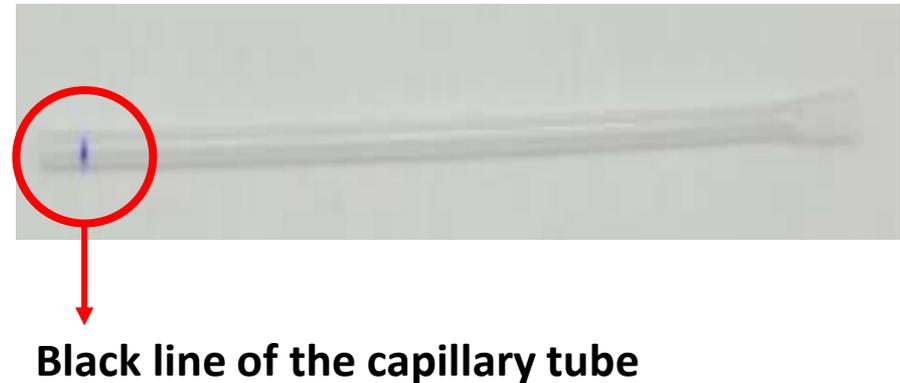
* Please open the aluminum pouch just before dropping the specimen.

Factor	Sample	Instruction
Insert the specimen	Micropipette use	Add 10 μ l of serum/plasma or load 20 μ l of whole blood into the sample well directly.
	Capillary tube use	Using a capillary tube, load 20 μ l of whole blood up to black line into the sample well.

<Micropipette use>



<Capillary tube use>

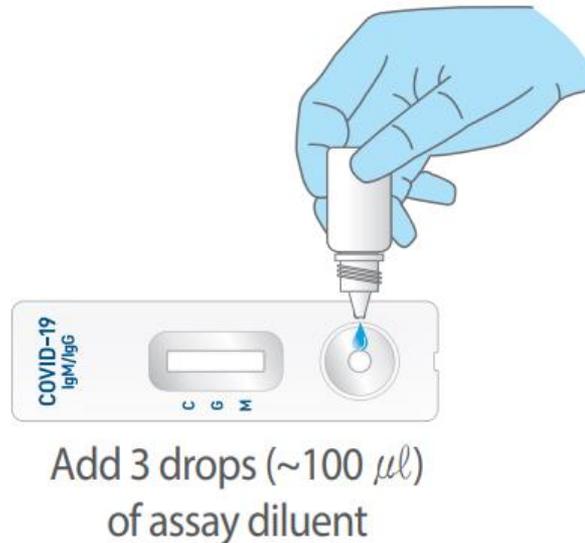


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7. Drop of solution into the test device

Factor	Instruction
Place device status	Place it on a flat and dry surface.
Amount of solution	Add 3 drops (approx. 100 μ l) of assay diluent into the sample well in the device. *Inaccurate drops of the assay diluent can result in reverse migration phenomenon and/or overall a little reddish unclear background.



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8. Interpretation of test result

Factor	Sample	Instruction
Test result valid time	All	Please read the result within 15 minutes from starting test * If the device is exposed for a long time, the color may change, so it may be mistaken for positive.
Interpretation of test result		If there is any blurry line or color change on the G/M line within 15 minutes, it should be read as positive.

Interpretation example

Positive serum 1 : IgM/IgG Positive	
Positive serum 2 : IgM/IgG Positive	
Negative serum : IgM/IgG Negative	
Interpretation : + : Positive, T : Trace, Blank (Without any mark) : Negative	