



Sample evaluation guide

GENEDIA W COVID-19 Ag

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 24 months (while sealed in the original aluminum foil pouch) from the date of manufacture when stored at 2~30°C
- 3) Allow kit to come to room temperature (15~30°C ; 59~86°F) before use.
- 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) A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- 2) The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.
- 3) To get the accurate result, recommend to test with the **specimen of a patient who has been symptom within 7 days. It is recommended to test with a specimen which of Ct value is between 11 and 23.**

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3. Preparation before test

Factor	Sample	Instruction			
Test temperature	All	Please test in room temperature(20~30°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		Extraction solution	Filter cap	Swab	Device
					
1) Verify if there is a sufficient extraction solution in the tube (350uL) 2) Check the packing status (ex: damage or leak)	Check the packing status (ex: damage or dust)	Check the packing status (ex: damage or tear)	Check the packing status (ex: damage or tear)		

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4. Specimen collection

Factor	Sample	Instruction
Specimen condition	Nasopharyngeal swab	<ol style="list-style-type: none">1. Carefully insert a sample collection swab into the nostril that presents the most secretion under visual inspection.2. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx.3. Rotate the swab several times then remove it from the nasopharynx.
	Sputum	<ol style="list-style-type: none">1. Sterile container is prepared to collect sputum samples. (Sterile containers are not provided in this kit.)2. Collect the sputum sample in a sterile container by deep coughing.
	Anterior nasal swab	<ol style="list-style-type: none">1. Open swab package at stick end and take swab out.2. Hold the swab approximately halfway up the handle and gently insert the entire absorbent tip of the swab 1/2 to 3/4 of an inch into the nostril, depending on the size of the person's nose.3. Slowly roll the swab around the inside wall of nostril at least 5 times. Take approximately 15 seconds to collect the sample.4. Remove swab and insert it into other nostril.
	All	<ol style="list-style-type: none">1. Be careful not to touch the swab head collecting specimen with your hands.2. Samples should be tested as soon as possible after collection.3. Recommend to test with the specimen of a patient who has been symptom within 7 days.
Specimen storage period	All	When the samples are not tested immediately, samples must be stored at below -20°C after collection.

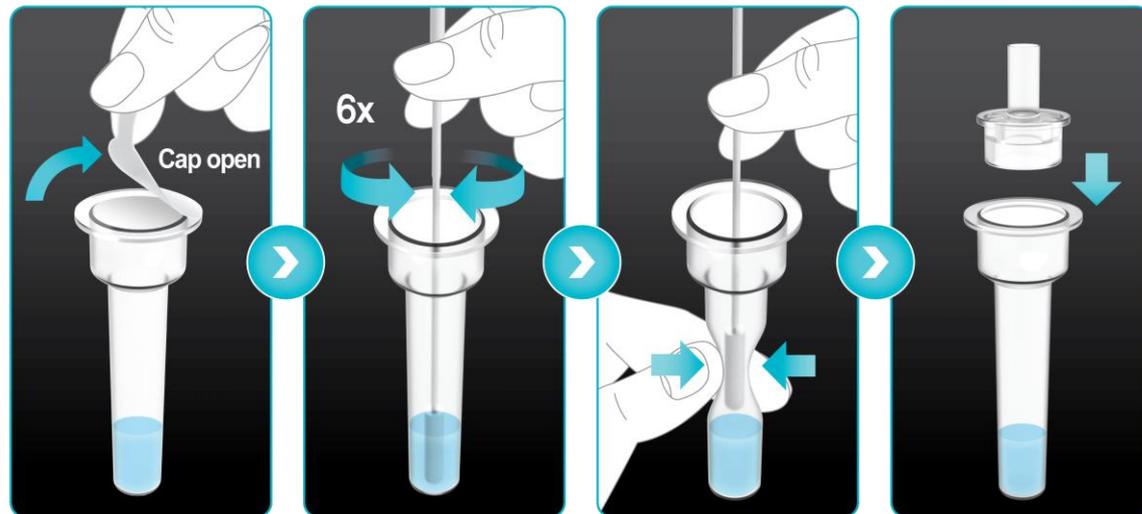
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5.1. Direct Nasopharyngeal Swab & Anterior nasal swab Test Procedure

1. Peel off aluminum foil seal from the top of the extraction solution vial.
2. Insert the patient swab into the extraction solution vial and swirl 6 times inside the tube while pressing the head against the bottom and side of the vial to mix well for extraction.
3. Roll the swab head against the inside of the vial as you remove it.
4. After the extraction, pull the swab out from the vial along the tube wall.
5. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
6. Bind the sample developing filter cap with the extraction vial.
7. After binding the sample developing filter cap with the extraction vial, test immediately.

Please open the extraction solution just before the test to prevent contamination





5.2. Nasopharyngeal Swab in VTM Test Procedure

Note

- ✓ *Only Noble Bioscience universal transport media or Hunan Vegas Biotech Co., Ltd. non-inactivated viral transport medium have been validated with the assay.*
1. Thaw frozen samples by using a water bath at 30°C for 30 minutes.
 2. Mix the specimen stored in VTM by vortexing for 20 seconds.
 3. Aliquot 350µl of vortexed swab specimen into extraction solution vial provided in the kit using micropipette.
 4. Bind the sample developing filter cap with the extraction vial.
 5. Vortex the extraction solution vial for 20 seconds.
 6. After binding the sample developing filter cap with the extraction vial, test immediately.



5.3. Sputum Swab Sample Test Procedure (Laboratory setting)

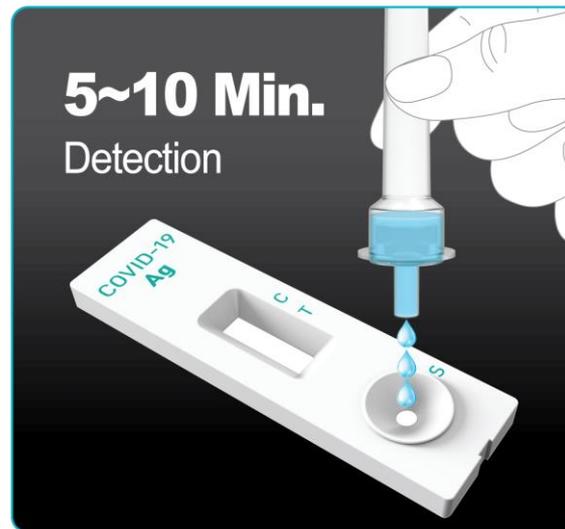
1. Thaw frozen samples by using a water bath at 30°C for 30 minutes.
2. Aliquot 175µl of sputum specimen into extraction solution vial provided in the kit using micropipette.
3. Bind the sample developing filter cap with the extraction vial.
4. Vortex the sputum sample in extraction solution vial for 20 seconds and test immediately.

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6. Drop of solution into the test device

Factor	Sample	Instruction
Device open	All	Remove the test device from an aluminum pouch * Please open the aluminum pouch just before dropping the extraction solution mixed with the specimen
Place device status		Place it on a flat and dry surface.
Amount of solution		Add 3 drops of the extraction solution with specimen into the sample well. *Inaccurate drops of the extraction solution can result in reverse migration phenomenon and/or overall a little reddish unclear background.

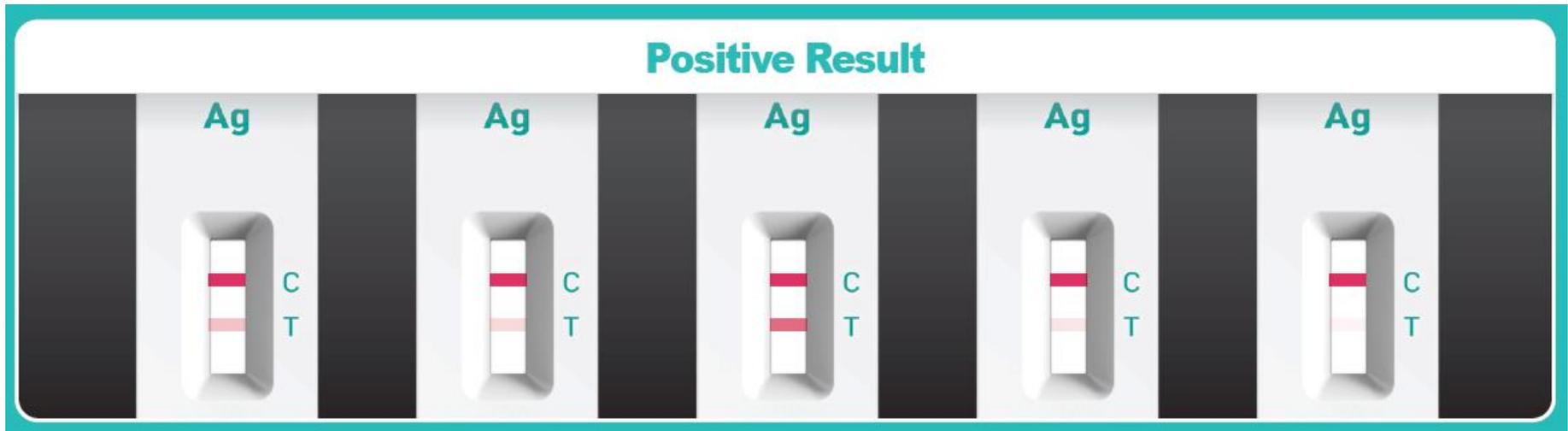


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7. Interpretation of test result

Factor	Sample	Instruction
Test result valid time	All	Please read the result within 15 minutes from starting test * If the membrane is exposed to the liquid 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 T line within 15 minutes, it should be read as positive.



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8. Fill in sample feedback form

Sample Feedback Form

Maximum Sample Order Quantity	5 Kit	Completion Reward	30% discount on samples after completion
Customer Information			
Country		Company name	
Name		C.P	
Date of receipt of products		E-mail	
Address			
Instrument	Sample KIT	Specimen	Quantity
N/A	GENEDIA W COVID-19 Ag	nasopharyngeal swab/sputum	
Please answer the following questions.			
1	Was there any issue when you got products?	① None ② Poor shipping condition ③ product breakage ④ Other : Please specify _____	
2	What type of institute was the sample evaluation conducted at?	① General Hospital ② Commerical Lab ③ Public health center ④ Other _____	
3	Who conducted the sample evaluation?	① Nurse ② Medical Laboratory Technologist ③ Doctor/medical specialist ④ Other _____	

Please send sample feedback form : claire.park@gccorp.com