



F E R C A M E D I C A L

# CORONAVIRUS AG RAPID TEST CASSETTE

(SWAB)



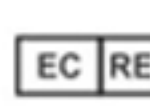

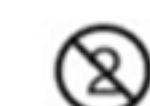



## PERFORMANCE

### 1. Clinical Sensitivity, Specificity, and Accuracy

An evaluation of the Coronavirus Ag Rapid Test Cassette (Swab) has been performed using samples from real patients using a commercialized molecular assay as reference and the results attest to the high overall relative accuracy of the Coronavirus Ag Rapid Test Cassette (Swab)

Method		PCR		Results
Coronavirus AG Rapid Test Cassette	Results	Positive	Negative	
	Positive	39	0	39
	Negative	6	116	122
Results		45	116	161

Relative Sensitivity: 87%    Relative Specificity: 100%  
Accuracy: 96.3%

	Refer to instructions		Units per kit		Authorized representative
	In vitro diagnostic only		Use by		Do not Reuse
	Store between 2~30°C		Lot number		Catalog Number

## TESTING PROCESS

1. Place test device found inside aluminum pouch, test tube filled with the extraction buffer, and filler cap on surface allowing them to reach room temperature for 30 minutes.



2. Remove test device from pouch and place it on a flat surface.



3. Insert swab with the specimen collected as by CDC guidelines in the extraction buffer tube, making sure the swab never dries in open air. If it has been more than 4 hours since the specimen is stored in extraction buffer without being tested, a new one should be collected.

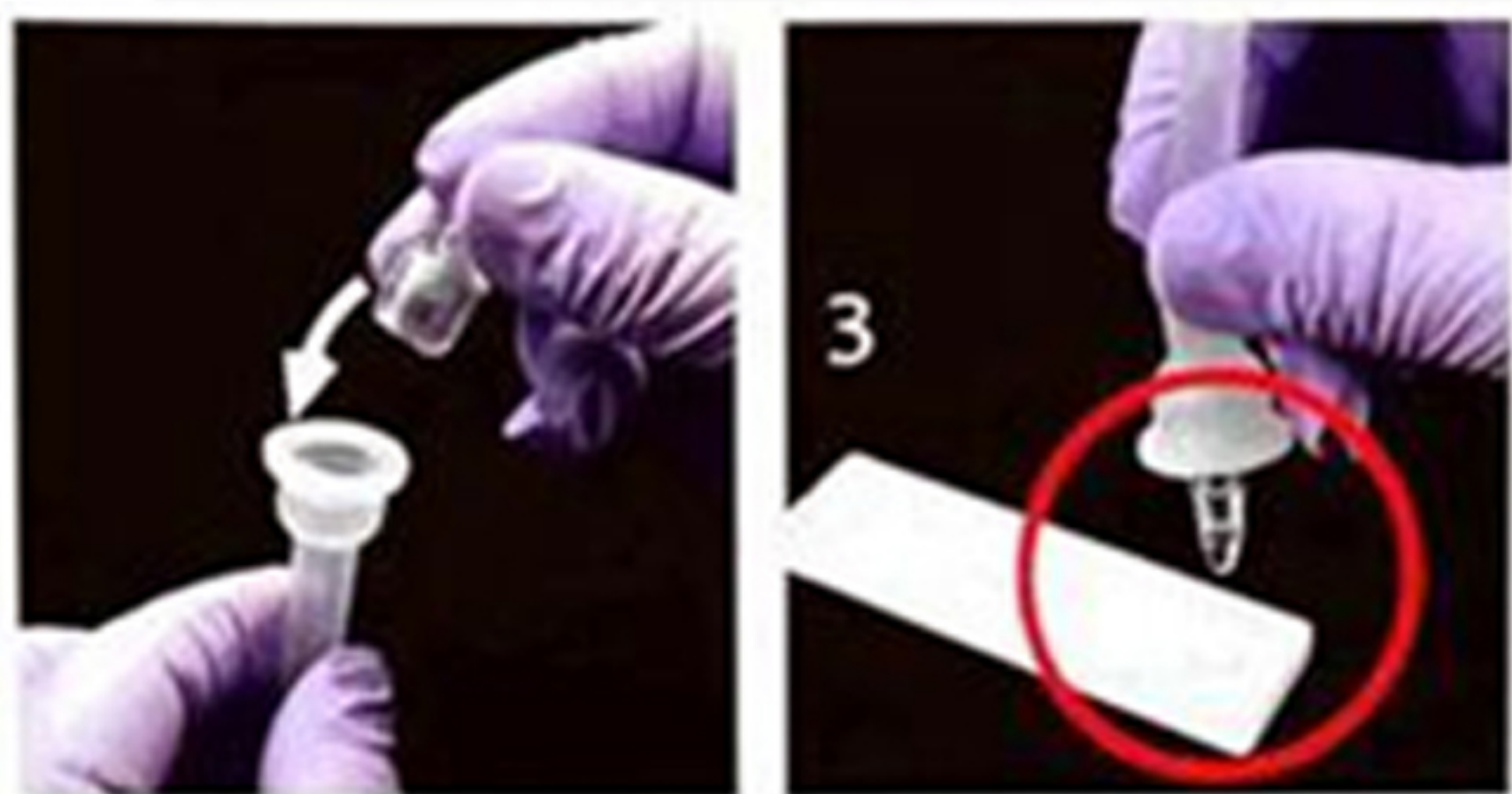
4. Shake the test tube to collect the buffer fluid and open the test tube.



5. Insert the swab with the specimen moving it in an up and down motion more than 10 times.



6. Remove swab squeezing it with the sides of the tube to ensure enough liquid is collected.



7. Replace filter cap on the test tube and apply three drops of the sample (100µL) inside the sample well of the device. If the device is dropped after application, it should be discarded, and the test must be repeated with a new device.

8. Wait 15 minutes to read results. (Results should not be read after 20 minutes)



## INTERPRETING THE RESULTS

Wait 15 minutes to read results.  
(Results should not be read after 20 minutes)



### NEGATIVE RESULT

Colored line is present in the Control Region (C) but there is no colored line in Test Line (T)



### POSITIVE RESULT

Colored line is present in both Test Line (T) and Control Line (C)



### INVALID RESULT

No colored line present in control region (C). Test is invalid and must be done again with a new device.

