



# GENEDIA Quantum COVID-19 Ag

GENEDIA Quantum COVID-19 Ag applies advanced immunofluorescence-based lateral flow technology for the qualitative detection of specific antigens to COVID-19 present in human nasopharyngeal swab and sputum. This assay is designed for professional personnel in laboratory and at point-of-care as an aid in screening patients suspected of being infected and asymptomatic patients. The GENEDIA Quantum COVID-19 Ag should be used with GENEDIA Quantum FR101.



## High sensitivity Quantum dot COVID-19 Ag kit

- World-first Quantum dot-based fluorescent chemistry for the detection of COVID-19
- Objective and accurate result that eliminates the subjectivity of a visual read
- Convenient data management via LIS connectivity

### Performance compared with other methods

For COVID-19 Ag		Comparator (RT-PCR)		Total
		Positive (+)	Negative (-)	
GENEDIA Quantum COVID-19 Ag	Positive (+)	82	0	82
	Negative (-)	8	100	108
Total		90	100	190


- Sensitivity = 91.11% (95% CI : 83.23% - 96.08%)
- Specificity = 100.0% (95% CI : 96.38% - 100%)
- Agreement: 95.79%

### Positive results broken down by days since symptom onset

Days Since Symptom Onset	RT-PCR Positive (+)	GENEDIA Quantum COVID-19 Ag Positive (+)	PPA (Positive Predictive Agreement)
≤7	41	40	98%
Asymptomatic	25	24	96%


# GENEDIA Quantum COVID-19 Ag

## TEST PROCEDURE




**1 STEP**

Open the extraction solution tube.



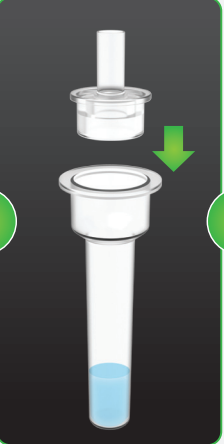
**2 STEP**

Insert the patient swab sample into the extraction solution tube. Then, swirl swab at least 6 times.




**3 STEP**

Roll the swab head against the inside of the tube as you remove it.



**4 STEP**

Bind the sample developing filter cap with the extraction tube.



**5 STEP**

The result is displayed  
**[ Scan mode ]**  
 Within 15 Sec.  
**[ Test mode ]**  
 After 20 min.

Add 3 drops of the extraction solution with specimen into the sample well.  
**[Scan mode]**  
 Leave the test device for 20 min. After 20 min, insert the test device and press the 'OK' icon.  
**[Test mode]**  
 Insert the test device and press 'OK' icon.

## INTERPRETATION OF THE RESULTS

POSITIVE

**Test Result** 2020-09-25 am 11:26

- Test Name : COVID-19  
 - Patient ID : 987654321  
 - Test Date : 25-09-2020

Cov.Ag POSITIVE

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NEGATIVE

**Test Result** 2020-09-25 am 11:26

- Test Name : COVID-19  
 - Patient ID : 987654321  
 - Test Date : 25-09-2020

Cov.Ag NEGATIVE

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INVALID

**Test Result** 2020-09-25 am 11:26

- Test Name : COVID-19  
 - Patient ID : 987654321  
 - Test Date : 25-09-2020

Cov.Ag INVALIDED

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## MATERIALS PROVIDED



- ① Test device : 20 EA
- ② Extraction solution : 20 EA(10X2)
- ③ Sample developing filter cap : 20 EA
- ④ Sterilized swabs for sample collection : 20 EA
- ⑤ Instructions for use : 1 EA

## SPECIFICATION

Method	Immuno-fluorescence chromatography
Packing unit	20 Tests / kit
Certification	CE-IVD
Specimen	Nasopharyngeal swab and sputum
LOD	6.25X10 <sup>1</sup> TCID <sub>50</sub> /mL

Running time	20 minutes
Equipment	GENEDIA Quantum FR101
Expiry date	12 months from the date of manufacture
Storage condition	2 ~ 30℃



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