

GENEDIA Quantum COVID-19 Ag



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Introduction of GENEDIA W COVID-19 Ag



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



Technical Detail

The GENEDIA Quantum COVID-19 Ag is a fluorescence immunoassay kit for rapid and qualitative determination of SARS CoV 2 infection from nasopharyngeal swab and sputum specimens. Test kit contains a membrane strip, which is immobilized with the anti SARS CoV 2 monoclonal antibody on the test line (T) and Goat anti mouse IgG on the control line (C) respectively.

And the strip is assembled in the test device. When the sample and the extraction solution are applied to the sample well, the sample is moved to the quantum dot bead conjugated pad and reacts with anti SARS CoV 2 monoclonal antibody coupled quantum dot bead conjugate followed by reaction with anti SARS CoV 2 monoclonal antibody immobilized in the test line. When the sample contains SARS CoV 2 antigens, an invisible fluorescence line appears in the test region on the membrane. The solution continues to migrate to encounter a control reagent, thereby producing another band in the control region. The GENEDIA Quantum FR101 will scan the test device and measure the fluorescent signal.

The GENEDIA Quantum FR101 will display the test results (Positive, Negative, or Invalid) on the screen. The GENEDIA Quantum COVID 19 Ag is very useful to directly detect SARS CoV 2 antigens from nasopharyngeal swab and sputum samples.



Unique selling Point



- 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



Product Package

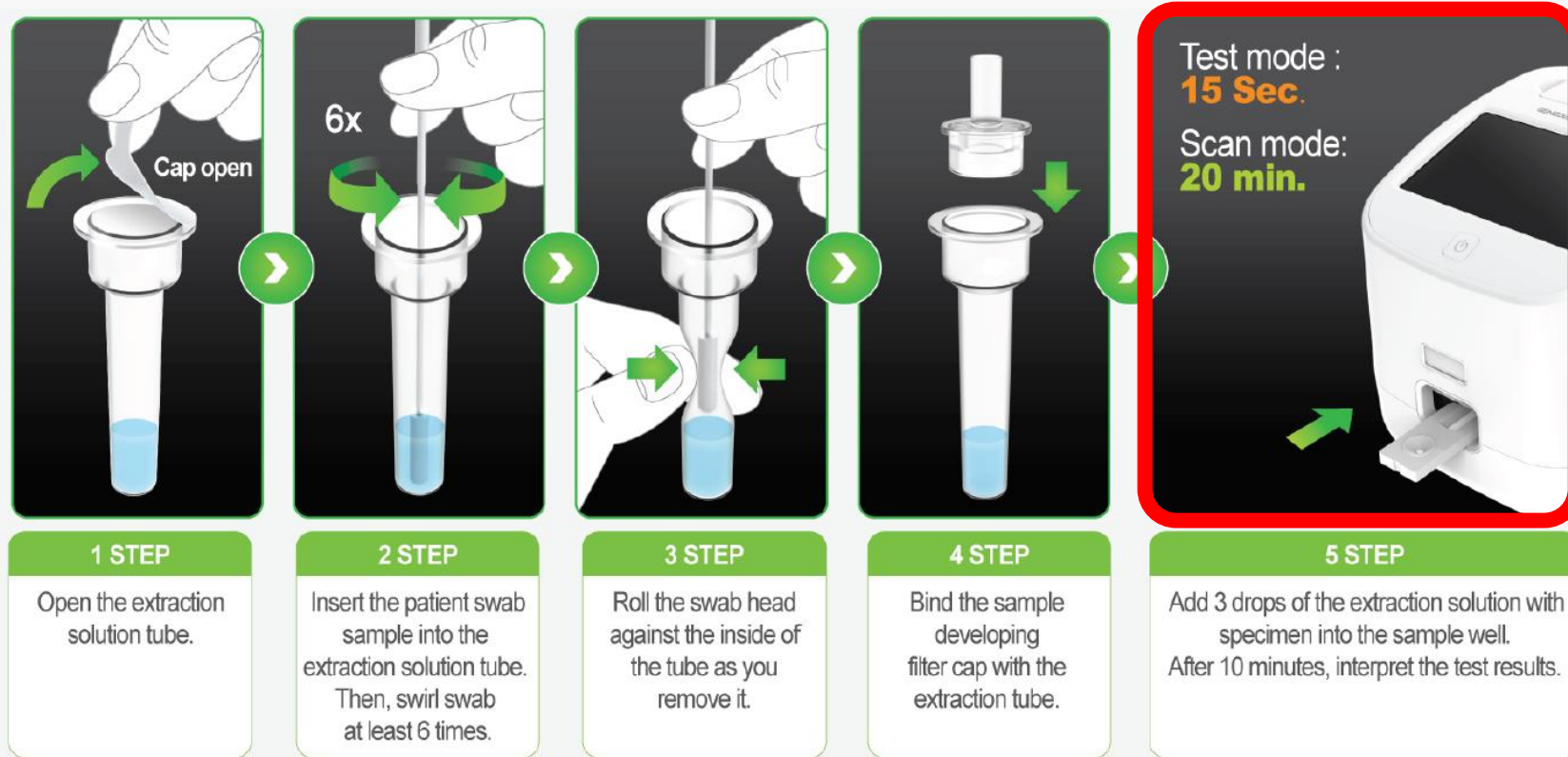


GENEDIA Quantum COVID-19 Ag

- ① Test device : 25 EA
- ② Extraction solution : 25 EA
- ③ Sample developing filter cap : 25 EA
- ④ Sterilized swabs for sample collection : 25 EA
- ⑤ Instructions for use: 1 EA

***GENEDIA Quantum FR101 is not provided**

Test procedure and result Interpretation



Automated read

Objective result that eliminates the subjectivity of a visual read.

POSITIVE

Test Result

2020-09-25 am 11:26

- Test Name : COVID-19

- Patient ID : 987654321

- Test Date : 25-09-2020

Cov.Ag

POSITIVE

Print

Home

Next Scan

NEGATIVE

Test Result

2020-09-25 am 11:26

- Test Name : COVID-19

- Patient ID : 987654321

- Test Date : 25-09-2020

Cov.Ag

NEGATIVE

Print

Home

Next Scan

INVALID

Test Result

2020-09-25 am 11:26

- Test Name : COVID-19

- Patient ID : 987654321

- Test Date : 25-09-2020

Cov.Ag

INVALIDED

Print

Home

Next Scan

Performance Data



Performance compared with other methods

For COVID-19 Ag		Comparator (RT-PCR)		Total
		Positive (+)	Negative (-)	
GENEDIA W 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 W COVID-19 Ag Positive (+)	*PPA
≤7	41	40	98%
Asymptomatic	25	24	96%

*PPA: Positive predictive agreement

Product Specification



Contents	Spec
Method	Immuno-fluorescence chromatography
Packing Unit	25 tests / kit
Certification	CE-IVD
Specimen	Nasopharyngeal swab and sputum
LoD	6.25X10 ¹ TCID ₅₀ /mL
Sensitivity / Specificity	Sensitivity: 91.11% (95% CI : 83.23% - 96.08%) Specificity: 100.0% (95% CI : 96.38% - 100%)
Running Time	20 minutes

Contents	Spec
Materials provided	① Test device : 25 EA ② Extraction solution : 25 EA ③ Sample developing filter cap : 25 EA ④ Sterilized swabs for sample collection : 25 EA ⑤ Instructions for use: 1EA *GENEDIA Quantum FR101 is not provided
Expiry Date	12 months from the date of manufacture
Storage Condition	2 ~ 30°C(35.6 ~ 86°F)

Packing information



Product	GENEDIA Quantum COVID-19 Ag
GENEDIA Quantum COVID-19 Ag	1 Kit (25 Tests)
Dimension of Kit	235*165*70 mm
Gross Weight /Kit	450 g/Kit
No. of Kits / Carton	30 Kits/Box
Dimension of Carton	530*490*375 mm
Gross Weight / Carton	13.5 Kg
Pallet Size	1000*1000*1250

Shipping type	Shipping by air
Packing Size / Pallet	1000*1060*1260mm 3 LEVEL * 4 Carton
No. of Carton /Pallet	12 Carton / Pallet
Gross Weight / Pallet	211 KGS
Total Kit / Pallet	360 Kits
Total Test / Pallet	9,000 Tests
HS Code	3002.15
Storage Temperature	2-30 °C



Thank you.