

Information

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EBS SARS-CoV-2 Ag Rapid Test



Lateral flow assay for the quick determination of SARS-CoV-2 antigens in nasopharyngeal and anterior nostril swabs

- Ready-to-use extraction units
- 10 minutes to result
- Clinically validated using a PCR Cut-Off of CT38
- Antigen recognition of the british virus variant
- Successfully validated by the Paul-Ehrlich Institute/Germany

Assay principle	Detection of SARS-CoV-2 Nucleocapsid Antigen
Technology	Qualitative Lateral Flow Immunoassay
Sample material	Nasopharyngeal swabs and anterior nostril
Time to result	10 minutes
Analytical sensitivity	Lower Detection Limit: 1.6×10^2 TCID/ml*
Diagnostic sensitivity	Nasopharyngeal: 95.7% (110/115); Anterior nostril: 93.28% (111/119)
Diagnostic specificity	Nasopharyngeal: 99.1% (209/211); Anterior nostril: 99.2% (124/125)
Description	EBS SARS-CoV-2 Ag Rapid Test
Produced by	EurobioScientific, Les Ulis, France
Packaging	20 tests
Reference	EBS 1020
State Listing	List of COVID-19 antigen tests from the German Federal Institute for Pharmaceuticals and Medical Products (BfArM)
Registration	ANSM (Agence nationale de sécurité de médicament et des produits de santé; France) HAS (Haute Autorité de santé; France)
Test-based approval	Swiss Federal Office of Public Health (BAG) / Paul-Ehrlich Institute

Corresponding to the state of the art
Paul-Ehrlich Institute 04/2021

* 50% tissue culture infectious dose (TCID50): unit for the infectious virus titer

Assay flow

1. SPECIMEN EXTRACTION

1.1. Remove the sealing film of the tube with extraction buffer and insert the extraction tube into the tube rack;

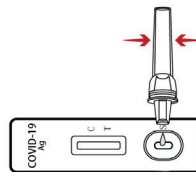
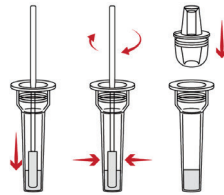
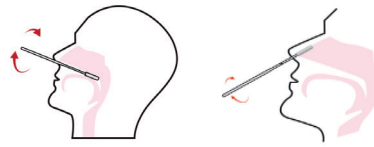
1.2. Insert the swab into the extraction tube containing the extraction buffer;

1.3. Rotate the swab at least 6 times while pressing the tip against the bottom and sides of the extraction tube;

1.4. Place the swab in the extraction tube for 1 minute;

1.5. Remove the swab from the extraction tube;

1.6. Press the nozzle cap tightly onto the tube. The extracted solution will be used as test sample.



2. TEST PROCEDURE

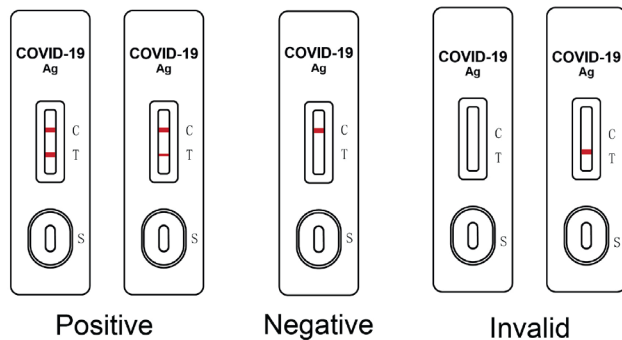
2.1. Carefully refer to the instruction for use prior to performing the test;

2.2. Take out the kits 30 mins before test, ensure that tests and samples are on room temperature;

2.3. Place test cassette on flat and clean bench; add 2 drops unknown extracted samples into the sample pad;

2.4 Read and record the results after 10 minutes (No longer than 20 minutes). Abnormal results may occur after 20 minutes

3. INTERPRETATION of RESULTS



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