WIZBIOTECH

SARS-CoV-2 Antigen Rapid Test (Saliva)

Speicheltest

INTENDED USE

SARS-CoV-2 Antigen Rapid Test (Saliva) is intended for the qualitative detection of SARS-CoV-2 Antigen in human saliva specimens in vitro.

FEATURES

- Easy to operate, no other equipment needed.
- High Accuracy, Specificity and Sensitivity.
- Show results within 20 minutes.
- Room temperature preservation.

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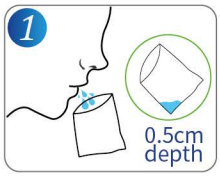
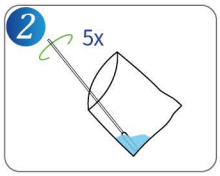
www.wizbiotech.com

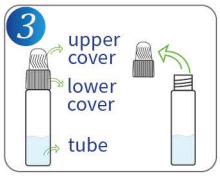
OPERATION PROCESS



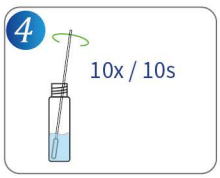
1. Gently spit saliva into the disposable sample container until the liquid saliva (non-bubble) reaches about 0.5cm depth of the container.



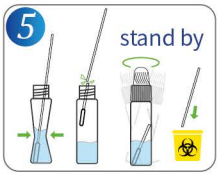
2. Hold a disposable sampling rod, and use its swab head to stir the saliva counter clockwise / clockwise (about 5 circles).



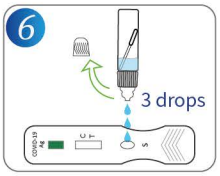
3. Loosen the lower cover (the extraction tube is composed of tube, lower cover and upper cover).



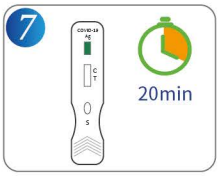
4. Immerse the swab head into the extraction solution in the extraction tube, and rotate it close to the wall of the sample extraction tube for about 10 seconds or 10 times to make the sample dissolve in the solution as much as possible.



5. Squeeze the swab head along the inner wall of the sample extraction tube to keep the liquid in the tube as much as possible, discard the disposable sampling rod or break the disposable sampling rod to leave the swab head in the extraction tube, tighten the cover, gently shake the extraction tube, gently mix and stand by.



6. Open the upper cover of the extraction tube (the extraction tube with processed specimens), add 3 drops vertically into the sample well of the test device.

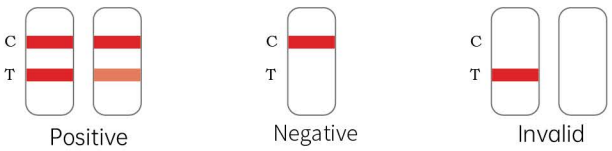


7. The test results should be interpreted within 20 minutes, the result is invalid If more than 30 minutes.

LIMIT OF DETECTION

1.7×10^2 TCID50/mL

INTERPRETATION OF RESULT



CLINICAL PERFORMANCE

(Saliva samples)

Test Results of Saliva samples	Reference PCR Results		
	POS	NEG	Total
POS	328	0	328
NEG	16	555	571
Total	344	555	899

PPA: 95.35% (C.I. 92.58%~97.12%) NPA: 100.00% (C.I. 99.31%~100.00%) OPA: 98.22% (C.I. 97.13%~98.90%)

SPECIFICATION

25Tests/Kit, 1Test/Kit

Xiamen Wiz Biotech Co., Ltd. *Web: www.wizbiotech.com*

- Tel: +86-592-6808278
- Fax: +86-592-6808279
- E-mail: sales@wizbiotech.com
- Address: 3-4 Floor, NO.16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R. China

CERTIFICATE

CE

EC Declaration of Conformity

Manufacturer	Xiamen Wiz Biotech Co., Ltd. 3-4 Floor, NO.16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R. China
European Representative	Qarad EC-REP BV Pas 257, 2440 Geel, Belgium
Product	SARS-CoV-2 Antigen Rapid Test (Saliva)
Model	1 test/kit, 2 tests/kit, 20 tests/kit, 25 tests/kit
Catalogue number	51232701,51232702, 51232703, 51232704
Classification	Others

Conformity assessment route: Annex III (IVDD 98/79 EC)

We, the manufacturer, herewith, declares that the product(s) as specified above meet(s) the applicable provisions of the European Directive 98/79/EC on *in vitro* Diagnostic Medical Devices. All supporting technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the Authorized Representative in Europe.

General applicable directive:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

Signed on 04 /(Day) 02 /(Month) of 2021 . Place Xiamen .

Represented by

Signature:

Name of authorized signatory: Xiaozhen Wang

Position held in the company: General Manager

Seal/Stamp:

Xiamen Wiz Biotech Co., Ltd. *Web: www.wizbiotech.com*

- Tel: +86-592-6808278
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SARS-CoV-2 Antigen Rapid Test (Sputum/Saliva/Stool)

Clinical Report

The performance of the SARS-CoV-2 Antigen Rapid Test (Sputum/Saliva/Stool) was established with collected from 1012 individual symptomatic patients who were suspected of COVID-19. It contains 1012 sputum samples, 899 saliva samples and 899 stool samples. The collection, treatment, storage, transportation and detection of samples met the relevant requirements of the Instruction for Use. At the same time, SARS-CoV-2 was detected by emergency nucleic acid detection reagent.

Table 1 .Performance summary of the WIZ's SARS-CoV-2 Antigen Rapid Test(Sputum/Saliva/Stool)

(Sputum samples)

WIZ Results	Reference PCR Results		
	POS	NEG	Total
POS	407	0	407
NEG	14	591	605
Total	421	591	1012

PPA：96.67%（C.I. 94.50%~98.01%）

NPA：100.00%（C.I. 99.35%~100.00%）

OPA：98.62%（C.I. 97.69%~99.17%）

Table 2 .Performance summary of the WIZ's SARS-CoV-2 Antigen Rapid Test(Sputum/Saliva/Stool)

(Saliva samples)

Test Results of Saliva samples	Reference PCR Results		
	POS	NEG	Total
POS	328	0	328
NEG	16	555	571
Total	344	555	899

PPA：95.35%（C.I. 92.58%~97.12%）

NPA：100.00%（C.I. 99.31%~100.00%）

OPA：98.22%（C.I. 97.13%~98.90%）

Table 3. Performance summary of the WIZ's SARS-CoV-2 Antigen RapidTest(Sputum/Saliva/Stool)

(Stool samples)

Test Results of Stool samples	Reference PCR Results		
	POS	NEG	Total
POS	330	0	330
NEG	14	555	569
Total	344	555	899

PPA：95.93%（C.I. 93.29%~97.56%）

NPA：100.00%（C.I. 99.31%~100.00%）

OPA：98.44%（C.I. 97.40%~99.07%）

EXPLANTION OF TERMS:

C.I.: Confidence Interval

PPA: Positive Percent Agreement=True Positives / (True Positives +False Negatives)

NPA: Negative Percent Agreement=True Negatives / (True Negatives +False Positive)

OPA: Overall Percent Agreement= (True Positives +True Negatives) /Total Samples


WIZBIOTECH
CE
SARS-CoV-2 Antigen Rapid Test
(Saliva)
Speicheltest
REF
51232704
LOT
20210208Q1
2023-02-07
Awarding ISO13485 Certification
SARS-CoV-2 Antigen Rapid Test
(Saliva)
Speicheltest
SARS-CoV-2 Antigen Schnelltest
(Speichel)
Gebrauchsanweisung
PEEL
Disposable sampling rod


WIZBIOTECH
CE
SARS-CoV-2 Antigen Rapid Test
(Saliva)
Speicheltest
REF
51232704
LOT
2021020801
2023-02-07
Awarding ISO13485 Certification
Disposable sample container
Disposable sampling rod
SARS-CoV-2 Antigen Schnelltest
(Speichel)
Gebrauchsanweisung
SARS-CoV-2 Antigen Rapid Test
(Saliva)
Test Device


WIZBIOTECH
CE
SARS-CoV-2 Antigen Rapid Test
(Saliva)
Speicheltest
REF
LOT
Awarding ISO13485 Certification
2℃
30℃
25
QC PASS
WIZ BIOTECH
CE
SARS-CoV-2 Antigen Rapid Test
(Saliva)
Speicheltest

CE

EC Declaration of Conformity

Manufacturer	Xiamen Wiz Biotech Co., Ltd. 3-4 Floor, NO.16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R. China
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Classification	Others

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General applicable directive:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

Signed on 04 /(Day) 02 /(Month) of 2021 . Place Xiamen .

Represented by

Signature:

Seal/Stamp:

Name of authorized signatory: Xiaozhen Wang

Position held in the company: General Manager

WIZBIOTECH

CE

SARS-CoV-2 Antigen Rapid Test
(Saliva)

Speicheltest

REF

LOT

2℃ 30℃

Σ 25

Awarding ISO13485 Certification

QC PASS

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SARS-CoV-2 Antigen Rapid Test
(Saliva)
Speicheltest

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