BETTER AG

Top quality at manufacturer prices

Bioteke

COVID-19 Rapid test for professional use

With an integrated buffer solution

3 in 1

Nasopharyngeal | Oropharyngeal | Nasal Swab

ID No.: 2067

Listed for EU-wide recognition in the "EU common list"
of the European Commission - Directorate General for Health and Food Safety
Common list of COVID-19 rapid antigen tests
Click here to check the validity of the CE certificate

Sensitivity	96,49%
Specificity	99,28%
Result in	15-20 Minutes
Packaging	25 pieces per box

It only takes 15 seconds for the antigen to be released into the swab

Visible result in 15-20 Minutes

03/2022 09/2023

SARS-CoV-2 Antigen Test Kit (colloidal gold method)

IVD CE

User Instruction Manual

PRODUCT NAME

SARS-CoV-2 Antigen Test Kit (colloidal gold method)

PACKAGE SPECIFICATION

1 Test/Kit; 3 Tests/Kit; 5 Tests/Kit; 20 Tests/Kit; 50 Tests/Kit

INTENDED USE

This kit is only used for the *in vitro* qualitative detection of SARS-CoV-2 antigen from human nasopharyngeal swabs, oropharyngeal swabs and anterior nasal swabs specimens. SARS-CoV-2 Antigen Test Kit (colloidal gold method) is an immunochromatographic double-antibody sandwich assay intended for the qualitative detection of nucleocapsid protein antigen of SARS-CoV-2 from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset to suspect COVID-19 infection. This kit is suitable for the auxiliary diagnosis of COVID-19, the results are for clinical reference only and cannot be used as the sole basis for diagnosis and exclusion decision. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment responses. Positive test result needs to be further confirmed, negative result does not preclude SARS-CoV-2 infection. This kit is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of *in vitro* diagnostic procedures.

TEST PRINCIPLE

The kit is immunochromatographic and uses double-antibody sandwich method to detect SARS-CoV-2 antigen. During detection, the treated specimens are loaded into the sample wells of the test card. When the concentration of SARS-CoV-2 antigen in specimen is higher than the minimum detection limit, the viral antigen will form complexes with labeled antibodies first. Under chromatography, the complexes move forward along the nitrocellulose membrane till captured by pre-coated monoclonal antibody of SARS-CoV-2 in detection zone on nitrocellulose film (T) to form a pink/purple reaction line on the detection zone, at this point the result is positive; conversely, if there is no viral antigen or the concentration of antigen in specimen is below the minimum detection limit, no pink/purple reaction line appears in the detection zone, at this point the result is negative. Regardless of whether the sample contains viral antigens or not, a pink/purple reaction line will appear in the quality control zone (C), the pink/purple reaction line that appears in the quality control zone (C) is the criterion for determining if the chromatography process is normal.

MATERIALS PROVIDED

The test kit consists of test card, sample diluent, sample extraction tube, Waste bag, Oropharyngeal swab.

Components	Main Ingredients	Loading quantity (Specification)				
		1 Test/Kit	3 Tests/Kit	5 Tests/Kit	20 Tests/Kit	50 Tests/Kit
Test card	Test strip containing SARS-CoV-2 monoclonal antibody, Anti-mouse IgG polyclonal antibody	1 pc	3 pcs	5 pcs	20 pcs	50 pcs
Sample diluent		0.5mL	0.5 mL *3	0.5 mL *5	0.5mL*20	0.5mL*50
Sample extraction tube		1 pc	3 pcs	5 pcs	20 pcs	50 pcs
Waste bag		1 pc	3 pcs	5 pcs	20 pcs	50 pcs
Oropharyngeal swab		1 pc	3 pcs	5pcs	20 pcs	50 pcs

Note:

1. Test cards are sealed together with desiccant in aluminum foil pouch.
2. Do not mix use different batches of test cards and sample diluent.

STORAGE CONDITIONS AND SHELF LIFE

The test card and sample diluent should be stored at 2℃~30℃, valid for 18 months. Test cards should be used as soon as possible within 1 hour after opening the foil pouch. The bottle of sample diluent should be capped immediately after use and stored at 2℃~30℃, please use it within the validity period.

Date of manufacture and expiration: See package label for details.

SPECIMEN REQUIREMENTS

	1. Nasopharyngeal swab collection: Ask the patient to keep the head still to remove surface secretions from the anterior nasal foramen; Gently and slowly insert the swab through the nasal cavity to the nasopharynx, it reaches the posterior nasopharynx when resistance is encountered. Remain for several seconds to aspirate secretions; remove the swab with gentle rotation.
	2. Oropharyngeal swab collection: Insert the swab in the mouth completely into the pharynx, centering on the red swelling of the pharynx wall and upper anterior tonsils. Wipe both sides of pharyngeal tonsils and pharynx posterior wall with moderate force, avoid touching the tongue, and remove the swab.
	3. Anterior nasal swab collection: Ask the patient to keep the head still to remove surface secretions from the anterior nasal foramen. Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. 2. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.

It is recommended that specimens be treated with the sample diluent provided with the kit as soon as possible after collection. If immediate processing is not possible, the specimen can be stored in a dry, sterilized and tightly sealed plastic tube at 2℃~8℃ for up to 8 hours, and -70 ℃ for long-term storage.

TEST PROCEDURE

Please read the instruction manual seriously before testing. If the reagents in kit are stored in refrigerator, please take them out and leave them at room temperature before testing. The test should be done at room temperature.

I. Specimen extraction (see Figure 1).

1. Twist the cap off

2. Insert the sampled swab into the sample diluent in the sample extraction tube, squeeze the villi part of the swab in the tube through the outer wall of the tube by finger 5 times to dissolve the potential viral antigen into solution from swab as much as possible, then remove and discard the swab.

3. Cover the dropper's lid on the sample extraction tube after step 2.

II. Testing procedures (see Figure 1).

1. Remove the test card by opening the aluminum foil pouch from tear notch and lay it flat.

2. Add 4 drops (approximately 80μL) of the treated specimen into the sample well of the test card.

3. Please read the chromogenic results in the detection zone between 15~20 minutes to ensure proper test performance. Do not read results after 30 minutes. Results read after 30 minutes are invalid.

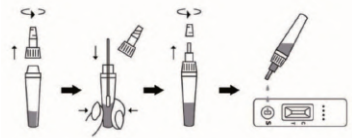

Figure 1

INTERPRETATION OF TEST RESULTS

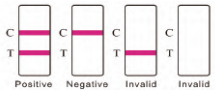

Figure 2

1. This kit contains quality control process, when the pink/purple reaction line appears in the C zone, it indicates the correct and effective operation. C line is the prerequisites to see if the test is valid. If the C line does not show color, regardless of whether the T line shows color or not, the test is invalid, and it is recommended to retest.

2. The detection results of the kit are interpreted according to the following table.

C Line	T Line	Result
Pink/purple	Pink/purple	Positive
Pink/purple	Colorless	Negative
Colorless	Whether color is visible or not	Invalid test, retest

LIMITATIONS OF THE TEST

1. The test results of this kit are only for the reference of clinicians and should not be used as the sole basis for clinical diagnosis and treatment. Clinical management of patients should be considered in the context of their symptoms/signs, medical history, other laboratory tests and response to treatment.

2. Sample collection and sample processing have a greater impact on the detection of pathogens, and a negative test result does not exclude the possibility of a viral infection.

3. Due to methodological limitations of antigen-based test, the analytical sensitivity of immunochromatographic method is generally lower than that of nucleic acid-based test. Therefore, the test provider should pay more attention to the negative results and make a comprehensive judgment based on other test results. It is suggested that the negative results in suspected patients should be checked by nucleic acid test or virus culture identification.

4. When the result of test kit is positive, it is recommended to combine the results of other methods (such as PCR and CT imaging) for further confirmation, and consult with local public health prevention institutions for treatment.

5. Analysis of the likelihood of false-negative results.

(i) Improper sample collection, transport and processing, and low viral titers in the sample may lead to false negative results.

(ii) The optimal sample type and the optimal sampling time after infection (peak viral titer) have not been validated, therefore, multiple sampling at multiple sites in the same patient may avoid false negatives.

PERFORMANCE CHARACTERISTICS

1. The width of the membrane strip of this kit is not less than 2.5 mm, and the liquid migration speed is not less than 10 mm/min.

2. Negative/positive reference coincidence rate

All the positive references are positive for the corresponding pathogens, which is consistent with the known results of the reference; all the negative references are negative for the corresponding pathogen.

3. Repeatability

Repeated testing was conducted for national or enterprise repeatable reference products for 10 times. The test results were consistent with the known results of the reference products and were uniform in color.

4. Limit of Detection (LoD)

The Limit of Detection (LoD) of SARS-CoV-2 Antigen Test Kit (colloidal gold method) is $1.75x10^2$ $TCID_{50}$/mL.

5. Analytical specificity

1) Sensitivity and Specificity

The SARS-CoV-2 Antigen Test Kit (colloidal gold method) was compared with the PCR Comparator Method on nasopharyngeal swab specimens.

Bioteke reagent	PCR reagent		Total
	Positive	Negative	
Positive	110	2	112
Negative	4	276	280
Total	114	278	392

Clinical sensitivity = 96.49% (95%CI: 91.26%~99.04%)

Clinical specificity = 99.28% (95%CI: 97.43%~99.91%)

Accuracy = 98.47% (95%CI: 96.70%~99.44%)

Kappa value = 0.9627

The SARS-CoV-2 Antigen Test Kit (colloidal gold method) Performance against PCR Comparator Method on oropharyngeal swab specimens.

BioTeke reagent	PCR reagent		Total
	Positive	Negative	
Positive	115	2	117
Negative	6	125	131
Total	121	127	248

Clinical sensitivity = A/(A+C)×100%= 95.04% (95%CI: 89.52%~98.16%)

Clinical specificity = D/(B+D)×100%= 98.43% (95%CI: 94.43%~99.81%)

Accuracy = (A+D)/(A+B+C+D)×100%= 96.77% (95%CI: 93.74%~98.60%)

Kappa value = 0.9354

The SARS-CoV-2 Antigen Test Kit (colloidal gold method) was compared with the PCR Comparator Method on anterior nasal swab specimens.

Bioteke reagent	PCR reagent		Total
	Positive	Negative	
Positive	131	1	132
Negative	12	163	175
Total	143	164	307

Clinical sensitivity = 91.61% (95% CI: 85.80%~95.59%)

Clinical specificity = = 99.39% (95% CI: 96.65%~99.98%)

Accuracy =95.77% (95% CI: 92.87%~97.73%); Kappa value = 0.9145

2) There is no cross-reactivity with the following pathogens: Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus, SARS-coronavirus, Human coronavirus HKU1, Respiratory adenovirus type 1, Respiratory adenovirus type 2, Respiratory adenovirus type 3, Respiratory adenovirus type 4, Respiratory adenovirus type 5, Respiratory adenovirus type 7, Respiratory adenovirus type 55, Human Metapneumovirus (hMPV), Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Influenza A virus 2009H1N1, Influenza A virus seasonal H1N1, Influenza A virus H3N2, Influenza B virus Yamagata, Influenza B virus Victoria, Enterovirus 71, Respiratory syncytial virus Rhinovirus, Haemophilus influenza, Streptococcus pneumonia, Streptococcus pyogenes, Candida albicans, Pooled human nasal wash – representative of normal respiratory microbial flora, Bordetella pertussis, Mycoplasma pneumonia, Chlamydia pneumonia, Legionella pneumophila, Staphylococcus aureus, Staphylococcus epidermidis, Mycobacterium tuberculosis, Pneumocystis jirovecii (PJP), Measles virus, Human cytomegalovirus, Rotavirus, Norovirus, Mumps virus and Varicella zoster virus.

Pathogens likely to cross react with the test kit	***Strain***	***Source/ Sample type***
Human coronavirus 229E	*ATCC VR-740，229E*	*Virus cultures*
Human coronavirus OC43	*ATCC VR-1558，OC43*	*Virus cultures*
Human coronavirus NL63	*BELRESOURCES NR-470*	*Virus cultures*
MERS-coronavirus	*Synthesis*	*Pseudovirus*
SARS-coronavirus	*Synthesis*	*Pseudovirus*
Human coronavirus HKU1	*GZ/1804-138*	*Virus cultures*
Respiratory adenovirus type 1	*ADV1/GZ/Hecin1 608-21*	*Virus cultures*
Respiratory adenovirus type 2	*ADV1/GZ/Hecin1 609-42/2016*	*Virus cultures*
Respiratory adenovirus type 3	*ADV11/GZ/Hecin 1608-21*	*Virus cultures*
Respiratory adenovirus type 4	*ATCC VR-1572*	*Virus cultures*
Respiratory adenovirus type 5	*ADV3/GZ/1609-2*	*Virus cultures*
Respiratory adenovirus type 7	*ATCC VR-7*	*Virus cultures*
Respiratory adenovirus type 55	*ADV55/GZ/1612-129*	*Virus cultures*
Human Metapneumovirus (hMPV)	*GZ/1803-107*	*Virus cultures*
Parainfluenza virus 1	*PIV1/Guangzhou/ 0701/2011*	*Virus cultures*
Parainfluenza virus 2	*ATCC VR-92，Greer*	*Virus cultures*
Parainfluenza virus 3	*PIV3/Guangzhou/ 0902/2012*	*Virus cultures*
Parainfluenza virus 4	*ATCC VR-1378，M-25*	*Virus cultures*
Influenza A virus 2009H1N1	*A/GZ/GIRD02/2009(2009H1N1)*	*Virus cultures*
Influenza A virus seasonal H1N1	*A/PR/8/34(H1N1)*	*Virus cultures*
Influenza A virus H3N2	*A/Aichi/2/68(H3N2)*	*Virus cultures*
Influenza B virus Yamagata	*B/Guangzhou/GIRD06/09(Yamagata)*	*Virus cultures*
Influenza B virus Victoria	*B/Guangzhou/GIRD08/09(Victoria)*	*Virus cultures*
Enterovirus 71	*EV71/Guangzhou/ 0401/2011*	*Virus cultures*
Respiratory syncytial virus	*RSVA/GZ/Hecin17*	*Virus cultures*
	05-74	
Rhinovirus	*A30/GZ/1710-89*	*Virus cultures*
Haemophilus influenzae	*GIM 1.961*	*Virus cultures*
Streptococcus pneumoniae	*GIM 1.550*	*Virus cultures*
Streptococcus pyogenes	*GDM1.546*	*Virus cultures*
Candida albicans	*FSCC 129002*	*Virus cultures*
Pooled human nasal wash – representative of normal respiratory microbial flora	*Clinical specimen*	*Clinical specimen*
Bordetella pertussis	*GDM 1.952*	*Virus cultures*
Mycoplasma pneumoniae	*ATCC 15531*	*Virus cultures*
Chlamydia pneumoniae	*ATCC VR-2282, TW-183*	*Virus cultures*
Legionella pneumophila	*GIM 1.840*	*Virus cultures*
Staphylococcus aureus	*FSCC 223005*	*Virus cultures*
Staphylococcus epidermidis	*GIM 1.143*	*Virus cultures*
Mycobacterium tuberculosis	/	/
Pneumocystis jirovecii (PJP)	/	/
Measles virus	*RA27/3*	*Virus cultures*
Human cytomegalovirus	*RC256*	*Virus cultures*
Rotavirus	*ATCC VR2018*	*Virus cultures*
Norovirus	*ATCC VR-3234SD*	*Virus cultures*
Mumps virus	*Jones*	*Virus cultures*
Varicella zoster virus	*CCTCC VR-1367*	*Virus cultures*

3) Interfering substance: Human blood and mucins will not interfere with the results of the kit. The following common drugs will not interfere with the results of the kit: Oxymetazoline, Dexamethasone, Flunisolide, Sulphur, Kim Anh, Benzocaine, Zanamivir, Mupirocin, Tobramycin, Kalii Dehydrographolidi Succinas, Aspirin (enteric-coated tablets), Ibuprofen (granules), Acetaminophen (slow-release tablets) and Nimesulide Tablets.

Interfering substance		***Test concentration***
Mucins		1%
Human blood		5%
Nasal spray	Oxymetazoline	1.125mg/mL
Nasal corticosteroids	Dexamethasone	0.009mg/mL
	Flunisolide	0.75mg/mL
Zicam Cold Remedy Nasal Gel	Sulphur	335mg/mL
Allergic symptom relief drug	Kim Anh	4.5mg/mL
Oral anesthetic	Benzocaine	1.875mg/mL
Antiviral drug	Zanamivir,	75mg/mL
Antibiotics, nasal ointments	Mupirocin	33.5mg/mL
Systemic antibiotics	Tobramycin	0.3mg/mL
Immune system medication	Kalii Dehydrographolidi Succinas	3.8mg/mL
Antipyretic	Aspirin (enteric-coated tablets)	0.04g/L
	Ibuprofen (granules)	0.2g/L
	Acetaminophen (slow-release tablets)	450mg/L
	Nimesulide Tablets	0.05g/L

4) Hook effect: This kit doesn't have hook effect.

PRECAUTIONS

1. This is a single-use *in vitro* diagnostic reagent, do not reuse, and do not use expired products.

2. All test specimens must be considered potentially infectious, and during collection, processing, storage, mixing of specimens and testing should be taken appropriate protective measures. Therefore, wear protective measures such as wearing gloves and masks should be done, and dispose of all wastes as potentially biohazardous items. (Used cotton swabs, test cards, extraction tubes, etc., should be decontaminated before disposal and tested for autoclaving.)

3. Use the swab and sample diluent provided with this reagent for sampling, and do not mix use different batches of test cards and sample diluent.

4. Use fresh specimens for testing, do not use repeated freeze-thaw samples.

5. Operate at room temperature. Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.

6. Do not use reagent kits with obvious damage or test cards with damaged or expired packaging.

7. The aluminum foil pouch contains desiccant and must not be taken orally.

8. Improper sample collection or processing may result in false-negative results.

9. Ensure proper sample loading volume, results of too much or too little sample loading volume may not be credible.

10. If the initial screen is a positive sample, contact your local public health agency.

11. As with the diagnostic reagents used, the final diagnosis should be made by a physician after combining the various test parameters and clinical symptoms.

12. If you have any questions or suggestions on the use of this kit, please contact the manufacturer.

13. For unknown reasons, long-term use of some drugs may lead to false positive results of the test, which are not covered by the interfering substances.

SYMBOLS


Date of manufacture


Do not use if package is damaged


CE mark of conformity


Keep away from sunlight

For *In Vitro* Diagnostic Use

Batch code


Keep dry


Consult instructions for use

Temperature limit


Do not re-use

Authorized representative in the European Community


Use-by date


Manufacturer


BIOTEKE CORPORATION (WUXI) CO., LTD
4th Floor, D5&2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719,
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Revision date: Jan 17, 2022
Edition: A6.1

Bioteke Corporation(wuxi) Co.,Ltd
Address: 4th floor, D5, No.1719,Huishan Avenue,Wuxi,China

BioTeke

Manufacturer's Declaration

To whom it may concerns,

Product name: SARS-CoV-2 Antigen Test Kit (colloidal gold method)

Country of Origin: China

We, Bioteke Corporation(wuxi) Co., Ltd, headquartered in, 4th floor, D5, No.1719, Huishan Avenue, Wuxi, China, do hereby declare "Better AG" located in General-Guisan-Str. 8, 6300 Zug, Switzerland, is authorized to import, sell, distribute the "Bioteke" branded in Europe and Africa.

We hereby confirm the authenticity of the SARS-CoV-2 Antigen Test Kit (colloidal gold method) sold by this distributor

Bioteke Corporation(wuxi) Co., Ltd
June 28, 2022

百泰克生物
BioTeke Corporation

Effectiveness Statement of BioTeke Novel Coronavirus (COVID-19) test kit for the SARS-CoV-2 Variants Detection

In quick response to the newly found variant of novel coronavirus Omicron (B.1.1.529) in Botswana, we have analyzed our Novel Coronavirus (COVID-19) test kit and the result shows that:

Our Freeze-dried Novel Coronavirus (COVID-19) nucleic acid detection kit (PR2019, PR2019-D, and PR2020-D) and SARS-CoV-2 Antigen Test Kit (colloidal gold method) (TC1002) can detect the new variant B.1.1.529 accurately, and for variants, which include but not limited to Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Lambda (C.37), Kappa (B.1.617.1), Eta (B.1.525), Lota (B.1.526), Mu (B.1.621), Zeta (P.2), and Omicron (B.1.1.529) etc., the results did not show any off-target and missing detection. The accuracy and sensitivity can be guaranteed.

BioTeke will continue to track and quickly respond to the latest variant of novel coronavirus and ensure that there will be no off-target and missing detection of our test kit.

BioTeke Corporation(wuxi) Co.,Ltd
November 27,2021

HZJZ

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VALIDATION STUDY REPORT

OBJECTIVE:

To establish the performance (sensitivity and specificity) of BioTeke SARS-CoV-2 Antigen Test Kit, BIOTEKE CORPORATION (WUXI) CO.,LTD, China (LOT No.: TC1002E2022L0404; MDD: 02/2024).

Samples included:

100 RT-PCR SARS-CoV-2 positive samples from persons within the first 7 days from the onset of COVID-19 symptoms during the Omicron wave (November 19-24, 2022)

50 RT-PCR SARS-CoV-2 negative symptomatic or asymptomatic persons.

Samples were taken at the drive-in test station of the Croatian Institute of Public Health from symptomatic and asymptomatic persons. The samples were collected by healthcare professionals. Nasopharyngeal swabs were taken and placed into the viral transport medium (2 ml). The swabs were transported to the laboratory and tested with the COVID-19 Antigen Rapid Test and with confirmatory RT-PCR test (Allplex™ 2019-nCoV Assay, Seegene Inc, Republic of Korea, Lot:RV9121L95, Exp.:1/2023). RT-PCR and COVID-19 Antigen Rapid Test were performed from the same nasopharyngeal swab.

Diagnostic acceptance criteria:

- Assay should have sensitivity over 80%, or over 90% for subjects with a Ct < 25
- Assays should have a specificity over 98%.

Ethical approval

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of the Croatian Institute of Public Health (Protocol No. 030-02/22-05/4, Approved on October 28, 2022).

Results:

	POSITIVE RT-PCR (all, Ct<30; Ct<25)	NEGATIVE RT-PCR	TOTAL
POSITIVE RAT	**67/67/65**	**0**	**67**
NEGATIVE RAT	**33/17/6**	**50**	**83/67/56**
TOTAL	**100/84/71**	**50**	**150/134/121**

All samples	**Statistic Value**	**95% CI**
Sensitivity	67.00%	56.88% to 76.08%
Specificity	100.00%	92.89% to 100.00%
Negative Likelihood Ratio	0.33	0.25 to 0.44
Positive Predictive Value (*)	100.00%	
Negative Predictive Value (*)	60.24%	53.40% to 66.70%
Accuracy (*)	78.00%	70.51% to 84.35%

Samples (Ct<30)	**Statistic Value**	**95% CI**
Sensitivity	79.76%	69.59% to 87.75%
Specificity	100.00%	92.89% to 100.00%
Negative Likelihood Ratio	0.20	0.13 to 0.31
Positive Predictive Value (*)	100.00%	
Negative Predictive Value (*)	74.63%	65.80% to 81.81%
Accuracy (*)	87.31%	80.47% to 92.43%

Samples (Ct<25)	**Statistic Value**	**95% CI**
Sensitivity	91.55%	82.51% to 96.84%
Specificity	100.00%	92.89% to 100.00%
Positive Predictive Value (*)	100.00%	
Negative Predictive Value (*)	89.29%	79.49% to 94.71%
Accuracy	95.04%	89.52% to 98.16%

The CT values for the tested samples were <=34. Statistical analysis was done using online tool (https://www.medcalc.org/calc/diagnostic_test.php).

The assay has sensitivity over 90% for subjects with a Ct < 25 (91.55%) and specificity 100.00% which is in line with the requirements MDCG Guidance on performance evaluation of SARS-CoV-2 *in vitro* diagnostic medical devices.

Zagreb, January 05, 2023

Irena Tabain, PhD, MD
Head of Virology Department
Croatian Institute of Public Health

CE Certification – CIBG Registration Letter
CE 证书-CIBG 注册信

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

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medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20205456

Bijlagen
-

Uw aanvraag
12 november 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 27 november 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Luo,

Op 12 november 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam BioTeke Corporation (Wuxi) Co., Ltd met Europees gemachtigde SUNGO Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

SARS-CoV-2 Antigen Test Kit (colloidal gold method)
(geen merknaam) (NL-CA002-2020-54271)
SARS-CoV-2 IgM/IgG Antibody Test Kit (colloidal gold method)
(geen merknaam) (NL-CA002-2020-54270)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

CE Certification – CIBG Registration Letter
CE 证书-CIBG 注册信

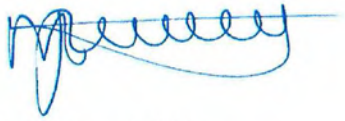
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, BioTeke Corporation (Wuxi) Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

CE Certification–EC Declaration of Conformity

CE 证书-EC 符合性声明

CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: BioTeke Corporation (Wuxi) Co., Ltd

Address: 4th Floor, D5&2nd Floor, D3& 1st and 2nd Floor,D16, No.1719, Huishan Avenue, Wuxi, JiangSu, CN 214174.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: SARS-CoV-2 Antigen Test Kit (colloidal gold method)

Specification: TC1002 (1 Test/Kit; 20 Tests/Kit; 50 Tests/Kit)

Classification: Others (IVDD)

Conformity Assessment

Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2012	EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN 13612:2002+AC:2002	EN ISO 23640:2015	EN 13641:2002

Signature:

Name/ Position: Zhitu Zhou / GM

Date: 9th November, 2020

Place: Wuxi, Jiangsu / China

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

MHRA Registration- UKCA Declaration of Conformity

英国 MHRA 注册-UKCA 符合性声明

UK CA

DECLARATION OF CONFORMITY

Regarding UK Medical Devices Regulations 2002

Manufacturer:	BioTeke Corporation（Wuxi） Co., Ltd
Address:	4th Floor, D5&2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, CN 214174
UK Responsible Person:	SUNGO Certification Company Limited
Address:	3rd floor, 70 Gracechurch Street, London. EC3V 0HR
Product Name:	SARS-CoV-2 Antigen Test Kit (colloidal gold method)
Model:	TC1002 (1 Test/Kit; 20 Tests/Kit; 50 Tests/Kit)
Category:	General IVDs
Conformity Assessment Procedure:	Annex III, Part IV of the UK MDR 2002

We herewith declare that the above-mentioned products meet the requirements of UK Medical Devices Regulations 2002 and the following standards.

BS EN ISO 14971:2019	BS EN ISO 23640: 2015
BS EN ISO 15223-1:2016	BS EN ISO 18113-1: 2011
BS EN 13612: 2002/ AC:2002	BS EN ISO 18113-2: 2011
BS EN 13641: 2002	

Signature: Zhitu Zhou

Name / Position: Zhitu Zhou / GM

Date: 2021/7/1

Place: Wuxi, Jiangsu / China

The declaration of conformity is valid in connection with the release technical document BTK-IVD/UKCA-TCF001.

All the supporting documentation is retained at the premises of the manufacturer. The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Bfarm Special approval

德国白名单

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV...

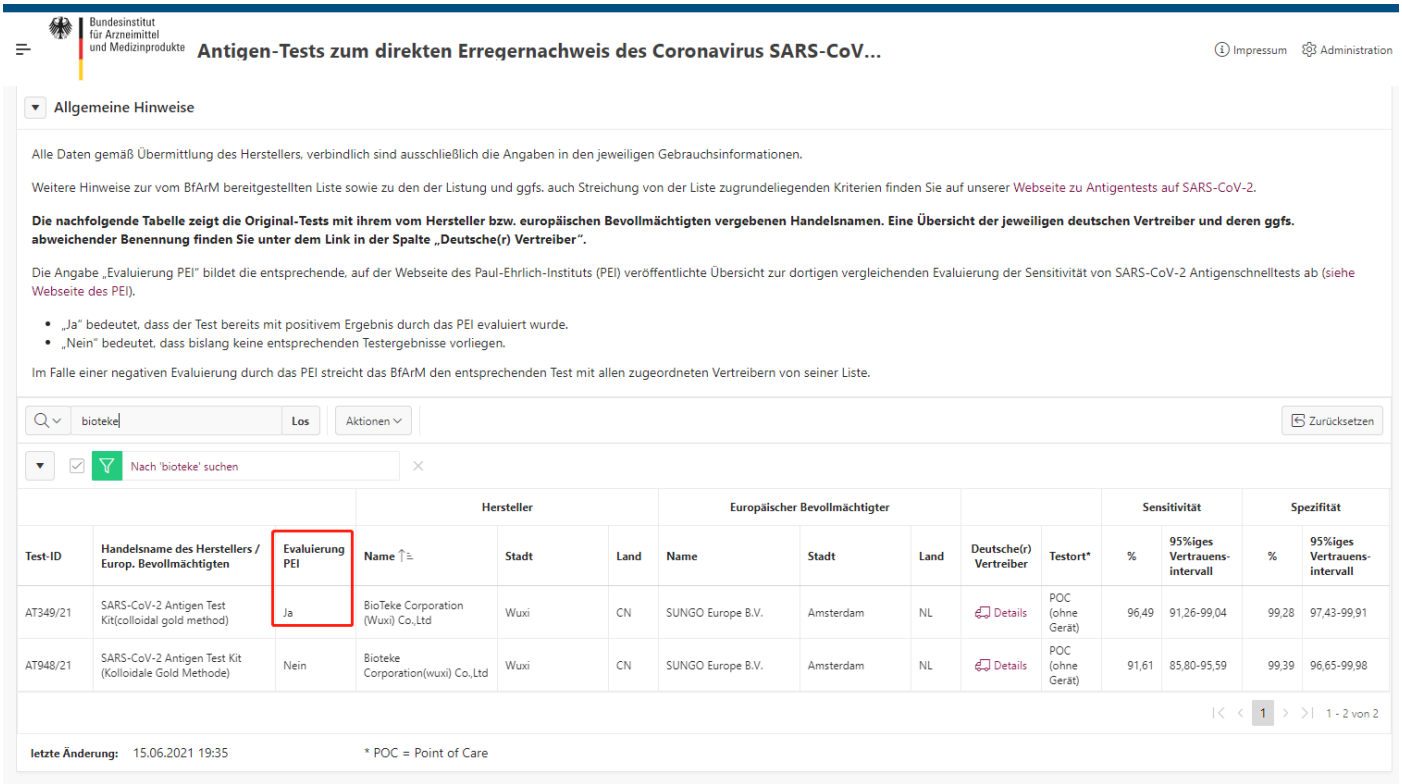
Impressum

Suchen: Alle Textspalten | Los | Aktionen

			Hersteller		Europäischer Bevollmächtigter			Sensitivität		Spezifität	
Test-ID	Name des Tests	Evaluierung PEI	Name	Land	Name	Land	Probennahme	%	95%iges Vertrauensinterv...	%	95%iges Vertrauensinterv...
5640-S-340/21	Covid-19 Antigen Speicheltest	Ja	ulti med Products (Deutschland) GmbH	DE	Caretechion GmbH	DE	Speichel	95,65	90,22 - 98,13	98,44	94,48 - 99,57
5640-S-339/21	SARS-CoV-2 Antigen Rapid Test Kit	Ja	Triplex International Biosciences (China) C...	CN	Lotus NL B.V.	NL	nasal	99,00	93,76 - 99,95	100,00	95,39 - 100
5640-S-316/21	Dia Sure COVID-19 Antigen Schnelltest	Ja	Azure Biotech Inc.	US	Lotus NL B. V.	NL	nasal	91,40	84,50 - 95,40	100,00	98,40 - 100
5640-S-310/21	COVID-19 Antigen Schnelltest (kolloidales...	Ja	Anbio (Xiamen) Biotechnology., Co Ltd	CN	Lotus Global Co Ltd	NL	nasal	93,87	89,01 - 97,02	100,00	98,92 - 100
5640-S-307/21	SARS-CoV-2 Antigen Schnelltest - Vorder...	Ja	BioTeke Corporation (Wuxi) Co.,Ltd	CN	SUNGO Europe B.V.	NL	nasal	91,61	85,80-95,59	99,39	96,63-99,98
5640-S-300/21	V-Chek SARS-CoV-2 Rapid Ag Test Kit (Co...	Ja	SGA Muhendislik Dans Egt Ic ve Dis Tic A.S.	TR			nasal				
5640-S-299/21	2019-nCoV Antigen Test (Lateral Flow Met...	Ja	Haemato Pharm GmbH	DE	Quarad BV	BE	Speichel / Sputum	97,60	93,15 - 99,50	99,09	96,75 - 99,89

Bfarm List of Antigen-tests of the coronavirus SARS-CoV-2

德国 Bfarm 注册的新冠诊断试剂清单



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV...

Impressum Administration

Allgemeine Hinweise

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Listung und ggfs. auch Streichung von der Liste zugrundeliegenden Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

Die nachfolgende Tabelle zeigt die Original-Tests mit ihrem vom Hersteller bzw. europäischen Bevollmächtigten vergebenen Handelsnamen. Eine Übersicht der jeweiligen deutschen Vertreiber und deren ggfs. abweichender Benennung finden Sie unter dem Link in der Spalte „Deutsche(r) Vertreiber".

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden Test mit allen zugeordneten Vertreibern von seiner Liste.

bioteke | Los | Aktionen | Zurücksetzen

Nach 'bioteke' suchen

			Hersteller			Europäischer Bevollmächtigter					Sensitivität		Spezifität	
Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Deutsche(r) Vertreiber	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall
AT349/21	SARS-CoV-2 Antigen Test Kit(colloidal gold method)	Ja	BioTeke Corporation (Wuxi) Co.,Ltd	Wuxi	CN	SUNGO Europe B.V.	Amsterdam	NL	Details	POC (ohne Gerät)	96,49	91,26-99,04	99,28	97,43-99,91
AT948/21	SARS-CoV-2 Antigen Test Kit (Kolloidale Gold Methode)	Nein	Bioteke Corporation(wuxi) Co.,Ltd	Wuxi	CN	SUNGO Europe B.V.	Amsterdam	NL	Details	POC (ohne Gerät)	91,61	85,80-95,59	99,39	96,65-99,98

1 - 2 von 2

letzte Änderung: 15.06.2021 19:35

* POC = Point of Care

PEI tests
PEI 检测

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

11.06.2021

Comparative evaluation of the sensitivities of SARS-CoV-2 antigen rapid tests

Aim

Comparison of different antigen rapid tests with using identical sample material

Material

Pools from nasopharyngeal and oropharyngeal swabs.

Dry swabs were included in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable CT values diluted 1:10 in negative samples in PBS. The CT values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standards. In the case of the PCRs used, a CT value of 25 corresponds to around 10^6 RNA copies/mL. 18 samples each were analysed with CT<25, 23 samples with CT between 25 and 30, and 9 samples with CT>30. The replication of the virus in cell culture was determined as a possible correlate for infectiousness as another characteristic of the samples.

Method

The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50 µL of the pool were analysed using the components of the test provided, e.g. swabs. Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

Summary

This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers with the same sample set allows an overview of the current state of art regarding sensitivity. The results do not allow any conclusions regarding specificity of the tests.

Those POCTs which have up to now been included in the evaluation and have been assessed as reflecting the current state of the art are listed in the table below. Other tests, which were assessed as not reflecting the state of the art were deleted from the list of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This comparative evaluation is constantly continued, and the table is amended accordingly.

You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for refunding, and that few other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

Contact

Email: sarscov2ivd@pei

PEI tests
PEI 检测

SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)	BioTeke Corporation (Wuxi) Co.,Ltd.
COVID-19 Antigentest	Artron Laboratories Inc.
Accu-Tell Rapid In-vitro Diagnostiktest	AccuBioTech Co.,Ltd.
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)	Hubei Jinjian Biology Co.,Ltd.
Cora Gentest-19	Abioteq
Jinwofu Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Kit	Beijing Jinwofu Bioengineering Technology Co.,Ltd.
STANDARD i-Q COVID-19 Ag Home Test	SD Biosensor, Inc.
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) SPUCKTEST	JOYSBIO (Tianjin) Biotechnology Co., Ltd.
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Shenzhen Dymind Biotechnology Co., Ltd.

EU HSC common list
欧盟抗原检测卡通用清单

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

EU health preparedness:

A common list of COVID-19 rapid antigen tests and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

This document was agreed by the HSC on 17 February 2021

Annex I

Common list of COVID-19 rapid antigen tests

A first update was agreed by the HSC on 10 May 2021; A second update was agreed by the HSC on 16 June 2021; A third update was agreed by the HSC on 7 July 2021; A fourth update was agreed by the HSC on 14 July 2021

IMPORTANT: A (interim) grace period of 8 weeks applies whenever updates are made to Annex I, the common list of COVID-19 rapid antigen tests

Annex II

Common standardised data set of to be included in COVID-19 test result certificates

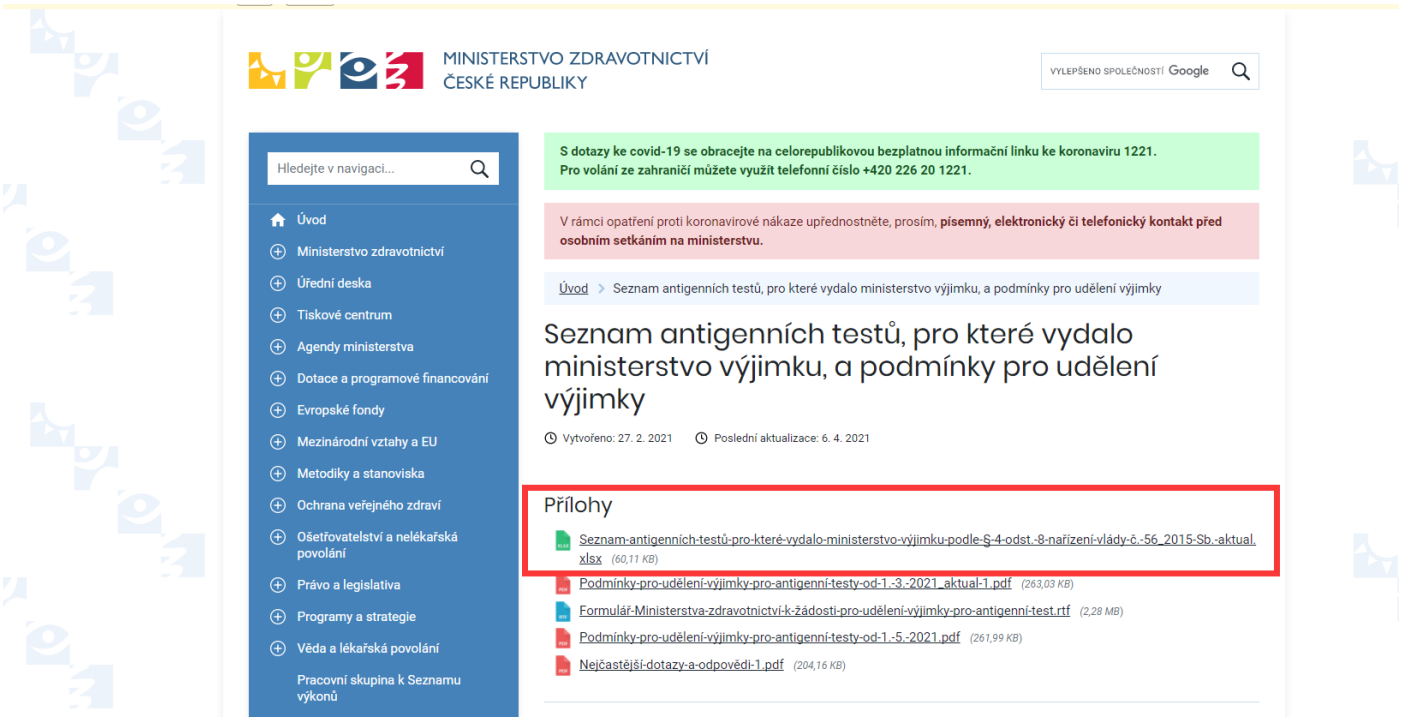
An update to Annex II was agreed by the HSC on 19 March 2021

EU HSC common list
欧盟抗原检测卡通用清单

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Completed validation studies	MS currently validating	In JRC database (Device ID #)[11]
				DE: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% **NL:** Independent field study, mainly symptomatic individuals, sensitivity Ct≤30: 96.0%; specificity overall: 100%					
BIOSYNEX SA	BIOSYNEX COVID-19 Ag+ BSS	Yes	Clinical Sensitivity: 97.5 %	**FR:** Validation study data: 125 positive and 118 negative samples; sensitivity 96%, specificity: 99%		FR		FR		Yes (1494)
BIOTEKE CORPORATION (WUXI) CO., LTD	SARS-CoV-2 Antigen Test Kit (colloidal gold method)	Yes	96.49 % sensitivity 99.28 % specificity OP/NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct25) + Manufacturer specificity: 99.28%		DE[2]		DE[2]		Yes (2067)
BTNX Inc	Rapid Response COVID-19 Antigen Rapid Test	Yes	90.2% sensitivity 100% specificity NP swab, NP swab, OP swab	**DE:** 94.55% sensitivity, 100% specificity		AT, DE[2], ES, SI		DE[2]		Yes (1236)
CerTest Biotec	CerTest SARS-CoV-2 Card test	Yes	92.9% sensitivity 99.6% specificity NP swab	**ES:** Ct ≤ 25, sensitivity: 94,0%; sensitivity for samples within the first 5 days after symptom onset: 84,8%		ES, PT, SI		DE[2], ES		Yes (1173)
Core Technology Co., Ltd	Coretests COVID-19 Ag Test	Yes	98.1% sensitivity 99.6% specificity NP swab	**DE:** 98.1% sensitivity, 99.6% specificity		AT, DE[2], RO		DE[2]		Yes (1919)
CTK Biotech, Inc	OnSite COVID-19 Ag Rapid Test	Yes	Clinical Sensitivity: 92.3 % Clinical Specificity: 100 % Nasal, NP swab	**ES:** 219 samples; Nasal swab - Clinical sensitivity 86% (90%: Ct <30) Specificity: 100% (Method B) **DK:** 107 samples; Nasal swab - clinical sensitivity 86%; (from asymptomatic and mild symptomatic individuals), Clinical specificity: 100%	*To start*	DK		DK, ES		Yes (1581)
DDS DIAGNOSTIC	Test Rapid Covid-19 Antigen (tampon nazofaringian)	Yes	98.77% sensitivity 99.03% specificity Nasal swab	**RO:** Meets the minimum performance requirements.		RO		RO China	RO	Yes (1225)

Czech List of antigenic tests for which issued by the ministry exemption

捷克白名单



MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

VYLEPŠENO SPOLEČNOSTÍ Google

Hledejte v navigaci...

- Úvod
- Ministerstvo zdravotnictví
- Úřední deska
- Tiskové centrum
- Agendy ministerstva
- Dotace a programové financování
- Evropské fondy
- Mezinárodní vztahy a EU
- Metodiky a stanoviska
- Ochrana veřejného zdraví
- Ošetřovatelství a nelékařská povolání
- Právo a legislativa
- Programy a strategie
- Věda a lékařská povolání
- Pracovní skupina k Seznamu výkonů

S dotazy ke covid-19 se obracejte na celorepublikovou bezplatnou informační linku ke koronaviru 1221.
Pro volání ze zahraničí můžete využít telefonní číslo +420 226 20 1221.

V rámci opatření proti koronavirové nákaze upřednostněte, prosím, **písemný, elektronický či telefonický kontakt před osobním setkáním na ministerstvu.**

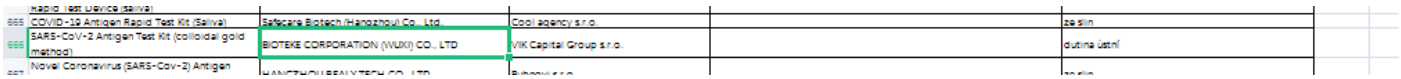
Úvod > Seznam antigenních testů, pro které vydalo ministerstvo výjimku, a podmínky pro udělení výjimky

Seznam antigenních testů, pro které vydalo ministerstvo výjimku, a podmínky pro udělení výjimky

Vytvořeno: 27. 2. 2021 Poslední aktualizace: 6. 4. 2021

Přílohy

- Seznam-antigenních-testů-pro-které-vydalo-ministerstvo-výjimku-podle-§-4-odst.-8-nařízení-vlády-č.-56_2015-Sb.-aktual.xlsx (60,11 KB)
- Podmínky-pro-udělení-výjimky-pro-antigenní-testy-od-1.-3.-2021_aktual-1.pdf (263,03 KB)
- Formulář-Ministerstva-zdravotnictví-k-žádosti-pro-udělení-výjimky-pro-antigenní-test.rtf (2,28 MB)
- Podmínky-pro-udělení-výjimky-pro-antigenní-testy-od-1.-5.-2021.pdf (261,99 KB)
- Nejčastější-dotazy-a-odpovědi-1.pdf (204,16 KB)



665	Rapid Test Device (Saliva) COVID-19 Antigen Rapid Test Kit (Saliva)	Safecare Biotech (Hangzhou) Co., Ltd.	Cool agency s.r.o.		ze slin
666	SARS-CoV-2 Antigen Test Kit (colloidal gold method)	BIOTEKE CORPORATION (WUXI) CO., LTD	VIK Capital Group s.r.o.		dutina ústní
667	Novel Coronavirus (SARS-CoV-2) Antigen	HANGZHOU REALY TECH CO., LTD	Rubicon s.r.o.		ze slin

Austria Registration
奥地利注册

Inverkehrbringer		Bezeichnung des Medizinprodukts	Name und Anschrift des Herstellers	Name und Anschrift des Bevollmächtigten
Firma	Anschrift			
BUN Pharma GmbH	Pollhammerstr. 5, 3542 Gföhl	SARS-CoV-2 Antigen Rapid Test Kit-PRO (Colloidal Gold)/ Test Kit für neuartiges Coronavirus-Antigen PRO (kolloidale Gold-Methode)	JOYSBIO (Tianjin) Biotechnology Co., Ltd. No. 220, Dongting Road, TEDA 300457 Tianjin, China	Lotus NL B.V. Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands
Rosen-Apotheke	Längdorfer Straße 2, 9184 St. Jakob im Rosental	Immunobio Sars-CoV-2 Antigen Schnelltest 4 in 1 (Speichel, anterio-nasal, nasopha ryngea len, oropharyngealen) 1,5,20 Stk.	Hangzhou Immuno Biotech Co.,Ltd., China, Zhejiang, Hangzhou, Jianggan District, No.3 St, 28	Lotus NL B.V. Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands
weforyou GmbH	Grieskai 16, 8020 Graz, Austria	SARS-CoV-2 Antigen Test Kit (Kolloidale Gold Methode)	BioTeke Corporation (Wuxi) Co., Ltd. 4th Floor, D5&2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, CN 214174.	SUNGO Europe B.V. Olympisch Stadion 24,1076 DE Amsterdam, Netherlands

Italy Registration
意大利注册

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante: **bioteke**
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:20/04/2021

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2092732	N	TC10022021	SARS-COV-2 ANTIGEN TEST KIT (COLLOIDAL GOLD METHOD)FOR SALIVA SAMPLE	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	16/04/2021		FABBRICANTE	BIOTEKE CORPORATION(WUXI) CO.,LTD			CN
									MANDATARIO	OACP IE LTD		IE3518703DH	IE
Dispositivo	2092737	N	TC10022021-1	SARS-COV-2 ANTIGEN TEST KIT (COLLOIDAL GOLD METHOD)FOR NASAL SWABS	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	16/04/2021		FABBRICANTE	BIOTEKE CORPORATION(WUXI) CO.,LTD			CN
									MANDATARIO	OACP IE LTD		IE3518703DH	IE

Swiss Lists of rapid tests for SARS-CoV-2 for professional use

瑞士供专业使用的 SARS-CoV-2 快速检测清单

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Taskforce BAG Covid-19

Listen der SARS-CoV-2-Schnelltests zur Fachanwendung und das Covid-Zertifikat für getestete.[1]
Listes des tests rapides pour le SARS-CoV-2 pour usage professionnel et le certificat COVID pour les personne testées.
Liste dei test rapidi per il SARS-CoV-2 per uso professionale e il certificato COVID per persone testate.

30.08.2021

Die Schnelltests sind ausschliesslich für **bestimmte Probematerialien** validiert und nur dementsprechend anzuwenden. Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19-Testung.

Les tests rapides sont validés exclusivement pour **certains types de prélèvements** et ne doivent ainsi être utilisés que pour ceux-ci. Ces informations sur l'emploi prévu des tests rapides sont disponibles sur le site web de l'OFSP Tests COVID-19.

I testi rapidi sono validati solo per **certi tipi di campioni** e possono essere utilizzati solo per questo scopo. Le informazioni su come utilizzare i test rapidi sono disponibili sul sito internet dell'UFSP «Test COVID-19».

Webseite Covid-19 Testung

Site internet Tests COVID-19

Sito web Test COVID-19

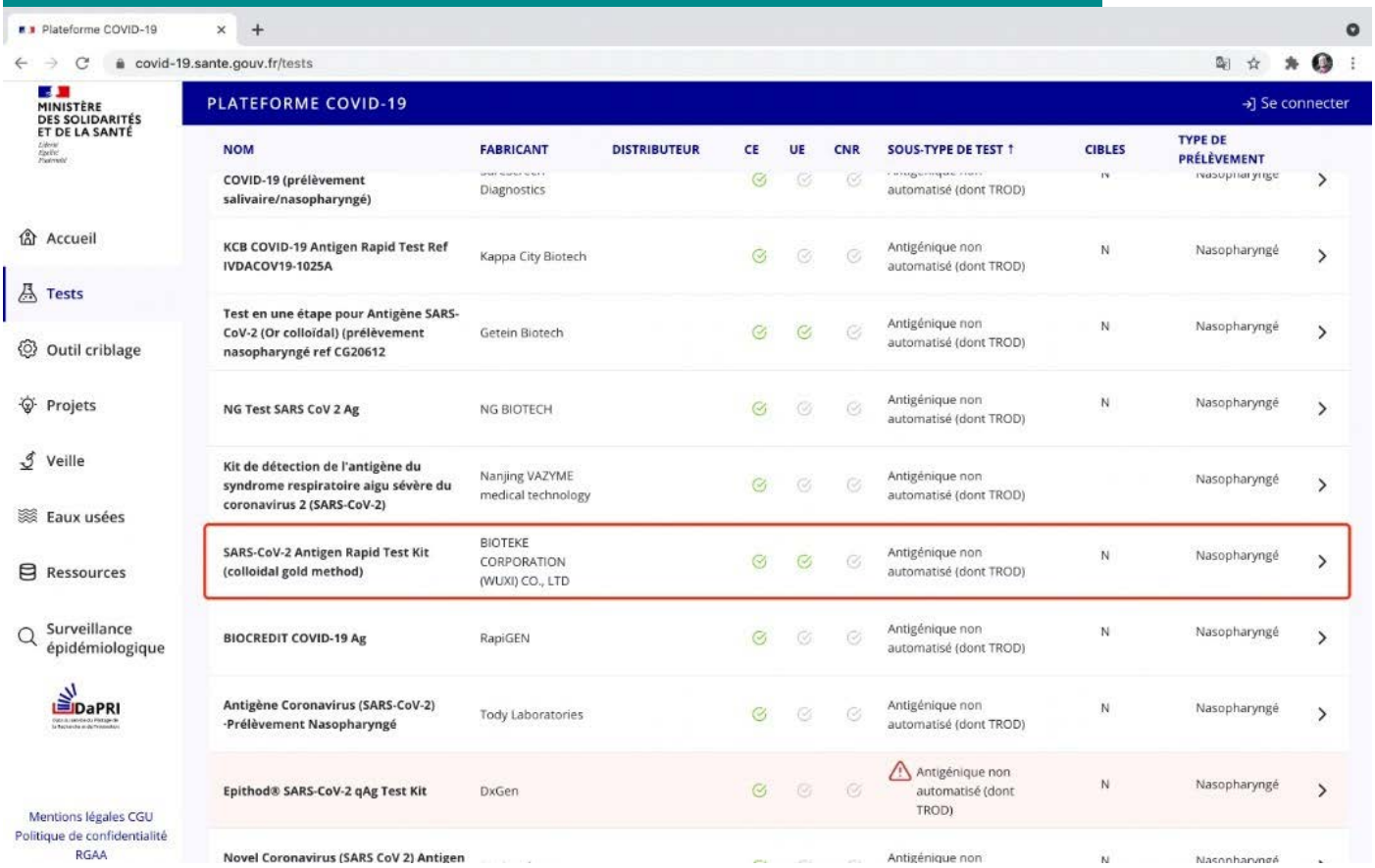
Hersteller, Antigen Schnelltest **Fabricant, Tests rapides antigéniques** **Azienda, Test antigenici rapidi**	**TestKitCode for electronic declaration[2]**	**Combi-Test[3]**	**JRD ID**	**Grace period until[4]**
AAZ-LMB, COVID-VIRO	26		1833	
Abbott Rapid Diagnostics, Panbio Covid-19 Ag Rapid Test	2		1232	
Acon Biotech (Hangzhou) Co., Ltd, SARS-CoV-2 Antigen Rapid Test	0		1457	
ACON Laboratories, Inc, Flowflex SARS-CoV-2 Antigen rapid test	0		1468	
AESKU.DIAGNOSTICS GmbH & Co. KG, AESKU.RAPID SARS-CoV-2	0		2108	
Affimedix, Inc., TestNOW® - COVID-19 Antigen Test	0		2130	
AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag	19		1304	
Anbio (Xiamen) Biotechnology Co., Ltd, Rapid COVID-19 Antigen Test(Colloidal Gold)	0		1822	
Anhui Deep Blue Medical Technology Co., Ltd, COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Nasal Swab	0		1815	
Anhui Deep Blue Medical Technology Co., Ltd, COVID-19 (SARS-CoV-2) Antigen Test Kit(Colloidal Gold)	0		1736	
ArcDia International Ltd, mariPOC SARS-CoV-2	0		768	
ArcDia International Oy Ltd, mariPOC Quick Flu+	0	x	2079	
ArcDia International Oy Ltd, mariPOC Respi+	0	x	2078	
Artron Laboratories Inc, Artron COVID-19 Antigen Test	0		1618	
Asan Pharmaceutical CO., LTD, Asan Easy Test COVID-19 Ag	0		1654	
Assure Tech. (Hangzhou) Co., Ltd, ECOTEST COVID-19 Antigen Rapid Test Device	0		770	
Assure Tech. (Hangzhou) Co., Ltd., ECOTEST COVID-19 Antigen Rapid Test Device	0		2350	
Atlas Link Technology Co., Ltd., NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	22		2010	
AVALUN SAS, Ksmart® SARS-COV2 Antigen Rapid Test	0		1800	
AXIOM Gesellschaft für Diagnostica und Biochemica mbH, COVID-19 Antigen Rapid Test	0		2101	
Azure Biotech Inc, COVID-19 Antigen Rapid Test Device	0		1906	
Becton Dickinson, BD Veritor™ System for Rapid Detection of SARS CoV 2	0		1065	
Beijing Hotgen Biotech Co., Ltd, Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	0		1870	
Beijing Jinwofu Bioengineering Technology Co.,Ltd., Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit	0		2072	
Beijing Lepu Medical Technology Co., Ltd, SARS-CoV-2 Antigen Rapid Test Kit	0		1331	
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold)	0		1485	
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, Wantai SARS-CoV-2 Ag Rapid Test (FIA)	0		1484	
Bio-Rad Laboratories / Zhejiang Orient Gene Biotech, Coronavirus Ag Rapid Test Cassette (Swab)	0		2031	
BioGnost Ltd, CoviGnost AG Test Device 1x20	0		2247	
BIOHIT HealthCare (Hefei) Co., Ltd, SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography)	0		1286	
BioMaxima SA, SARS-CoV-2 Ag Rapid Test	0		2035	
Biomerica, Inc., Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)	0		1599	
Bionote, Inc, NowCheck COVID-19 Ag Test	11		1242	
BIOSYNEX S.A., BIOSYNEX COVID-19 Ag BSS	17		1223	
BIOSYNEX S.A., BIOSYNEX COVID-19 Ag+ BSS	18		1494	
BIOTEKE CORPORATION (WUXI) CO., LTD, SARS-CoV-2 Antigen Test Kit (colloidal gold method)	0		2067	
Biotical Health S.L.U., biotical SARS-CoV-2 Ag Card	0		2013	
Boditech Med Inc, AFIAS COVID-19 Ag	0		1989	
BTNX Inc, Rapid Response COVID-19 Antigen Rapid Test	0		1236	

Bulgaria list of rapid antigen test
保加利亚抗原快速检测清单

SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography)	BIOHIT HealthCcare (Hefei) Co., Ltd.
SARS-CoV-2 Ag Rapid Test	BioMaxima SA
Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)	Biomerica Inc.
NowCheck COVID-19 Ag Test	BIONOTE
CORONAVIRUS AG RAPID TEST CASSETTE	BIO-RAD
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX S.A.
BIOSYNEX COVID-19 Ag+ BSS	BIOSYNEX SA
SARS-CoV-2 Antigen Test Kit (colloidal gold method)	BIOTEKE CORPORATION (WUXI) CO., LTD
biotical SARS-CoV-2 Ag Card	Biotical Health S.L.U.BIOTICAL HEALTH S.L.U
AFIAS COVID-19 Ag	Boditech Med Inc
Rapid Response COVID-19 Antigen Rapid Test	BTNX Inc
CerTest SARS-CoV-2 Card test	CerTest Biotec
Coretests COVID-19 Ag Test	Core Technology Co., Ltd
OnSite COVID-19 Ag Rapid Test	CTK Biotech, Inc
Test Rapid Covid-19 Antigen (tampon nazofaringian)	DDS DIAGNOSTIC
DIAQUICK COVID -19 Ag Cassette	DIALAB GmbH
COVID-19 Antigen Detection Kit	DNA Diagnostic
Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	Edinburgh Genetics Limited
EBS SARS-CoV-2 Ag Rapid Test	Eurobio Scientific
ESPLINE SARS-CoV-2	Fujirebio
GA CoV-2 Antigen Rapid Test	GA Generic Assays GmbH
Genbody COVID-19 Ag Test	GenBody Inc
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Genrui Biotech Inc
GenSure COVID-19 Antigen Rapid Test Kit	GenSure Biotech Inc
SARS-CoV-2 Antigen (Colloidal Gold)	Getein Biotech, Inc
One Step Test for SARSCoV-2 Antigen (Colloidal Gold)	Getein Biotech, Inc.
SARS-CoV-2 Antigen Kit (Colloidal Gold)	Goldsite Diagnostic Inc.
GENEDIA W COVID-19 Ag	Green Cross Medical Science Corp.
2019-nCoV Antigen Test Kit (colloidal gold method)	Guangdong Hecin Scientific, Inc.
COVID-2019-nCoV Ag Rapid TestDetection Kit (ImmunoChromatography)	Guangdong Longsee Biomedical Co., Ltd.
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co. Ltd

France COVID-19 Diagnostic test list - For nasopharyngeal swab

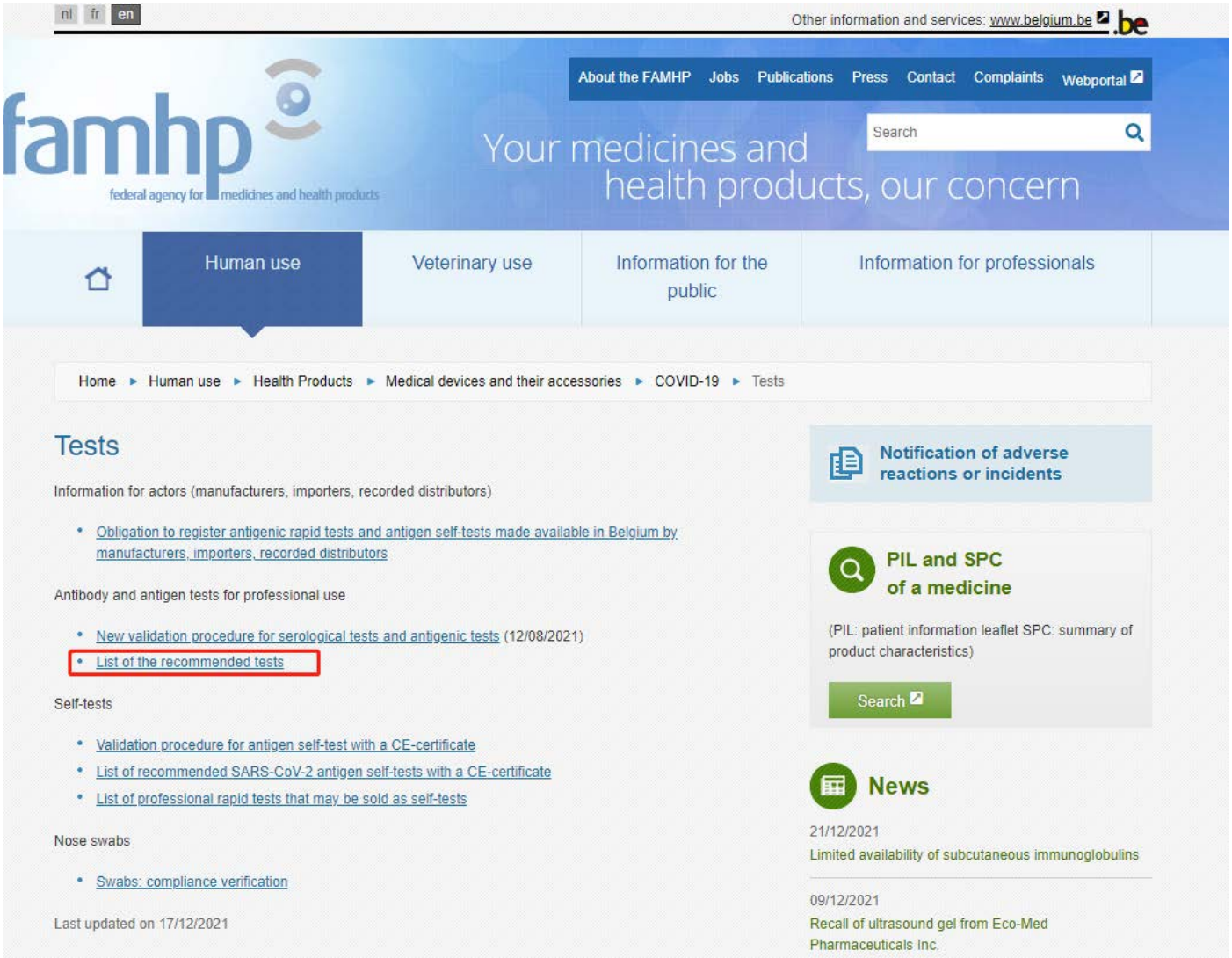
法国 COVID-19 诊断试剂清单-鼻咽拭子



https://covid-19.sante.gouv.fr/tests

Belgium famhp List of the recommended tests

比利时 famhp 检测试剂推荐清单



https://www.famhp.be/en/human_use/health_products/medical_devices_accessories/covid_19/tests

Free Sale Certificate
自由销售证明书

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

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1076 DE Amsterdam

Farmatec

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T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20210404

Bijlagen
4

Uw aanvraag
26 januari 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 5 februari 2021
Betreft: exportverklaring(en) medische hulpmiddelen/IVD

Geachte heer Luo,

Hierbij ontvangt u de door u aangevraagde exportverklaring(en) voor:

INDIA (30565)
INDONESIA (30562)
MALAYSIA (30564)
THE PHILIPPINES (30563)

Afgegeven exportverklaringen IVD Klasse other producten of gecombineerde exportverklaringen van IVD Klasse other producten met hogere risicoklasse producten vervallen per 26 mei 2022.
Valt uw IVD product onder een hogere risicoklasse (lijst A, B of zelftesten)? Dan mag uw product tot en met uiterlijk 25 mei 2025 op de markt blijven als IVD product.

Met vriendelijke groet,
Farmatec

Medewerker Medische Hulpmiddelen

ISO 13485 Certificate-MDSAP
ISO 13485 证书-MDSAP

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BioTeke Corporation(wuxi)Co., Ltd
4th Floor
D5 No.1719
Huishan Avenue
Wuxi City, Jiangsu P.R
214174
China

Facility ID Number: F005548

Holds Certificate No: **MDSAP 751219**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, Production, Distribution and Service of Automated Nucleic Acid Extraction System, Nucleic Acid Extraction Kits, Disposable virus sampling Swab kits, Colloidal Gold test kits, Immunoassay Test Kits, Fluorescence PCR test kits and PCR in-vitro diagnostic instrument.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-11-28 Effective Date: 2021-11-28 Expiry Date: 2024-11-24

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

ISO 13485 Certificate-MDSAP
ISO 13485 证书-MDSAP

Certificate No: **MDSAP 751219**

Location	Registered Activities
BioTeke Corporation(wuxi)Co., Ltd 4th Floor D5 No.1719 Huishan Avenue Wuxi City, Jiangsu P.R 214174 China Facility ID Number: F005548	Design and Development, Production, Distribution and Service of Automated Nucleic Acid Extraction System, Nucleic Acid Extraction Kits, Disposable virus sampling Swab kits, Colloidal Gold test kits, Immunoassay Test Kits, Fluorescence PCR test kits and PCR in-vitro diagnostic instrument.
BioTeke Corporation(wuxi)Co.,Ltd 2nd Floor, D3 No.1719,Huishan Avenue Wuxi City China Facility ID Number: F005548	Manufacture for Nucleic Acid Extraction kits.
BioTeke Corporation(wuxi)Co.,Ltd 1st and 2nd Floor D16,No.1719,Huishan Avenue WuXi Jiangsu 214174 China Facility ID Number: F005548	Manufacture for Automated Nucleic Acid Extraction System and Disposable virus sampling Swab kits.
BioTeke Corporation(wuxi)Co.,Ltd No. 330, Qiyang South Road, Jiangyin Qingyang Jiangsu 214401 China Facility ID Number: F005548	Manufacture for SARS-CoV-2 Antigen Test Kit (colloidal gold method), Nucleic Acid Extraction Kit ,Freeze-dried Novel Coronavirus (COVID-19) Nucleic Acid Detection Kit (Fluorescence PCR) ,Novel Coronavirus (SARS-CoV-2) nucleic acid detection kit Fluorescence PCR method, and Disposable virus sampling Swab kits.

Original Registration Date: 2021-11-28 Effective Date: 2021-11-28 Expiry Date: 2024-11-24

ISO 45001 Certificate
职业健康安全管理体系认证证书

CERTIFICATE

The Governing Board of
ARES International Certification Co., Ltd.
Hereby Grants To:

BIOTEKE CORPORATION (WUXI) CO., LTD.
Organization Credit Code: 913202065617502076

4th Floor, D5&2nd Floor, D3& 1st and 2nd Floor,D16, No.1719, Huishan Avenue, Wuxi

Has been assessed and found to be in accordance with the requirements of standard detailed below
GB/T 45001-2020/ISO 45001:2018

Scope
Manufacture of disposable virus sampling swab and nucleic acid extraction Management of Related Occupational Health and Safety Aspects.

Certificate No.: ARES/CN/I2101044S
Certificate Issue Date: 2021-02-07 Registration Expiration Date: 2024-02-06

The time interval between each surveillance audit and the last on-site audit shall not exceed 12 months, and the organization must obtain "surveillance audit approval notification" issued by ARES to ensure the validity of the certificate.

IAS ACCREDITED Management Systems Certification Body ACC NO. MSCB - 171

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Authorized by :

ARES International Certification Co., Ltd.
No.12-2, Ln. 187, Wenping Rd., Anping Dist., Tainan City 708, Taiwan
TEL / 06-295 9696 (Rep. Line) FAX / 06-295 9667 www.ares-registration.com
Check the validity of this certificate on the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn) or www.ares-china.cn.

ISO 14001 Certificate
环境管理体系认证证书

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: GXZT002-21E10015R0S

We hereby certify that the organization:

Bioteke (wuxi) Corporation Co., Ltd

Unified social credit code/Organization code: 913202065617502076

is in conformity with Environmental Management System Standard:

GB/T24001-2016/ISO14001:2015

The certificate is valid to the following product(s)/service:

the manufacture of disposable virus sampling swab kits and nucleic acid extraction system and related management action

Registration Address: 4th floor, D5, 3rd floor, D3, 1st &2 nd floor, D16, No.1719, Huishan Avenue, Wuxi

Audit Address: 4th floor, D5, 3rd floor, D3, 1st &2 nd floor, D16, No.1719, Huishan Avenue, Wuxi

Date of Issue : 14-01-2021

Date of Expiry: 13-01-2024

Certificates Appropriation

The Effectiveness of the Certificate is Subject to QR Code in the Left.
Meanwhile, You Can Search the CNCA Website:www.cnca.gov.cn
or Website of Certification Body www.isogx.cn

Guo Xin Zheng Tong (Beijing) Inspection & Certification Co.,Ltd.

Room 508, Building 42, Zone 2, Tiantongyuan, Changping District, Beijing, China (102218)

IPMS Certificate
知识产权管理体系认证证书

Intellectual Property Management System (IPMS) Certificate

【RegistrationNumber：ZJLH20IP0299R0M】

This is to certify that the organization

BIOTEKE CORPORATION (WUXI) CO., LTD

Registered Address: 4th Floor, D5& 2nd Floor, D3 & 1st and 2nd Floor D16,No.1719, Huishan Avenue, Wuxi City,214174 Jiangsu, China

OperationAddress: 4th Floor, D5& 2nd Floor, D3 & 1st and 2nd Floor D16,No.1719, Huishan Avenue, Wuxi City,214174 Jiangsu, China.

Forthefollowingactivities meets the Chinese National StandardGB/T 29490-2013

Authentication Scope:

Intellectual property management in the development of a fluorescence quantitative PCR instrument; also in the research and development, production and sales of nucleic acid extraction equipment and reagents, disposable virus sampling tubes, laboratory disinfection equipment and related procurement activities (within the scope of qualification permit).

Note: The authentication scope shall not include the scope of products and services that have not obtained the relevant administrative licenses and qualification licenses approved by the government.

First Issue Date: Dec 01, 2020

Issue On: Dec 01, 2020

Validity Date: Nov 30, 2023

Information about this certificate is available on the official website(www.cnca.gov.cn) of National Certification and AccreditationAdministration of PRC.The validity of this certificate is maintained by annual supervision in a supervision period.This certificate can only be valid if it is combined with the approval notice issued by thecertification institution.To check the valid status of this certificate, please visit our website www.zjlhbjrz.com or www.cnca.gov.cn, or scan 2-dimensional bar code.

IPMS 中际连横认证

签发：

ZhongjiLianheng (Beijing) Certification Co., LTD

Address: Room 309, Tianjian Building, No. 6, Huixin Nanli, Chaoyang District, Beijing

Postal Code: 100029

Further references and information

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