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Document No.: CE-DOC-CG27
Rev.: 1/0

Declaration of Conformity

Manufacture Address:	Beijing Lepu Medical Technology Co., Ltd. Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China
European Representative:	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Product information:	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) Model: 1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit
Classification:	Others (not in List A and List B)
Conformity Assessment Route:	Section 2 to 5 in annex III of IVDD 98/79/EC We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premise of the manufacturer.
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
Standards Applied:	All applicable harmonized standards (published in the official journal of the European Communities on 25th March 2020). The applicable standards are listed in Annex 1.
Place, date of issue	Beijing, P.R. China, 3th, Sept., 2020
Signature of Management Representative	Zhao Chengjie

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Annex 1

EN ISO 13485:2016 Medical devices – quality management systems - requirements for regulatory purposes

EN ISO 14971:2019 Medical devices – application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 18113-1:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 1: terms, definitions and general requirements

EN ISO 18113-2:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 2: in vitro diagnostic reagents for professional use

EN ISO 23640:2015 In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic regents

EN 13612:2002/AC: 2002 Performance evaluation of in vitro diagnostic medical devices

IEC 62366-1:2015 Application of usability engineering to medical devices

Revision history:

Version	Revision history	Author	Date
1/0	First procedure	Wenna Li	3th, Sept., 2020

Clinical Validation Report on IVD Reagents

Product name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

Model and specification: 25 tests/kit, each test strip packaged separately

Type of clinical trial: Clinical validation

Completion date: August 21, 2020

Testing agency: IPE Center for Clinical Laboratory

Abstract

To evaluate the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) (the "Test Kit" for short) produced by Beijing Lepu Medical Technology Co., Ltd. ("the Company" for short) for clinical application in qualitative detection of the content of SARS-CoV-2 antigen in clinical samples (nasal swab samples), IPE Center for Clinical Laboratory conducted a clinical study on the test strip therein. A total of 210 nasal swab samples were selected as the study objects, including 75 positive samples and 135 negative samples confirmed by COVID-19 diagnosis and treatment protocol. The kits used for diagnosis was 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd. was used as the reference kit. Based on the test result of the reference kit, the study objects were divided into 2019-nCoV antigen positive group and 2019-nCoV antigen negative group. At the same time, these samples were tested with the Test Kit, and the test results of the Test Kit and the reference kit were compared and statistically analyzed. The results showed that the negative coincidence rate, positive coincidence rate and total coincidence rate between the Test Kit and the reference kit all were greater than 90%, indicating that the Test Kit is in good consistency with the reference kit, and suitable for clinical auxiliary diagnosis.

I. Introduction

As a large virus family, 2019-nCoV is a single strand plus RNA virus with an envelope. It can cause major diseases such as colds, Middle East Respiratory Syndrome (MERS), and severe acute respiratory syndrome (SARS). SARS-CoV-2 was officially named by the World Health Organization on January 12, 2020. The core protein of SARS-CoV-2 is N protein (Nucleocapsid) inside. It is relatively conserved among β-coronaviruses and is often used for the diagnosis of coronaviruses. As the key recipient for SARS-CoV-2 to enter the cells, ACE2 is of great significance to study the viral infection mechanism.

The research and development work of the Test Kit produced by the Company has been completed. Clinical validation work has been started in order to validate the suitability and accuracy of the test strip in clinical application. Entrusted by the Company, IPE Center for Clinical Laboratory undertook the clinical trial on 210 test samples with the Test Kit produced hereby in the clinical study.

II. Purpose

The clinical performance of the Test Kit produced by the Company will be systematically studied in order to validate its suitability and accuracy in clinical application.

The purpose of this clinical trial is to conduct the comparative experimental study for the same clinical sample with the Test Kit "SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)" produced by the Company and the reference kit "2019-nCoV PCR Kit (fluorescent PCR method)" (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd.. Statistical analysis was carried out on the test results to calculate the negative coincidence rate, positive coincidence rate and total coincidence rate. According to the results of statistical analysis, it was validated that the Test Kit is equivalent to the reference kit, so as to validate the suitability and accuracy of the Test Kit for clinical auxiliary diagnosis.

The results of this clinical trial are an important basis for evaluating the efficacy and safety of the Test Kit.

III. Test Management

1. Introduction to management structure

The clinical trial was conducted by the clinical trialing agency IPE Center for Clinical Laboratory. As the applicant, the Company was responsible for communication and contact during the clinical trial.

2. Quality control in the laboratory

1) All researchers participating in this clinical trial passed the qualification examination and had professional background and capacity related to clinical trial. Before the clinical trial, all researchers had a full understanding of the specific contents about the clinical trial protocol and all indexes through training.

2) The quality control of the laboratory met the requirements of quality control of clinical laboratory to ensure the standardization of test procedure.

3) Quality control before the analysis: Sample collection and treatment was checked for compliance with the requirements and, sample number and other information were checked for correctness.

4) The execution and completion of clinical trial was inspected regularly. The completeness and precision of clinical sample information was checked and the test results were verified.

3. Statistics and data management

1) All selected cases were filled in the clinical outcome summary sheet, including the subjects' sample number, age, gender, and so on. The testers filled the test results of the reference kit and the Test Kit in the clinical outcome summary sheet.

2) After finishing data entry, the main researchers, testers and applicant jointly reviewed the data and locked the data when they had no doubt.

3) The clinical outcome summary sheet was then sent to analysts for statistics and analysis. The obtained statics and analysis results were incorporated into corresponding parts of the clinical report.

4. Data preservation

The testing agency and the applicant kept one copy of clinical trial data respectively, including the following contents:

Clinical Trial Agreement, Clinical Test Protocol, Ethics Committee Instructions, Clinical Test Report (testing agency's report), General Report on Clinical Trial, and Clinical Outcome Summary Sheet.

5. Problems found in the study and treatment measures

In clinical trials, when a small number of samples are tested, the results of control samples and test samples are inconsistent. In this case, the clinical quantitative data of these samples or other common clinical strips produced with the same principle are used for re-test.

IV. Test Design

1. Description of overall test design and protocol

With reference to the *Guideline of Clinical Study on In Vitro Diagnostic Reagents*, the appropriate study objects are selected and the 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) that was approved for marketing was used as the reference kit to conduct blinding simultaneous comparison, for analyzing the negative coincidence rate, positive coincidence rate and total coincidence rate of the Test Kit and the reference kit.

The trial protocol was to select 210 nasal swab samples as the study objects. Samples were divided into positive group and negative group according to the test results of reference kit. At the same time, the samples were tested with qualitative test strip and reference agent, the test results of the Test Kit and the reference agent were compared and statistically analyzed to

calculate the negative coincidence rate, positive coincidence rate and total coincidence rate, so as to judge the clinical suitability and accuracy of the Test Kit, and whether the test result of the Test Kit was consistent with that of the reference kit.

2. Research method

1) Sample collection, storage, transportation

After the samples were collected, they were placed in the sample treatment solution, stored at 2-8℃ and tested within 24 h. The samples should not be stored for a long time at room temperature.

2) Determination of method for comparison

Since the 2019-nCoV PCR Kit (fluorescent PCR method) produced by Beijing Applied Biological Technologies Co., Ltd. (GXZZ 20203400179) is a 2019-nCoV PCR Kit approved for marketing in China earlier, it is 2019-nCoV antigen test kit just like the Test Kit produced by the Company, both of which are new coronavirus detection products and widely used in clinical practice and generally considered to be of good quality. The purpose and scope of clinical use of this product are the same as the Test Kit. The product is therefore selected as a reference kit for clinical study.

The samples with inconsistent test results in the test group and the control group can be compared and checked by clinical quantitative results and clinical diagnosis results.

3) Names, specifications, sources, lot number, expiry dates and preservation conditions of the products for clinical study

Product name for clinical study is SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), and the specification is 25 tests/kit. The product is provided by the Company. The lot number is 20CG2701X, and its shelf-life is 12 months. The storage condition is 4℃- 30°C.

The reference kit is 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd., the specification is 48 tests/kit, its shelf-life is 6 months and the storage condition is dark place with -20℃±5℃.

4) Quality control method

The execution and completion of clinical trial is inspected on a regular basis. The completeness and precision of clinical sample information is checked and the test results are verified.

5) Clinical trial method

All test samples were simultaneously tested with the control test strip and the Test Kit, and the test results of the two were compared. When all clinical samples were tested, the recorded test results of the Test Kit and the reference kit were statistically analyzed, to calculate the negative coincidence rate, positive coincidence rate and total coincidence rate and then evaluate whether they were equivalent according to these statistical indexes.

6) Statistical analysis methods for clinical study data

Calculate the negative coincidence rate, positive coincidence rate and total coincidence rate of the test results of the Test Kit and the reference kit. Determine whether each index meets the

clinical evaluation criteria to validate the accuracy and suitability of the product in clinic. Test the Test Kit with different types of samples and statistically analyze the test results. At the same time, test different types of samples of subjects simultaneously with the Test Kit, and compare the test results. When all clinical samples are tested, the recorded test results are statistically analyzed to calculate the negative coincidence rate, positive coincidence rate and total coincidence rate. And then evaluate whether they are equivalent according to these statistical indexes.

7) Clinical evaluation criteria

Compare the Test Kit with the marketed reference kit to calculate coincidence rate. Product performance shall meet the following requirements.

1) Negative coincidence rate: the proportion of samples whose test results obtained with the Test Kit and the reference kit are negative in the samples whose test results obtained with the reference kit are negative. The negative coincidence rate shall be greater than 90%.

2) Negative coincidence rate: the proportion of samples whose test results obtained with the Test Kit and the reference kit are positive in the samples whose test results obtained with the reference kit are positive. The positive coincidence rate shall be greater than 90%.

3) Total coincidence rate: the proportion of samples whose test results obtained with the Test Kit and the reference kit are the same in the total number of samples. Total coincidence rate shall be larger than 90%.

		Control system		Total
		Positive	Negative	
Test system	Positive	a	b	a+b
	Negative	c	d	c+d
Total		a+c	b+d	a+b+c+d

Generally, formulas of positive coincidence rate and negative coincidence rate are as follows:

Positive coincidence rate = a/ (a+c) * 100%

Negative coincidence rate = d/ (b+d) * 100%

Total coincidence rate = (a+d)/(a+c+b+d) * 100%

If the positive coincidence rate and negative coincidence rate meet the clinical requirements, the two methods or products are considered to be equivalent; if the difference between the positive coincidence rate and negative coincidence rate is too large, the clinical protocol shall be redesigned.

8) Modification of the protocol during the study

No modification.

V. Results and Analysis of Clinical Trial

A total of 210 samples were selected. All selected samples were tested.

Make consistency statistics on the test results of Test Kit (test product) produced by the Company and the 2019-nCoV PCR Kit, analyze their diagnostic sensitivity and specificity, and list them in the form of four-fold table.

	Test result of reference kit		Total
Test Kit	Positive	Negative	
Positive	True positive (A)	False positive (B)	A+B
Negative	False negative (C)	True positive (D)	C+D
Total	A+ C	B+D	A+B +C+D

Generally, formulas of diagnostic sensitivity and specificity are as follows:

Diagnostic sensitivity = A/ (A+C) × 100%

Diagnostic specificity = D/ (B+D) × 100%

Total coincidence rate= (A+D)/ (A+B+C+D) × 100%

Table 1: Statistics of Test Results of Test Kit and Reference Kit

	Positive result of reference kit	Negative result of reference kit	Total
Positive result of Test Kit	69	1	70
Negative result of Test Kit	6	134	140
Total	75	135	210

Item	**Formula**	**Results**	95% CI
Diagnostic sensitivity (%)	A/(A+C)*100%	92.00%	83.63%~96.28%

Diagnostic specificity (%)	D/(B+D)*100%	99.26%	95.92%~99.87%
Total coincidence rate (%)	(a+d)/(a+b+c+d)*100%	96.67%	

It can be seen from Table 1 that among the 75 samples in the positive group tested with the Test Kit, 69 cases are positive and 6 cases are negative. Among the 135 samples in the negative group tested with the Test Kit, 134 cases are negative and 1 cases are positive. The results show that the negative coincidence rate, positive coincidence rate and total coincidence rate all are greater than 90%, indicating that they are in good consistency with those of the reference kit.

VI. Discussion and Conclusion

(I) Discussion

The SARS-CoV-2 antigen rapid test strip produced by the Company contains SARS-CoV-2 N protein monoclonal antibody labeled by colloidal gold that is pre-coated on the colloidal gold labeled pad, SARS-CoV-2 N protein monoclonal antibody fixed in the test area and the corresponding antigen in the quality control area (C). The rapid test of SARS-CoV-2 antibodies in nasal swab samples is used clinically for auxiliary screening of COVID-19 patients. The purpose of the clinical trial is to evaluate the clinical performance of the product. The test conditions are presented as follows:

Comparative analysis results of the Test Kit and 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd.:

Test results of the Test Kit and the reference kit: The diagnostic sensitivity and specificity are greater than 90%, indicating that they are in good consistency with those of the reference kit.

(II) Test conclusion

After validation, the negative coincidence rate, positive coincidence rate and total coincidence rate between the test results of the Test Kit and 2019-nCoV PCR Kit (fluorescent PCR method) (GXZZ 20203400179) produced by Beijing Applied Biological Technologies Co., Ltd. are relatively high, and the results of the statistical analysis also show that there is no significant difference between the test results of the Test Kit and the reference kit, the two methods have good diagnosis consistency and are equivalent. At the same time, the diagnostic sensitivity and specificity of the Test Kit and the nucleic acid test results are both greater than 90%, indicating that they are in good consistency with those of the reference kit.

VI. Description of Special Circumstances on Clinical Studies

There is no special circumstance to be explained in this clinical study.

Annex I Instruction for Use of All Diagnostic Reagents Used in Clinical Trials

Instruction for Use of the Test Kit

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SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold Immunochromatography)

【Product name】

SARS-CoV-2 Antigen Rapid Test Kit
(Colloidal Gold Immunochromatography)

【Model】

1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 30 tests/kit.

【Intended Use】

The product is intended for the qualitative detection of antigen against SARS-CoV-2 in clinical samples (nasal swab).

【Summary】

Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is the N protein (Nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses. ACE2, as a key receptor for SARS-CoV-2 to enter cells, is of great significance for the research of viral infection mechanism.

【Principle】

The current test card is based on the specific antibody-antigen reaction and immunoanalysis technology. The test card contains colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad, matched SARS-CoV-2 N protein monoclonal antibody immobilized on the Test area (T) and corresponding antibody in the quality control area (C). During testing, the N protein in the sample combines with the colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad. The conjugates migrate upward under capillary effect, and subsequently captured by the N protein monoclonal antibody immobilized in the Test area (T). The higher the contents of N protein in the sample, the more the conjugates captures and the darker the color in the test area is. If there is no virus in the sample or the virus content is lower than the detection limit, then there is no color demonstrated in the test area (T). Regardless of the presence or absence of the virus in the sample, a purple stripe will appear in the quality control area (C). The purple stripe in the quality control area (C) is a criterion for the judgment of whether or not there is enough sample and whether or not the chromatography procedure is normal.

【Components】

The product consists of test cards, Instructions for use, sample treatment solution. And in each test card bag, it includes one SARS-CoV-2 antigen detection card and one package of desiccant.

Model	Test card	Instructions for use	Sample treatment solution
1 test/kit	1 test	1	1ml×1
5 tests/kit	5 tests	1	1ml×1
10tests/kit	10 tests	1	2ml×1
25 tests/kit	25 tests	1	3ml×2
30 tests/kit	30 tests	1	5ml×2

For each test card bag, it contains one test card and one package of desiccant.

The test card consists of gold standard mat (coated with colloidal gold labelled SARS-CoV-2 N protein monoclonal antibody), sample mat, nitrocellulose membrane (Test area (T) is coated with an SARS-CoV-2 N protein monoclonal antibody; the quality control area (C) is coated with goat anti-mouse antibody), absorbing paper, and hydrophobic stiff card.

【Storage and Stability】

It should be stored at 4 ~ 30℃, be kept dry and away from sunlight. The shelf life is 12 months.
For per test card, it should be used within 1 hour after unsealing.
Production Date and Expiration date are shown in the package label.

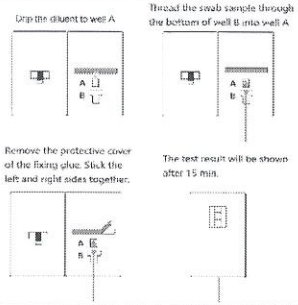
【Sample Requirements】

The product is used to test the human nasal swab sample.
Sample collection: During the collection procedures for samples, take care to make proper protection, and avoid direct contact with the sample. In case of accidental contact, disinfection treatment should be carried out in time and necessary measures should be taken.

Nasal swab sample: gently and slowly insert the swab into the nasopharynx through the nasal cavity. When resistance is encountered, the swab will arrive at the posterior nasopharynx. After a few seconds of suction, gently rotate the swab, then take out the swab to obtain the nasal swab sample.
Sample preservation: after sample collection, please complete the test within 1 hour.
The sample should come to room temperature before testing.

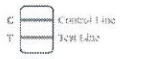
【Test Method】

Please read the instruction for use carefully before performing the test. Before testing, restore the reagents and sample to room temperature.
1. Remove the test card from the test card bag and use it within 1 hour, especially in the environment with room temperature higher than 30 °C or in high humidity.
2. Place the test card on a clean platform. Drip 6 drops of the sample treatment solution to well A.
3. Thread the swab head through the bottom of well B into well A and rotate it two rounds clockwise and counterclockwise respectively in the sample treatment solution.
4. Remove the protective cover of the fixing glue. Stick the left and right sides together and start timing. Wait until the purple band appears. The test result should be read within 15-20 minutes.



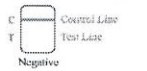
【The Explanation of the Testing Results】

• Positive (+). There appear purple stripes in both quality control area (C) and either test area (T).



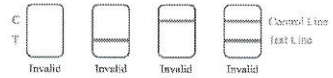
Positive

• Negative (-). There is only one purple stripe in the quality control area (C), and without purple stripe in either test area (T).



Negative

• Invalid: There is no purple stripe in the quality control area (C), or there is blue stripe in the quality control area (C), indicating incorrect operating procedures or the test card has already deteriorated. Under this condition, it must read the instruction for use again carefully, and then use the new test card to test again. If the problem still exists, stop using the products with same lot number and contact the local suppliers immediately.



Invalid Invalid Invalid Invalid

【Limitation of Procedure】

1. The test results of this product should be comprehensively judged by the physician in combination with other clinical information, and should not be used as the only criterion;
2. The product is used to test the SARS-CoV-2 antigen of the clinical sample.

【Product Performance Index】

1 Physical Property
1.1 Appearance

The test card should be clean and integral, no burrs, no damage, no pollution; the material should be firmly adhered; the label should be clear and not damaged. The sample dilution should be clear without impurities and flocs.
1.2 Liquid migration speed
The liquid migration speed should be no less than 10mm/min.
1.3 Membrane Strip Width
The membrane strip width of the testing card should be≥2.5mm.
1.4 The preparation quantity of the diluent for the samples
The volume of the diluents for the sample is no less than the indicated value.
2 Detection Limit
For the detection of sensitivity reference material, the positive detection rate should be no less than 90%.
3 Negative reference products compliance rate
For the detection of negative reference material, the negative detection rate should be 100%.
4 Positive reference products compliance rate
For the detection of positive reference material, the positive detection rate should be 100%.
5 Repeatability
For the detection of enterprise reference material P2 and P4, the results should be positive and the color rendering should be uniform.
6 Cross-reactivity
Cross-reactivity: This test device has no cross reactivity with endemicity human coronavirus OC43, influenza a virus, influenza B virus, respiratory syncytial virus, adenovirus, EB virus, measles virus, cytomegalovirus, rotavirus, Norovirus, mumps virus, varicella zoster virus, mycoplasma pneumoniae, Human metapneumovirus.

【Precautions】

1. The test is only suitable for professionals to use in vitro auxiliary diagnosis. Do not use expired products.
2. Do not freeze or use after the expiration date (see the packaging for the expiration date).
3. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should be 15-30 °C and the humidity should be below 70%.
4. The test card bag contains desiccant, and it should not be taking orally.
5. When testing, please wear protective clothing, medical mask, gloves and goggles.
6. Do not use the test card with broken single packaging, unclear marks, and past the expiration date.
7. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.

【Explanation of Symbols】

	DO NOT USE IF PACKAGE IS DAMAGED		CONSULT INSTRUCTIONS FOR USE
	DO NOT REUSE		USE-BY DATE
	TEMPERATURE LIMIT		DATE OF MANUFACTURE
	MANUFACTURER	LOT	BATCH CODE
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	CE	CE MARK
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

【Basic Information】

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【Approval Date and Revision Date of the Instruction】

Approved on 2nd, Sept., 2020.
Version number: CR-InCG27 REV.01

Annex II Clinical Trial Data

Sample number	Test result of Product tested	Test result of reference product
1	positive	positive
2	negative	negative
3	positive	positive
4	negative	negative
5	negative	negative
6	negative	negative
7	positive	positive
8	positive	positive
9	positive	positive
10	negative	negative
11	negative	negative
12	negative	negative
13	positive	positive
14	positive	positive
15	positive	positive
16	negative	negative
17	negative	negative
18	positive	negative
19	positive	positive
20	negative	negative
21	negative	negative
22	negative	negative
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175	negative	negative
176	negative	negative
177	negative	negative
178	positive	positive
179	negative	negative
180	positive	positive
181	positive	positive
182	positive	positive
183	positive	positive
184	negative	negative
185	negative	negative
186	negative	negative
187	negative	negative
188	negative	negative
189	negative	negative
190	negative	negative
191	negative	negative
192	positive	positive
193	negative	negative
194	negative	negative
195	positive	positive
196	negative	negative

197	positive	positive
198	negative	negative
199	positive	positive
200	negative	negative
201	negative	negative
202	negative	negative
203	negative	negative
204	positive	positive
205	positive	positive
206	negative	negative
207	negative	negative
208	negative	negative
209	positive	positive
210	negative	negative

SARS-CoV-2 Antigen Schnelltest
(Nasenabstrich)

Eigenschaften

| Bestimmungsgemäßer Gebrauch

Das Produkt ist für den qualitativen Nachweis von Antigenen gegen SARS-CoV-2 in klinischen Proben (Nasenabstrich) bestimmt. Der SARS-CoV-2-Antigen-Schnelltest soll in Verbindung mit klinischen Manifestationen und anderen Labortestergebnissen verwendet werden, um die Diagnose von Patienten mit Verdacht auf eine SARS-CoV-2-Infektion zu erleichtern. Der Test darf nur von medizinischem Personal verwendet werden. Er liefert nur ein erstes Screening-Testergebnis und es sollten spezifischere, alternative Diagnosemethoden durchgeführt werden, um die Bestätigung einer SARS-CoV-2-Infektion zu erhalten.

Bundesinstitut für Arzneimittel und Medizinprodukte
GELISTET

| Zusammenfassung

Coronavirus ist als große Virusfamilie ein einsträngiges positives RNA-Virus mit Hülle. Das Virus ist dafür bekannt, schwere Krankheiten wie Erkältungen, das Nahost-Atemwegssyndrom (MERS) und das schwere akute Atemwegssyndrom (SARS) zu verursachen. Das Kernprotein von SARS-CoV-2 ist das N-Protein (Nukleokapsid), eine Proteinkomponente, die sich im Inneren des Virus befindet. Es ist bei β-Coronaviren relativ konserviert und wird häufig als Hilfsmittel für die Diagnose von Coronaviren verwendet. ACE2 ist als Schlüsselrezeptor für den Eintritt von SARS-CoV-2 in Zellen von großer Bedeutung für die Erforschung des viralen Infektionsmechanismus.

| Prinzip

Die aktuelle Testkarte basiert auf der spezifischen Antikörper-Antigen-Reaktion und der Immunoanalyse-Technologie. Die Testkarte enthält einen kolloidalen goldmarkierten monoklonalen Antikörper mit dem Protein SARS-CoV-2 N, der auf dem Kombinations-Pad vorbeschichtet ist, einen passenden monoklonalen Antikörper mit dem Protein SARS-CoV-2 N, der auf dem Testbereich (T) immobilisiert ist, und einen entsprechenden Antikörper im Qualitätskontrollbereich (C). Während des Tests verbindet sich das N-Protein in der Probe mit dem kolloidalen, goldmarkierten monoklonalen N-Protein-Antikörper SARS-CoV-2, der auf dem Kombinations-Pad vorbeschichtet ist. Die Konjugate wandern unter Kapillarwirkung nach oben und werden anschließend von dem im Testbereich (T) immobilisierten monoklonalen N-Protein-Antikörper aufgefangen. Je höher der Gehalt an N-Protein in der Probe ist, desto mehr Konjugate werden von den Konjugaten eingefangen und desto dunkler ist die Farbe im Testbereich. Befindet sich kein Virus in der Probe oder ist der Virusgehalt niedriger als die Nachweisgrenze, so ist im Testbereich (T) keine Farbe zu erkennen. Unabhängig davon, ob das Virus in der Probe vorhanden ist oder nicht, erscheint ein violetter Streifen im Qualitätskontrollbereich (C). Der violette Streifen im Qualitätskontrollbereich (C) ist ein Kriterium für die Beurteilung, ob genügend Probe vorhanden ist oder nicht und ob das Chromatographieverfahren normal ist oder nicht.

SARS-CoV-2 Antigen Schnelltest
(Nasenabstrich)

| Produkt-Leistungsindex

1. Physikalische Eigenschaft
1.1 Erscheinungsbild
Die Testkarte soll sauber und unbeschädigt sein, keine Grate, keine Schäden, keine Verschmutzung; das Material soll fest angebracht sein; das Etikett soll klar und nicht beschädigt sein. Die Probenverdünnung soll ohne Verunreinigungen und Flocken klar sein.
1.2 Geschwindigkeit der Flüssigkeitsmigration
Die Flüssigkeitsmigrationsgeschwindigkeit soll nicht weniger als 10mm/min betragen.
1.3 Membran-Streifen-Breite
Die Membranstreifenbreite der Prüfkarte soll ≥ 2,5 mm betragen.
1.4 Die Zubereitungsmenge des Verdünnungsmittels für die Proben
Das Volumen der Verdünnungsmittel für die Probe beträgt nicht weniger als den angegebenen Wert.

2. Nachweisgrenze
Für die Erkennung von Empfindlichkeitsreferenzmaterial soll die positive Erkennungsrate nicht weniger als 90% betragen.

3. Negativreferenz-Produkte Compliance-Rate
Für die Erkennung von negativem Referenzmaterial soll die negative Erkennungsrate 100 % betragen.

4 Positivreferenz-Produkte Compliance-Rate
Für den Nachweis von positivem Referenzmaterial soll die positive Nachweisrate 100 % betragen.

5 Wiederholbarkeit
Für die Erkennung des Referenzmaterials P2 und P4 solln die Ergebnisse positiv und die Farbwiedergabe einheitlich sein.

6. Kreuzreaktivität
Kreuzreaktivität: Dieses Testgerät verfügt über keine Kreuzreaktivität mit dem endemischen menschlichen Coronavirus OC43, Influenza-A-Virus, Influenza-B-Virus, respiratorisches Rynctical-Virus, Adenovirus, das EB-Virus, Masernvirus, Zytomegalie-Virus, Rotavirus, Norwalk Virus, Mumpsvirus, Varizella-Zoster-Virus, Mycoplasma Pneumoniae, humanes Metapneumovirus.

7. Klinische Leistung
210 klinische Proben, die auf den Testergebnissen der Nukleinsäure-Nachweismethode (PCR) basierten, wurden zum Testen erhalten, darunter 75 positive und 135 negative Proben. Das SARS-CoV-2 Antigen-Schnelltest-Kit wurde mit der Nukleinsäuremethode (PCR) unter Verwendung der gesammelten klinischen Proben verglichen. Die Ergebnisse wurden in der folgenden Tabelle zusammengefasst

Methode		PCR		Gesamtergebnis
SARS-CoV-2 Antigen Schnelltest	Ergebnisse	Positiv	Negativ	
	Positiv	69	1	70
	Negativ	6	134	140
Gesamtergebnis		75	135	210

Diagnostische Sensitivität: 69/(69+6)×100% = 92%
95% Konfidenzintervall: [0.8363,0.9628]
Diagnostische Spezifizität: 134/(1+134)×100% = 99,26%
95% Konfidenzintervall: [0.9592,0.9987]

SARS-CoV-2 Antigen Schnelltest
(Nasenabstrich)

Inhalt

Materialien zur Verfügung gestellt	Menge (1 Test / Box)	Menge (25 Tests / Box)
SARS-CoV-2-Antigen-Nachweiskarte	1 Stück	25 Stück
Trockenmittel	1 Stück	25 Stück
Tupfer	1 Stück	25 Stück
Musterbehandlungslösung	1 x 1 ml	2 x 3 ml
Gebrauchsanweisung	1 Stück	1 Stück

Das Produkt besteht aus Testkarten, Gebrauchsanweisung, Musterbehandlungslösung. Und in jedem Testkartenbeutel ist eine SARS-CoV-2-Antigen-Nachweiskarte und eine Packung Trockenmittel enthalten. Die Testkarte besteht aus einer Goldstandard-Matte (beschichtet mit einem kolloidalen, goldmarkierten monoklonalen SARS-CoV-2 N-Protein-Antikörper), einer Probenmatte, einer Nitrozellulose-Membran (Testbereich (T) ist mit einem monoklonalen SARS-CoV-2 N-Protein-Antikörper beschichtet; Der Qualitätskontrollbereich (C) ist mit einem Ziegen-Anti-Maus-Antikörper beschichtet, enthält Saugpapier und eine hydrophoben, steifen Karte.

Lagerung

Der Testkit soll bei 4°C~ 30°C gelagert, trocken und vor Sonnenlicht geschützt aufbewahrt werden. Die Haltbarkeit beträgt 12 Monate. Jede Testkarte soll innerhalb von 1 Stunde nach der Entsiegelung verwendet werden. Produktionsdatum und Verfallsdatum sind auf dem Beipackzettel angegeben.

Probenanforderungen

Das Produkt wird zum Test von menschlichen Nasenabstrichproben verwendet.
Probenentnahme: Achten Sie während der Probenentnahme auf einen angemessenen Schutz und vermeiden Sie direkten Kontakt mit der Probe. Bei versehentlichem Kontakt soll die Desinfektionsbehandlung rechtzeitig durchgeführt und die erforderlichen Maßnahmen ergriffen werden.
Nasenabstrichprobe: Während der Probenahme soll der Tupferkopf vollständig in die Nasenhöhle eingeführt und vorsichtig 5 mal gedreht werden. Nach der Entfernung soll mit dem Tupferkopf in der anderen Nasenhöhle auf die gleiche Weise eine Probe entnommen werden, um sicherzustellen, dass genügend Probenmaterial entnommen wurde.
Probenkonservierung: nach der Probenentnahme schließen Sie bitte den Test innerhalb von 1 Stunde ab.
Die Probe soll vor dem Testen Raumtemperatur erreichen.

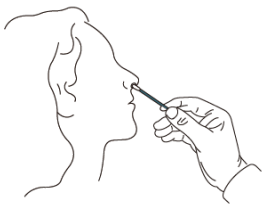
SARS-CoV-2 Antigen Schnelltest
(Nasenabstrich)

Anwendung

Testverfahren

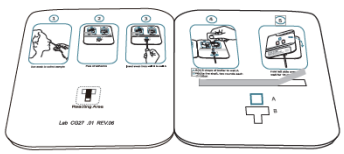
Bitte lesen Sie die Anleitung sorgfältig durch, bevor Sie den Test durchführen. Bringen Sie die Reagenzien und die Probe vor dem Testen wieder auf Raumtemperatur.

1



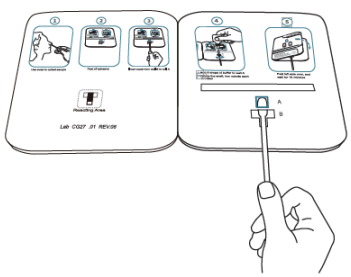
Während der Probennahme soll der Tupferkopf vollständig in die Nasenhöhle eingeführt und vorsichtig 5 Mal gedreht werden. Nach der Entfernung soll mit dem Tupferkopf in der anderen Nasenhöhle auf die gleiche Weise eine Probe entnommen werden, um sicherzustellen, dass genügend Probenmaterial entnommen wurde.

2



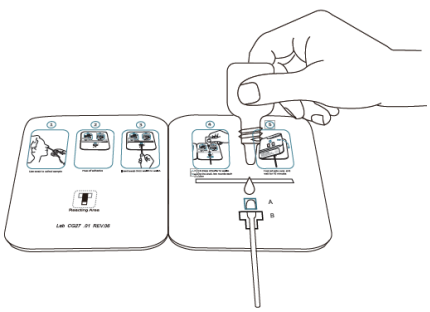
Vor dem Test soll die doppelseitig haftende Schutzschicht entfernt werden, um ein Spritzen von Flüssigkeit zu verhindern. Wenn die doppelseitig haftende Schutzschicht nach Zugabe von Verdünnungsmittel abgerissen wird, kann leicht Flüssigkeitsspritzen verursacht werden.

3



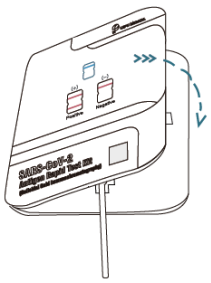
Fädeln Sie die Tupferprobe durch den Boden der Vertiefung B in die Vertiefung A.

4



Geben Sie 6 Tropfen des Verdünnungsmittels in Vertiefung A. Tropfen Sie kein Verdünnungsmittel in die anderen Vertiefungen. Drehen Sie den Tupferkopf, zwei Runden in jede Richtung. Während des Tests soll die Testkarte auf dem horizontalen Desktop platziert werden. Die Testkarte soll fixiert sein. Entfernen Sie die Testkarte nicht.

5



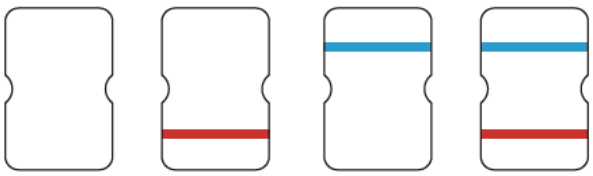
Drücken Sie nach dem Abdecken der linken Seite vorsichtig auf die Klebeposition, damit die beiden Seiten vollständig passen, und beginnen Sie mit der Zeitmessung. Warten Sie, bis das lila Band erscheint. Das Testergebnis soll innerhalb von 15-20 Minuten abgelesen werden.

SARS-CoV-2 Antigen Schnelltest
(Nasenabstrich)

Interpretation Ergebnisse

Positiv (+)
Es erscheinen violette Streifen sowohl im Qualitätskontrollbereich (C) als auch im Testbereich (T).

Negativ (-)
Es gibt nur einen violetten Streifen im Qualitätskontrollbereich (C) und keine violetten Streifen in beiden Testbereichen (T).



Ungültig
Es gibt keinen violetten Streifen im Qualitätskontrollbereich (C), oder es gibt einen blauen Streifen im Qualitätskontrollbereich (C), was auf falsche Betriebsverfahren hinweist, oder die Testkarte ist bereits nicht verwendbar. In diesem Fall lesen Sie nochmal sorgfältig die Gebrauchsanweisung und verwenden Sie dann eine neue Testkarte. Wenn das Problem weiterhin besteht, stellen Sie die Verwendung der Produkte mit derselben Chargennummer ein und wenden Sie sich umgehend an die örtlichen Lieferanten.

Verfahrenseinschränkung

1. Die Testergebnisse dieses Produkts sollen vom Arzt in Kombination mit anderen klinischen Informationen umfassend beurteilt werden und sollen nicht als einziges Kriterium herangezogen werden;
2. Das Produkt wird verwendet, um das SARS-CoV-2-Antigen der klinischen Probe zu testen.

SARS-CoV-2 Antigen Schnelltest
(Nasenabstrich)

Warnung

1. Der Test ist nur für Fachleute geeignet, die eine In-vitro-Hilfsdiagnostik anwenden. Abgelaufene Produkte dürfen nicht verwendet werden.
2. Nicht einfrieren oder nach dem Verfallsdatum verwenden (das Verfallsdatum ist auf der Verpackung angegeben).
3. Vermeiden Sie übermäßige Temperatur und Feuchtigkeit in der Experimentalumgebung. Die Reaktionstemperatur soll 15-30° C betragen und die Luftfeuchtigkeit unter 70% liegen.
4. Der Testkartenbeutel enthält Trockenmittel und darf nicht oral eingenommen werden.
5. Bitte tragen Sie beim Testen Schutzkleidung, medizinische Maske, Handschuhe und Schutzbrille.
6. Verwenden Sie die Testkarte nicht mit zerbrochener Einzelverpackung, undeutlichen Markierungen und nach Ablauf des Verfallsdatums.
7. Entsorgen Sie gebrauchte Proben, Testkarten und andere Abfälle in Übereinstimmung mit den einschlägigen örtlichen Gesetzen und Vorschriften.
8. Die Testkarte soll innerhalb von 1 Stunde nach Entnahme aus dem Aluminiumfolienbeutel verwendet werden.
9. Die Benutzer sollen Proben gemäß den Anforderungen der IFU entnehmen.
10. Vor dem Test die doppelseitig haftende Schutzschicht entfernen, um Flüssigkeitsspritzer zu vermeiden. Wenn die doppelseitig haftende Schutzschicht nach Zugabe von Verdünnungsmittel abgerissen wird, kann es leicht zu Flüssigkeitsspritzern kommen.
11. Das Verdünnungsmittel nicht in die falsche Vertiefung tropfen lassen.
12. Während des Tests soll die Testkarte auf den horizontalen Tisch platziert werden. Die Testkarte soll fixiert sein und darf nicht entfernt werden.

CE Dieses Produkt erfüllt die Anforderungen der Richtlinie 98/79/EG über In-vitro Diagnostik und Medizinprodukte

Bitte lesen Sie sich vor dem Gebrauch die Bedienungsanleitung sorgfältig durch.

Zum einmaligen Gebrauch.

Lagern Sie die Tests bei einer Temperatur zwischen 4°C und 30°C.

Vor Sonnenlicht schützten

Trocken lagern

SARS-CoV-2 Antigen Schnelltest
(Nasenabstrich)

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security and Vaccination

EU health preparedness:

A common list of COVID-19 rapid antigen tests, including those of which their test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

on 17 February 2021

I. Introduction

Robust testing strategies are an essential aspect of preparedness and response to the COVID-19 pandemic, allowing for early detection of potentially infectious individuals and providing visibility on infection rates and transmission within communities. Moreover, they are a prerequisite to adequate contact tracing to limit the spread through prompt isolation. Also in the context of the circulation of SARS-CoV-2 variants of concern, surge testing in addition to existing testing deployment has proven to be key for controlling and suppressing further spread of the virus.

While the reverse transcription real-time polymerase chain reaction (RT-PCR) assay, which is a nucleic acid amplification test (NAAT) remains the 'gold standard' for COVID-19 diagnosis, new tests are rapidly entering the market, allowing faster and cheaper ways to detect ongoing infection. Rapid antigen tests, which detect the presence of viral proteins (antigens), are increasingly being used by Member States as a way of further strengthening countries' overall testing capacity, particularly in case of limited NAAT capacities or where prolonged testing turnaround times results in no clinical utility.

The Health Security Committee agreed on 17 September 2020 on Recommendations for a common EU testing approach for COVID-19[1], setting out various actions for consideration by countries when updating or adapting their testing strategies. The Recommendations included Member States' first experiences with rapid antigen tests and their deliberations concerning the settings and situations in which these tests should be used. Since then, the Committee has been discussing the use and application of rapid antigen tests in great depth, and has brought together a wealth of (technical) information on the types of tests used in European countries and the conditions applied.

On 21 January 2021, Member States unanimously agreed on a Council recommendation setting a common framework for the use of rapid antigen tests and the mutual recognition of COVID-19 test results across the EU[2]. The Council recommendation called on Member States to agree on three concrete deliverables:

1. **A common list of COVID-19 rapid antigen tests** that are considered appropriate for use in the context of the situations described in the Council Recommendation, that are in line with countries' testing strategies and that:
    a. carry CE marking;
    b. meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and
    c. have been validated by at least one Member State as being appropriate for their use in the context of COVID-19, providing details on the methodology and results of such studies, such as the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

[1] https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/common_testingapproach_covid-19_en.pdf
[2] https://data.consilium.europa.eu/doc/document/ST-5451-2021-INIT/en/pdf

2. A selection of rapid antigen tests of which Member States will **mutually recognise the test results for public health measures**.
3. **A common standardised set of data to be included in COVID-19 test result certificates**, further facilitating the mutual recognition of COVID-19 test results.

Based on the information collected by the Health Security Committee, and taking into consideration the current epidemiological situation and the testing strategies and approaches that have been put in place across the EU, this document sets out the three deliverables as agreed by Member States. Its content is prepared based on the criteria set out in the Council Recommendation and considers the relevant recommendations published by the Commission[3] and technical guidance issued the European Centre for Disease Prevention and Control (ECDC)[4] and the World Health Organization (WHO)[5].

II. Common list of rapid antigen tests

Point 11 of the Council Recommendation of 21 January 2021, calls on Member States to, without prejudice to Directive 98/79/EC, agree on and maintain a common and updated list of COVID-19 rapid antigen tests that are considered appropriate for use in the context of the situations described under point 6 and are in line with countries' testing strategies. Moreover, the antigen tests included in the list should:

(a) Carry CE marking;
(b) Meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and
(c) Have been validated by at least one Member State as being appropriate for their use in the context of COVID-19, providing details on the methodology and results of such studies, such as the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

This list should be shared with ECDC and the Commission to prevent duplication of work and to feed into ongoing initiatives, particularly in the context of the redevelopment of the "COVID-19 In Vitro Diagnostic Devices and Test Methods" database[6], hosted by the Joint Research Centre (JRC). As referred to in the Commission Communication of 19 January[7], the JRC will play a role in establishing a common list of rapid antigen tests and their uses, as agreed by Member States and with support from the Health Security Committee.

Annex I to this document sets out a common list of rapid antigen tests that, as of 17 February 2021 meet the criteria as specified above. This list will serve as a basis for the JRC to redevelop and update its COVID-19 testing database, with the aim of incorporating the

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595 and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H1743&from=EN
[4] https://www.ecdc.europa.eu/en/publications-data/options-use-rapid-antigen-tests-covid-19-eueea-and-uk
[5] https://www.who.int/publications/i/item/9789240017740
[6] https://covid-19-diagnostics.jrc.ec.europa.eu/devices
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0035&from=EN

information in this platform and ensuring that the common list as agreed by Member States will be publicly available online.

The common list of rapid antigen tests will be regularly reviewed by Member States in the context of Health Security Committee meetings, and, if necessary, be updated in line with new results from independent validation studies becoming available and new tests entering the markets. Future updates to the list should also take into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of NAAT, in particular RT-PCR assays, will also be kept under review.

Future updates to the common list of rapid antigen tests will be published as an update to the JRC database on COVID-19 In Vitro Diagnostic Devices and Test Methods.

III. Rapid antigen tests of which the test results are mutually recognised

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, Member States agree that the results of the following rapid antigen tests will be mutually recognised for public health measures:

- Abbott Rapid Diagnostics, Panbio™ COVID-19 Ag Rapid Test
- AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag
- Becton Dickinson, BD Veritor System for Rapid Deteciton os SARS-CoV-2
- Beijing Lepu Medical Technology, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)
- BIOSYNEX SWISS SA, BIOSYNEX COVID-19 Ag BSS
- CerTest Biotect S.L., CerTest SARS-CoV-2 CARD TEST
- Hangzhou Clongene Biotech, Clungene COVID-19 Antigen Rapid Test Kit
- Healgen Scientific Limited, Coronavirus Ag Rapid Test Cassette (Swab)
- LumiraDX UK LTd, LumiraDx SARS-CoV-2 Ag Test
- nal von minden GmbH, NADAL COVID -19 Ag Test
- Quidel Corporation, Sofia 2 SARS Antigen FIA
- SD BIOSENSOR, Inc.; Roche, STANDARD F COVID-19 Ag FIA
- SD BIOSENSOR, Inc.; Roche, STANDARD Q COVID-19 Ag Test
- Siemens Healthineers, CLINITEST Rapid COVID-19 Antigen Test
- Xiamen Boson Biotech Co, Rapid SARS-CoV-2 Antigen Test card
- Zhejiang Orient Gene Biotech Co.,Ltd, Coronavirus Ag Rapid Test Cassette (Swab)

The JRC will specify in its updated database the specific rapid antigen tests of which Member States mutually recognise their test results.

Whenever Member States will review the common list of rapid antigen tests and consider whether any tests should be added or deleted, they will also take into account – also based on new results from independent national validation studies - whether any rapid antigen tests should be removed from or added to the selection of rapid antigen tests of which their results are being mutually recognised. This information will be provided to the JRC, who will update its database accordingly.

Future updates to the agreed list of rapid antigen tests of which the results are mutually recognised, will be published as an update to the JRC database on COVID-19 In Vitro Diagnostic Devices and Test Methods.

IV. Common standardised set of data for COVID-19 test certificates

In order to facilitate in practice the mutual recognition of results of rapid antigen tests as well as NAAT, including RT-PCR assays, point 18 of Council Recommendation 2020/1475 defines that Member States should agree on a common standardised set of data to be included in the form for test result certificates.

Based on information that was submitted by members of the Health Security Committee in response to a survey on mutual recognition on COVID-19 test results and further discussions that took place in the context of the Health Security Committee, Member States agree on the common standardised set of data for COVID-19 test result certificates as presented in Annex II.

Member States agree that COVID-19 test results should be made available in the national language(s) of the country where the test was taken, as well as English.

The dataset was agreed by taking into consideration the guidelines that were published by the eHealth Network on proof of vaccination for medical purposes, setting out basic interoperability elements[8]. While these guidelines aim to support interoperability between vaccination certificates rather than COVID-19 test results, they provided helpful input regarding minimum data that would enable basic information to be captured and represented in a structured manner that facilitates sharing and interpretation. Moreover, should Member States wish to standardise COVID-19 test results and COVID-19 vaccination, streamlining of datasets facilitates such processes.

The Health Security Committee will discuss, whenever relevant, possible updates to the agreed common standardised set of data for COVID-19 test certificates, and publish, if necessary, an updated agreed document.

[8] https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

V. Continuous discussions and further work on the common rapid antigen tests list and common dataset for COVID-19 test result certificates

As described in the sections above, the content of this document, as agreed by the Health Security Committee on 17 February 2021, will continue to be discussed by Member States and updated whenever deemed relevant.

Whenever updates are required, these will either be published as an update to this current document or as an update to the JRC database on COVID-19 In Vitro Diagnostic Devices and Test Method, depending on scope of the required update and when the redeveloped database by JRC will be available.

In the context of the ongoing discussions and, if relevant, future updates to the current document, Member States have raised the following points that require particular attention:

Common RAT list

- **Harmonised methodology for national validation studies on the clinical performance of rapid antigen tests**

This will be addressed by future guidelines to be developed by the JRC and the ECDC, also taking into consideration the implementation guide published by WHO on 21 December 2020 on SARS-CoV-2 antigen-detecting rapid diagnostic tests[9].

Moreover, Member States will continue sharing details via the HSC on the implementation of national validation studies, particularly concerning the validation methodologies and protocols applied.

- **Quality of data produced through independent validation studies**

It is key that the sensitivity levels of the rapid antigen tests, as reported by independent national validation studies, reflect clinical performance as measures in practice, rather than the sensitivity reported by the manufacturer. In this context, the JRC is planning to verify the science behind the validation data that has been made available from the Member States through the Health Security Committee, and to verify the findings (eventually in laboratory settings). For the validation of rapid antigen tests, the JRC plans to use the "gold standard" method of NAAT, in particular RT-PCR, by benchmarking the antigen test samples against qPCR and digital PCR.

Moreover, Member States will continue sharing details via the HSC on the results produced by national validation studies, particularly concerning the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

[9] https://www.who.int/publications/i/item/9789240017740

- **Occurrence of SARS-CoV-2 variants of concern**

Future updates to the common rapid antigen tests list should also take into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARSCoV-2 virus on the efficacy of RT-PCR tests should also be kept under review. In particular, in the current context of circulation of variants of concern, the use of rapid antigen tests does not allow samples to be used for subsequent detection of new variants (by NAAT and/or sequencing).

Mutual recognition of COVID-19 test results

- **Criteria to be used for the mutual recognition of rapid antigen test results**

At the moment, the extent to which rapid antigen tests are being used in practice by Member States differs greatly. In this context, Member States have agreed that, for now, the criterion that at least 3 Member States should be using a specific type of rapid antigen test in practice for it to be mutually recognised, applies. Member States will further discuss and explore whether other criteria should be used in the future. It is key that such discussions are held in the context of quality assurance measures.

- **Context in which mutual recognition should be applied**

Member States should further discuss the situation in which there is a need for mutual recognition of rapid antigen test results (as well as other COVID-19 test results). In addition to the context of travel, it is relevant to further discuss between countries when the list of rapid antigen tests of which their results will be mutually recognised should be applied.

COVID-19 test result certificates

- **Possible creation of a digital platform**

As also called for by the Council Recommendation of 21 January, Member States will explore the need and possibility, including time and cost considerations, for the creation of a digital platform, that can be used to validate the authenticity of standardised COVID-19 test certificates. Member States that are developing or that have already such digital systems in place will share their experiences in this regards. In the context of these discussions, the eHealth Network and in particular their semantic experts in Member States, will be closely involved.

ANNEX I: Common list of rapid antigen tests, as agreed by Member States on 17 February 2021

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	Yes	91.4% sensitivity, 99.8% specificity NP swab	FIND Evaluation - Studies in DE and CH, NP swab, 10 Dec 2020	93.3% sensitivity 99.4% specificity NP Swab 98.1% sensitivity 99.8% specificity Nasal swab	91.4% sensitivity 99.8% specificity		AT, BE, BG, CY, CZ, DE[2], EL, ES, FR[1], HR, IT, MT, NL[5], PL, PT, RO, SE, SK	CH, ME, MK, NO, UK, UA	DE, ES, NL[5], CH, NO	CY, ES, HR, HU, IE, LU, PT, SE	Yes	Yes
AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	Yes	97.3% sensitivity 100% specificity NP swab 97.3% sensitivity 98.8% specificity Nasal swab		97.3% sensitivity 100% specificity NP swab		97.3% sensitivity 100% specificity NP swab	BE, BG, DE[2] HR, SI,	CH, UA	DE	HR	Yes	Yes
Becton Dickinson	BD Veritor System for Rapid Deteciton os SARS-CoV-2	Yes	93.5% sensitivity 99.3% specificity Nasal swab					DE[2], ES, NL[5], SE	CH, UA	DE, ES, NL[5]	SE[3]	Yes	Yes
Beijing Lepu Medical Technology	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	92% sensitivity unknown specificity Nasal swab		92% sensitivity 99.3% specificity Nasal swab		92% sensitivity 99.2% specificity NP swab	BE, DE[2], SI	UA	DE		Yes	Yes
Beijing Wantai Biological Pharmacy Enterprise Co Ltd	WANTAI SARS-CoV-2 Ag Rapid Test (FIA)	Yes	96.6% sensitivity unknown specificity Nasal swab					DE[2]		DE		Yes	Yes
BIONOTE	NowCheck® COVID-19 Ag Test	Yes	89.2% sensitivity 97.6% specificity NP/Nasal swab	FIND Evaluation - Study in Brazil, NP swab, 10 Dec 2020				DE[2]	CH	DE		Yes	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	Yes	Not specified		96% sensitivity 100% specificity NP swab			BE, DE[2], FR, NL[5]	CH	DE, NL[5]		Yes	Yes
CerTest Biotect S.L.	CerTest SARS-CoV-2 CARD TEST	Yes	92.9% sensitivity 99.6% specificity NP swab		92.9% sensitivity 99.6% specificity NP swab		92.9% sensitivity 98.4% specificity NP/OP swab	DE[2], ES, SI		ES		Yes	No
GenBody Inc	GenBody COVID-19 Ag Test	Yes	90% sensitivity 98% specificity NP/OP swab	Withdrawn				DE[2]	UA	DE		Yes	Yes
Guangdong Wesail Biotech Co. Ltd	COVID-19 AG Test Kit	Yes	90% sensitivity 98% specificity NP/Nasal swab				90% sensitivity 98% specificity NP/Nasal swab	DE[2], SI		DE		Yes	No
Hangzhou Clongene Biotech	Clungene COVID-19 Antigen Rapid Test Kit	Yes	98.5% sensitivity unknown specificity Nasal swab		91.4% sensitivity 100% specificity NP/OP swab		91.4% sensitivity 100% specificity NP/OP swab	BE, DE[2], FR, SI	CH	DE	HR	Yes	No
Healgen Scientific Limited	Coronavirus Ag Rapid Test Cassette (Swab)	Yes					96.7% sensitivity 99.2% specificity NP/Nasal swab	DE[2], NL[5], SE, SI		NL[5]	SE[3]	No	No
Joinstar Biomedical Technology	COVID-19 Antigen Rapid Test (Colloidal Gold)	Yes	96.1% sensitivity 98.1% specificity Nasal swab				96.1% sensitivity 98.1% specificity NP swab	DE[2], SI		DE		Yes	Yes
LumiraDX UK LTd	LumiraDx SARS-CoV-2 Ag Test	Yes	97.6% sensitivity 96.7% specificity Nasal swab				97.6% sensitivity 97.7% specificity NP/Nasal swab	DE[2], ES, SI	CH	DE, ES		Yes	No
MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	Yes	92.5% sensitivity 99.8% specificity NP/OP swab		92.5% sensitivity 99.8% specificity Nasal/OP swab			BE, DE[2]	CH	DE		Yes	No

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
MP Biomedicals Germany	Rapid SARS-CoV-2 Antigen Test Card	Yes	96.39% sensitivity 99.03% specificity Nasal swab		96.4% sensitivity 99% specificity NP/OP swab			BE, DE[2]	CH	DE		Yes	No
nal von minden GmbH	NADAL COVID -19 Ag Test	Yes	97.6% sensitivity 99.9% specificity Nasal swab		97.6% sensitivity 99.9% specificity NP/OP swab		97.6% sensitivity 99.9% specificity NP/OP swab	AT, BE, DE[2], SI		DE	HR	Yes	No
Precision Biosensor Inc (Axon Lab SG)	Exdia COVI-19 Ag Test	Yes	93.9% sensitivity 98% specificity NP swab				93.9% sensitivity 98% specificity NP swab	SI	CH	DE		Yes	Yes
Qingdao Hightop Biotech Co Ltd	SARS-CoV-2 Antigen Rapid Test	Yes	95% sensitivity unknown specificity Nasal swab					DE[2]		DE		Yes	No
Quidel Corporation	Sofia 2 SARS Antigen FIA	Yes	96.7% sensitivity 100% specificity NP/Nasal swab		96.7% sensitivity 100% specificity NP/nasal swab		96.7% sensitivity 100% specificity NP/Nasal swab	AT, BE, DE[2], FI, NL[5], SI	CH	DE, NL[5]	SI	Yes	Yes
Safecare Biotech Hangzhou Co	COVID-19 Ag Rapid Test Kit (Swab)	Yes	97.04% sensitivity unknown specificity Nasal swab					DE[2], FR	CH	DE		Yes	No
SD BIOSENSOR, Inc.; Roche	STANDARD F COVID-19 Ag FIA	Yes		FIND Evaluation - Studies in DE and Brazil, 10 Dec 2020	96.5% sensitivity 99.7% specificity NP swab			BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK		DE, IT, NL[5]	LU, PT	No	Yes
SD BIOSENSOR, Inc.; Roche	STANDARD Q COVID-19 Ag Test	Yes	96.52% sensitivity 99.68% specificity NP swab	FIND Evaluation - Studies in DE, CH and Brazil, 10 Dec 2020	96.5% sensitivity 99.7% specificity NP swab		96.5% sensitivity 99.7% specificity NP swab	AT, BE, BG, CY, DE[2], ES, FI, FR, HR, IT, LU, LV, MT, NL[5], RO, SE, SK, SI	ME, NO, CH	DE, ES, IT, NL[5], CH, UA	HR, IE, LU, SI, SE	Yes	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	Yes	96.72% sensitivity 96.72% specificity Nasal swab		98.32% sensitivity 99.6% specificity NP swab 97.25% sensitivity 100% specificity Nasal swab		96.7% sensitivity 99.2% specificity NP/Nasal swab	AT, BE, DE[2], FR, HR, NL[5], SE, SI		DE, NL[5]	ES, HR, PT, SE[3]	Yes	Yes
Xiamen Boson Biotech Co	Rapid SARS-CoV-2 Antigen Test card	Yes	Not specified		93.8% sensitivity 100% specificity NP swab			BE, BG, DE[2], FR	CH	DE		Yes	Yes
Zhejiang Orient Gene Biotech Co.,Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	Yes	96.72% sensitivity unknown specificity Nasal swab		98.32% sensitivity 99.6% specificity NP swab 97.25% sensitivity 100% specificity Nasal swab			AT, BE, BG, DE[2]	UK	DE	SE[3]	Yes	No

Notes:

[1] FR: Reference to validation study (not specifying which specific RAT is being recommended or was tested in practice): https://www.has-sante.fr/upload/docs/application/pdf/2020-10/synthese_tests_antigeniques_vd.pdf

[2] DE: Rapid antigen tests that fulfils the defined minimum criteria for reimbursement in Germany. See: https://antigentest.bfarm.de/ords/antigen/r/antigentests-auf-sars-cov-2/liste-der-antigentests?session=13130597074531

[3] SE: Smaller evaluations ongoing in some of the regions.

[4] BE: In the clinical performance study performed in three different clinical laboratories during the ascendant phase of the epidemiological curve, we found an overall sensitivity and specificity of 57.6 and 99.5%, respectively with an accuracy of 82.6%.

[5] NL: Collected validation data from accredited laboratories in the Netherlands. The report includes evaluations of various RAT that labs performed at their own initiative. https://lci.rivm.nl/antigeensneltesten

ANNEX II: Common standardised set of data to be included in COVID-19 test result certificates, as agreed by Member States on 17 February 2021

Section	Data element	Description	Preferred Code System
Person identification	Person name	The legal name of the tested person	
	Person identifier (optional)	An identifier of the tested person, according to the policies applicable in each country. It should be captured what type of identifier is used. Examples: citizen ID card or identifier within the health system/IIS/e-registry.	
	Person date of birth	Tested person's date of birth. Mandatory if no Person identifier is provided.	Complete date, without time, following the ISO 8601.
Test information	Type of test	Description of the type of test that was conducted, e.g. RT-PCR or rapid antigen test. In the case of a rapid antigen tests, the form should provide details on the manufacturer and commercial name of the test used.	
	Disease or agent targeted	Specification that it concerns the detection of SARS-CoV-2 infection	
	Sample origin (optional)	The type of sample that was taken (e.g. nasopharyngeal swab, oropharyngeal swab, nasal swab, saliva)	
	Date and time	Date and time when the test was taken. In case of NAAT, e.g. RT-PCR, the certificate should also specify when the test result was produced.	Complete date, without time, following ISO 8601
	Result of the test	Negative or positive	
	Testing centre or facility	Name/code of testing centre, facility or a health authority responsible for the testing event. Optional: address of the testing facility	
	Health Professional identification (optional)	Name or health professional code responsible for conducting (and validating) the test	
	Country where the test was taken	The country in which the individual was tested	ISO 3166 Country Codes
Test certificate metadata	Test result issuer	Entity that issued the COVID-19 test result certificate (allowing to check the certificate)	
	Certificate identifier (optional)	Reference of the COVID-19 test result certificate (unique identifier)	

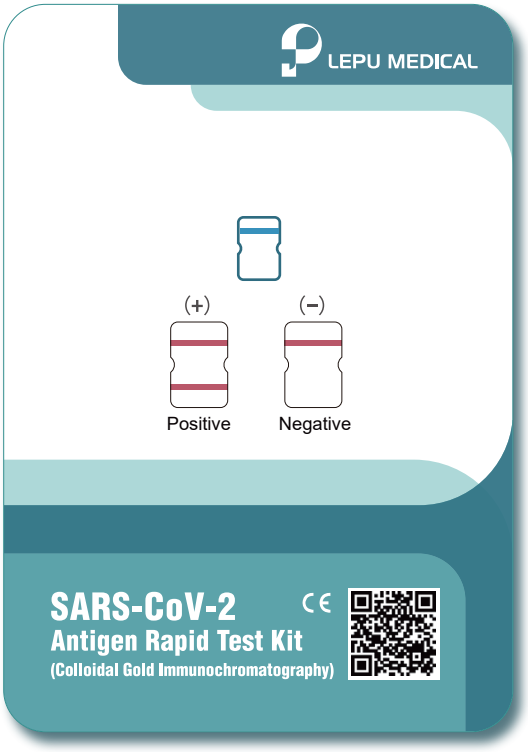
OSSENBERG
Qualität fest im Griff

SARS-CoV-2

CE

Antigen Schnelltest

(Kolloidale Gold-Immunochromatographie)



① Nicht-invasiv

② Einfach zu bedienen

③ Bequem, keine Geräte erforderlich

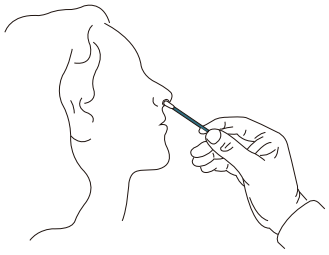
④ Schnell, Ergebnis in 15 Minuten

⑤ Stabil, mit hoher Genauigkeit

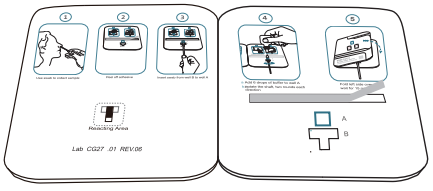
⑥ Kostengünstig, Kosteneffizient

Krankenhaus | Testzentrum | Flughafen | Nah- und Fernverkehr | Hotel | Unternehmen | Massen Untersuchung

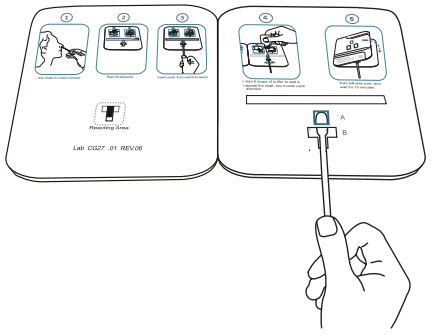
Anweisung



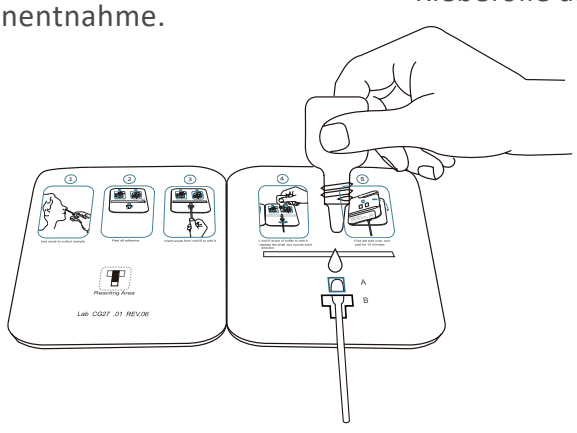
Schritt 1:
Verwenden Sie den Tupfer zur Probenentnahme.



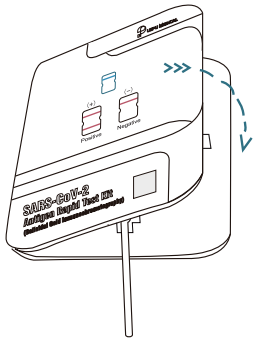
Schritt 2:
Ziehen Sie die Klebefolie ab.



Schritt 3:
Tupfer von Vertiefung B in Vertiefung A fädeln.



Schritt 4:
a. Geben Sie 6 Tropfen des Verdünnungsmittels in Vertiefung A.
b. Drehen Sie den Tupferkopf, zwei Runden in jede Richtung.



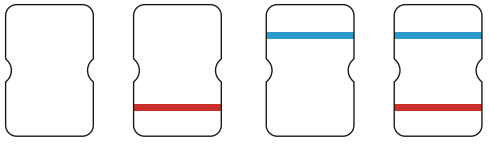
Schritt 5:
Falten Sie die linke Seite um und warten Sie 15 Minuten

Ergebnis-Interpretation

Positiv (+)

Negativ (–)

Ungültig



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