Bundesinstitut für Arzneimittel und Medizinprodukte

Paul-Ehrlich-Institut

AmonMed

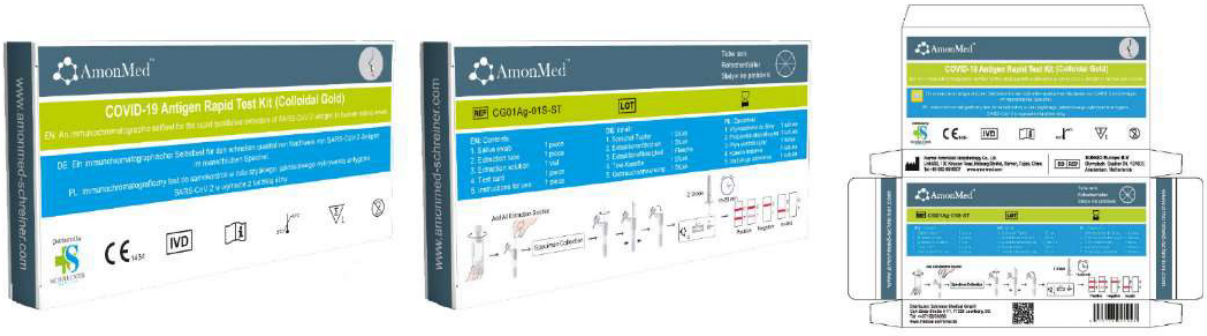
AmonMed Covid-19 Antigen Lollitest

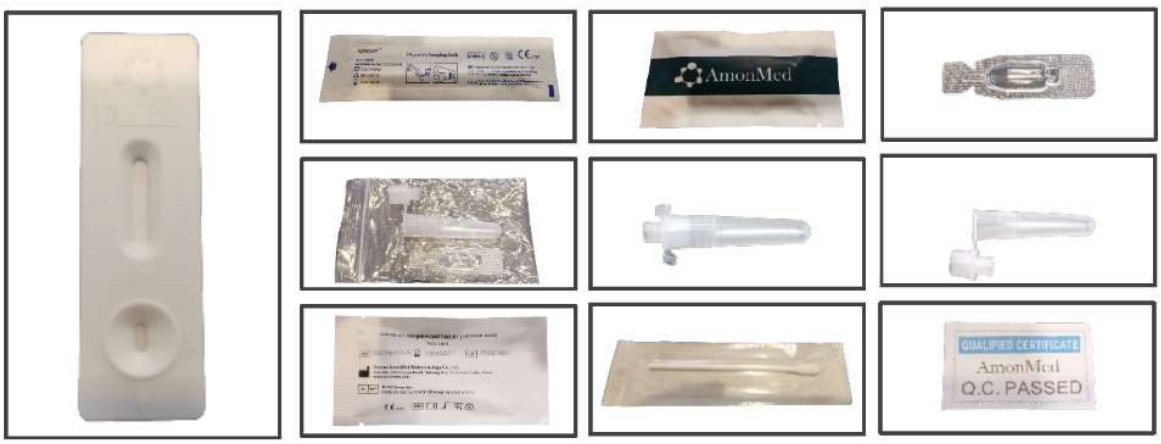
Laientest / Selbsttest mit CE1434 (1er verpackt)

Omikron-Variante (B.1.1.529) erkennen

Hersteller	Xiamen AmonMed Biotechnology Co., Ltd
Rep	SUNGO Europe B.V.
CE	**CE1434 seit 15.10.2021**
BfArM Nummer	**AT1279/21**
Paul-Ehrlich-Institut	**evaluiert**
EU List	**Device #1763**
HSC Common List	**ja**
Empfindlichkeit	96,55%
Spezifität	99,00%
Genauigkeit	98,86%

Varianten (SKU)	**1er verpackt**
Inhalt pro Karton/VPE	**500 St.**
Abmessungen Karton	
Gebrauchsanleitung	auf Deutsch





			Hersteller		Europäischer Bevollmächtigter		
Test-ID	Name des Tests	Evaluierung PEI	Name	Land	Name	Land	Probennahme
AT1279/21	COVID-19 Antigen Rapid Test Kit (Colloidal G...	Ja	Xiamen AmonMed Biotechnology Co., Ltd.	CN	SUNGO Europe B.V.	NL	Speichel

letzte Änderung: 09.12.2021 15:09

Comparative sensitivity evaluation for 122 CE-marked rapid diagnostic tests for SARS-CoV-2 antigen

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25–<30	Cq ≥ 30	Cq 17–36
Subgroup of RDT with detection rates of 100% for Cq ≤ 25 and of >75% for Cq >25–<30						
77	Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	100.0%	95.7%	40.0%	86.0%
84	Toda Pharma	Toda Coronadiag Ag	100.0%	95.7%	40.0%	86.0%
79	Shenzhen Watmind Medical Co.,Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	100.0%	95.7%	20.0%	82.0%
86	ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	100.0%	95.7%	20.0%	82.0%
50	LumiQuick Diagnostics, Inc.	QuickProfile Covid-19 Antigen Test Card	100.0%	91.3%	20.0%	80.0%
72	ScheBo Biotech AG	ScheBo SARS-CoV-2 Quick Antigen	100.0%	91.3%	10.0%	78.0%
7	AmonMed (Xiamen) Biotechnology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	100.0%	87.0%	30.0%	80.0%
19	Beijing Tigsun Diagnostics Co.;Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	100.0%	87.0%	30.0%	80.0%

CERTIFICATE

EC Certificate No. 1434-IVDD-467/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Xiamen AmonMed Biotechnology Co., Ltd

Unit 503, 120 Xinyuan Road, Haicang District,
Xiamen, Fujian, China

in vitro diagnostic medical devices
for self-testing

COVID-19 Antigen Rapid Test Kit (Colloidal Gold)

Saliva specimen

CG01Ag-01S-ST, CG01Ag-05S-ST, CG01Ag-25S-ST

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 15.10.2021 to 27.05.2024

The date of issue of the Certificate: 15.10.2021

The date of the first issue of the Certificate: 15.10.2021

CE 1434

Issued under the Contract No. MD-128/2021
Application No: 233/2021
Certificate bears the qualified signature.
Warsaw, 15/10/2021
Module A1
FBM-30-E_10

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.10.15 13:27:16 +02'00'

Vice-President

中国科学院海西研究院转化医学中心

Translational Medicine Research Center, Haixi Institutes
Chinese Academy of Sciences

Report of COVID-19 Antigen Rapid Test Kit (Colloidal Gold) about Omicron variant strain

Date: 2021-12-02

Product Name: COVID-19 Antigen Rapid Test Kit (Colloidal Gold)

Package: 1 Test/Kit

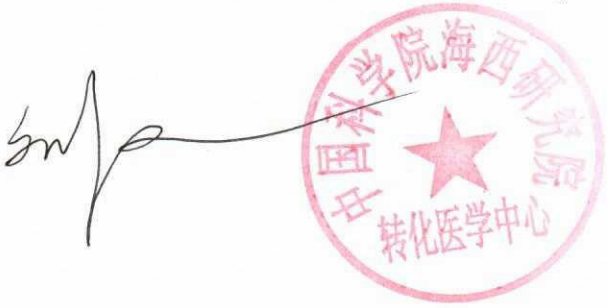
REF. No.: CG01Ag-01

Manufacturer: Xiamen AmonMed Biotechnology Co., Ltd.

Company Address: Unit 503, No. 120 Xinyuan Road, Haicang District, Xiamen, Fujian, China

Translational Medicine Research Center, Haixi Institutes, Chinese Academy of Sciences

Authorized Signature & Seal:



Tel: +86-592-3594011/01
E-mail: xiaozhang@fjirsm.ac.cn
http://www.xmirem.ac.cn/kydw/kytd/ktz9/ktz9/
No. 258 Duishan Xiheng Road, Jimei District, Xiamen 361021, P.R. China

Information of AmonMed COVID 19 Antigen Rapid Test Kit (Colloidal Gold) about Omicron variant strain

The Translational Medicine Research Center was conducted from Alpha variant strains base on routine bioinformatics analysis and laboratory verification have been carried out. Computer stimulation data and key mutant sites pseudovirus experimental results have comfrimed that AmonMed COVID 19 Antigen Rapid Test Kit (Colloidal Gold) can detect major Novel coronavirus variant strain, including the Delta variant strain which has been validated by a large number of clinical tests. According to bioinformatics comparison of the novel Coronavirus "Omicron" variant strain found in South Africa at present. The new variant strain B.1.1.529 has about more than 50 mutation sites, including 32 mutation sites on S protein and 4 mutation sites on N protein, of which 3 mutation sites have appeared in the last year. Therefore, AmonMed COVID 19 Antigen Rapid Test Kit (Colloidal Gold) can detect Omicron mutant strain.

Conclusion

AmonMed COVID 19 Antigen Rapid Test Kit (Colloidal Gold) can detect Omicron mutant strain.

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Certificate of Registration

This is to certify that the Quality Management System of

Xiamen AmonMed Biotechnology Co., Ltd.

Unified Social Credit Code: 91350205089918191 2

Operation Address: Unit 503 & 1203, 120 Xinyuan Road, Haicang District, Xiamen City, Fujian Province, China(Production); 5F and 6F, No.253, Duiying South Road, Jimei District, Xiamen City, Fujian Province, China(Production, Office)

Registered Address: Unit 503, 120 Xinyuan Road, Haicang District, Xiamen City, Fujian Province, China

applicable to

Production and sales of in vitro diagnostic reagents (within the scope of qualification, see attachment for details); production and sales of COVID-19 IgM/IgG test kit(Colloidal Gold); COVID-19 antigen rapid test kit(Colloidal Gold), COVID-19 neutralizing antibody test kit(Colloidal Gold), COVID-19/influenza A /influenza B virus antigen assay kit(Colloidal Gold)(export to EU)

has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number **46652**

Date: 09 July 2019

Reissue Date: 01 July 2021

Valid Until: 09 July 2022

UKAS MANAGEMENT SYSTEMS

0015

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.

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Certificate of Registration

Xiamen AmonMed Biotechnology Co., Ltd.

Annex

1. Kit for the Determination of D-Dimer (Fluorescence Immunochromatography)
2. Kit for the Determination of Procalcitonin (Fluorescence Immunochromatography)
3. Kit for the Determination of Urine Microalbumin(U-ALB) (Fluorescence Immunochromatography)
4. Kit for the Determination of The whole course of C-Reactive Protein (hsCRP+CRP) (Fluorescence Immunochromatography)
5. Bacterial Vaginosis Test Kit (Sialidase)
6. Occult Blood (Hemoglobin/Transferrin) Test Kit (Colloidal Gold)
7. Kit for the Determination of Troponin I (Fluorescence Immunochromatography)
8. Kit for the Determination of Credine Kinase-MB (Fluorescence Immunochromatography)
9. Kit for the Determination of Myoglobin (Fluorescence Immunochromatography)
10. Kit for the Determination of Cystatin C (Fluorescence Immunochromatography)
11. Kit for the Determination of N-terminal pro-brain natriuretic (Fluorescence Immunochromatography)
12. Kit for the Determination of Hemoglobin Alc (Fluorescence Immunochromatography)
13. Kit for the Determination of Heart-type Fatty Acid Binding Protein(Fluorescence Immunochromatography)
14. Kit for the Determination of β2 Microglobulin (Fluorescence Immunochromatography)
15. Kit for the Determination of Neutrophil gelatinase-associated (Fluorescence Immunochromatography)
16. Kit for the Determination of 25-OH Vitamin D(Fluorescence Immunochromatography)
17. Kit for the Determination of Troponin Ⅰ/CKMB/Myoglobin(Fluorescence Immunochromatography)
18. COVID-19 IgM/IgG Test Kit (Rare Earth Nano Fluorescence Immunochromatography)

Managing Director

Certificate Number **46652**

Date: 09 July 2019
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CE 1434 IVD

COVID-19 Antigen Rapid Test Kit (Colloidal Gold)

Instructions for Use with Saliva Swab Specimen

For self-testing/home use/private use

【INTENDED USE】

This test kit is used for in vitro qualitative detection of SARS-CoV-2 antigens in human saliva swab samples. It is intended for rapid detection of suspected COVID-19 cases within the first 7 days of symptom onset.

A positive test result indicates that the sample contains SARS-CoV-2 antigen. A negative test result does not rule out the possibility of infection.

This test kit is for self-testing by lay person in a non-laboratory setting (such as user's home or certain non-traditional sites such as airports, offices, schools, stadiums, etc.). The test results of this test kit are for preliminary screening and clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the user's clinical manifestations and other laboratory tests.

【TEST PRINCIPLE】

This kit uses immunochromatography for detection. The specimen will move forward along the test card under capillary action. If the specimen contains a novel corona virus antigen, the antigen will bind to the colloidal gold-labeled new corona virus monoclonal antibody. The immune complex will be captured by corona virus monoclonal antibodies which are membrane fixed, form the fuchsia line, display will be corona virus antigen positive, if the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

【MATERIALS PROVIDED】

Components	Specification		
	1 Test/Kit	5 Tests/Kit	25 Tests/Kit
	CG01Ag-01S-ST	CG01Ag-05S-ST	CG01Ag-25S-ST
Test card	1	5	25
Extraction solution	1	5	25
Saliva swab	1	5	25
Extraction tube	1	5	25
Instructions for use	1	1	1
Tube rack	1(packaging)	1	1

【PERFORMANCE CHARACTERISTICS】

Sensitivity: 96.55% (95% CI，93.05% ~98.32%)

Sensitivity: The true positive rate

Specificity: >99% (95% CI，99.19% ~100.00%)
Specificity: The true negative rate

Accuracy: 98.86% (95% CI，97.87% ~99.50%)
Accuracy: The true negative and positive rate

Limit of Detection: 5×10^2TCID$_{50}$/mL

【Cross-reactivity】

The sample with human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, adenovirus, human metapneumovirus, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, and etc. have no cross reaction.

【INTERFERENCES】

Common interfering substances in the sample, such as blood, mucin and etc. have no effect on the test results.

【WARNINGS AND PRECAUTIONS】

1. Children under 18 years of age should be assisted by an adult.
2. Read the Instructions for Use (this leaflet) carefully before use.
3. Do not re-use. Do not drink any liquid in the test kit.
4. Do not use the test kit beyond the expiry date.
5. Do not use the test kit if any of the kit components are missing, broken, or unsealed.
6. Store the test kit at 2-30℃. Do not freeze.
7. Handle all specimens as potentially infectious.
8. The specimens should be tested immediately after collection.
9. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
10. Correct specimen collection is a quite important step during the testing procedures. Make sure to collect enough specimens with the saliva swab.
11. The test should be used at room temperature (8-30 ℃). If the test has been stored in a cool area (less than 8℃), leave it at normal room temperature for 30 minutes before using.
12. Use the saliva swab provided in the test kit to ensure optimal performance of the test.
13. Apply the drops of test specimen only to the specimen well (S) on the test card.
14. Too many or too few drops of extraction solution may result in invalid or incorrect test result.
15. The specimen collection procedures may be uncomfortable. Do not insert the saliva swab too much deeper, please stop the test if you feel strong resistance or pain.
16. Keep the test kit and kit components out of the reach of children and pets before and after use.
17. Wear safety mask or other face covering when collecting saliva swab specimen from child or another individual.
18. Use of gloves is recommended when conducting testing.

【LIMITATIONS】

1. The components of this test kit are to be used exclusively for the qualitative detection of SARS-CoV-2 antigen in saliva swab specimens. Other specimen types may lead to incorrect results and must not be used.
2. The test kit is used for rapid detection of suspected COVID-19 cases within the first 7 days of symptom onset, so asymptomatic individuals may get a false-negative test result.
3. Failure to follow the instructions for test procedures and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A negative test result may occur if the specimen was collected or extracted improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by a molecular assay.
5. Improper storage, collection, or even freezing and thawing of the specimen can lead to inaccurate test results.
6. Positive test results do not rule out co-infections with other pathogens.
7. If the viral load of the specimen is below the detection limit of the test, the test may produce a negative result.
8. Test results must be evaluated in conjunction with other clinical data available to the physician laboratory test results.
9. The amount of antigen in a sample may decrease as the duration of illness develops. Specimens collected after 5-7 days of symptom onset of illness are more likely to be tested negative compared to a molecular assay.

【STORAGE AND SHELF LIFE】

1. The test kit should be stored at 2-30℃, and the shelf life is 18 months.
2. After the aluminum foil pouch is unsealed, it is recommended to use the test card within 1 hour at room temperature.
3. The extraction solution is recommended to be used within 1 hour after opening at room temperature.

【PREPARATION BEFORE TEST PROCEDURES】

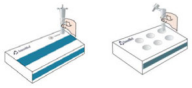
1. Make sure all kit components are equilibrated to room temperature on the flat and clean surface.
2. Make sure the kit components are complete without any missing or damaged after opening.
3. Make sure to check the kit expiry date before testing.
4. Make sure to wash or sanitize your hands, and make sure they are dry before starting.
5. Make sure to prepare the following materials required but not provided in the kit.
   - Timer (watch)
   - Any necessary personal protective equipment (gloves, glasses etc.)
   - Waste container

【OPERATION OF TEST PROCEDURES】

1. Take out the Instructions for Use and read it carefully.

2. Take out the tube rack and assemble it. Gently press one tube rack well and place the extraction tube into the tube rack.

Note: For specification of 1 Test/Kit, tube rack is on the kit packaging



3. Hold the extraction solution vial with your fingers and make sure the tail is upward. Rotate the tail of the extraction solution vial.

Caution: Safely unseal the vial away from your eyes and face. Be careful of the sharp edge of the vial. Do not pour out the liquid.

4. Squeeze all extraction solution from the vial into the extraction tube.

Caution: Avoid touching the vial against the tube.

5. Find the saliva swab in the sealed wrapper. Identify the fabric, soft tip of the saliva swab. Peel off the swab packaging and gently take out the saliva swab.

Caution: Never touch the fabric, soft tip of the saliva swab with your fingers to avoid pollution.

6. Specimen Collection

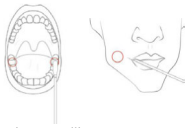
Do not eat or drink anything, such as gum, tobacco, liquor, etc. 30 minutes prior to sampling.

6.1 Insert the saliva swab by one hand into the mouth cavity.

6.2 Place the saliva swab tip between upper and lower molar teeth, then gently bite the swab tip with upper and lower molar teeth for no less than 10 seconds and meanwhile close the mouth for complete saliva absorption in the depths of the mouth.

6.3 After saliva collection, gently take out the swab.

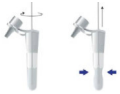
NOTE: False negative results may occur if the saliva specimen is not collected properly.



7. Specimen Handling

7.1 Insert the saliva swab into extraction tube. Stir the saliva swab more than 5 times. Leave saliva swab in extraction tube for about 1 minute.

7.2 Squeeze the swab against the inner wall of extraction tube to release the liquid as much as possible when you remove the swab. Dispose of the test swab with normal household waste in accordance with applicable local regulations.



8. Press the cap onto the extraction tube tightly.

9. Unseal the foil pouch and take out the test card. Place the card on the flat surface.

10. Apply 2 drops of extracted specimens to the specimen well of the test card, and then start timing.

11. Read the test results in 15-20 minutes, and test results after 20 minutes may not be accurate.

【WASTE DISPOSAL AFTER TEST PROCEDURES】

1.Place the used test card, extraction solution and saliva swab in a disposal bag and seal the disposal bag.

2.Dispose all used devices and other components into normal household waste container in compliance with the applicable local regulations.

3.Wash or sanitize your hands again.

【INTERPRETATION OF TEST RESULT】

Positive:

If both the control line (C) and the test line (T) appear within 15-20 minutes, the result is positive.

Caution: No matter how faint the colored band is in the test line(T), the result should be considered as positive.

Negative:

If there is only a control line (C) and test line (T) is colorless within 15-20 minutes, the test result is negative.

Invalid:

If the control line (C) is not observed within 15-20 minutes, the test is invalid. And the test shall be conducted again with a new test card.

【FREQUENTLY ASKED QUESTIONS (FAQ)】

1. When can/should I test myself?

You can have a test on yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to local regulations.

2. What should I pay attention to in order to have the optimal test result?

Always follow the instructions for use correctly. Perform the test immediately after collecting the sample. Apply two drops from the extraction tube into the specimen well of the test card. Too many or too few drops can lead to an incorrect or invalid test result.

3. The test strip is very discolored. What may be the reasons?

The reason for a clearly visible discoloration of the test strip is that too many drops has been dispensed from the extraction tube into the specimen well of test card. The indicator strip can only hold a limited amount of liquid. If the control line (C) does not appear or the test strip is very discolored, please retest by using a new test card according to the instructions for use.

4. I have taken the test, but the control line (C) doesn't appear. What should I do?

According to the instructions for use, this test result is invalid. Please retest by using a new test card.

5. I am not sure about reading test result. What should I do?

Read the instructions for use again, and if this doesn't help, please contact the nearest health facility recommended by your local authorities for help.

6. If my test result is positive, what should I do?

There is possibility of hospitalization, complications and even death after infection with SARS-CoV-19. You should immediately contact the nearest health facility recommended by your local authorities.

7. If my test result is negative, what should I do?

If you test result is negative by the test, you also need to obey the local regulations. If you experience symptoms such as fever, headaches, migraines, loss of sense of smell and taste, contact the nearest health facility recommended by your local authorities.

8. Will this test hurt?

No, the saliva swab is not sharp and it should not hurt. Sometimes the saliva swab can make slightly uncomfortable or tickly. If you feel pain, please stop the test and ask for help from a healthcare provider.

【ACCESSORY】

Accessory	Manufacturer	EC-Representative	CE-Mark
Saliva Swab	Shenzhen Kangdaan Biological Technology Co. Ltd. 3rd floor, Building A2, Shunheda factory, Liuxiandong industrial zone, Xilli street, Nanshan district, Shenzhen, China.	Share Info Consultant Service LLC Repräsentanzbüro Heerdter Lohweg 83 40549 Düsseldorf, Deutschland	CE 0197 acc. 93/42/EEC

【EXPLANATION FOR SYMBOLS】

	Expiry date	LOT	Batch Number		See Instructions for use
Σ	Test (s) per kit	2°C 30°C	Store at 2-30℃	REF	Catalogue Number
	Manufacturer	CE 1434	CE Mark		Do not reuse
IVD	In Vitro diagnostic use	EC REP	European Authorized Representative		

【ISSUE DATE AND VERSION NO.】

Issue Date: Oct 15th, 2021; Version 4.0

Xiamen AmonMed Biotechnology Co., Ltd.

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EC REP **SUNGO Europe B.V.**
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