BETTER AG

Top quality at manufacturer prices

Getein

COVID-19 Rapid Test Kit

For self-tests

With integrated buffer solution

Packaging

1 Test per Bag

CARTON	**450** tests pro Karton

Packaging

5 Tests per Box

CARTON	600 tests pro Karton

Details

Supplier listed on the "EU common list" - Directorate General for Health and Food Safety

Click to check the validity of the CE certificate

SAMPLING	Nasal Swab
SENSITIVITY	97,06 %
SPECIFICITY	98,71 %
RESULT IN	10 - 15 Minutes
CE CERTIFICATE NO	IVDD-447 / 2021 / CE 1434

基蛋生物 GeteinBiotech

English

CE 1434 IVD

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) User Manual for self-testing

INTENDED USE

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 antigens in human nasal swab samples and is intended to aid in the diagnosis of COVID-19. This test is used for individuals suspected of COVID-19 within the first seven days of the onset of symptoms, such as headache, fever, cough, sore throat, loss of the sense of smell or taste, shortness of breath, and muscle pain. The test can also be applied to screen for asymptomatic infections. Positive results indicate that SARS-CoV-2 antigens are detected in the nasal swab sample; negative results indicate that no SARS-CoV-2 antigen is detected. Negative results for individuals displaying COVID-19-like symptoms should preferably be confirmed by molecular assays such as RT-PCR. This test is used for self-testing.

CONTENTS

SARS-CoV-2 antigen test card N test	Extraction tube with sample extraction solution and tip N pc	Biohazard sample bag N pc
User manual 1 pc/kit	Sterile swab N pc	

PREPARING THE TEST

Check integrity of the out package,components and the expiration date.

Read the user manual before starting the test.Check operation video for more help.

Operation Video

Open the pouch. Check the result window and sample well (S).

TEST PROCEDURE

1. Remove the lid from the top of the extraction tube with sample extraction solution.
2. Open the swab package.Gently insert the tip of the swab into one nostril. Do not insert the swab more than 1.5 cm into your nose.
3. Rotate 4 times. Rotate the swab around the inside wall of your nostril at least 4 times. Repeat the same process with the same swab in the other nostril.
4. Rotate 10 times. Insert the swab after sampling to the extraction tube and rotate the swab 10 times in the solution.
5. Squeeze 3 times. Squeeze the swab tip along the inner wall of the extraction tube 3 times.
6. Sample: 2-3 drops. Push the tip into the extraction tube and ensure it fit tightly. Gently squeeze the extraction tube and add 2-3 drops of solution into the sample well (S).
7. 10-15 min. Read the result visually in 10-15 min, don't read results after 20 min.
8. Put all the used test kit contents in the biohazard sample bag provided and discard it in household waste. Dispose of all used tests in accordance with local regulations. Wash your hands thoroughly after disposal.

TEST RESULTS

Positive

Positive (+):
Both the control line (C) and test line (T) appear indicates the presence of SARS-CoV-2 antigen. Any faint line in the test line (T) should be considered positive.
Note: positive results indicate very likely SARS-CoV-2 infection. Contact your doctor or the local health department immediately. Follow the local regulations for self-isolation. A subsequent molecular testing may be required to confirm your infection status.

Negative

Negative (-):
Only the control line (C) and no test line (T) appear indicates no SARS-CoV-2 antigen was detected.
Note: Negative results indicate unlikely SARS-CoV-2 infection. Continue to follow all applicable rules and protective measures when contacting with others. You might still be infected with SARS-CoV-2 even if the test result is negative. If you still suspect that you have been infected despite a negative test result, repeat the test after 1-2 days or conduct molecular testing.

Invalid

Invalid :
If the control area (C) fails to appear, the test result is invalid. Insufficient sample volume and/or incorrect operation are possible reasons for an invalid result. Read the instructions again and test with a new test strip. If the same situation reappears, please stop using this batch of products and contact your doctor or a COVID-19 test center.

SPECIMEN COLLECTION

Note: Please follow your local guideline for specimen collection.

STORAGE AND STABILITY

The test kit can be stored at 4-30 ℃ with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened.

PRINCIPLE

The test uses anti-SARS-CoV-2 nucleocapsid protein (N protein) monoclonal anti-body I conjugated with colloidal gold coated on the sample pad, and another anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ coated on test line. After the samples have been applied to the test strip, thecolloidal gold-labelled anti-SARS-CoV-2 N protein monoclonal antibody I bind with SARS-CoV-2 antigens in sample and form marked antigen-anti body complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on test line by anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ. The color intensity of each test line increases in proportion to the amount of SARS-CoV-2 antigen in sample.

PRECAUTIONS

1. Always keep the kit out of the reach of children. Small parts of the kit can be a choking hazard.
2. Sample extraction solution is a phosphate buffer contained low concentration of sodium chloride, tween, hexadecyl trimethyl ammonium bromide and sodium azide. If extraction solution splashes your body or into eyes, please wash with water.

LIMITATIONS

1. False-negative result may occur if the level of antigen in sample is below the detection limit of the test or the sample was collected incorrectly.
2. Clinical diagnosis and treatment cannot be made without consulting with the physician.
3. Negative results for individuals displaying COVID-19-like symptoms should preferably be confirmed by molecular assays such as RT-PCR.
4. The product One Step Test For SARS-CoV-2 Antigen (Colloidal Gold) showed no drop off in sensitivity when compared with the wild type with respect to the following variants-VOC1 UK, Alpha, VOC2 South Africa, Beta, VOC3 Brazil Gamma, VOI1 America Iota and VOI2 India Kappa. We will keep evaluating the impact of new variants.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection (LoD)

The LoD for nasal swab was established using heat-inactivated SARS-CoV-2 isolate strain. The strain was spiked with negative human nasal swab into a series of concentrations. The estimated LoD found from the initial twofold serial dilution test was confirmed by testing 20 replicates.The confirmed LoD for nasal swab was 200 $TCID_{50}$/mL.

2. Clinical Agreement Study

The clinical performance of One Step Test for SARS-CoV-2 Antigen (Collo-idal Gold) was evaluated by testing a total of 480 nasal swab samples.It is compared to the results of RT-PCR assays. Overall study results were shown in the tables below.

Total		BGI's RT-PCR kit		
		Positive	Negative	Subtotal
Getein's kit	Positive	165	4	169
	Negative	5	306	311
	Subtotal	170	310	480

Positive percent agreement (Diagnostic sensitivity) = 165 / (165 + 5) ×100%= 97.06% (95% CI: 93.30%-98.74%)
Negative percent agreement (Diagnostic specificity) = 306 / (306 +4) ×100%= 98.71% (95% CI: 96.73%-99.50%)
Total percent agreement = (165 + 306) / 480 × 100% = 98.13% (95% CI:96.48%-99.01%)

3. Analytical Specificity

1) Cross-Reactivity & Microbial Interference

Each organism and virus was tested in triplicate in the absence and presence of SARS-CoV-2 respectively. According to the test results, there was no crossreactivity with the following viruses or organisms.

Viruses or organisms		
Human coronavirus 229E	Influenza A	Bordetella pertussis
Human coronavirus OC43	Influenza B	Mycoplasma pneumoniae
Human coronavirus NL63	Enterovirus	Chlamydia pneumoniae
MERS coronavirus	Respiratory syncytial virus	Legionella pneumophila
Adenovirus (e.g. C1 Ad. 71)	Rhinovirus	Mycobacterium tuberculosis
Human Metapneumovirus (hMPV)	Haemophilus influenzae	Pneumocystis jiroveci
Parainfluenza virus Type 1	Streptococcus pneumoniae	Pseudomonas Aeruginosa
Parainfluenza virus Type 2	Streptococcus pyogenes	Staphylococcus Epidermidis
Parainfluenza virus Type 3	Candida albicans	Streptococcus Salivarius
Parainfluenza virus Type 4a	Pooled human nasal wash	

2) Interferences

The potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects (including over the counter medications). No false positive or false negative results were seen at the following concentrations.

Potentially Interfering Substances		
Blood (human)	Zicam Cold Remedy	Tamiflu (Oseltamivir phosphate)
Mucin	Homeopathic (Alkalol)	Biotin
CVS Nasal Drops (phenylephrine)	Sore Throat Phenol Spray	Methanol
Nasal GEL (NeilMed)	Tobramycin	Diphenhydramine
Afrin (Oxymetazoline)	Mupirocin	Dextromethorphan
CVS Nasal Spray (Cromolyn)	Fluticasone	Dexamethasone

4. Precision

For repeatability study, the agreement percent of both negative samples and positive samples are 100%. For reproducibility study, the agreement percent of both negative samples and positive samples are 100%.

Key to symbols used

Manufacturer	Use-by date	Do not re-use	Date of manufacture	Consult *instructions for use* or consult electronic *instructions for use*	LOT Batch code	Temperature limit	IVD In vitro diagnostic medical device	Contains sufficient for <n> tests
Keep dry	REF Catalogue number	Keep away from sunlight	Biological risks	For self-testing	CE 1434 CE mark	Do not use if package is damaged and consult *instructions for use*	EC REP Authorized representative in the European Community/ European Union	

Specification (N)	REF	Specification (N)	REF
1 T/kit	CG20615	9 T/kit	CG206159
2 T/kit	CG206152	10 T/kit	CG2061510
3 T/kit	CG206153	12 T/kit	CG2061512
5 T/kit	CG206155	15 T/kit	CG2061515
6 T/kit	CG206156	20 T/kit	CG2061520
7 T/kit	CG206157	25 T/kit	CG2061525
8 T/kit	CG206158		

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China

EC REP
CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Importer:
Better AG,
General-Guisan-Str. 8,
6300 Zug, Switzerland

Tel: +353 1 513 75 11
E-Mail: info@OdemShop.com
Shop: www.OdemShop.com

Version: WCG93-EFDISD-DXF4-S-04
Last Edition:18/07/2022

2406

CERTIFICATE

EC Certificate No. 1434-IVDD-447/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

GETEIN Biotech, Inc.

Nanjing, ul. Bofu Road, Luhe District 9, China

in vitro diagnostic medical devices
for self-testing

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)

Ref. codes: CG20615, CG206152, CG206153, CG206155, CG206156, CG206157, CG206158, CG206159, CG2061510, CG2061512, CG2061515, CG2061520, CG2061525

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 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 30.07.2021

CE 1434

Issued under the Contract No. MD-66/2021
Application No: 142/2021
Certificate bears the qualified signature.
Warsaw, 30.07.2021
Module A1

Vice-President

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

Paul-Ehrlich-Institut

01.04.2021

Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests

Ziel

Vergleich verschiedener Antigenschnelltests mit identischem Probenmaterial

Material

Pools von naso- und oropharyngealen Abstrichen.

Trockene Tupfer wurden in PBS aufgenommen, feuchte Tupfer waren bereits in Transportmedium unterschiedlicher Zusammensetzung. Pools sind zufällige Mischungen aus bis zu 10 Proben vergleichbarer CT Werte, die 1:10 in negativen Proben in PBS verdünnt wurden. Die CT Werte eines Pools wurden mit verschiedenen PCR Assays bestimmt und die mutmassliche Anzahl an RNA-Kopien mit Hilfe des INSTAND Standards berechnet. Bei den verwendeten PCRs entspricht ein CT Wert von 25 etwa 10^6 RNA Kopien / mL. Es wurden jeweils 18 Proben mit CT<25, 23 Proben mit CT zwischen 25 und 30 und 9 Proben mit CT>30 analysiert. Vermehrung des Virus in Zellkultur wurde als mögliches Korrelat für Infektiosität als weiteres Merkmal der Proben bestimmt.

Durchführung

Die Pools wurden aliquotiert, eingefroren, versendet, und zur Evaluierung der Tests aufgetaut. Für jeden Test wurden 50µL des Pools mit den vom Test bereitgestellten Komponenten z.B. Tupfer, analysiert. An der vergleichenden Evaluierung beteiligte Labors sind u. a. Robert Koch-Institut, Paul-Ehrlich-Institut, Konsiliarlabor für Coronaviren (Charité), Institut für Mikrobiologie der Bundeswehr.

Zusammenfassung

Diese vergleichende Evaluierung einer großen Anzahl von SARS-CoV-2 Antigenschnelltests (point of care tests; POCT) verschiedenen Designs und verschiedener Hersteller mit demselben Probenset ermöglicht einen Überblick über den derzeitigen Stand der Technik hinsichtlich ihrer Sensitivität. Die Ergebnisse lassen keine Rückschlüsse auf die Spezifität der Tests zu.

Diejenigen POCT, die bislang in die vergleichende Evaluierung eingegangen sind und hier als dem derzeitigen Stand der Technik entsprechend bewertet wurden, sind in der folgenden Tabelle aufgeführt. Weitere Tests, die als nicht dem Stand der Technik entsprechend bewertet wurden, wurden aus der Liste des BfArM entfernt. Die Untersuchungen werden kontinuierlich fortgeführt, die Tabelle entsprechend ergänzt.

Es sei ausdrücklich darauf hingewiesen, dass diese vergleichende Evaluierung nur eine Stichprobe der beim BfArM gelisteten und somit erstattungsfähigen SARS-CoV-2 Antigenschnelltests berücksichtigen kann, und manche Tests bislang (noch) nicht berücksichtigt werden konnten, trotz entsprechendem Interesse seitens Herstellern / Vertreibern.

Kontakt:

E-Mail: sarscov2ivd@pei.de

ISO-Certificate

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Getein Biotech, Inc.
No.9 Bofu Road
Luhe District
Nanjing
Jiangsu
211505
China

Facility ID Number: F004902

Holds Certificate No: **MDSAP 728434**

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

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-10-18 Effective Date: 2020-10-18 Expiry Date: 2023-07-25

bsi. MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

Clinic Study

Getein One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) (For Self-Test)	
Sensitivity	97.06%
Specificity	98.71%
Total Percent Agreement	98.13%

The clinical performance of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was evaluated by testing a total of 480 nasal swab samples. It is compared to the results of RT-PCR assays. Overall study results were shown in the tables below.

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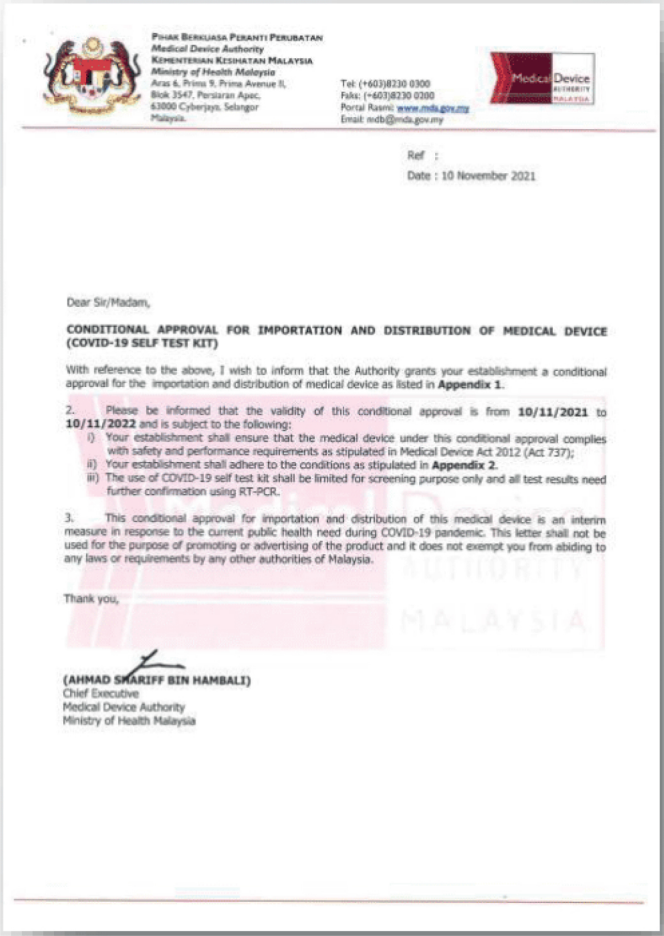
Approved by the Medical Devices Authority in Malasia



PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Aras 6, Prima 9, Prima Avenue II, Blok 3547, Persiaran Apec, 63000 Cyberjaya, Selangor Malaysia.
Tel: (+603)8230 0300
Faks: (+603)8230 0200
Portal Rasmi: www.mdb.gov.my
Email: mdb@mda.gov.my

Ref :
Date : 10 November 2021

Dear Sir/Madam,

CONDITIONAL APPROVAL FOR IMPORTATION AND DISTRIBUTION OF MEDICAL DEVICE (COVID-19 SELF TEST KIT)

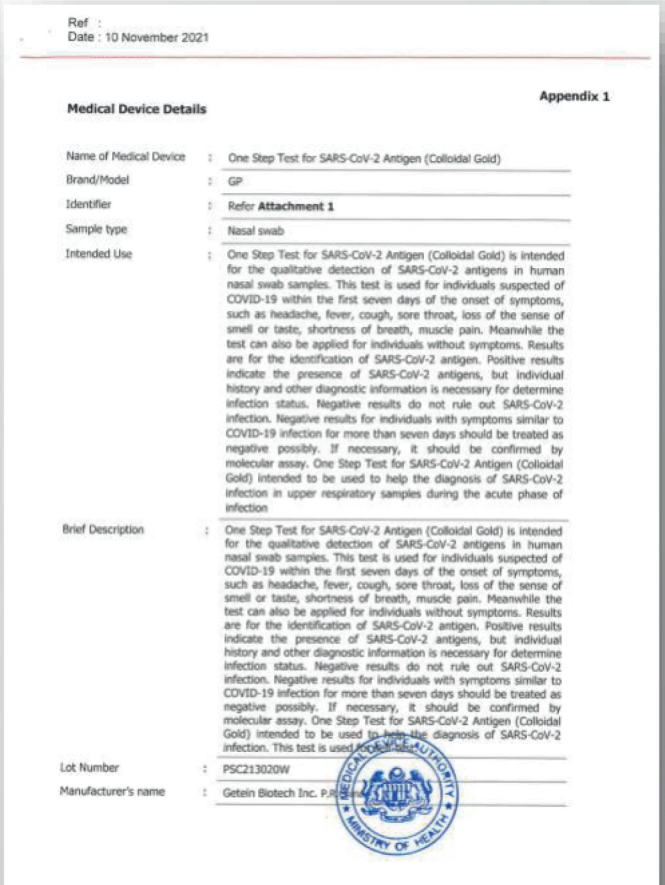
With reference to the above, I wish to inform that the Authority grants your establishment a conditional approval for the importation and distribution of medical device as listed in **Appendix 1**.

2. Please be informed that the validity of this conditional approval is from **10/11/2021** to **10/11/2022** and is subject to the following:
i) Your establishment shall ensure that the medical device under this conditional approval complies with safety and performance requirements as stipulated in Medical Device Act 2012 (Act 737);
ii) Your establishment shall adhere to the conditions as stipulated in **Appendix 2**.
iii) The use of COVID-19 self test kit shall be limited for screening purpose only and all test results need further confirmation using RT-PCR.

3. This conditional approval for importation and distribution of this medical device is an interim measure in response to the current public health need during COVID-19 pandemic. This letter shall not be used for the purpose of promoting or advertising of the product and it does not exempt you from abiding to any laws or requirements by any other authorities of Malaysia.

Thank you,

(AHMAD SHARIFF BIN HAMBALI)
Chief Executive
Medical Device Authority
Ministry of Health Malaysia



Ref :
Date : 10 November 2021

Appendix 1

Medical Device Details

Name of Medical Device	:	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)
Brand/Model	:	GP
Identifier	:	Refer **Attachment 1**
Sample type	:	Nasal swab
Intended Use	:	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 antigens in human nasal swab samples. This test is used for individuals suspected of COVID-19 within the first seven days of the onset of symptoms, such as headache, fever, cough, sore throat, loss of the sense of smell or taste, shortness of breath, muscle pain. Meanwhile the test can also be applied for individuals without symptoms. Results are for the identification of SARS-CoV-2 antigen. Positive results indicate the presence of SARS-CoV-2 antigens, but individual history and other diagnostic information is necessary for determine infection status. Negative results do not rule out SARS-CoV-2 infection. Negative results for individuals with symptoms similar to COVID-19 infection for more than seven days should be treated as negative possibly. If necessary, it should be confirmed by molecular assay. One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) intended to be used to help the diagnosis of SARS-CoV-2 infection in upper respiratory samples during the acute phase of infection
Brief Description	:	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 antigens in human nasal swab samples. This test is used for individuals suspected of COVID-19 within the first seven days of the onset of symptoms, such as headache, fever, cough, sore throat, loss of the sense of smell or taste, shortness of breath, muscle pain. Meanwhile the test can also be applied for individuals without symptoms. Results are for the identification of SARS-CoV-2 antigen. Positive results indicate the presence of SARS-CoV-2 antigens, but individual history and other diagnostic information is necessary for determine infection status. Negative results do not rule out SARS-CoV-2 infection. Negative results for individuals with symptoms similar to COVID-19 infection for more than seven days should be treated as negative possibly. If necessary, it should be confirmed by molecular assay. One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) intended to be used to help the diagnosis of SARS-CoV-2 infection. This test is used for [illegible]
Lot Number	:	PSC213020W
Manufacturer's name	:	Getein Biotech Inc. P.R.

MEDICAL DEVICE AUTHORITY MINISTRY OF HEALTH

Further references and information

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SCAN ME

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