This product is for in vitro diagnostic use only and should not be used for any other purposes.
Please read these instructions carefully before use.

SARS-COV-2/RSV/ADV/ MP&FLU A/B ANTIGEN RAPID TEST KIT

REF RNS92146

CE

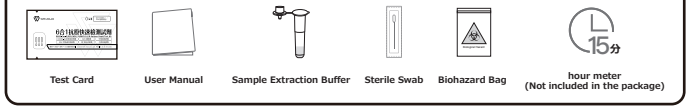
USER MANUAL

Latest update:20250109

PRODUCT USAGE

This product is used for in vitro qualitative detection of SARS-CoV-2/RSV/ADV/MP & Influenza A/B antigens in nasal swab samples. It is intended for rapid testing of six types of antigens by non-professionals. Please consult a physician for medical evaluation.
It is applicable for individuals aged 18 and above. Users under 18 years old should perform the test with assistance from an adult. It can detect symptomatic and asymptomatic infections.

PACKAGE CONTENTS



Test Card | User Manual | Sample Extraction Buffer | Sterile Swab | Biohazard Bag | hour meter (Not included in the package)

PREPARATION BEFORE INSPECTION

Before collecting the sample, blow your nose several times. Make sure your hands are clean and dry before performing the test.

Please read the user manual carefully.

Inspect all components of the test kit, and ensure that all components are complete and undamaged.

Check the expiration date printed on the aluminum foil pouch of the test device.

INTRODUCTION

The coronavirus (CoV) belongs to the order Nidovirales under the family Coronaviridae with 4 genera: α, β, γ and δ. The genera α and β are only for Mammals are pathogenic, while genera γ and δ are mainly pathogens in birds cause infections.CoV is mainly transmitted through direct contact with secretions orby aerosols and droplets. But there is also evidence for onefecal-oral transmission.So far, 7 types of human coronaviruses (HCoV) have been identified thatcause respiratory diseases in humans, including: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 is one of the most contagious viral pathogens that human respiratory infections (RTI). Currently, patients who with SARS-CoV-2, the main source of infection. Asymptomatic infected people can also be a source of infection.According to the current epidemiological investigations, the Incubation period 1 to 14 days, mostly 3 to 7 days. to the clinical symptoms include fever, fatigue, cough and other symptoms, accompanied by shortness of breath, which can quickly progress to severe, life-threatening pneumonia, respiratory failure, acute respiratory vesicle syndrome, septic shock, multiple organ failure and severe metabolic acid-base imbalance. Respiratory syncytial virus belongs to the Pneumovirus genus of the Paramyxoviridae family. It can be transmitted through the air and through close contact, mainly causing lower respiratory tract infections such as bronchiolitis and pneumonia in infants under 6 months old, and upper respiratory tract infections such as rhinitis and colds in older children and adults. Clinically, patients with respiratory syncytial virus infection can present with fever, nasal congestion, dyspnea, and even respiratory failure or heart failure when the symptoms are severe, and active treatment is required.
Adenovirus（ADV） is an unenveloped DNA virus that mainly infects a wide variety of vertebrates, including humans. Human infection can lead to a variety of clinical manifestations and diseases, including respiratory diseases (such as the common cold, bronchitis, pneumonia, etc.), digestive tract diseases (such as diarrhea, gastroenteritis, etc.), conjunctivitis and cystitis. Individual cases can become severe and critical, and even die. Mycoplasma pneumoniae (M.pneumoniae) is the causative agent of mycoplasma pneumonia in humans. The pathological changes of mycoplasma pneumonia are mainly interstitial pneumonia, sometimes complicated by bronchopneumonia, which is called primary atypical pneumonia. The infection is mainly transmitted by droplets. The incubation period is 2 to 3 weeks, and the incidence is highest in adolescents. The clinical symptoms were mild, or even no symptoms at all, and if there were only general respiratory symptoms such as headache, sore throat, fever, and cough, but there were some reports of death. It can occur all year round, but mostly in autumn and winter.
Influenza, commonly referred to as the flu, is an acute respiratory infection by the influenza virus is caused. It is highly contagious. It will mainly by coughing and sneezing and usually breaks out in spring and winter. It is mainly divided into influenza A and influenza B viruses. Influenza A viruses are highly variable, followed by influenza B viruses. Therefore are Influenza A viruses more common and severe, followed by influenza B viruses.Influenza A includes H1N1, H3N2, H5N1, H7N9, and influenza B includes influenza B (Victoria) and Influenza B (Yamagata).

INTENDED USE

This kit is only used for the in vitro qualitative detection of Multiple Respiratory Multipathogen Antigen (SARS-CoV-2/Respiratory Syncytial virus/Influenza A virus/Influenza B virus/Adenoviruses/M.pneumoniae) from human nasopharyngeal swabs specimens.SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit is an immunochromatographic double-antibody sandwich assay intended for the qualitative detection and differentiation of SARS-CoV-2/Respiratory Syncytial virus/Influenza A virus/Influenza B virus/Adenoviruses/M.pneumoniae from individuals who are suspected of respiratory tract disease infection.This kit is suitable for the auxiliary diagnosis of respiratory diseases the results are for clinical reference only and cannot be used as the sole basis for diagnosis and exclusion decision. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs medical historyother laboratory tests and treatment responses, Positive test result needs to be further confirmed negative result does not preclude respiratory diseases viruses infection.

PRINCIPLE

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

VIRUS MUTATION DETECTION COMPATIBILITY

The SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit detects the nucleocapsid protein, not the spike protein of SARS-CoV-2. And all of the following variants can be can be effectively detected with the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit

ALPHA	BETA	GAMMA	KAPPA	DELTA	OMIKRON	IOTA	EPSILON
B.1.1.7	B.1.351	P.1	B.1.617.1	B.1.617.2	B.1.1.529	B.1.526	B.1.427/B.1.429

WARNINGS AND PRECAUTIONS

- This test kit is for in vitro diagnostic use only.
- This test kit is intended for persons aged 18 and over.
- Bring the contents of the kit to room temperature before testing.
- Appropriate protection should be worn while performing the test to avoid splashes when adding the sample.
- If the SARS-CoV-2 test is positive, there is a suspicion of a COVID-19 infection, contact your doctor/GP immediately or the local health department, follow local guidelines Self-isolate and perform a confirmatory PCR test.
- If the result of the ADV, RSV, MP, influenza A/B test is positive: There is currently the Suspected ADV, RSV, influenza A/B, MP infection and what to do next be undertaken according to local guidelines.
- Do not reuse the test kit.
- Do not use the test kit if the pouch breaks the seal broken or the test cassette is wet or dirty.
- Do not use the contents of the test kit after the expiry date on the expiry date printed on the outside of the packaging.

STORAGE INSTRUCTIONS

- The test kit should be protected from direct sunlight at 4 to 30℃, with the shelf life stated on the packaging.
- This test kit should be used within 1 hour of opening the foil bags.

⚠ Keep out of reach of children

DIRECTIONS FOR USE

⚠ Allow the test device, sample extraction buffer to equilibrate to room temperature (20- 30°C) prior to testing, blowing the nose before taking a nasal swab .

Nasal Swab Specimen Collection :

BEFORE STARTING: Wash and sanitise your hands, then clean the nostrils.

1. Remove the swab from the package.

2. While gently rotating the swab, insert swab about 1.5cm into nostril until resistance is met at turbinates.

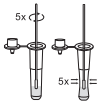
3. Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.

Specimen Transport and Storage :

After swabbing, process the swab in the extraction buffer as soon as possible. Do not place the swab back into the swab packaging sleeve after specimen collection.
Specimens should be tested within 30 minutes. Do not freeze or transport the sample for later testing.

Testing Procedure :

1. Peel off the aluminum foil seal from a sample extraction buffer.



2. Immerse the sampled swab into the sample extraction buffer to make the sample extraction buffer completely penetrate the swab, rotate and squeeze the swab 5 times, take out and discard the swab.

3. Insert the tube cap firmly on the sample extraction tube.Gently shake the extraction tube for about 5 seconds to make sure sample mix well with extraction buffer.

4. Transfer 3 drops of mixed sample into the test card vertically, start the timer. Read the result at 15 minutes. Don't interpret the result after 20 minutes.
**Read the result at 15 minutes. Result after 20 mins will not be valid.

⚠ Put used product components in the biohazard bag. Close the bag and put it in medical waste recycling bin.

INTERPRETATION OF RESULTS

POSITIVE (+)

- Positive COV: Two blue lines in the COV/MP test window, a blue line in the determination section(C) and another blue line in the determination section(COV) area.
- Positive MP: Two blue lines in the COV/MP test window, a blue line in the determination section(C) and another blue line in the determination section(MP) area.
- Positive COV/MP: Three blue lines in the COV/MP test window, a blue line in the determination section(C) , a blue line in the determination section (COV) and a blue line in the determination section(MP).
- Positive RSV: Two blue lines in the RSV/ADV test window, a blue line in the determination section(C) and another blue line in the determination section(RSV) area.
- Positive ADV: Two blue lines in the RSV/ADV test window, a blue line in the determination section(C) and another blue line in the determination section(ADV) area.
- Positive RSV/ADV: Three blue lines in the RSV/ADV test window, a blue line in the determination section(C) , a blue line in the determination section (RSV) and a blue line in the determination section(ADV).
- Positive Flu A: Two blue lines in the Flu A/B test window, a blue line in the determination section(C) and another blue line in the determination section(A) area.
- Positive Flu B: Two blue lines in the Flu A/B test window, a blue line in the determination section(C) and another blue line in the determination section(B) area.
- Positive Influenza A/B: Three blue lines in the FluA/B test window, a blue line in the determination section(C), a blue line in the determination section (A) and a blue line in the determination section(B).

**Note:The intensity of the colour of the lines(COV/MP/RSV/ADV/A/B) may vary depending on the concentration of SARS-CoV-2/ADV/RSV/MP and Influenza A/B antigens in the sample. Therefore, a positive result is judged as long as there is a confirmed band in the decision area(COV/MP/RSV/ADV/A/B),even if it is a very faint line. A positive result means that you are likely to be infected with SARS-CoV-2, ADV, RSV, MP, Influenza A,or influenza B.Test results should always be considered in the context of clinical observations and epidemiological data when making final diagnoses and patient management decisions. As recommended by the CDC,you should avoid spreading the virus to others by self-isolating at home and avoiding contact with others.

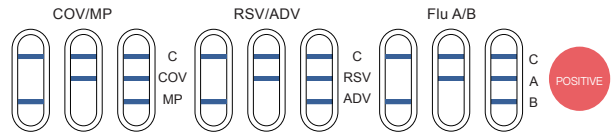


Fig. 1 Positive Result

NEGATIVE (-)

The presence of a line at the COV/ADV/RSV/MP test window and at the determination part (C) of the FluA/B test window, but not at the determination part(COV/MP/RSV/ADV/A/B),indicates that SARS-CoV-2, ADV ,RSV, MP, Influenza A,or Influenza B is not detected in the sample,but a negative result does not exclude the absence of SARS-CoV-2, ADV, RSV, MP, influenza A or influenza B infection and should not be used as the sole basis for treatment or patient management decisions.Negative results should be considered in the context of the individual's recent exposure history medical history and the presence of clinical signs and symptoms consistent with SARS-CoV-2, ADV, RSV, MP,Influenza A,Influenza B and confirmed by PCR testing as necessary for patient management.

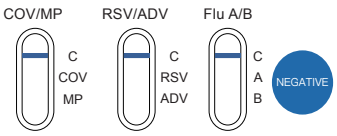


Fig. 2 Negative Result

INVALID

No coloured line appears in the control region (C) after performing the test. The directions may not have been followed correctly or the test may have deteriorated. You need review the instruction for use again and repeat the test with a new test card

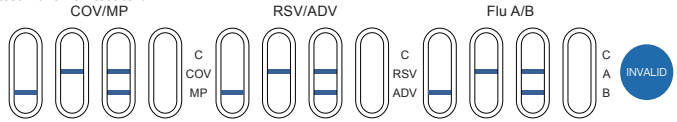


Fig. 3 Invalid Result

TEST METHOD LIMITATIONS

- The accuracy of the test depends on the quality of the sample. Improper sampling or storage, use of expired samples or repeatedly frozen and thawed samples can do this affect the test result. The test results can also by temperature and humidity are affected.
- Low levels of SARS-CoV-2, RSV, MP, influenza A and Influenza B/Adenoviruses antigens in the sample can produce negative results, so that an infection cannot be completely ruled out.
- Some medications (such as high levels of over-the-counter or prescription drugs such as nasal spray) in the samples taken may affect the test result. Please perform the test again if the result is doubtful.
- This product is for qualitative testing only. The specific concentration of each indicator must be related to other quantitative methods are measured.
- The results of this test are for clinical reference only and should be used not be the only basis for the diagnosis. The results should be in combination with clinical observations and other test methods be used.

CLINICAL PERFORMANCE

1.COVID-19 test

The performance of the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit was established using 340 swabs collected from Patients with COVID-19 symptoms within 7 days of onset symptoms . In the same people were two swabs taken, a nasopharyngeal swab that goes directly to the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit was tested,and a nasopharyngeal swab tested with the RT-PCR test kit.The clinical specimens were found positive by the RT-PCR reference method or rated negative.

Method		COVID-19 Nucleic Acid Test Kit (RT-PCR)		Total Results
SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit	COVID-19	Positive	Negative	
	Positive	152	2	154
	Negative	6	180	186
Total Results		158	182	340

Clinical Sensitivity = 152/158=96.20%（95%CI:90.84%~98.46%）
Clinical Specificity =180/182=98.90%（95%CI:96.55%~99.95%）
Accuracy:332/340= 97.65%（95%CI:93.28%~99.55%）

2.RSV test

The performance of the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit was evaluated using 340 swabs from patients with RSV symptoms within 7 days of symptom onset determined. Two swabs were taken from the same people a nasopharyngeal swab directly associated with the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit and a nasopharyngeal swab tested with the RT-PCR test kit. The clinical samples were positive or negative using the RT-PCR reference method.

Method		RSV Nucleic Acid Test Kit (RT-PCR)		Total Results
SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit	RSV	Positive	Negative	
	Positive	153	1	154
	Negative	5	181	186
Total Results		158	182	340

Clinical Sensitivity = 153/158=96.84%（95%CI:91.64%~98.75%）
Clinical Specificity =181/182=99.45%（95%CI:97.18%~99.98%）
Accuracy:334/340= 98.24%（95%CI:94.36%~99.62%）

3.Influenza A/B test

The performance of the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit was evaluated using 340 swabs from patients with Influenza symptoms within 7 days of symptom onset determined. Two swabs were taken from the same people a nasopharyngeal swab directly associated with the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit and a nasopharyngeal swab tested with the RT-PCR test kit. The clinical samples were positive or negative using the RT-PCR reference method.

Method		Influenza A/B Nucleic Acid Test Kit (RT-PCR)		Total Results
SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit	Influenza A/B	Positive	Negative	
	Positive	154	1	155
	Negative	4	181	185
Total Results		158	182	340

Clinical Sensitivity = 154/158=97.47%（95%CI:92.84%~98.75%）
Clinical Specificity =181/182=99.45%（95%CI:97.28%~99.90%）
Accuracy:335/340= 98.53%（95%CI:94.76%~99.94%）

4.ADV test

The performance of the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit was evaluated using 340 swabs from patients with ADV symptoms within 7 days of symptom onset determined. Two swabs were taken from the same people a nasopharyngeal swab directly associated with the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit and a nasopharyngeal swab tested with the RT-PCR test kit. The clinical samples were positive or negative using the RT-PCR reference method.

Method		ADV Nucleic Acid Test Kit (RT-PCR)		Total Results
SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit	ADV	Positive	Negative	
	Positive	155	2	157
	Negative	3	180	183
Total Results		158	182	340

Clinical Sensitivity = 155/158=98.10%（95%CI:93.24%~98.56%）
Clinical Specificity =180/182=98.9%（95%CI:97.28%~99.90%）
Accuracy:335/340= 98.53%（95%CI:95.16%~99.83%）

5.MP test

The performance of the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit was evaluated using 340 swabs from patients with MP symptoms within 7 days of symptom onset determined. Two swabs were taken from the same people a nasopharyngeal swab directly associated with the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit and a nasopharyngeal swab tested with the RT-PCR test kit. The clinical samples were positive or negative using the RT-PCR reference method.

Method		MP Nucleic Acid Test Kit (RT-PCR)		Total Results
SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit	MP	Positive	Negative	
	Positive	157	1	158
	Negative	1	181	182
Total Results		158	182	340

Clinical Sensitivity = 157/158=99.37%（95%CI:95.44%~99.46%）
Clinical Specificity =181/182=99.45%（95%CI:96.87%~99.80%）
Accuracy:338/340= 99.41%（95%CI:96.23%~99.85%）

Cross Reaction

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Species	Name of pathogen	Concentration
Coronavirus	Coronavirus HKU1	1.0 x 10^6copies/mL
	Coronavirus OC43	1.0 x 10^6copies/mL
	Coronavirus 229E	1.0 x 10^6copies/mL
	Coronavirus NL63	1.0 x 10^6copies/mL
Adenovirus	Type 1	1.0 x 10^6copies/mL
	Type 2	1.0 x 10^6copies/mL
	Type 3	1.0 x 10^6copies/mL
	Type 4	1.0 x 10^6copies/mL
	Type 5	1.0 x 10^6copies/mL
	Type 7	1.0 x 10^6copies/mL
	Type 55	1.0 x 10^6copies/mL
Influenza A	Novel Influenza A (H1N1) Virus	1.0 x 10^6copies/mL
	H5N1	1.0 x 10^6copies/mL
	H3N2	1.0 x 10^6copies/mL
	H7N9	1.0 x 10^6copies/mL
	Seasonal H1N1 influenza virus	1.0 x 10^6copies/mL
Influenza B	Yamagata	1.0 x 10^6copies/mL
	Victoria	1.0 x 10^6copies/mL
Respiratory virus	Parainfluenza virus type 1	1.0 x 10^6copies/mL
	Parainfluenza virus type 2	1.0 x 10^6copies/mL
	Parainfluenza virus type 3	1.0 x 10^6copies/mL
Pneumonia virus	Respiratory syncytial virus type A	1.0 x 10^6copies/mL
	Respiratory syncytial virus type B	1.0 x 10^6copies/mL
Rhinovirus	Rhinovirus A	1.0 x 10^6copies/mL
	Rhinovirus B	1.0 x 10^6copies/mL
	Rhinovirus C	1.0 x 10^6copies/mL
Metapneumovirus	Human metapneumovirus	1.0 x 10^6copies/mL
Enterovirus	Enterovirus A	1.0 x 10^6copies/mL
	Enterovirus B	1.0 x 10^6copies/mL
	Enterovirus C	1.0 x 10^6copies/mL
	Enterovirus D	1.0 x 10^6copies/mL
Lymphophilic viruses	EB virus	1.0 x 10^6copies/mL
Measles virus	Measles virus	1.0 x 10^6copies/mL
Cytomegalovirus	Human cytomegalovirus	1.0 x 10^6copies/mL
Rotavirus	Rotavirus	1.0 x 10^6copies/mL
Norovirus	Norovirus	1.0 x 10^6copies/mL
Mumps virus	Mumps virus	1.0 x 10^6copies/mL
Herpes virus	Herpes zoster virus	1.0 x 10^6copies/mL
Mycoplasma	Mycoplasma pneumoniae	1.0 x 10^6CFU/mL

Interfering Substances Reaction

When tested using the SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit, there was no interference between the device reagents and the Potential interference substances listed in below table that would create.

Substance	Concentration	Substance	Concentration
Mucin	120mg/dL	Azithromycin	2mg/mL
Human Blood	20% (v/v)	Tobramycin	1.2mg/mL
Phenylephrine	4mg/mL	Histamine Dihydrochloride	10 mg/mL
Oxymetazoline	4mg/mL	Lopinavir	1000mg/mL
Sodium Chloride	40mg/mL	Ritonavir	120mg/mL
Beclomethasone	40mg/mL	Arbidol	1400ng/mL
Dexamethasone	40mg/mL	Ceftriaxone	80μg/mL
Flunisolide	40μg/mL	Meropenem	400mg/mL
Triamcinolone Acetonide	4mg/mL	Peramivir	2mg/mL
Budesonide	4mg/mL	Interferon-α	1600IU/mL
Mometasone	4mg/mL	Ribavirin	20mg/mL
Fluticasone	4mg/mL	Oseltamivir	120ng/mL
Zanamivir	40mg/mL	Levofloxacin	20μg/mL

Symbol

Symbol	Meaning	Symbol	Meaning
IVD	In Vitro Diagnostic Medical Device		Storage Temperature Limit
	Manufacturer	EC REP	Authorized Representative In The European Community
	Date of Manufacture		Use By Date
	Do Not Reuse		Consult Instruction For Use
LOT	Batch Code	CE	CE Conformity Marking
REF	Catalogue number	Σ	Contains Sufficient For <n> Tests
	This Way Up		Do Not Use If Package Is Damaged
	Keep Away From Sunlight		Keep Dry
	Keep out of reach of children		Biological Hazard

Shenzhen Reagent Technology Co.,Ltd.
R777, Hangcheng Wisdom Science Park, Hangcheng street, Bao'an District, Shenzhen 518128, China.

EC REP
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+34 951214054 Info@cmcmedicaldevices.com

SARS-Cov-2/RSV/ADV/ MP&FLU A/B Antigen Rapid Test Kit

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