WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT

Product: Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold)
Manufacturer: Shanghai Kehua Bio-engineering Co., Ltd.
EUL Number: EUL 0658-037-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: a desktop review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- Product Dossier Review: assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) with product codes R-425-25-T, Rest of World regulatory version manufactured by Shanghai Kehua Bio-engineering Co., Ltd., 1189 Qinzhou North Rd, Caohejing Hi-Tech Park, Xuhui District Shanghai 200233, China, was listed as eligible for WHO procurement on 6 June 2022.

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the accepted product under EUL, for which WHO has been notified and has undertaken a review. Amendments to the report are summarized, and details of each amendment are
provided below.

Version	Summary of amendment	Date of report amendment
2.0	Acceptance of additional cross-reactivity testing results and closing the commitment in the public report. The IFU was amended to include additional cross-reactivity testing results.	6 December 2022

Intended use

According to the claim of intended use from Shanghai Kehua Bio-engineering Co., Ltd., "*the Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 in human Nasopharyngeal swab specimens. It is for in vitro diagnostic use only. This test is intended for use in point of care and clinical settings as an aid to early diagnosis of SARS-CoV-2 infection in a patient with clinical symptoms of SARS-CoV-2 infection by healthcare providers and laboratory professional. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis."*

Specimen type that was validated: Nasopharyngeal swab specimens.

Assay description

According to the claim of assay description from Shanghai Kehua Bio-engineering Co., Ltd., "*the Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) has two pre-coated lines, "C" control line, "T" test line on the surface of the nitrocellulose membrane. Anti-SARS-CoV-2 antibody is coated on the test line region and anti-chicken IgY antibody is coated on the control line region. Anti-SARS-CoV-2 antibody conjugated with color particles are used as detectors for SARS-CoV-2 antigen device. During the test, SARS-CoV-2 antigen in the specimen interact with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making antigen-antibody color particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. If SARS-CoV-2 antigens are not present in the specimen, then no color appears in the test line. Chicken IgY conjugated with color particles are used as detectors for control line. The control line is used for procedural control, and should always appear if the test procedure is performed properly. It demonstrates only that flow of liquid has occurred."*

Test kit contents

Component	25 tests/kit (product code R-425-25-T)
Test strip and test tube	1 x 25 pieces
Extraction solution	6ml × 2 bottles
Nasopharyngeal swab	1 × 25 pieces
Instructions for use	1
Sponge base	1

Items required but not provided

- Personal protective equipment (i.e., laboratory coats, disposable gloves, masks, or eye protection)
- Clock, timer, or stopwatch
- Biohazard disposal container

Storage
The test kit should be stored at 2 to 30°C.

Shelf-life upon manufacture
12 months (real-time stability studies are ongoing)

Warnings/limitations
Please refer to the attached instructions of use (IFU).

Product dossier assessment

Shanghai Kehua Bio-engineering Co., Ltd. submitted a product dossier for the Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen (PQDx_0347)"*. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and an external assessor appointed by WHO.

Post listing Commitments for EUL

As a requirement for listing, the manufacturer is required to:

1. Demonstrate that the BSA supplied is from BSE-free cattle, when available.
2. When available, demonstrate the traceability of the materials used to validate the product with the WHO International Standard for SARS-CoV-2 antigen and provide the report to WHO.

3. Estimate the LoD of the product with the WHO International Standard for SARS when available and provide the report to WHO within one month of completion of the study.
4. Partake in an independent performance evaluation conducted by a laboratory commissioned by WHO. Any such performance evaluation testing will be performed using the protocol and technical criteria established by WHO.
5. Submit additional cross-reactivity testing results by 31 August 2022. The additional data was assessed and accepted. The issue is closed.

Risk-benefit assessment conclusion is acceptable.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Shanghai Kehua Bio-engineering Co., Ltd. was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff and external technical experts (assessors), it was established that sufficient information was provided by Shanghai Kehua Bio-engineering Co., Ltd. to fulfill the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen(PQDx_ 347)"*.

The quality management documentation assessment conclusion is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods, and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-prequalification activities are required to maintain the prequalification status:
1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics"* (ISBN 978-92-4-001531-9).

Shanghai Kehua Bio-engineering Co., Ltd. is also required to report complaints related to the product. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality, and performance monitoring activities are in place, which are in accordance with WHO guidance "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics."*[1]

Scope and duration of procurement eligibility

The Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) with product code R-425-25-T, manufactured by Shanghai Kehua Bio-engineering Co., Ltd., is considered eligible for WHO procurement for 12 months from the day of listing. The assay may detect the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, Shanghai Kehua Bio-engineering Co., Ltd. must engage in post-market surveillance activities to ensure that the product meets safety, quality, and performance requirements. Shanghai Kehua Bio-engineering Co., Ltd. must notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes made to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

[1] https://www.who.int/publications/i/item/9789240015319

Labelling

1. **Labels**
2. **Instructions for use**

1.0 Labels

1.1 Kit box

KHB 科华生物

KHB 科华生物

Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold)

REF R-425-25-T

CONTENT

1. Test strip and test tube ×25
2. Extraction solution 6ml×2 bottles
3. Nasopharyngeal swab×25
4. Instructions for use×1
5. Sponge base×1

25 TESTS/KIT

/ Production date

LOT / Lot number

/ Expiry date

30°C
4°C
/ Store at 4°C–30°C

SHANGHAI KEHUA BIO-ENGINEERING CO., LTD.

KHB 科华生物

上海科华生物工程股份有限公司

Shanghai Kehua Bio-engineering Co., Ltd.
1189 North Qinzhou Road, 200233, Shanghai, P.R. China
Tel: +86-21-54500744
+86-8008203370
Fax: +86-21-64854051
Website:http://www.skhb.com

Please refer instructions for use IVD

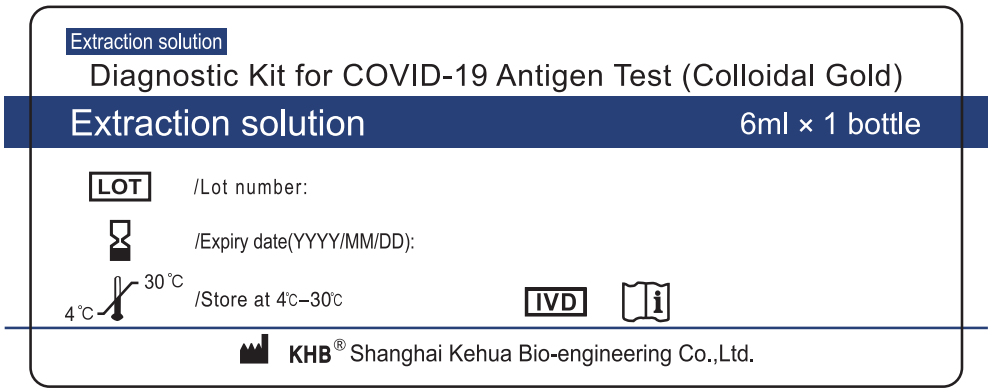
Σ 25

1.2 Extraction solution label

20210721
54X22MM

卷标

P293C K100



1.3 Foil pouch label

Tube

For *In Vitro* Diagnostic Use Only **1Test**

Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold)

/Production date (YYYY/MM/DD):

LOT /Lot number:

/Expiry date (YYYY/MM/DD):

4℃ 30℃ /Store at 4℃-30℃

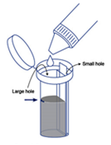
IVD

KHB® Shanghai Kehua Bio-engineering Co.,Ltd.
Website: Http:// www.skhb.com

1

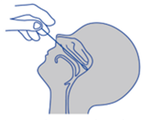
Open package:
Take out the test tube containing the test strip from the foil pouches.

2



Add solution:
Insert the test tube into the sponge base and add extraction solution into the large hole of the test tube to the scale mark (approximately 13 drops).
The extraction solution should not touch the test strip or be added to the small hole with the test strip inserted.

3



Collect nasopharyngeal swab sample:
Insert the swab into the nasopharynx and swab over the surface of the posterior nasopharynx (Swab should reach depth equal to distance from nostrils to outer opening of the ear). Slowly rotate the swab at least 5 times. Leave the swab in place for several seconds to absorb secretions. Then slowly withdraw the swab from the nasal cavity.

4

Mix:
Insert the swab into the test tube, stir for 5 times, and mix well (Do not touch the test strip with the nasopharyngeal swab) .

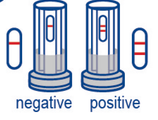
5

Break the swab:
Completely break off the swab at the crease point.

6

Close the tube cover and let stand:
Close the tube cover and press it tightly, turn the test tube upside down, and let it insert into the large hole of the sponge base (The test tube cannot be turned over again or tilt)

7



Read the result:
The test result can be read after 15 minutes and the result is valid for the following 60 minutes.

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2.0 Instructions for use (IFU)[2]

[2] English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

KHB® IVD

DIAGNOSTIC KIT FOR COVID-19 ANTIGEN TEST

(COLLOIDAL GOLD)

Instructions for use

REF

R-425-25-T (25 Tests)

⚠*PLEASE USE IN STRICT ACCORDANCE WITH THE INSTRUCTIONS FOR USE*

【PRODUCT NAME】

Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold)

【PACKAGE SIZE】

25 Tests/Kit

【INTRODUCTION】

Since the COVID-19 pandemic, laboratories have been using nucleic acid amplification testing (NAAT) to detect the SARS-CoV-2 virus that causes the disease, such as real-time reverse transcription polymerase chain reaction (rRT PCR). However, It can be challenging to use NAATs to diagnose active SARS-CoV-2 infection in many countries where NAAT testing capacity is limited. Thus, it is urgent to introduce rapid antigen-detecting diagnostic tests (Ag-RDTs) using upper respiratory secretions to offer a faster and less expensive way for SARS-CoV-2 testing.

At present, data on antigen-detecting tests from different brands show that the detection performance of currently available antigen-detecting tests is relatively good for use in patients early in the course of infection (1-3 days after symptom onset and within the first 5-7 days of illness). This provides an opportunity for early diagnosis and for blocking transmission by targeted isolationof the most infectious cases and their close contacts. Patients who present more than 5-7 days after the onset of symptoms are more likely to have lower viral load and the likelihood of false negative results is higher.

【INTENDED USE】

The Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 in human Nasopharyngeal swab specimens**.** It is for in vitro diagnostic use only.This test is intended for use in point of care and clinical settings as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms of SARS-CoV-2 infection by healthcare providers and laboratory professional. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis.

【PRINCIPLES OF PROCEDURE】

Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) has two pre-coated lines, “C” control line, “T” test line on the surface of the nitrocellulose membrane. Anti-SARS-CoV-2 antibody is coated on the test line region and anti-chicken IgY antibody is coated on the control line region. Anti-SARS-CoV-2 antibody conjugated with color particles are used as

detectors for SARS-CoV-2 antigen device. During the test, SARS-CoV-2 antigen in the specimen interact with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making antigen-antibody color particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. If SARS-CoV-2 antigens are not present in the specimen, then no color appears in the test line. Chicken IgY conjugated with color particles are used as detectors for control line. The control line is used for procedural control, and should always appear if the test procedure is performed properly. It demonstrates only that flow of liquid has occurred.

【MATERIALS PROVIDED】

1. Test strip and test tube 1×25 pieces
2. Extraction solution 6ml×2 bottles
3. Nasopharyngeal swab 1×25 pieces
4. Instructions for use 1 piece
5. Sponge base 1 piece

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Personal protective equipment (i.e. laboratory coats, disposable gloves, masks or eye protection)
- Clock, timer or stopwatch
- Biohazard disposal container

【STORAGE AND SHELF-LIFE】

Store the kit at 4-30°C until expiration date. The shelf-life is 12 months.

Do not use frozen or expired kit components.

For production date and expiry date, please refer to packing label.

The test strip and test tube should be used immediately upon opening the pouch.

The extraction solution should be stored at 4-30°C and used within 3 months after opening.

【WARNING】

1. This product is only used for in-vitro diagnostic purposes; the Instructions for Use should be read in detail before use.
2. Incorrect or false results may occur if not used in strict accordance with the instructions for use.
3. Do not use the test tube if the pouch is damaged or the seal is broken.
4. Do not use the accessories in the kit if the accessories are damaged or broken.
5. Do not reuse the test tube or the nasopharyngeal swab.
6. It is recommended that test cards, extration solution and samples after use should be treated as biohazardous waste and disposed according to applicable local regulations.
7. The extraction solution in this kit contains sodium azide (≤ 0.1%) as the preservative. Be cautious while using with the kit and do not ingest the extraction solution. The extraction solution should be avoided direct contact with skin and eyes. In case of contact with eyes and/or skin, flush affected area with copious amount of water. Do not dispose the extraction solution directly in drains and it should be treated as biohazardous waste. If disposed down a sink or other plumbing system by accident, use copious amounts of water to flush the system.
8. This product requires visual reading. In order to ensure the correct interpretation of the results, please do not read in the dark environment.
9. Negative results with the antigen tests do not preclude SARS-CoV-2 infection and such results must be combined with patients' symptoms, medical history, other laboratory tests, treatment response, epidemiology and other

information.

【PRECAUTIONS】

1. Wear protective clothing such as laboratory coats, disposable gloves, masks or eye protection, and take other appropriate safety precautions when handling patient samples.
2. Do not eat, drink or smoke in the area where samples and kit reagents are handled. Avoid any contact between hands, eyes or mouth during sample collection and testing.
3. Dispose of used gloves as biohazard waste. Wash hands thoroughly after handling specimens and kit reagents.
4. Avoid splashing or aerosol formation.
5. Clean up drops or spills thoroughly using an appropriate disinfectant, such as 10,000 parts per million [ppm] (1%) sodium hypochlorite, 70% ethanol, benzalkonium chloride (0.1%), etc.
6. Decontaminate and dispose of all used specimens, test devices, nasopharyngeal swabs, and empty extraction solution bottle, in a biohazardous waste container.
7. KHB® Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) requires the handling of human specimens. All human-sourced materials and all consumables contaminated with potentially infectious materials should be considered potentially infectious and therefore should be handled in accordance with appropriate national, state or local regulations.

【SPECIMEN COLLECTION】

1. Tilt the patient's head back slightly about 45°-70° to straighten the passage from the front of the nose.
2. Insert the swab with a flexible shaft through the nostril parallel to the palate.

Caution: Use dedicated nasopharyngeal swab provided in the kit for specimen collection.

3. Swab should reach depth equal to distance from nostrils to outer opening of the ear.

Caution: If resistance is encountered during insertion of the swab, remove it and attempt insertion in the opposite nostril.

4. Gently rub and roll the swab for at least 5 times. Leave the swab in place for several seconds to absorb secretions.
5. Slowly remove swab while rotating it and insert into the extraction tube.

【SPECIMEN TRANSPORT AND STORAGE】

Do not return the nasopharyngeal swab to the original paper packaging.

The intended environment of the kit is point of care and clinical setup. For best performance, it is highly recommended to test direct swab specimens immediately after collection. Specimens stored in viral transport media (VTM) or other media have not been validated.

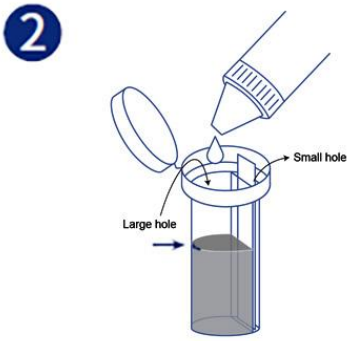
If immediate testing is not possible, the swab specimen can be kept in the test tube containing extraction solution (up to the scale mark), with cover capped tightly at 10-30°C for up to 1 hour prior to testing.

【TEST PROCEDURE】

Equilibrate the devices to 10-30°C and perform the assay at this temperature. Only the extraction solution provided in the kit can be used and extraction solution from different batches cannot be mixed.

Open package:

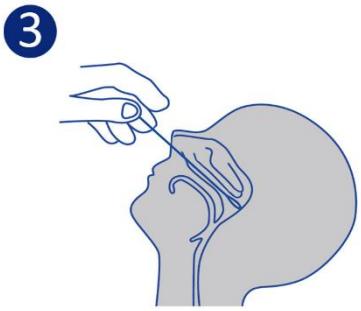
Take out the test tube containing the test strip from the foil pouches.



Add solution:

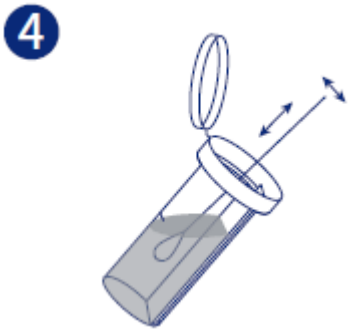
Insert the test tube into the sponge base and add extraction solution into the large hole of the test tube to the scale mark (approximately 13 drops).

The extraction solution should not touch the test strip or be added to the small hole with the test strip inserted.



Collect nasopharyngeal swab sample:

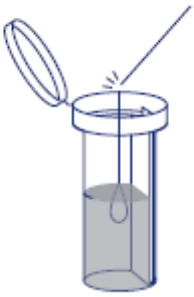
Insert the swab into the nasopharynx and swab over the surface of the posterior nasopharynx (Swab should reach depth equal to distance from nostrils to outer opening of the ear). Slowly rotate the swab at least 5 times. Leave the swab in place for several seconds to absorb secretions. Then slowly withdraw the swab from the nasal cavity.



Mix:

Insert the swab into the test tube at once after collection, stir for 5 times, and mix well **(Do not touch the test strip with the nasopharyngeal swab)**.

5

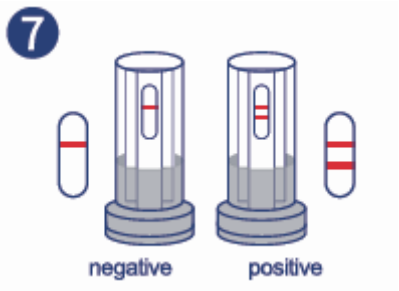


Break the swab: Completely break off the swab at the crease point.

6

Close the tube cover and let stand: Close the tube cover and press it tightly, turn the test tube upside down, and let it insert into the large hole of the sponge base **(The test tube cannot be turned over again or tilt)**.

7



Read the result:

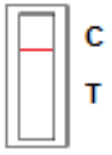
The test result can be read after 15 minutes and the result is valid for the following 60 minutes.

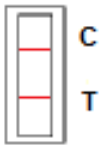
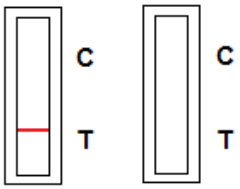
In order to ensure proper test performance, the results need to be read after 15 minutes and within 60 minutes. Read results within 15 minutes or over 60 minutes are invalid.

Note: When reading test results, tilt the test tube to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.

【RESULT INTERPRETATION】

T: test line; C: control line

Negative A negative specimen will give a single purplish red colored control line in the top half of the window, indicating a negative result. It means no SARS-CoV-2 antigen was detected.	

Positive A positive specimen will give two purplish red colored lines. This means that SARS-CoV-2 antigen was detected. Specimens with low levels of antigen may give a faint test line. This must still be interpreted as Positive.	
Invalid If no lines are seen, or just the test line is seen, the assay is invalid. Please repeat the test.	

【LIMITATIONS】

1. Test performance depends on the amount of virus antigen in the sample and validity of sampling.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. The performance of Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) was only evaluated using the procedures provided in this product insert. Modifications to these procedures may alter the performance of the test.
4. False negative results may occur if a specimen is improperly collected, transported, or handled.
5. The swab must be put into the extraction buffer at once and tested within 1 hour of collection. False results may occur if specimens are tested past 1 hour of collection
6. Positive test results do not rule out co-infections with other pathogens.
7. Negative test results are not intended to rule in other viral or bacterial infections.
8. Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
9. The highest concentration of β-propiolactone inactivated SARS-CoV-2 (1 x 107 $TCID_{50}$/mL) and recombinant SARS-CoV-2 nucleocapsid (N) protein (5.5mg/ml) were tested. There was no hook effect detected. False-negative results may still occur above the highest concentration investigated.

【CLINICAL PERFORMANCE】

The clinical study was performed to evaluate the performance of the Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) using nasopharyngeal swab samples. In total, 140 positive specimens and 400 negative samples were used for diagnostic sensitivity and specificity study using RT-PCR as reference test.

1. Diagnostic sensitivity

   The overall diagnostic sensitivity or positive percent agreement of the Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) tested on all 140 nasopharyngeal swab samples from SARS-CoV-2 positive patients compared to the Roche Cobas® SARS-CoV-2 RT-PCR was 82.9% (116/140) (Wilson 95% CI [75.8% - 88.2%]). When excluding all samples with Ct-values > 30, a diagnostic sensitivity of 96.5% (109/113) (Wilson 95% CI [91.3% - 98.6%]) was obtained. The detailed information is shown as follows:

	KHB® Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold)	
	Positive	Negative
Roche Cobas® SARS-CoV-2	116	24

Including Ct-values > 30		
Roche Cobas® SARS-CoV-2 Excluding Ct-values > 30	109	4
Diagnostic sensitivity Including Ct-values > 30	**82.9% (116/140) (Wilson 95% CI [75.8% - 88.2%])**	
Diagnostic sensitivity Excluding Ct-values > 30	**96.5% (109/113) (Wilson 95% CI [91.3% - 98.6%])**	

2. Diagnostic specificity

The diagnostic specificity or negative percent agreement of the Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) tested on nasopharyngeal swab samples from SARS-CoV-2 negative patients compared to the Roche Cobas® SARS-CoV-2 RT-PCR was 98.3% (393/400) (Wilson 95% CI [96.4% -99.1%]). The detailed information is shown as follows:

	KHB® Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold)	
	Negative	Positive
Roche Cobas® SARS-CoV-2	393	7
Diagnostic specificity	**98.3% (393/400) (Wilson 95% CI [96.4% - 99.1%])**	

【ANALYTICAL PERFORMANCE】

1. Limit of Detection (LoD)

The Limit of Detection (LoD) of Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) was determined by using different concentrations of β-propiolactone inactivated SARS-CoV-2 (BetaCov/Wuhan/IPBCAMS-WH-01/2019). The material was supplied at 2-8℃ at a concentration of 10^7 $TCID_{50}$/mL.

Inactivated SARS-CoV-2 virus was diluted into different concentrations of samples with pooled human nasal wash for testing.

The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) LoD was confirmed as 5 x 10^2 $TCID_{50}$/mL.

2. High dose hook effect

The highest concentration of β-propiolactone inactivated SARS-CoV-2 (1 x 10^7 $TCID_{50}$/mL) and recombinant SARS-CoV-2 nucleocapsid (N) protein (5.5mg/ml) were tested. There was no hook effect detected.

3. Analytical specificity

- Specificity performance in general population

  31 of 31 PCR negative specimens tested with Diagnostic Kit for COVID-19 Antigen Test (Colloidal Gold) at the same time were negative, yielding a specificity of 100%. The data come from voluntary testing.

- Cross-reactivity & Microbial interference

  Each organism listed below was tested in triplicate in the absence or presence of inactivated SARS-CoV-2 at 1 x

10^3 $TCID_{50}$/mL (2 x LOD) and there was no cross-reactivity or interference found when they were tested at the concentration presented in the table below.

Potential Cross-Reactant	Type/Strain	Concentration
Human coronavirus	229E	2.5×10^5 $TCID_{50}$/mL
	OC43	1.8×10^5 $TCID_{50}$/mL
	NL63	1.8×10^5 $TCID_{50}$/mL
	HKU1	2.24×10^5 $TCID_{50}$/mL
SARS-coronavirus	2003-00592	13mg/mL
MERS-coronavirus	Florida/USA-2_Saudi Arabia_2014	1.17×10^5 $TCID_{50}$/mL
Adenovirus	B1 group type 3	1.8×10^5 $TCID_{50}$/mL
	B1 group type 7	1.8×10^5 $TCID_{50}$/mL
	B1 group type 55	2.0×10^5 $TCID_{50}$/mL
	C group type 1	4.0×10^5 $TCID_{50}$/mL
	C group type 2	2.8×10^5 $TCID_{50}$/mL
	C group type 5	1.8×10^5 $TCID_{50}$/mL
	E group type 4	1.4×10^5 $TCID_{50}$/mL
Human Metapneumovirus (hMPV)	type A2	1.6×10^5 $TCID_{50}$/mL
	type B1	2.4×10^5 $TCID_{50}$/mL
	type B2	1.2×10^5 $TCID_{50}$/mL
Parainfluenza virus	type 1	1.8×10^5 $TCID_{50}$/mL
	type 2	4.3×10^5 $TCID_{50}$/mL
	type 3	1.6×10^5 $TCID_{50}$/mL
	type 4a	1.3×10^5 $TCID_{50}$/mL
Influenza A	2009-H1N1	1.8×10^5 $TCID_{50}$/mL
	H1N1	2.0×10^5 $TCID_{50}$/mL
	H3N2	2.0×10^5 $TCID_{50}$/mL
	Avian influenza virus H5N1	1.0×10^4 $TCID_{50}$/mL
	Avian influenza virus H7N9	1.0×10^4 $TCID_{50}$/mL
Influenza B	lineages Yamagata	2.0×10^5 $TCID_{50}$/mL
	lineages Victoria	2.8×10^5 $TCID_{50}$/mL
Enterovirus	type 70	3.1×10^5 $TCID_{50}$/mL
	type 71	4.3×10^5 $TCID_{50}$/mL
	Coxsackie virus type A6	1.8×10^5 $TCID_{50}$/mL
	Coxsackie virus type A10	3.8×10^5 pfu/mL
	Coxsackie virus type A16	5.6×10^5 $TCID_{50}$/mL
	Coxsackie virus type A24	2.0×10^5 $TCID_{50}$/mL
	Coxsackie virus type B1	1.1×10^5 $TCID_{50}$/mL
	Coxsackie virus type B2	1.9×10^5 $TCID_{50}$/mL
	Coxsackie virus type B3	2.1×10^5 pfu/mL

	Coxsackie virus type B4	1.5×10^5 $TCID_{50}$/mL
	Coxsackie virus type B5	2.4×10^5 $TCID_{50}$/mL
	Echovirus type 6	1.4×10^5 $TCID_{50}$/mL
Respiratory syncytial virus	type A	2.4×10^5 $TCID_{50}$/mL
	type B	2.4×10^5 $TCID_{50}$/mL
Rhinovirus	type A2	1.6×10^5 $TCID_{50}$/mL
	type A30	1.4×10^5 $TCID_{50}$/mL
	type A31	1.0×10^5 $TCID_{50}$/mL
	type A81	1.1×10^5 $TCID_{50}$/mL
	type B52	2.0×10^5 $TCID_{50}$/mL
	type B70	1.0×10^5 $TCID_{50}$/mL
	type B72	1.2×10^5 $TCID_{50}$/mL
Chlamydia pneumoniae	TW-183	1.0×10^5 $TCID_{50}$/mL
Haemophilus influenzae	L-378	2.7×10^6 cfu/mL
Legionella pneumophila	Philadelphia-1	2.0×10^6 cfu/mL
Streptococcus pneumoniae	type 14	1.8×10^6 cfu/mL
Bordetella pertussis	MN2531	5.8×10^6 cfu/mL
Mycoplasma pneumoniae	FH	1.3×10^7 copies/mL
Pooled human nasal wash	Represent diverse microbial flora in the human respiratory tract	/
Mycobacterium tuberculosis	/	2.57×10^7 cfu/mL
Pseudomonas aeruginosa	CMCC 10104	1.4×10^6 cfu/mL
Pneumocystis carinii rat prototype	ATCC 50385	1.0×10^8 nuclei/mL
Staphylococcus epidermis	FDA strain PCI 1200	1.2×10^7 cfu/mL
Staphylococcus aureus	CMCC(B)26003	1.0×10^8 $TCID_{50}$/mL
Streptococcus pyogenes	ATCC 19615	1.0×10^7 cfu/mL
Bordetella parapertussis	NCTC 5952[522]	2.2×10^6 cfu/mL
Human herpesvirus	Epstein-Barr virus	5.0×10^7 copies/mL
	Human cytomegalovirus	2.1×10^5 $TCID_{50}$/mL
Measles virus	Edmonston	1.8×10^5 $TCID_{50}$/mL
Mumps virus	Jones	3.2×10^5 $TCID_{50}$/mL
Varicella Zoster Virus	82	4.28×10^8 copies/mL
Rotavirus	WA	1.15×10^7 U/mL
Norovirus(Recombinant)	Group I	1.02×10^8 U/mL

*Human coronavirus HKU1 has not been tested. There may be cross-reaction with Human coronavirus HKU1, even though the % identity of the nucleocapsid protein sequence of HKU1 with the nucleocapsid protein sequence of SARS-CoV-2 was 35.22%, which is considered as low homology.

- Potential endogenous and exogenous interfering substances

  Each substance listed below was tested in triplicate in the absence or presence of inactivated SARS-CoV-2 at 1 x 10^3 $TCID_{50}$/mL (2 x LOD) and there was no interference found when they were tested at the concentration presented in the table below.

Interfering Substances	Concentration
Oseltamivir Phosphate (Influenza)	10 mg/mL
Doxycycline Hyclate (Malaria)	70 μM
Lamivudine (Retroviral Medication)	1 mg/mL
Ribavirin (HCV)	1 mg/mL
Acetaminophen	200 μM
Compound Acetyl-Salicylic Acid	3.7 mM
Mupirocin	6.25 mg/mL
Tobramycin	5 μg/mL
Erythromycin Lactobionate	81.6 μM
Ciprofloxacin Hydrochloride	31 μM
Physiological Seawater Nasal Spray	10% (v/v)
Anti-bacterial Gel	5% (v/v)
Budesonide Nasal Spray	10% (v/v)
Throat Candy (Mint)	5% (w/v)
Blood (Human)	10% (v/v)
HAMA Serum	10% (v/v)
Sulfo-NHS-LC-LC-Biotin	100 μg/mL
Ibuprofen	2.5 mM

4. Repeatability and reproducibility

   Two different operators tested 3 specimens (including one negative specimen, one weak positive specimen and one medium positive specimen) independently with three batches of products in two different sites, continuously for 5 days. Each specimen was repeated 10 tests in a run.

   The expected negative specimens showed negative results and the positive specimens showed positive results in all tests. The intensity of T lines of a same specimen was consistent and uniform and did not show any obvious difference among all measures.

【REFERENCE】

1. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays: interim guidance. WHO 11 September 2020
2. Antigen-detection in the diagnosis of SARS-CoV-2 infection: interim guidance. WHO 6 October 2021

Key symbols used

	**Caution**		**Temperature limitation (4-30 °C)**
	**Batch code**		**Date of manufacture**
	**In vitro diagnostic use medical device**		**Consult instructions for use**
	**Catalogue number or order number**		**Do not use if package is damaged**
	**Use by**		**Sufficient for "n" use**
	**Do not reuse**		**Biological risks**
	**Manufacturer**		**Sterilized using Ethylene Oxide**

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