

FOR INVESTIGATIONAL USE ONLY Please read this instruction for use, before unpacking any other content or

performing the test.

This product has not been FDA cleared or approved but has been intended to be authorized by FDA under an Emergency Use Authorization (EUA). For professional testing either from anterior nasal or nasopharyngeal area with nasopharyngeal swab. For the most up to date information on COVID-19, please visit:

For In Vitro Diagnostic (IVD) use only. www.cdc.gov/COVID19 **MATERIALS SUPPLIED**

3. Test cassette Instruction for Use (IFU) 5. Positive External Control Swab

for use.

Nasopharyngeal Swab

- 6. Negative External Control Swab
- MATERIALS REQUIRED BUT NOT PROVIDED Timer Waste for biological hazard materials

2. Tube with antigen extraction solution

- Personal protective equipment Scissor
- INTENDED USE The CHIL® COVID-19 Antigen Rapid Test is a lateral flow immunoassay

intended for the qualitative detection of two different protein antigens (multiple targets) of SARS-CoV-2 in anterior nasal (nares) or nasopharyngeal swab specimens. This instruction for use (IFU) must be

read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions

The CHIL® COVID-19 Antigen rapid test is intended for use by healthcare provider operators which specifically instructed and trained in the techniques of in vitro diagnostic procedures and proper infection control procedures for using at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation and also in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C.

§263a, the meet requirements to perform high or moderate complexity tests. In the United States, the CHIL® COVID-19 Antigen test is intended only for investigational use under the Food and Drug Administration's Emergency Use Authorization process The CHIL® COVID-19 Antigen Rapid Test is intended to be authorized for patients who are suspected of COVID-19 by a healthcare provider within the first 7 days of symptom onset or for screening of individuals without symptoms or other reasons to suspect COVID-19 infection. The CHIL* COVID-19 antigen rapid test does not differentiate between SARS-CoV and SARS-CoV-2 Results are for the identification of the two different protein antigens (multiple targets) of SARS-CoV-2. The antigen is generally detectable in anterior nasal (nares) and nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with a past medical history and other

diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses The agent detected may not be the definite cause of the disease. Individuals who test positive for the CHIL® COVID-19 Antigen Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

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CH)iL STORAGE AND STABILITY Store the kit at 2-30°C / 36-86°F. · Do not freeze. If the tests were refrigerated, keep them at room temperature for 30 minutes prior to use · Protect the kit from direct sunlight and avoid staying in a humid environment. • Under favorable conditions, the product is stable until the expiry date

without being opened in its own package.

room temperature before they wanted to be used.

· The test cassette should be used within 15 minutes after being removed from its aluminium pouch, in the proper environment. Tests or specimens stored at low temperatures should be balanced to

IVESTIGATIONAL USE ONLY under the Food and Drug Administration's Emergency Use Authorization processes This instruction for use (IFU) must be read and followed carefully This product has not been FDA cleared or approved; but has been

pathogens

prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use

WARNINGS AND PRECAUTIONS

- intended to be authorized by FDA under EUA for use at the Point of Care (POC) fields, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of
- complexity tests For in vitro diagnosis made by professional healthcare providers only. This product has been intended to be authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or

Accreditation and also in laboratories certified under the Clinical

Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C.

§263a, the meet requirements to perform high or moderate

The test is a disposable in vitro diagnostic test, which is only used for the detection of human nasal and nasopharyngeal specimens

collected by nasopharyngeal swab. The application should be carried

The handle of the nasopharyngeal swab is longer and tip of it is

The test should be kept away from moisture. Tests or specimens

stored at low temperatures should be balanced to room temperature

out strictly according to the instructions.

before they can be used.

biohazards waste container.

samples in the provided extraction solution

1. Deep Nose (Nasopharyngeal) Swab:

about 10 seconds. Additional swab rotations

contamination.

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Do not use expired and damaged products.

Tests should be used as quickly as possible after removal from aluminium pouches, to avoid exposure to air for too long and to possibility of affecting test results due to humidity. 10. No test components are to be used inside the body except the swab. 11. Do not use specimens that have been placed for too long or contaminated. Please operate in accordance with the laboratory testing procedures for infectious diseases. Waste after use should be treated in accordance with infectious substances and should be discarded. Discard used test tubes, cassettes or swabs in suitable

12. Use a clean and sterile swab for every patient to avoid cross-

samples without any transport media (VTM, UTM etc.) and/or testing

1) Nasopharyngeal Swab Choose one of the sampling methods:

Tilt patient's head back 70°. A swab specimen is needed from both

nasopharyngeal area, and this is taken using the same swab. Insert swab

into the first nostril until the nasopharyngeal area while gently rotating the swab. Spin the swab at least 4 times against the nasopharyngeal area for

8-10 seconds. Remove the swab and repeat this process by using the same

swab into the second nasopharyngeal area. Then, place the swab into the

extraction tube. Insert the nasopharyngeal swab into the extraction tube

and rotate the swab at least 3 times against the bottom of the tube for

negatively affect performance. Squeeze center of the extraction tube and press the swab head against the tube wall to release the antigen in the

swab. Remove the swab while keeping the center of the tube squeezed. Squeeze the swab over the head to remove as much liquid as possible from

the swab. Then continue with the step 9 of the Test Procedure for

the single-use test is suggested to be used under low environment

1. Allow all kit components and specimens to reach room temperature

2. Remove the test cassette from the pouch, place it on a clean dry surface

4. A swab specimen is needed from both nasopharyngeal area, and this is

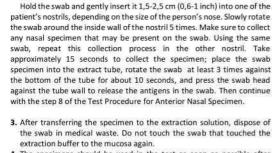
5. While gently rotating the swab, insert swab into the first nostril until

between 18°C - 26°C (65-75 °F) prior to testing.

and identify a test cassette for each patient.

the posterior wall of the nasopharyngeal area.

See the application illustration below;



collected (within minutes).

humidity (RH<60%) within 1 hour.

3. Tilt patient's head back 70°

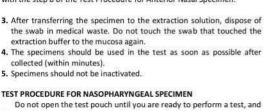
CHIL

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taken using the same swab.

Nasopharyngeal Specimen.

2. Only Anterior Nasal Swab



are not expected to

.0

COVID-19 ANTIGEN RAPID TEST EXTERNAL POSITIVE AND

One positive external control swab and one negative external control swab is supplied in each box. The positive and negative external control swabs

should be used to demonstrate that if any test kit properly differentiates

the positive and negative specimens. It is recommended that positive and

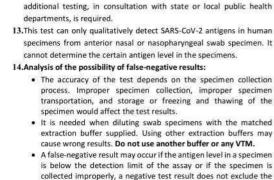
The external control should be tested as the any of the test procedure

If the control line does not appear or the correct results are not obtained

12.If the differentiation of specific SARS viruses and strains is needed,

negative external control swabs are run once.

To watch How to Perform - Instruction Video, check the QR below:



solution.

results.

Chemical

Name/ CAS No

Sodium Azide

26628-22-8

Tween 20 /

9005-64-5

1.3. Repeatability Page 5 / 6

Human coronavirus

Interference Substances

Substances

Mucin

Tobramycin

Chloraseptic

Whole blood

(Cromolyn)

Homeopathic

Sore Throat Phenol

Zicam

(Alkalol)

Spray

4.

Mupirocin

Fluticasone

Propionate Tamiflu (Oseltamivir

)Phosphate)

Antigen Rapid Test

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High Dose Hook Effect

(Menthol/Benzocain

HKU1

PERFORMANCE CHARACTERISTICS

Reference Control Material Study

1.1. The coincidence rate of positive controls

the coincidence rate (+ / +) was 100/100. The coincidence rate of negative controls

the coincidence rate (- / -) was 200/200.

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NEGATIVE CONTROLS

explained above, step 7.

· Cross-contamination of specimens may lead to false-positive 16. Analysis of the possibility of an invalid result: · If the specimen volume is less or over than required, the chromatography cannot be carried out successfully.

. The test would be invalid if the package was crashed. The

packaging status including expiration date must be checked

The extraction solution contains potentially harmful chemicals (see

table below). If the solution contacts the skin or eye, flush with

copious amounts of water. If irritation persists, seek medical advice:

Concentration

0,01%

0,4 %

Negative

Negative

epidermidis

tuberculosis Pneumocystis jirovecii

Mycobacterium

Pooled human nasal

normal respiratory

microbial flora

wash-representative of

visit https://www.poison.org/contact-us or 1-800-222-1222

GHS Code for applicable

LD50 Oral - Rat - 27 mg/kg

Acute Toxicity Oral, H302

LD50- rat - 38900 mg/kg

Ingredient

positive results. Do not use another buffer or any VTM.

· Inappropriate specimen collection, using another non-matching

· Non-standardized elution operation may lead to false-positive

Using any other buffer solutions including VTMs may lead to false-

possibility of SARS-CoV-2 infection.

carefully prior to the application.

17. Hazardous Ingredients for Reagent Solution

15. Analysis of the possibility of false-positive results:

105 pfu/mL

105 pfu/mL

Test was evaluated by testing a panel of related pathogens, high prevalence disease agents and normal or pathogenic flora including various microorganisms and viruses and negative matrix that are reasonably likely to be encountered in the clinical specimen and could

potentially cross-react or interfere with the CHIL® Covid-19 Antigen Rapid

Test. No cross-reactivity or interference was seen with the microorganisms when tested at the concentration presented in the table above

The following substances, naturally present in respiratory specimens or

Tested with 100 positive controls, the results were all positive, and

Tested with 200 negative controls, the results were all negative, and

that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the CHIL® Covid-19 Antigen Rapid Test at the concentrations listed below and were found not to affect test performance. CHIL® CHIL COVID-19 COVID-19

Concentratio

ns

0.5%

4%

4 mg/L

1.5 mg/ml

Antigen

Rapid

Results

Negative

2

Test

on

Antigen

Rapid

Results

Positive

Positive

Positive

Positive

Positive

Positive

Positive

Positive

Positive

403

Test

on

Naso GEL (NeilMed) Negative Positive 5% v/v CVS Nasal Drops Positive Negative 15% v/v (Phenylephrine) Positive Afrin(Oxymetazoline Negative 15% v/v CVS Nasal Spray Negative Positive

15% v/v

5% v/v

15% v/v

5% v/v

5 mg/mL

10 mg/ml

1:10 dilution

virus did not show hook-effect at 9.73x106TCID50/mL. Analysis of coincidence rate of previously performed COVID-19 Antigen Rapid Test and PCR Test study on deep nasal (nasopharyngeal) specimens: **PCR Test** Total Positive Negative CHIL® COVID-19 Negative 4 464 468

401

Positive

COVID-19 Antigen Rapid Test (Nasopharyngeal Swab – Cassette)

management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection such as in an individual with close contact with COVID-19 or with suspected exposure to COVID-19 or in

communities with a high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary if there is a low likelihood of SARS-CoV-2 infection such as in individuals without known exposures to SARS-CoV-2 or residing in communities with a low prevalence of infection.
Individuals who test negative and continue to experience COVID-like

WHAT IS COVID-19? Coronavirus disease is an infectious disease caused by the coronavirus belonging to the Coronaviridae family. It is a 27~32 kb RNA virus species commonly found in birds and mammals and had not been previously identified in humans. Coronavirus Disease 2019 (COVID-19) is a disease

first recognized in 2019 that is caused by a type of novel coronavirus called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Most estimates of the incubation period for COVID-19 up to 14 days It spreads primarily through respiratory droplets when a person coughs or

there is a test line.

provider.

experienced aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Individuals who test result negative and continue to experience COVID-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care from their healthcare provider. For up-to-date information on COVID-19, visit the CDC COVID-19 website: https://www.cdc.gov/coronavirus/2019-ncov/index.html The CHIL® COVID-19 antigen rapid test is a lateral flow immunoassay intended for the qualitative detection of two different protein antigens (multiple targets) from SARS-CoV-2 in anterior nasal or nasopharyngeal

specimens taken directly from people. Nasal or nasopharyngeal specimens which are collected nasopharyngeal swab by a trained healthcare provider operator

dissolved and migrate along with the specimen.

If any of the two different antigens of SARS-CoV-2 is present in the specimen, a complex formation between the anti-SARS-CoV-2 conjugate

Issued Date & Revision 2022.04.29/01 COM.RIFU.230 CKS-114 COVID-19 Antigen Rapid Test (Nasopharyngeal Swab – Cassette)

The extraction reagent contains Sodium Azide which may cause skin and eye irritation. If the solution makes contact with the skin or eye, wash/flush with copious amounts of water. If skin irritation or rash occurs, get medical advice/attention.

There should be appropriate biosafety assurance procedures for

Universal transport medium (UTM) or viral transport medium (VTM)

must not be used with CHIL® COVID-19 antigen rapid test. This may

Infection should be avoided by using gloves and masks.

Any kit components should not be swallowed.

result in erroneous patient results.

expired test kit.

following are relevant considerations: Handle specimens and tests with gloves. Do not suck specimens with your mouth. Do not smoke, eat, drink, cosmetic or handle contact lenses while handling these items.

Disinfect the surfaces after usage of the test. Disinfect and treat all specimens, Tests, and potential pollutants in accordance with relevant local regulations. Each component of the test remains stable until the expiry date

under proper handling and storage conditions. Do not use the

Please read your results in a well-lit area to avoid any mistakes.

- SERIAL TESTING COVID-19, especially when there are no symptoms.
 - likely has COVID-19. If both the first and second test results are negative, you may not have COVID-19, but the test may be supplemented with RT-PCR if the patient is at high risk for COVID-19.

If the first or second test result is positive, proteins from the virus

that causes COVID-19 were found in the sample and the patient

be performed 24-48 hours later with a new test.

SPECIMEN COLLECTIONS AND PREPARATION

into the extraction tube.

down.

down

12.Optimum reading time of results is 15 minutes. The results after 30 with the external positive and/or negative controls then discard the test

negatively affect performance.

minutes are no longer valid.

humidity (RH≤60%) within 1 hour.

test which is designed to detect antigen from the SARS-CoV-2 in nasal or nasopharyngeal specimens from directly humans with nasopharyngeal swab. Chil® Covid-19 Antigen Rapid Test is performing by healthcare providers to individuals within the first 7 days of the symptom onset or

The Chil® Covid-19 Antigen Rapid Test is a lateral flow immunoassay

(Nasopharyngeal Swab - Cassette) Product code: CCOV-201 Chil* Covid-19 Antigen Rapid Test is validated for testing direct 6. Rotate the swab at least 4 times against the posterior nasopharyngeal wall for 8-10 seconds. Remove and repeat this process by using the same swab into the second nasopharyngeal area. Then place the swab

> 7. Insert the nasopharyngeal swab collected from the patient all the way into the extraction tube and rotate the swab at least 3 times against the bottom of the tube. Additional swab rotations are not expected to

> 8. Squeeze center of the extraction tube and press the swab head against the tube wall to release the antigen in the swab. Remove the swab

> over the head to remove as much liquid as possible from the swab. Dispose of swabs according to the biohazard waste disposal procedure. 10.Keep the tube vertical as the breaking part will be upward to avoid

between 18°C - 26°C (65-75 °F) prior to testing. 2. Remove the test cassette from the pouch, place it on a clean dry surface and identify a test cassette for each patient. 3. Tilt patient's head back 70°. 4. A swab specimen is needed from both nostrils, and this is taken using the same swab. 5. While gently rotating the swab, insert swab less than one inch into the

- keeping the center of the tube squeezed. Squeeze the swab over the head to remove as much liquid as possible from the swab. Dispose of swabs according to the biohazard waste disposal procedure. 9. Close the cap of the extraction tube. 10.Keep the tube vertical as the breaking part will be upward to avoid
 - Issued Date & Revision 2022.04.29/01 COM.RIFU.230 CKS-114 COVID-19 Antigen Rapid Test (Nasopharyngeal Swab - Cassette)

Product code: CCOV-201

positive. Negative: If only quality control line (C) appears, and the test line (T) is colourless, it means that SARS-CoV-2 antigen has not been detected and the result is negative. Invalid: If the quality control line (C) is not observed, it will be invalid

regardless of whether there is a test line (T), and the test shall be

Note: Test line (T) color intensity may differ according to density of the collected specimen. However, within the specified observation time, regardless of the density of the colored line, even a very weak line should

1. This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the specimen and may or may not correlate with viral culture results

2. The result of the product should not be taken as a confirmed diagnosis,

of CHIL® COVID-19 antigen rapid test. However, the interpretation of the results is not affected during seasons without SARS infection. 11. The performance of this test will be established based on the evaluation of a limited number of clinical specimens collected.

Issued Date & Revision 2022.04.29/01 COM.RIFU.230 CKS-114

COVID-19 Antigen Rapid Test

106 cfu/mL Negative Streptococcus pyogenes Candida albicans 106 cfu/mL Negative Bordetella pertussis 106 cfu/mL Negative Chlamydia pneumoniae 10⁶ cfu/mL Negative Legionella pneumophila 106 cfu/mL Negative 106 cfu/mL Staphylococcus aurens Negative Staphylococcus 106 cfu/mL Negative

106 pfu/mL

106 pfu/mL

106 pfu/mL

Negative

Negative

Negative

Specificity: 99.57% (95%CI: 98.46% - 99.95%)*
Accuracy: 99.54% (95%CI: 98.83% - 99.88%)* *95 % Confidence Interval: (%-%) Disease prevalence accepted as 5%. Analysis of coincidence rate of previously performed COVID-19 Antigen Rapid Test and PCR Test study in anterior nasal specimens:

Positive Negative 2 Positive 100 102

Sensitivity: 99.01% (95%CI: 97.49% - 99.73%)*

but for clinical reference only. Diagnosis should be made along with RT-PCR results, clinical symptoms, epidemic conditions, and further clinical 3. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result. 4. Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test 5. Positive test results do not differentiate between SARS-CoV-2 and

Tested with repeatable control 1 for 10 times, the results were all positive and consistent. Tested with repeatable control 2 for 20 times, the results were all

Influenza B 106 pfu/ml Negative Rhinovirus 105 pfu/ml Adenovirus Negative Enterovirus 105 pfu/mL Negative Respiratory syncytial virus 105 pfu/ml Negative Negative 105 pfu/ml Rhinovirus Mycoplasma pneumoniae 106 cfu/mL Negative Parainfluenza virus 1 105 pfu/ml Negative

Human coronavirus 229E	10° pfu/mL	Negative
Human coronavírus OC43	10 ^s pfu/mL	Negative
Human coronavirus NL63	105 pfu/mL	Negative
MERS-coronavirus	105 pfu/mL	Negative
Issued Date &Revision	2022.04.29/01 CO	M.RIFU.230 CKS

(2)	For single use	IVD	In vitro di device
ш	Manufacturer	Σ	Contains :
Ω	Expire date	Δ	Caution! instructio warnings on packag
	MANUFACTI CHII® TIRRI	URER MAL. SAN. TÎ	C LTD ST

positive and consistent. Reference Control Material with 100980 catalogue number, supplied from NIBSC UK is used. Limit Detection: Limit of detection is 250 TCID₅₀/mL Cross-Reactivity respiratory pathogens on the detection performance of CHIL® COVID-19 Antigen Test. The following respiratory pathogens are selected for cross-reactivity tests: Influenza A virus H1N1, influenza B virus, Mycoplasma pneumoniae, Rhinovirus A, Rotavirus, Large intestine Escherichia, respiratory syncytial virus, adenovirus, etc. The concentration of bacterial

Concentrations Antigen Rapid Test Results Human Metapneumovirus 105 pfu/ml Negative 105 pfu/ml Negative 105 pfu/mL Negative

Rapid Test

-		v	tests
.?	Expire date	Δ	Caution! Con- instruction for use warnings except writ on package.
•	10028 sok. N Phone: +90	MAL. SAN. Tid lo.11 AOSB 35 232 2901688,	c. LTD. ŞTİ. 6620 Cigli-Izmir/Turk Fax: +90 232 29013 www.chil.com.tr

specimens is set to 10° cfu/ml (cfu: colony-forming units) or higher, and the concentration of virus specimens is set to 10° pfu/ml (pfu: plaqueforming unit) or higher. The test results are shown in the table below. High priority organisms likely present in respiratory specimens; Pathogen

> 105 pfu/mL Negative 10⁵ pfu/ml Negative 105 pfu/mL Negative 105 pfu/mL Negative 106 cfu/mL

man coronavirus NL63	105 pfu/mL	Negative
RS-coronavirus	10 ⁵ pfu/mL	Negative
Issued Date & Revision	2022.04.29/01 CO	M.RIFU.230 CKS
cov	VID-19 Anti	igen Rapid
(Nasoph	naryngeal S	wab - Cass
	Product co	de: CCOV

Store between Batch number

For asymptomatic individuals, testing should be performed at least twice over three days, with a minimum of 24 hours and a maximum of 48 hours between tests. Additional testing may be needed to perform this serial (repeat) test. If the first test result is negative for the serial test, a retest should

- 6. Rotate the swab at least 4 times against the nasal wall or 10-15 seconds. Remove and repeat this process by using the same swab into the second nostril. Then place the Swab into the Extraction Vial. 7. Insert the nasopharyngeal swab collected from the patient all the way into the extraction tube and rotate the swab at least 3 times against the bottom of the tube. Additional swab rotations are not expected to negatively affect performance.
- 11. Break the top part of the tube (If there is a problem cut tip of the tube with scissors, then disinfect the scissors) and add 3-4 drops to the specimen well of the test cassette and start the timer.
- swab without any infectious organisms or antigens including SARS-CoV-2. Remove the Positive/Negative Control swab from the pouch and do not touch the soft end with your hand. The external control procedure is the same as the test procedures beginning from step 7.

Positive: If both the quality control line (C) and the test line (T) appears, it means that SARS-CoV-2 antigen has been detected and the result is

INTERPRETATION OF TEST RESULTS

be interpreted as a positive result.

performed on the same specimen.

conducted again.

LIMITATIONS

results.

SARS-CoV.

1.4.

bacterial infections.

7. Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 8. The extraction buffer and test cassette must be equilibrated to room

6. Positive results do not rule out co-infections with other pathogens. Test results are not intended to rule out or diagnose other non-SARS viral or

- This cross reaction study is performed to verify the influence of common
 - Parainfluenza virus 2 Parainfluenza virus 3 Parainfluenza virus 4 Haemophilus influenzae Streptococcus Negative pneumoniae

High priority pathogens from the same genetic family, Pathogen Concentrations

***	MANUFACTURER CHIL® TIBBİ MAL. SAN. TİC. LTD. ŞTİ. 10028 sok. No.11 AOSB 35620 Cigli-Izmir/Turke		
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Issued Date & Revision 2022.04.29/01 COM.RIFU.230 CKS-114

inserted into the extraction tube and the specimen on the swab is eluted with the liquid in the extraction tube. When the specimen is added to the specimen well of the test cassette, conjugates dried in the reagent pad are and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T). If the (T) line does not show any color, the test result is negative. The test cassette also contains a quality control line (C), which shall appear in color regardless of whether

Product code: CCOV-201

Negative results are presumptive, do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient

symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care from their healthcare

sneezes, or by contact with an infected person through droplets of saliva or nasal discharge. The most common symptoms of COVID-19 are fever, tiredness, dry cough, and loss of smell or taste. Some patients may have

Product code: CCOV-201 13. Incorrect operation may affect the accuracy of the results, such as, insufficient specimen amount, insufficient specimen mixing, inaccurate detection time, etc. The components in different batches of the kit can not be used by

those substances containing and suspected sources of infection. The

- individuals without symptoms or other epidemiological reasons to suspect COVID-19. Issued Date & Revision 2022.04.29/01 COM.RIFU.230 CKS-114 COVID-19 Antigen Rapid Test
- 9. Close the cap of the extraction tube. specimen solution spills. Make sure that the liquid in the conical part goes down, if necessary, you can tap it gently so that the liquid goes

11.Break the top part of the tube (If there is a problem cut tip of the tube

12.Optimum reading time of results is 15 minutes. The results after 30

specimen well of the test cassette and start the timer.

TEST PROCEDURE FOR ANTERIOR NASAL SPECIMEN

first nostril until resistance is met at Turbinates.

with scissors, then disinfect the scissors) and add 3-4 drops to the

Do not open the test pouch until you are ready to perform a test, and

the single-use test is suggested to be used under low environment

1. Allow all kit components and specimens to reach room temperature

8. Squeeze center of the extraction tube and press the swab head against the tube wall to release the antigen in the swab remove the swab while

specimen solution spills. Make sure that the liquid in the conical part

goes down, if necessary, you can tap it gently so that the liquid goes

Positive Control Swab: The positive control swab consists of non-infectious recombinant SARS-CoV-2 antigen onto a sterile swab. Negative Control Swab: The Negative Control Swab consists of a sterile

test, report the problem to CHIL® technical support at: +90 232 2901688.

results may be incorrect. 9. Sensitivity may decrease if the specimen was not tested directly. Please test the specimen as soon as possible. 10. Cross-reactions is not expected due to two protein targeted structure

CHIL® COVID-19

CHIL® COVID-19 Antigen

temperature (18°C-26°C/65-75 °F) before the use, otherwise, the

l Test sette) V-201

280 INDEX OF SYMBOLS

(Nasopharyngeal Swab - Cassette) Product code: CCOV-201

Total 405 466 871

LOT iagnostic medical sufficient for <n>

PCR Test Total

Sensitivity: 98.04% (95 % CI: 93.10 % - 99.76 %) Specificity: 99,64 % (95 % CI: 98,03 % - 99,99 %)* Accuracy: 99,56% (95% CI: 98,26% - 99,96%)* *95 % Confidence Interval: (%-%) Disease prevalence accepted as 5%. Consult instruction for use i Keep dry

Negative 279 281

101 382

CHIL®-COVID 19 Antigen Rapid Test

SARS-CoV-2 cultured virus was spiked into specimen. SARS-CoV-2 cultured