Abbott

REF 41FK10

Panbio™

COVID-19 Ag Rapid Test Device

(NASOPHARYNGEAL)

***In vitro* diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen (Ag)**
***In-vitro* diagnostischer Schnelltest zum qualitativen Nachweis von SARS-CoV-2 Antigen (Ag)**
Prueba rápida de diagnóstico *In vitro* para la detección cualitativa del antígeno (Ag) del SARS-CoV-2
Test rapide de diagnostic *in vitro* pour la détection qualitative de l'antigène SARS-CoV-2 (Ag)
Test diagnostico rapido *in vitro* per la ricerca qualitativa dell'antigene SARS-CoV-2 (Ag)
Teste rápido de diagnóstico *in vitro* para detecção qualitativa do antígeno SARS-CoV-2 (Ag)
Экспресс-тест *in vitro* для качественного определения антигена SARS-CoV-2 (Ag)

ENGLISH

About the Test

Introduction

The Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[1]. The SARS-CoV-2 is a β-coronavirus, which is an enveloped non-segmented positive-sense RNA virus[2]. It is spread by human-to-human transmission via droplets or direct contact, and infection has been estimated to have a mean incubation period of 6.4 days and a basic reproduction number of 2.24-3.58. Among patients with pneumonia caused by SARS-CoV-2, fever was the most common symptom, followed by cough[3]. The main IVD assays used for COVID-19 employ real-time reverse transcriptase-polymerase chain reaction (RT-PCR) that takes a few hours[4]. The availability of a cost-effective, rapid point-of-care diagnostic test is critical to enable healthcare professionals to aid in the diagnosis of patients and prevent further spread of the virus[5]. Antigen tests will play a critical role in the fight against COVID-19[6].

Test Principle

Panbio™ COVID-19 Ag Rapid Test Device contains a membrane strip, which is pre-coated with immobilized anti-SARS-CoV-2 antibody on the test line and mouse monoclonal anti-chicken IgY on the control line. Two types of conjugates (human IgG specific to SARS-CoV-2 Ag gold conjugate and chicken IgY gold conjugate) move upward on the membrane chromatographically and react with anti-SARS-CoV-2 antibody and pre-coated mouse monoclonal anti-chicken IgY respectively. For a positive result, human IgG specific to SARS-CoV-2 Ag gold conjugate and anti-SARS-CoV-2 antibody will form a test line in the result window. Neither the test line nor the control line are visible in the result window prior to applying the patient specimen. A visible control line is required to indicate a test result is valid.

Intended Use

Panbio™ COVID-19 Ag Rapid Test Device is an *in vitro* diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.
The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.

Materials Provided

- 25 Test devices with desiccant in individual foil pouch
- Buffer (1 x 9 ml/bottle)
- 25 Extraction tubes
- 25 Extraction tube caps
- 1 Positive control swab
- 1 Negative control swab
- 25 Sterilized nasopharyngeal swabs for sample collection
- 1 Tube rack
- 1 Quick reference guide (Nasopharyngeal)
- 1 Instructions for use

Materials Required but not Provided

- Personal Protective Equipment, Timer, Biohazard container

Active Ingredients of Main Components

- 1 Test device
  Gold conjugate: Human IgG specific to SARS-CoV-2 Ag gold colloid and Chicken IgY - gold colloid, Test line: Mouse monoclonal anti-SARS-CoV-2, Control line: Mouse monoclonal anti-Chicken IgY
- Buffer
  Tricine, Sodium Chloride, Tween 20, Sodium Azide (<0.1%), Proclin 300

Storage and Stability

1. The test kit should be stored at a temperature between 2-30 °C. Do not freeze the kit or its components. Note: When stored in a refrigerator, all kit components must be brought to room temperature (15-30 °C) for a minimum of 30 minutes prior to performing the test. Do not open the pouch while components come to room temperature.
2. The Buffer bottle may be opened and resealed for each assay. The Buffer cap should be firmly sealed between each use. The Buffer is stable until expiration date if kept at 2-30 °C.
3. Perform the test immediately after removing the test device from the foil pouch.
4. Do not use the test kit beyond its expiration date.
5. The shelf life of the kit is as indicated on the outer package.
6. Do not use the test kit if the pouch is damaged or the seal is broken.
7. Direct swab specimens should be tested immediately after collection. If immediate testing is not possible, the swab specimen can be kept in an extraction tube filled with extraction buffer (300 µl) at room temperature (15-30 °C) for up to two hours prior to testing.

Warnings

1. For *in vitro* diagnostic use only. Do not reuse the test device and kit components.
2. These instructions must be strictly followed by a trained healthcare professional to achieve accurate results. All users have to read the instruction prior to performing a test.
3. Do not eat or smoke while handling specimens.
4. Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
5. Avoid splashing or aerosol formation of specimen and buffer.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials (i.e. swab, extraction tube, test device) in a biohazard container as if they were infectious waste and dispose according to applicable local regulations.
8. Do not mix or interchange different specimens.
9. Do not mix reagent of different lots or those for other products.
10. Do not store the test kit in direct sunlight.
11. To avoid contamination, do not touch the head of provided swab when opening the swab pouch.
12. The provided sterilized swabs in the package should be used only for nasopharyngeal specimen collection.
13. To avoid cross-contamination, do not reuse the sterilized swabs for specimen collection.
14. Do not dilute the collected swab with any solution except for the provided extraction buffer.
15. The buffer contains <0.1% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with a large volume of water.[7]

Test Procedure (Refer to Figure)

Nasopharyngeal Swab Specimens

Note: Healthcare professionals should comply with personal safety guidelines including the use of personal protective equipment.

Test Preparation

1. Allow all kit components to reach a temperature between 15-30 °C prior to testing for 30 minutes.
2. Remove the test device from the foil pouch prior to use. Place on a flat, horizontal and clean surface.
3. Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300 µl).
   ⚠ **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.
4. Place the extraction tube in the tube rack.

Specimen Collection & Extraction

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 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, 3-4 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.
6. Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.
7. Break the swab at the breakpoint and close the cap of extraction tube.

Reaction with Test Device

1. Open the dropping nozzle cap at the bottom of the extraction tube.
2. Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.
   ⚠ **Caution:** Bubbles that occur in the extraction tube can lead to inaccurate results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.
3. Close the nozzle and dispose of the extraction tube containing the used swab according to your local regulations and biohazard waste disposal protocol.
4. Start timer. Read result at 15 minutes. Do not read results after 20 minutes.
5. Dispose of the used device according to your local regulations and biohazard waste disposal protocol.

Positive / Negative Control Swab

1. Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300 µl).
   ⚠ **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.
2. Place the extraction tube in the tube rack.
3. Insert the positive or negative control swab in the buffer fluid inside of the extraction tube and soak the swab for 1 minute. Swirl the control swab tip in the buffer fluid inside of the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.
4. Dispose of the used control swab in accordance with your biohazard waste disposal protocol.
5. Close the cap of the extraction tube.
6. Follow the above test procedure [Reaction with Test Device].

Test Interpretation (Refer to Figure)

1. Negative result: The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.
2. Positive result: The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a positive result.
   ⚠ **Caution:** The presence of any test line (T), no matter how faint, indicates a positive result.
3. Invalid result: If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.

Test Limitations

1. The contents of this kit are to be used for the professional and qualitative detection of SARS-CoV-2 antigen from nasopharyngeal swab. Other specimen types may lead to incorrect results and must not be used.
2. Failure to follow the instructions for test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
3. A negative test result may occur if the specimen was collected, extracted or transported improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by viral culture or a molecular assay or ELISA.
4. Positive test results do not rule out co-infections with other pathogens.
5. For further information on immune status, additional follow-up testing using other laboratory methods is recommended.
6. Test results must be evaluated in conjunction with other clinical data available to the physician.
7. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.
8. Panbio™ COVID-19 Ag Rapid Test Device is not intended to detect from defective (non-infectious) virus during the later stages of viral shedding that might be detected by PCR molecular tests.[8]

Quality Control

1. Internal Quality Control:

The test device has a test line (T) and a control line (C) on the surface of the test device. Neither the test line nor the control line are visible in the result window before applying a specimen. The control line is used for procedural control and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

2. External Quality Control:

The controls are specifically formulated and manufactured to ensure performance of the Panbio™ COVID-19 Ag Rapid Test Device and are used to verify the user's ability to properly perform the test and interpret the results. The Positive Control will produce a positive test result and has been manufactured to produce a visible test line (T). The Negative Control will produce a negative test result.
Good laboratory practice suggests the use of positive and negative controls to ensure that:

- Test reagents are working, and
- The test is correctly performed.

Run the external controls under the following circumstances:

- With each new operator prior to performing testing on patient specimens,
- When receiving a new test shipment,
- At periodic intervals as dictated by local, state and country requirements, and/or by the user's Quality Control procedures.

Performance Characteristics

1. External evaluation of Panbio™ COVID-19 Ag Rapid Test Device

Clinical performance of Panbio™ COVID-19 Ag Rapid Test Device was determined by testing 60 positive and 181 negative specimens for SARS-CoV-2 antigen (Ag) to have a sensitivity of 93.3% (95% CI: 83.8-98.2%) and specificity of 99.4% (95% CI: 97.0-100%). Clinical specimens were determined to be positive or negative using an FDA EUA RT-PCR reference method.

Panbio™ COVID-19 Ag Rapid Test Device Results

		PCR Test Result		
		Positive	Negative	Total
Panbio™ COVID-19 Ag Rapid Test Device Results	Positive	56	1	57
	Negative	4	180	184
	Total	60	181	241
		Sensitivity	Specificity	Overall Percent Agreement
		93.3% [83.8%; 98.2%]	**99.4%** [97.0%; 100.0%]	**97.9%** [95.2%; 99.3%]

- Performance data was calculated from a study of individuals suspected of exposure to COVID-19 or who have presented with symptoms in the last 7 days.
- Stratification of the positive specimens post onset of symptoms or suspected exposure between 0-3 days has a sensitivity of 100.0% (n=21) and 4-7 days has a sensitivity of 89.7% (n=39).
- Positive agreement of the Panbio™ COVID-19 Ag Rapid Test Device is higher with samples of Ct values ≤33 with a sensitivity of 98.2%. As suggested in References 8 and 9, patients with Ct value >33 are no longer contagious.[8, 9]

2. Detection Limit

Panbio™ COVID-19 Ag Rapid Test Device was confirmed to detect $2.5X10^{1.8}$ $TCID_{50}$/ml of SARS-CoV-2 which was isolated from a COVID-19 confirmed patient in Korea.

3. Hook Effect

There is no hook effect at $1.0x10^{5.8}$ $TCID_{50}$/ml of SARS- CoV-2 which was isolated from a COVID-19 confirmed patient in Korea.

4. Cross Reactivity

Cross-reactivity of Panbio™ COVID-19 Ag Rapid Test Device was evaluated by testing 20 viruses and 12 other microorganisms. The final test concentrations of viruses and other microorganisms are documented in the Table below. The following viruses and other microorganisms have no effect on the test results of Panbio™ COVID-19 Ag Rapid Test Device.

No.	Types of Specimen	Cross Reaction Substance	Final Test Concentration	Test Result
1	Virus	Adenovirus Type3	$2.0 X 10^{6.5}$ $TCID_{50}$/ml	No cross reaction
2		Adenovirus Type7	$2.0 X 10^{4.75}$ $TCID_{50}$/ml	No cross reaction
3		Echovirus2	$1.0 X 10^{6.5}$ $TCID_{50}$/ml	No cross reaction
4		Echovirus11	$2.0 X10^{5.25}$ $TCID_{50}$/ml	No cross reaction
5		Human herpesvirus (HSV) 1	$2.0 X 10^{6.25}$ $TCID_{50}$/ml	No cross reaction
6		Human herpesvirus (HSV) 2	$2.0 X 10^{4.75}$ $TCID_{50}$/ml	No cross reaction
7		Mumps Virus Ag	$2.0 X 10^{3.5}$ $TCID_{50}$/ml	No cross reaction
8		Influenza virus A (H1N1) Strain (A/Virginia/ATCC1/2009)	$2.6 X 10^{5.0}$ PFU/ml	No cross reaction
9		Influenza virus A (H1N1) Strain (A/WS/33)	$5.0 X 10^{7.25}$ $TCID_{50}$/ml	No cross reaction
10		Influenza virus A(H3N2) Strain (A/Hong Kong/8/68)	N/A*	No cross reaction
11		Influenza virus B Strain (B/Lee/40)	$2.0 X 10^{5.25}$ $TCID_{50}$/ml	No cross reaction
12		Parainfluenza Type 1	N/A*	No cross reaction
13		Parainfluenza Type 2	N/A*	No cross reaction
14		Parainfluenza Type 3	N/A*	No cross reaction
15		Respiratory syncytial virus (RSV) type A	$4.22 X 10^{5.0}$ $TCID_{50}$/ml	No cross reaction
16		Respiratory syncytial virus (RSV) type B	$5.62 X 10^{5.0}$ $TCID_{50}$/ml	No cross reaction
17		HCoV-HKU1	10 ug/ml	No cross reaction
18		HCoV-NL63	$1.7 X 10^{5.0}$ $TCID_{50}$/ml	No cross reaction
19		HCoV-OC43	$8.9 X 10^{5.0}$ $TCID_{50}$/ml	No cross reaction
20		HCoV-229E	$1.51 X 10^{6.0}$ $TCID_{50}$/ml	No cross reaction

No.	Types of Specimen	Cross Reaction Substance	Final Test Concentration	Test Result
1	Other Microorganism	*Staphylococcus aureus*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
2		*Staphylococcus saprophyticus*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
3		*Neisseria sp.(Neisseria lactamica)*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
4		*Escherichia coli*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
5		*Staphylococcus haemolyticus*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
6		*Streptococcus pyogenes*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
7		*Streptococcus salivarius*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
8		*Hemophilus parahaemolyticus*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
9		*Proteus vulgaris*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
10		*Moraxella catarrhalis*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
11		*Klebsiella pneumoniae*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction
12		*Fusobacterium necrophorum*	1.0 X $10^{6.0}$ CFU/ml	No cross reaction

** No concentration provided by supplier. Undiluted stock solution was tested.*

5. Interfering Substances

The following 28 potentially interfering substances have no impact on Panbio™ COVID-19 Ag Rapid Test Device. The final test concentrations of the interfering substances are documented in the Table below.

No.	Types of Specimen	Interfering Substances	Final Test Concentration	Test Result
1	Endogenous Substance	Mucin	0.5%	No Interference
2		Hemoglobin	100 mg/L	No Interference
3		Triglycerides	1.5 mg/L	No Interference
4		Icteric (Bilirubin)	40 mg/dL	No Interference
5		Rheumatoid factor	200 IU/ml	No Interference
6		Anti-nuclear antibody	>1:40	No Interference
7		Pregnant	10-fold dilution	No Interference
8	Exogenous Substance	Guaiacol glyceryl ether	1 μg/ml	No Interference
9		Albuterol	0.005 mg/dL	No Interference
10		Ephedrine	0.1 mg/ml	No Interference
11		Chlorpheniramine	0.08 mg/dL	No Interference
12		Diphenhydramine	0.08 mg/dL	No Interference
13		Ribavirin	26.7 μg /ml	No Interference
14		Oseltamivir	0.04 mg/dL	No Interference
15		Zanamivir	17.3 μg /ml	No Interference
16		Phenylephrine hydrochloride	15% v/v	No Interference
17		Oxymetazolin hydrochloride	15% v/v	No Interference
18		Amoxicillin	5.4 mg/dL	No Interference
19		Acetylsalicylic acid	3 mg/dL	No Interference
20		Ibuprofen	21.9 mg/dL	No Interference
21		Chlorothiazide	2.7 mg/dL	No Interference
22		Indapamide	140 ng/ml	No Interference
23		Glimepiride (Sulfonylureas)	0.164 mg/dL	No Interference
24		Acarbose	0.03 mg/dL	No Interference
25		Ivermectin	4.4 mg/L	No Interference
26		Lopinavir	16.4 μg/L	No Interference
27		Ritonavir	16.4 μg/L	No Interference
28		Chloroquine phosphate	0.99 mg/L	No Interference

6. Repeatability & Reproducibility

Repeatability & Reproducibility of Panbio™ COVID-19 Ag Rapid Test Device was established using in-house reference panels containing negative specimens and a range of positive specimens. There were no differences observed within-run, between-run, between-lots, between-sites, and between-days.

Nr.	Art der Probe	Kreuzreaktionssubstanz	Finale Testkonzentration	Testergebnis
1	Andere Mikroorganismen	*Staphylococcus aureus*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
2		*Staphylococcus saprophyticus*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
3		*Neisseria sp,(Neisseria lactamica)*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
4		*Escherichia coli*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
5		*Staphylococcus haemolyticus*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
6		*Streptococcus pyogenes*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
7		*Streptococcus salivarius*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
8		*Hemophilus parahaemolyticus*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
9		*Proteus vulgaris*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
10		*Moraxella catarrhalis*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
11		*Klebsiella pneumoniae*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion
12		*Fusobacterium necrophorum*	1,0 X $10^{6,0}$ CFU/ml	Keine Kreuzreaktion

** Keine Konzentrationsangabe durch den Lieferanten. Unverdünnte Stammlösung wurde getestet.*

5. Interferierende Substanzen

Die folgenden 28 potenziell interferierenden Substanzen haben keinen Einfluss auf Panbio™ COVID-19 Ag Rapid Test Device. Die endgültigen Testkonzentrationen der Störsubstanzen sind in der folgenden Tabelle dokumentiert.

Nr.	Art der Probe	Interferierende Substanzen	Finale Testkonzentration	Testergebnis
1	Endogene Substanz	Mucin	0,5%	Keine Interferenz
2		Hämoglobin	100 mg/L	Keine Interferenz
3		Triglyceride	1,5 mg/L	Keine Interferenz
4		Icteric (Bilirubin)	40 mg/dL	Keine Interferenz
5		Rheuma-Faktor	200 IU/ml	Keine Interferenz
6		Anti-nuklearer Antikörper	>1:40	Keine Interferenz
7		Schwanger	10-fach verdünnt	Keine Interferenz
8	Exogene Substanz	Guajakol-Glyceryl-Ether	1 μg/ml	Keine Interferenz
9		Albuterol	0,005 mg/dL	Keine Interferenz
10		Ephedrin	0,1 mg/ml	Keine Interferenz
11		Chlorpheniramin	0,08 mg/dL	Keine Interferenz
12		Diphenhydramin	0,08 mg/dL	Keine Interferenz
13		Ribavirin	26,7 μg /ml	Keine Interferenz
14		Oseltamivir	0,04 mg/dL	Keine Interferenz
15		Zanamivir	17,3 μg /ml	Keine Interferenz
16		Phenylephrin-Hydrochlorid	15% v/v	Keine Interferenz
17		Oxymetazolin-Hydrochlorid	15% v/v	Keine Interferenz
18		Amoxicillin	5,4 mg/dL	Keine Interferenz
19		Acetylsalicylsäure	3 mg/dL	Keine Interferenz
20		Ibuprofen	21,9 mg/dL	Keine Interferenz
21		Chlorothiazid	2,7 mg/dL	Keine Interferenz
22		Indapamid	140 ng/ml	Keine Interferenz
23		Glimepirid (Sulfonylharnstoffe)	0,164 mg/dL	Keine Interferenz
24		Acarbose	0,03 mg/dL	Keine Interferenz
25		Ivermectin	4,4 mg/L	Keine Interferenz
26		Lopinavir	16,4 μg/L	Keine Interferenz
27		Ritonavir	16,4 μg/L	Keine Interferenz
28		Chloroquinphosphat	0,99 mg/L	Keine Interferenz

6. Wiederholbarkeit & Reproduzierbarkeit

Die Wiederholbarkeit und Reproduzierbarkeit von Panbio™ COVID-19 Ag Rapid Test Device wurde unter Verwendung eines internen Referenzpanels mit negativen Proben und einer Reihe positiver Proben festgestellt. Es wurden keine Unterschiede innerhalb der Testreihe, zwischen den Testreihen, zwischen den Chargen, zwischen den Standorten und zwischen den Tagen festgestellt.

6. Repetibilidad y reproducibilidad

La repetibilidad y reproducibilidad de Panbio™ COVID-19 Ag Rapid Test Device se estableció utilizando paneles de referencia internos que contienen muestras negativas y una variedad de muestras positivas. No se observaron diferencias dentro de las evaluaciones, entre evaluaciones, entre lotes, entre sitios y entre días.

6. Répétabilité et reproductibilité

La répétabilité et la reproductibilité du Panbio™ COVID-19 Ag Rapid Test Device ont été établies à l'aide de panels de référence internes contenant des échantillons négatifs et une gamme d'échantillons positifs.. Aucune différence n'a été observée à l'intérieur des séries, entre les séries, entre les lots, entre les sites et entre les jours.

6. Ripetibilità e riproducibilità

La ripetibilità e la riproducibilità di Panbio™ COVID-19 Ag Rapid Test Device sono state stabilite utilizzando pannelli di riferimento interni contenenti campioni positivi alti, positivi medi, positivi deboli e negativi. Non sono state osservate differenze all'interno della serie, tra le serie, tra i lotti, tra i siti e tra i giorni.

6. Repetibilidade e Reprodutibilidade

Repetibilidade e reprodutibilidade do Panbio™ COVID-19 Ag Rapid Test Device foram estabelecidas usando painéis de referência internos contendo amostras negativas e uma gama de amostras positivas. Não houve diferenças observadas dentro da execução, entre execuções, entre lotes, entre locais e entre dias.

6. Повторяемость и воспроизводимость

Повторяемость и воспроизводимость Экспресс-тест Panbio™ COVID-19 Ag (Panbio™ COVID-19 Ag Rapid Test Device) была определена с использованием собственных эталонных панелей, содержащих отрицательные образцы и ряд положительных образцов. Различий в внутри одной серии, между сериями, между центрами и между днями не наблюдали.

PREPARATION / VORBEREITUNG / PREPARACIÓN / PREPARATION / PREPARAZIONE / PREPARAÇÃO / ПОДГОТОВКА

1

EN Allow all kit components to reach a temperature between 15-30°C prior to testing for 30 minutes.
Note: Healthcare professionals should comply with personal safety guidelines including the use of personal protective equipment.

DE Lassen Sie alle Komponenten des Test-Kits 30 Minuten vor Beginn des Testens eine Temperatur von 15-30°C erreichen.
Hinweis: Das medizinische Personal sollte die persönlichen Sicherheitsrichtlinien einschließlich der Verwendung persönlicher Schutzausrüstung einhalten.

ES Permita que todos los componentes del kit alcancen una temperatura entre 15 y 30 °C durante 30 minutos antes de realizar la prueba.
Note: Los profesional de la salud deben cumplir con las pautas de seguridad personal, incluido el uso de equipo de protección personal.

FR Laissez tous les composants du kit atteindre une température comprise entre 15 et 30 ° C avant de procéder au test pendant 30 minutes.
Remarque: le professionnel de santé doit se conformer aux directives de sécurité personnelle, y compris l'utilisation d'équipements de protection individuelle.

IT Consentire a tutti i componenti del kit di raggiungere una temperatura tra 15-30°C per 30 minuti prima dell'esecuzione del test.
Nota: Gli operatori sanitari devono rispettare le linee guida per la sicurezza personale, incluso l'uso di dispositivi di protezione personale.

PT Deixe todos os componentes do kit atingirem uma temperatura entre 15-30°C antes do teste por 30 minutos.
Nota: Profissionais de saúde devem cumprir as diretrizes de segurança pessoal, incluindo o uso de equipamento de proteção individual.

RU Перед тестированием выдержите все компоненты набора в течение 30 минут при температуре 15-30 °C
Примечание: Медицинский работник должен соблюдать правила техники безопасности, включая использование средств индивидуальной защиты.

2

EN Open the package and look for the following:
1. Test device with desiccant in individual foil pouch
2. Buffer
3. Extraction tube
4. Extraction tube cap
5. Positive control swab
6. Negative control swab
7. Sterilized nasopharyngeal swabs for sample collection
8. Tube rack
9. Quick reference guide (Nasopharyngeal)
10. Instructions for use

DE Öffnen Sie die Verpackung und Entnehmen Sie Folgendes:
1. Testkassetten verpackt in Folienbeutel mit Trockenmittel
2. Puffer
3. Extraktionsröhrchen
4. Deckel für Extraktionsröhrchen
5. Positivkontrolltupfer
6. Negativkontrolltupfer
7. Sterilisierte nasopharyngeale Tupfer zur Probenahme
8. Ständer für Röhrchen
9. Kurzanleitung (Nasopharyngeal)
10. Gebrauchsanweisung

ES Abra el paquete y revise los siguientes componentes:
1. Dispositivo de prueba con desecante en bolsa de aluminio individual
2. Solución tampón
3. Tubo de extracción
4. Tapa de tubos de extracción
5. Hisopo control positivo
6. Hisopo control negativo
7. Hisopos nasofaríngeos esterilizados para la recolección de muestras
8. Gradilla para tubos
9. Guía de referencia rápida (nasofaríngea)
10. Instrucciones de uso

FR Ouvrez la boite et recherchez les éléments suivants
1. Testeur avec déshydratant dans un sachet individuel en aluminium
2. Solution tampon
3. Tube d'extraction
4. Bouchon pour les tubes d'extraction
5. Écouvillon de contrôle positif
6. Écouvillon de contrôle négatif
7. Écouvillons nasopharyngés stérilisés pour le prélèvement d'échantillons
8. Porte tubes
9. Guide de référence rapide (nasopharyngé)
10. Notice d'utilisation

IT Aprire la confezione e cercare quanto segue:
1. Dispositivo di test confezionato singolarmente in busta di alluminio con essiccante
2. Buffer
3. Provetta di estrazione
4. Tappo della provetta di estrazione
5. Tampone di controllo positivo
6. Tampone di controllo negativo
7. Tamponi sterili nasofaringei per la raccolta del campione
8. Rack portaprovette
9. Guida rapida di riferimento (Nasofaringeo)
10. Istruzioni per l'uso

PT Abra o pacote e observe o seguinte:
1. Dispositivo de teste com dessecante em bolsa individual
2. Tampão
3. Tubo de extração
4. Tampa de tubos de extração
5. Swab controle positivo
6. Swab controle negativo
7. Swabs nasofaríngeos esterilizados para coleta de amostra
8. Suporte para tubos
9. Guia de referência rápida (nasofaríngea)
10. Instruções de uso

RU Откройте упаковку и проверьте комплектность:
1. Тест-кассета в индивидуальной вакуумной упаковке с осушителем
2. Буфер
3. Пробирка экстракционная
4. Колпачок для пробирки экстракционной
5. Положительный контрольный образец
6. Отрицательный контрольный образец
7. Стерильные назофарингеальные тампоны (тупферов) для сбора образцов
8. Штатив
9. Краткое руководство (назофарингеальный тампон)
10. Инструкция по применению

3

EN Carefully read these instructions prior to using Panbio™ COVID-19 Ag Rapid Test Device kit.

DE Lesen Sie diese Anleitung vor Verwendung des Panbio™ COVID-19 Ag Rapid Test Device sorgfältig durch.

ES Lea cuidadosamente estas instrucciones de uso antes de usar Panbio™ COVID-19 Ag Rapid Test Device kit.

FR Lisez attentivement ces instructions avant d'utiliser le kit de Panbio™ COVID-19 Ag Rapid Test Device.

IT Leggere attentamente queste istruzioni prima di utilizzare il kit Panbio™ COVID-19 Ag Rapid Test Device.

PT Leia atentamente estas instruções antes de usar o kit Panbio™ COVID-19 Ag Rapid Test Device.

RU Перед использованием Экспресс-теста Panbio™ COVID-19 Ag (Panbio™ COVID-19 Ag Rapid Test Device) внимательно прочитайте данные инструкции.

4

EN Look at the expiration date of the kit box. If the expiration date has passed, use another kit.

DE Beachten Sie das Verfallsdatum der Kit-Box. Wenn das Verfallsdatum abgelaufen ist, verwenden Sie einen anderen Kit

ES Revise la fecha de vencimiento de la caja del kit. Si la fecha de vencimiento ha pasado, use otro kit.

FR Regardez la date d'expiration de la boîte du kit. Si la date d'expiration est dépassée, utilisez un autre kit.

IT Guarda la data di scadenza della scatola del kit. Se la data di scadenza è trascorsa, usa un altro kit.

PT Observe a data de validade da caixa do kit. Se a data de validade já passou, use outro kit.

RU Проверьте срок годности набора. Если срок годности прошел, используйте другой набор.

5

EN Open the foil pouch and look for the following:
1. Result window
2. Specimen well

Then, label the device with the patient identifier.

DE Öffnen Sie den Folienbeutel und schauen Sie nach Folgendem:
1. Testergebnislesefenster
2. Probenvertiefung

Beschriften Sie die Testkassette mit der Patient-ID.

ES Abra la bolsa de aluminio y revise lo siguiente:
1. Ventana de resultados
2. Pocillo de muestra

Luego, rotule el dispositivo con el identificador del paciente.

FR Ouvrez la pochette en aluminium et recherchez les éléments suivants:
1. Fenêtre de résultats
2. Échantillon bien

Ensuite, étiquetez l'appareil avec l'identifiant du patient.

IT Aprire la busta di alluminio e cercare quanto segue:
1. Finestra dei risultati
2. Pozzetto del campione

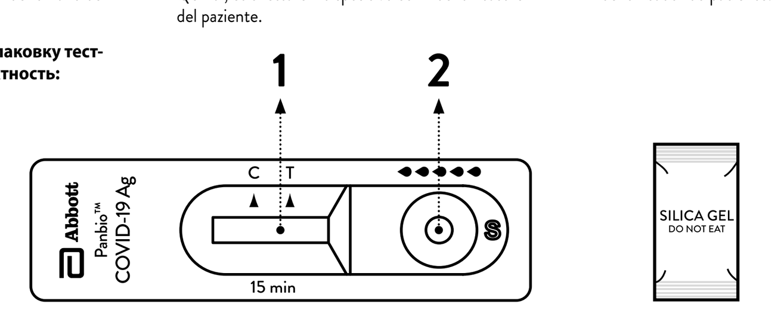
Quindi, etichettare il dispositivo con l'identificatore del paziente.

PT Abra a bolsa de alumínio e observe o seguinte:
1. Janela de resultados
2. Cavidade de amostra

Em seguida, rotule o dispositivo com o identificador do paciente.

RU Откройте индивидуальную упаковку тест-кассеты и проверьте комплектность:
1. Окно результата
2. Ячейка для образца

Затем наклейте на тест-кассету идентификатор пациента.



◆◆◆◆◆: 5 drops of the extracted specimen / 5 Tropfen der extrahierten Probe / 5 gotas de la muestra extraída / 5 gouttes de l'échantillon extrait / 5 gocce del campione estratto / 5 gotas da amostra extraída / 5 капель раствора из экстракционной пробирки

TEST PROCEDURE / TESTVERFAHREN / PROCEDIMIENTO DE LA PRUEBA / PROCEDURE / PROCEDURA DEL TEST / PROCEDIMENTO DE TESTE / ПРОЦЕДУРА ТЕСТИРОВАНИЯ

1

EN Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300μl).
⚠ **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.

DE Halten Sie das Pufferfläschchen vertikal und füllen Sie das Extraktionsröhrchen mit Pufferflüssigkeit, bis die Fülllinie des Extraktionsröhrchens erreicht ist (300 μl).
⚠ **Achtung:** Bei einer zu hohen oder geringen Puffermenge sind falsche Testergebnisse möglich.

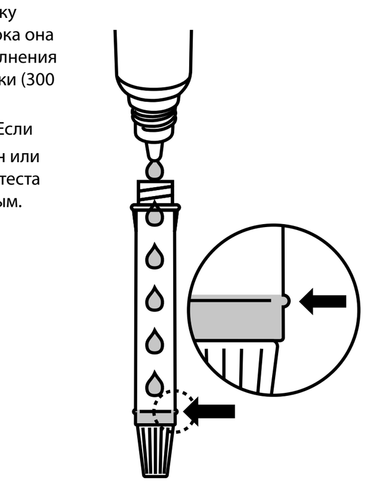
ES Sostenga el frasco de tampón verticalmente y llene el tubo de extracción con solución tampón hasta que fluya hasta la línea de llenado del tubo de extracción (300μL).
⚠ **Precaución:** Si la cantidad de tampón es excesiva o insuficiente, puede producirse un resultado de prueba incorrecto.

FR Tenez le flacon de tampon verticalement et remplissez le tube d'extraction avec du liquide tampon jusqu'à ce qu'il s'écoule jusqu'à la ligne de remplissage du tube d'extraction (300 μl).
⚠ **Attention:** Si la quantité de tampon est excessive ou insuffisante, un résultat de test incorrect peut se produire.

IT Tenere il flacone del buffer verticalmente e riempire la provetta di estrazione fino alla linea di riempimento della provetta di estrazione (300 μl).
⚠ **Attenzione:** Se la quantità di buffer è eccessiva o insufficiente, potrebbe verificarsi un risultato di test errato.

PT Segure o frasco de tampão verticalmente e encha o tubo de extração com fluido de tampão até que ele flua até a linha de enchimento do tubo de extração (300μL).
⚠ **Cuidado:** Se a quantidade de tampão for excessiva ou insuficiente, um resultado de teste impróprio pode ocorrer.

RU Держа флакон с буфером вертикально наполните экстракционную пробирку буферным раствором, пока она не дойдет до линии заполнения экстракционной пробирки (300 мкл).
⚠ **Предупреждение:** Если объем буфера чрезмерен или недостаточен, результат теста может быть неправильным.



2

EN Place the extraction tube in the tube rack.

DE Stellen Sie das Extraktionsröhrchen in den Röhrchenständer.

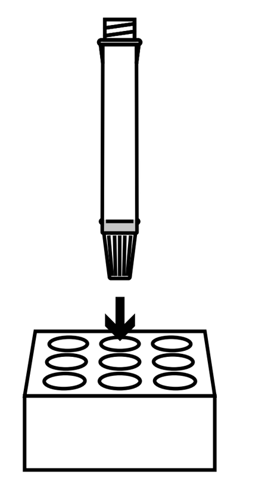
ES Coloque el tubo de extracción en la gradilla para tubos.

FR Placez le tube d'extraction dans le support de tubes.

IT Posizionare la provetta di estrazione nel rack portaprovette.

PT Coloque o tubo de extração no suporte de tubos.

RU Установите экстракционную пробирку в штатив.



3

EN Tilt the patient's head back. Insert the swab through the nostril. Gently rub and roll the swab, 3-4 times. Leave the swab in place for several seconds. Slowly remove swab.

DE Neigen Sie den Kopf des Patienten nach hinten. Führen Sie den Tupfer durch das Nasenloch ein. Reiben und rollen Sie den Tupfer vorsichtig 3-4 Mal. Lassen Sie den Tupfer für einige Sekunden an Ort und Stelle. Entfernen Sie den Tupfer langsam.

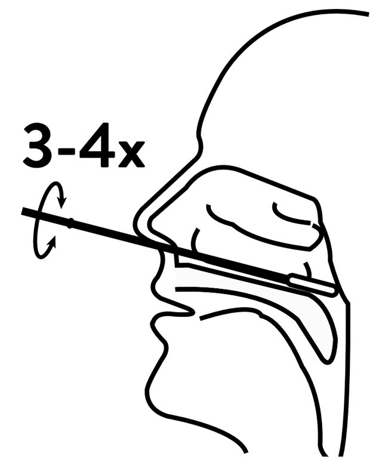
ES Incline la cabeza del paciente hacia atrás. Inserte el hisopo a traves de la fosa nasal. Frote y gire suavemente el hisopo, 3 a 4 veces. Deje el hisopo en su lugar durante varios segundos. Retire lentamente el hisopo.

FR Inclinez la tête du patient en arrière. Insérez l'écouvillon dans la narine. Frottez et roulez doucement l'écouvillon, 3 à 4 fois. Laissez l'écouvillon en place pendant plusieurs secondes. Retirez lentement l'écouvillon.

IT Inclinare la testa del paziente all'indietro. Inserire il tampone attraverso la narice. Strofinare e ruotare delicatamente il tampone 3-4 volte. Lasciare il tampone in posizione per alcuni secondi. Rimuovere lentamente il tampone.

PT Incline a cabeça do paciente para trás. Insira o swab pela narina. Esfregue e role suavemente o swab, 3-4 vezes. Deixe o swab no lugar por alguns segundos. Remova o swab lentamente.

RU Наклоняют голову пациента назад. Вставляют тампон через. Аккуратно потрите поверхность тампоном и поверните его 3-4 раза. Оставляют тампон на несколько секунд. Медленно извлекают тампон.



4

EN Insert the swab specimen in the extraction tube. Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.

DE Führen Sie die Abstrichprobe in das Extraktionsröhrchen ein. Schwenken Sie die Tupferspitze in der Pufferflüssigkeit des Extraktionsröhrchens. Drücken Sie dabei den Tupfer mindestens fünfmal an die Wand des Extraktionsröhrchens und drücken Sie anschließend denn Tupfer aus, indem Sie mit den Fingern das Extraktionsröhrchen zusammendrücken.

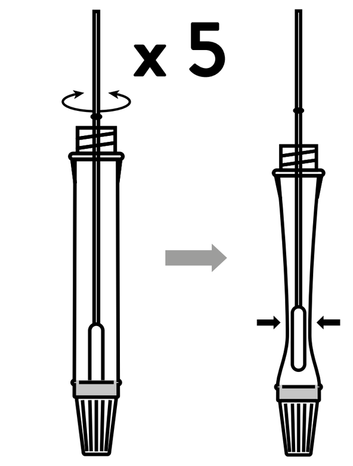
ES Inserte la muestra de hisopado en el tubo de extracción. Gire la punta del hisopo en la solución tampón dentro del tubo de extracción, empujando hacia la pared del tubo de extracción al menos cinco veces y luego exprima el hisopo apretando el tubo de extracción con los dedos.

FR Insérez l'échantillon sur écouvillon dans le tube d'extraction. Faites tourbillonner la pointe de l'écouvillon dans le fluide tampon à l'intérieur du tube d'extraction, en poussant dans la paroi du tube d'extraction au moins cinq fois, puis faites sortir l'écouvillon en pressant le tube d'extraction avec vos doigts.

IT Inserire il tampone di campionamento nella provetta di estrazione. Ruotare la punta del tampone nel liquido all'interno della provetta di estrazione, spingendo sulla parete della provetta di estrazione almeno cinque volte e poi premere il tampone strizzando la provetta di estrazione con le dita.

PT Insira a amostra de esfregaço no tubo de extração. Gire a ponta do swab no fluido tampão dentro do tubo de extração, empurrando na parede do tubo de extração pelo menos cinco vezes e, em seguida, aperte o swab apertando o tubo de extração com os dedos.

RU Вставьте тампон с образцом в экстракционную пробирку. Наконечник тампона проворачивают в буферном растворе внутри экстракционной пробирки, вдавливая его в стенку экстракционной пробирки не менее пяти раз, а затем тампон выжимают, сдавливая экстракционную пробирку пальцами.



5

EN Break the swab at the breakpoint and close the cap of extraction tube.

DE Brechen Sie den Tupfer an der Bruchstelle ab und schließen Sie den Deckel des Extraktionsröhrchens.

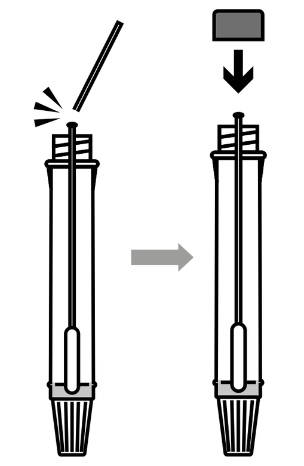
ES Quiebre el hisopo en el punto de ruptura y cierre la tapa del tubo de extracción.

FR Cassez l'écouvillon au point de rupture et fermez le capuchon du tube d'extraction.

IT Spezzare il tampone nel punto di rottura e chiudere il tappo della provetta di estrazione.

PT Quebre o swab no ponto de quebra e feche a tampa do tubo de extração.

RU Тампон разламывают в точке разлома, и колпачок для пробирки экстракционной закрывают.



6

EN Open the dropping nozzle cap at the bottom of the extraction tube.

DE Öffnen Sie die Kappe der Dosieröffnung am Boden des Extraktionsröhrchens.

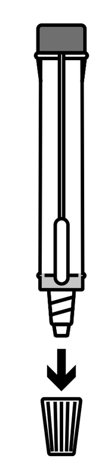
ES Abra la tapa de la boquilla de goteo en la parte inferior del tubo de extracción.

FR Ouvrez le capuchon de la buse à goutte au bas du tube d'extraction.

IT Aprire il tappo dell'ugello posizionato nella parte inferiore della provetta di estrazione.

PT Abra a tampa do bico de gotejamento na parte inferior do tubo de extração.

RU Откройте крышку колпачка - капельницы в нижней части экстракционной пробирки.



7

EN Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.
⚠ **Caution:** Bubbles that occur in the extraction tube can lead to inaccurate results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.

DE Geben Sie 5 Tropfen der extrahierten Proben senkrecht in die Probenvertiefung (S) der Testkassette. Bewegen Sie die Testkassette nicht, bis der Test abgeschlossen und zum Ablesen bereit ist.
⚠ **Achtung:** Blasen, die im Extraktionsröhrchen auftreten, können zu ungenauen Ergebnissen führen. Wenn Sie nicht in der Lage sind, genügend Tropfen zu erzeugen, kann dies an einer Verstopfung der Dosieröffnung liegen. Schütteln Sie das Röhrchen leicht, um die Verstopfung zu lösen, bis Sie eine freie Tropfenbildung beobachten können.

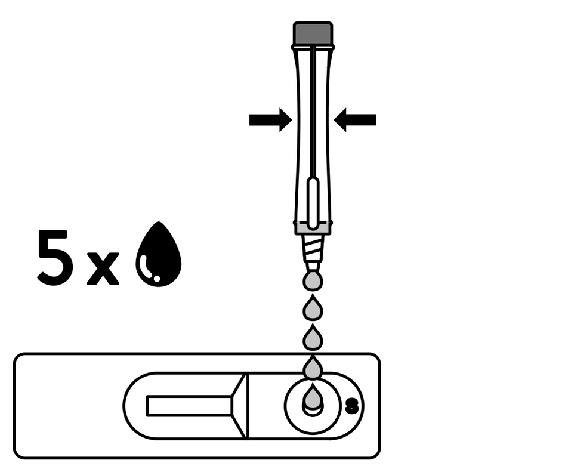
ES Dispense 5 gotas de las muestras extraídas verticalmente en el pocillo de la muestra (S) en el dispositivo. No manipule ni mueva el dispositivo de prueba hasta que la prueba esté completa y lista para leer.
⚠ **Precaución:** Las burbujas que se forman en el tubo de extracción pueden dar lugar a resultados incorrectos. Si no puede crear suficientes gotas, esto puede deberse a una obstrucción en la boquilla dispensadora. Agite el tubo suavemente para liberar el bloqueo hasta que observe la formación de gotas libres.

FR Distribuer verticalement 5 gouttes d'échantillons extraits dans le puits d'échantillon (S) de l'appareil. Ne pas manipuler ni déplacer le dispositif de test tant que le test n'est pas terminé et prêt pour la lecture.
⚠ **Attention:** les bulles qui se produisent dans le tube d'extraction peuvent conduire à des résultats inexacts. Si vous ne parvenez pas à créer suffisamment de gouttes, cela peut être dû à un colmatage de la buse de distribution. Secouez doucement le tube pour libérer le blocage jusqu'à ce que vous observiez la formation de gouttes libres.

IT Dispensare 5 gocce di campione estratto verticalmente nel pozzetto del test (S) sul dispositivo. Non maneggiare o spostare il dispositivo fino a quando il test non è completo e pronto per la lettura.
⚠ **Attenzione:** La comparsa di bolle nella provetta di estrazione può portare a risultati imprecisi. Se non si riuscisse ad ottenere un numero di gocce sufficienti, ciò potrebbe essere causato dall'intasamento dell'ugello di erogazione. Agitare delicatamente la provetta per rimuovere l'ostruzione fino a osservare la formazione di goccia libera.

PT Dispense 5 gotas das amostras extraídas verticalmente na cavidade da amostra (S) do dispositivo. Não manuseie ou mova o dispositivo de teste até que o teste esteja concluído e pronto para leitura.
⚠ **Cuidado:** As bolhas que ocorrem no tubo de extração podem levar a resultados imprecisos. Se você não conseguir criar gotas suficientes, isso pode ser causado por entupimento no bico dispensador. Agite o tubo suavemente para liberar o bloqueio até observar a formação livre de gotas.

RU Внесите 5 капель раствора из экстракционной пробирки вертикально в ячейку для образца (S) на тест-кассете. Не трогайте и не перемещайте тест-кассету, пока тест не будет завершен и готов к считыванию.
⚠ **Предупреждение:** Пузырьки, возникающие в экстракционной пробирке, могут привести к неточным результатам. Если отмерить достаточное количество капель не удается, это может быть вызвано засорением колпачка-капельницы. Осторожно встряхните пробирку, чтобы устранить обструкцию, пока не образуется свободные капли.



8

EN Close the nozzle and dispose of the extraction tube containing the used swab according to your local regulations and biohazard waste disposal protocol.

DE Schließen Sie die Dosieröffnung und entsorgen Sie das Extraktionsröhrchen mit dem gebrauchten Tupfer gemäß den örtlichen Vorschriften und dem Entsorgungsprotokoll für biologisch gefährliche Abfälle.

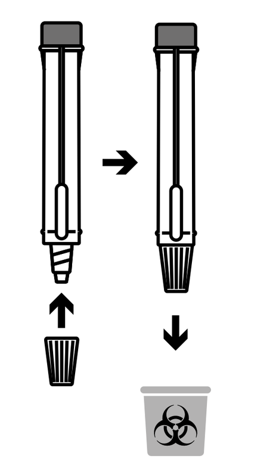
ES Cierre la boquilla y deseche el tubo de extracción que contiene el hisopo usado de acuerdo con las regulaciones locales y el protocolo de eliminación de desechos de riesgo biológico.

FR Fermez la buse et jetez le tube d'extraction avec l'écouvillon usagé conformément à vos réglementations locales et au protocole d'élimination des déchets biologiques.

IT Chiudere l'ugello e smaltire la provetta di estrazione contenente il tampone usato in base alle normative locali e al protocollo di smaltimento dei rifiuti biologici.

PT Feche o bico e descarte o tubo de extração contendo o swab usado de acordo com os regulamentos locais e o protocolo de descarte de resíduos de risco biológico.

RU Закройте колпачок-капельницу, и утилизируйте экстракционную пробирку, содержащую использованный тампон в соответствии с местными правилами и протоколом утилизации биологически опасных отходов.



9

EN Start timer. Read result at 15 minutes. Do not read results after 20 minutes.

DE Starten Sie die Uhr und lesen Sie das Ergebnis nach 15 Minuten ab. Lesen Sie das Ergebnis nicht mehr nach 20 Minuten ab.

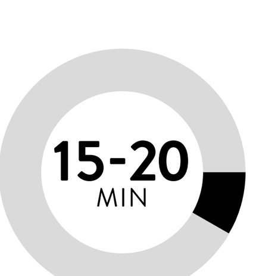
ES De inicio al temporizador. Leer resultado a los 15 minutos. No lea los resultados después de 20 minutos.

FR Démarrer le minuteur, lire le résultat à 15 minutes. Ne pas lire le résultat après 20 minutes.

IT Avviare il timer. Leggere il risultato a 15 minuti. Non leggere i risultati dopo 20 minuti.

PT Inicie o cronômetro. Leia o resultado do teste em 15 minutos. Não leia os resultados após 20 minutos.

RU Запустите таймер. Результат можно считывать через 15 минут. Не считывайте результаты, если прошло 20 минут и больше.



10

EN Dispose of the used device according to your local regulations and biohazard waste disposal protocol.

DE Entsorgen Sie die gebrauchte Testkassette gemäß den örtlichen Vorschriften und dem Entsorgungsprotokoll für biologisch gefährlichen Abfall.

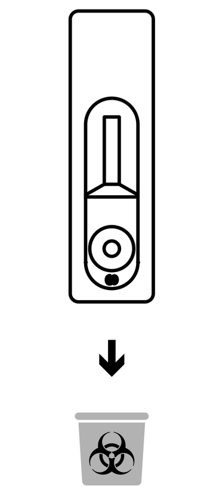
ES Deseche el dispositivo usado de acuerdo con las regulaciones locales y el protocolo de eliminación de desechos de riesgo biológico.

FR L'Elimination des appareils usagés se fait conformément à la réglementation locale en vigueur et selon le protocole d'élimination des déchets dangereux.

IT Smaltire il dispositivo usato in base alle normative locali e al protocollo di smaltimento dei rifiuti biologici.

PT Descarte o dispositivo usado de acordo com os regulamentos locais e o protocolo de descarte de resíduos de risco biológico.

RU Использованную тест-кассету утилизируют в соответствии с местными правилами и протоколом утилизации биологически опасных отходов.



TEST INTERPRETATION / TEST INTERPRETATION / INTERPRETACIÓN DE LA PRUEBA / INTERPRETATION DU TEST / INTERPRETAZIONE DEL TEST / INTERPRETAÇÃO DE TESTE / ИНТЕРПРЕТАЦИЯ ТЕСТА

NEGATIVE / NEGATIV / NEGATIVA / NEGATIF / NEGATIVO / NEGATIVO / ОТРИЦАТЕЛЬНЫЙ

EN The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.

DE Erscheinen eine Kontrolllinie (C) und keine Testlinie (T) innerhalb des Testergebnislesefensters, ist das Ergebnis negativ.

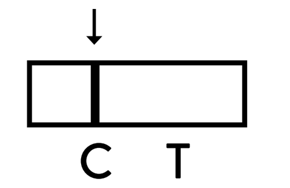
ES La presencia de solo la línea de control (C) y ninguna línea de prueba (T) dentro de la ventana de resultados indica un resultado negativo.

FR La présence seule de la ligne de contrôle (C) et aucune ligne de test (T) dans la fenêtre de résultat indique un résultat négatif.

IT La presenza della sola linea di controllo (C) e nessuna linea di test (T) all'interno della finestra dei risultati indica un risultato negativo.

PT A presença apenas da linha de controle (C) e nenhuma linha de teste (T) dentro da janela de resultado indica um resultado negativo.

RU Наличие только контрольной линии (C) и отсутствие тестовой линии (T) в окошке для считывания указывает на отрицательный результат теста.



POSITIVE / POSITIV / POSITIVA / POSITIF / POSITIVO / POSITIVO / ПОЛОЖИТЕЛЬНЫЙ

EN The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a positive result.
⚠ **Caution**: The presence of any test line (T), no matter how faint, indicates a positive result.

DE Erscheinen eine Kontrolllinie (C) und eine Testlinie (T) innerhalb des Testergebnislesefensters, unabhängig davon, welche Linie zuerst erscheint, ist das Ergebnis positiv.
⚠ **Achtung:** Jede Testlinie (T), unabhängig davon, wie schwach diese Linie ist, ist als positives Testergebnis zu bewerten.

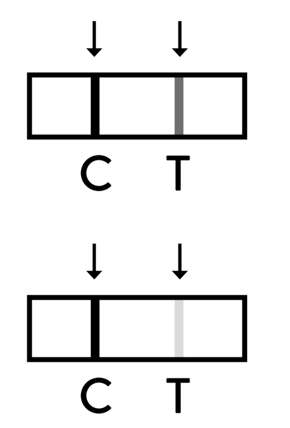
ES La presencia de la línea de prueba (T) y la línea de control (C) dentro de la ventana de resultados, independientemente de la línea que aparezca primero, indica un resultado positivo.
⚠ **Precaución:** La presencia de cualquier línea de prueba (T), no importa cuán débil sea, indica un resultado positivo.

FR La présence de la ligne de test (T) et de la ligne de contrôle (C) dans la fenêtre de résultat, quelle que soit la ligne qui apparaît en premier, indique un résultat positif.
⚠ **Attention:** la présence d'une ligne de test (T), aussi faible soit-elle, indique un résultat positif.

IT La presenza della linea di test (T) e della linea di controllo (C) all'interno della finestra dei risultati, indipendentemente dalla linea visualizzata per prima, indica un risultato positivo.
⚠ **Attenzione:** La presenza di qualsiasi linea di test (T), non importa quanto debole, indica un risultato positivo.

PT A presença da linha de teste (T) e da linha de controle (C) dentro da janela de resultados, independentemente de qual linha apareça primeiro, indica um resultado positivo.
⚠ **Cuidado:** A presença de qualquer linha de teste (T), não importa o quão tênue, indica um resultado positivo.

RU Положительный результат: Наличие тестовой (T) и контрольной (C) линии в окне результата, независимо от того, какая линия появляется первой, указывает на положительный результат.
⚠ **Предупреждение:** Наличие тестовой линии (T), какой бы слабой она ни была, свидетельствует о положительном результате.



INVALID / UNGÜLTIG / NO VÁLIDA / INVALIDE / INVALIDO / INVÁLIDO / НЕВЕРНЫЙ РЕЗУЛЬТАТ

EN If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly. It is recommended to read the IFU again before re-testing the specimen with a new test device.

DE Ist die Kontrolllinie (C) nach der Testdurchführung innerhalb des Testergebnislesefensters nicht sichtbar, ist das Ergebnis ungültig.
Die Anweisungen wurden möglicherweise nicht korrekt befolgt. Es wird empfohlen, die IFU erneut zu lesen, bevor die Probe mit einer neuen Testkassette erneut getestet wird.

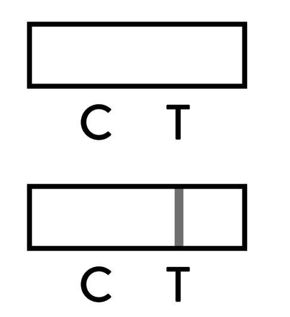
ES Si la línea de control (C) no está visible dentro de la ventana de resultados después de realizar la prueba, el resultado se considera inválido. Es posible que las instrucciones no se hayan seguido correctamente. Se recomienda volver a leer las instrucciones de uso antes de volver a analizar la muestra con un nuevo dispositivo de prueba.

FR Si la ligne de contrôle (C) n'est pas visible dans la fenêtre de résultat après l'exécution du test, le résultat est considéré comme invalide. Les instructions peuvent ne pas avoir été suivies correctement. Il est recommandé de relire la notice d'utilisation avant de tester à nouveau l'échantillon avec un nouveau dispositif de test.

IT Se la linea di controllo (C) non è visibile all'interno della finestra dei risultati dopo l'esecuzione del test, il risultato viene considerato non valido. Le istruzioni potrebbero non essere state seguite correttamente. Si consiglia di leggere nuovamente il foglietto illustrativo prima di testare nuovamente il campione con un nuovo dispositivo di test.

PT Se a linha de controle (C) não estiver visível na janela de resultados após a realização do teste, o resultado é considerado inválido. As instruções podem não ter sido seguidas corretamente. É recomendável ler o a instrução de uso novamente antes de testar novamente a amostra com um novo dispositivo de teste.

RU Если контрольная линия (C) не видна в окне результатов после выполнения теста, результат считается неверным. Инструкции могли быть выполнены неправильно. В этом случае рекомендуется снова прочитать инструкцию по применению перед повторным тестированием образца с использованием новой тест-кассетой.



GLOSSARY OF SYMBOLS / SYMBOLVERZEICHNIS / GLOSARIO DE SÍMBOLOS / GLOSSAIRE DES SYMBOLES / GLOSSARIO DEI SIMBOLI / GLOSSÁRIO DE SÍMBOLOS / ГЛОССАРИЙ ОБОЗНАЧЕНИЙ

Temperature limitation / Temperaturbegrenzung / Limitación de temperatura / Limitation de température / Limitazione di temperatura / Limitação de temperatura / Температурный диапазон

LOT — Lot Number / Chargencode / Número de lote / Numéro de lot / Numero di lotto / Número de Lote / Номер серии

Manufacturer / Hersteller / Fabricante / Fabricant / Produttore / Fabricante / Производитель

Contains sufficient for X tests / Ausreichend für X Prüfungen / Contiene suficiente para X pruebas / Contient suffisamment pour les tests X / Contenuto sufficiente per X test / Contém suficiente para X testes / Содержит материалы, достаточные для выполнения X тестов

IVD — For *in vitro* diagnostic use only / Medizinprodukt für *in-vitro* Diagnostik / Sólo para uso diagnóstico *in vitro* / Pour un usage de diagnostic *in vitro* uniquement / Ad uso esclusivo diagnostico *in vitro* / Somente para uso para diagnóstico *in vitro* / Медицинское изделие для диагностики *In Vitro*

REF — Catalog Number / Artikelnummer / Número de catalogo / Numéro de catalogue / Numero di catalogo / Número no Catálogo / Каталожный номер

Date of manufacture / Herstellungsdatum / Fecha de manufactura / Date de fabrication / Data di produzione / Data de fabricação / Дата производства

Biological Risks / Biologisches Risiko / Riesgos biológicos / Risques biologiques / Rischi biologici / Riscos Biológicos / Биологическая опасность

Do not reuse / Nicht wiederverwenden / No reutilizar / Ne pas réutiliser / Non riutilizzare / Não reutilizar / Не использовать повторно

Consult instructions for use / Gebrauchsanleitung beachten / Consultar instrucciones de uso / Consulter les instructions d'utilisation / Consultare le istruzioni per l'uso / Consulte as instruções de uso / См. Инструкцию по применению

Keep away from sunlight / Von Sonnenlicht fernhalten / Mantener alejado de la luz solar / Tenir à l'écart de la lumière du soleil / Tenere lontano dalla luce solare / Manter longe da luz solar / Беречь от попадания солнечных лучей

Do not use if package is damaged / Bei beschädigter Verpackung nicht verwenden / No lo use si el paquete está dañado / Ne pas utiliser si le colis est endommagé / Non utilizzare se la confezione è danneggiata / Não use se o pacote estiver danificado / Не используйте, если упаковка повреждена

YYYY.MM.DD — Use By / Verwendbar bis / Usar por / Utiliser par / Utilizzare per / Usar até / Использовать до

Keep dry / Trocken aufbewahren / Mantener seco / Garder au sec / Mantenere asciutto / Manter seco / Хранить в сухом месте

Caution / Achtung / Precaución / Attention / Attenzione / Cuidado / Предупреждение

CE mark / CE Zeichen / Marca CE / Marquage CE / Marcatura CE / Marca CE / Знак соответствия продукции техническим регламентам ЕС

Do not re-sterilize / Nicht sterilisieren / No volver a esterilizar / Ne pas re-stériliser / Non risterilizzare / Não reesterilize / Не стерилизуйте повторно

STERILE R — Sterilized using irradiation / Sterilisiert durch Bestrahlung / Esterilizado mediante irradiación. / Stérilisé par irradiation / Sterilizzato con irradiazione / Esterilizado por irradiação / Стерилизовано с использованием облучения

STERILE EO — Sterilized using ethylene oxide / Sterilisiert mit Ethylenoxid / Esterilizado con óxido de etileno. / Stérilisé à l'oxyde d'éthylène / Sterilizzato con ossido di etilene / Esterilizado com óxido de etileno / Стерилизовано окисидом этилена

References / Referenzen / Referencias / Références /Riferimenti / Referências / Использованная литература

1. Rothan HA, Byrareddy SN. The epidemiology and pathogenesis of coronavirus disease (COVID-19) outbreak. J Autoimmun. 2020; Feb 26:102433. doi: 10.1016/j.jaut.2020.102433.
2. Guo YR, Cao QD, Hong ZS, et al. The origin, transmission and clinical therapies on coronavirus disease 2019 (COVID-19) outbreak-an update on the status. Mil Med Res. 2020; Mar 13; 7(1):11.doi:10.1186/s40779-020-00240-0.
3. Lai CC, Shih TP, Ko WC, et al. Severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges. Int J Antimicrob Agents. 2020; Mar 55(3): 105924.doi: 10.1016/j.ijantimicag.2020.105924.
4. *In Vitro* Diagnostic Assays for COVID-19: Recent Advances and Emerging Trends (Sandeep Kumar Vashist, 2020 April 05: diagnostics)
5. Nano Research for COVID-19 (http://dx.doi.org/10.1021/acsnano.0c02540)
6. Coronavirus (COVID-19) Update: FDA Authorizes First Antigen Test to Help in the Rapid Detection of the Virus that Causes COVID-19 in Patients (Stephen M, Hahn M.D. 2020 May 09: Commisioner of Food and Drugs
7. Current Intelligence Bulletin 13: Explosive Azide Hazard DHHS (NIOSH) Publication Number 78-127 August 16, 1976
8. CDC. Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance). (2020).
9. CDC. Duration of Isolation and Precautions for Adults with COVID-19. (2020).

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