Instructions for Use

minoo Teststation

minoo

Contents

1 Intended use of the minoo Teststation

Version B/IN, 27-03-2024
REF Nr. MM100001/IN

For use with throat swabs

1.1 Purpose

The minoo Teststation is a test device for detecting the novel coronavirus SARS-CoV-2, which causes COVID-19. This test station is intended for testing persons aged 3 and older with suspected COVID-19 who have had throat swab samples taken by their physician or healthcare provider. This test is approved for point-of-care (POC) diagnostic use when conducted by a physician or healthcare provider at the point of care (POC).

The minoo Teststation is intended for use by trained personnel who are able to competently carry out tests with the minoo Teststation in professional point-of-care facilities.

1.2 Summary and explanations

The minoo Teststation is a test device that is used for the qualitative detection of SARS-CoV-2 nucleic acids by measuring the changes in the fluorescence signal during recombinance polymerase amplification (RPA) using optical spectrometry. The minoo Teststation contains some of the components required to conduct the tests. Furthermore, the minoo Testkit, which contains the components for the RPA, and the minoo app must be purchased in order to be able to use the minoo Teststation properly.

2 The minoo Testsystem

2.1 Test station components

1. **minoo Teststation**
   A test station designed for multiple use.
2. **USB cable**
   A USB cable protected by plastic wrapping for charging the test station. Dispose of the plastic wrapping after unpacking the USB cable.
3. **Black protective cap**
   A black protective cap for covering the optical port of the minoo Teststation.
4. **Instructions for use**
   Document with instructions on how to use the minoo Teststation.

2.2 Other materials required

In order to be able to use the minoo Teststation for the purpose described in this instructions for use, the following components and/or materials are additionally required.

minoo SARS-CoV-2 Testkit

1 x Positive control test
10 x Swabs
11 x Buffer vials
10 x Test vials with reagents
11 x Pipette tips
1 x Sample station
1x Instructions for use

Detailed instructions on how to use the minoo Testkit can be found in the instructions for use of the minoo Testkit.

Laboratory pipette

You need a laboratory pipette that is capable of dosing 50 microliters (µL) with a minimum accuracy of ±1 µL. It is important to choose a pipette model that is compatible with the included test kit tips, such as the 200 µl laboratory pipettes from the Brand® or Eppendorf® brands.

Android® smartphone

You need a smartphone equipped with an Android® 7+ operating system, camera, Bluetooth LE (BLE), NFC and a wireless internet connection to download and operate the minoo app.

minoo app (on your smartphone)

Download the minoo app from the Google Play Store, as it is required to control the test station. The device location and camera must be shared with the minoo app in the smartphone‘s settings. The minoo app will notify you of this while you are using it. The minoo app does not store any personal data.

Power adapter for the USB-A connector

The minoo Teststation comes with a USB cable, but no power supply. When choosing a power supply, please consider the following:

Only use power supplies that comply with IEC 60950-1 or IEC 62368 and are marked with ”LPS“ (Limited Power Source) and the double-square symbol (IEC Class II) on their security label.

3 Safety precautions

3.1 General

1. Only suitable for in vitro diagnostics.
2. This test station is only intended for the detection of the nucleic acid of SARS-CoV-2 by means of throat swabs, not for other viruses or pathogens.
3. For reliable results, follow all instructions and safety precautions in this document. Incorrect or inappropriate sample collection, handling, preparation and/or storage may affect the accuracy of the results.
4. The performance characteristics of this test station were determined using only the sample types mentioned in section 1.1 "Purpose". The performance of the test station using other sample types or samples has not been investigated.

3.2 Point-of-Care

1. In the diagnostic environment, it is important to clean the work surface in order to avoid any contamination by the environment. Therefore, before starting the test, wipe the corresponding area with a surface disinfection cloth (e.g. Sani-Cloth disinfecting wipes) or 70% ethanol.
2. Observe existing precautions and standard procedures for handling samples. All samples should be considered potentially hazardous to health and should be treated as infectious material.

3.3 Before conducting the test

1. Do not use a test station with visible damage.
2. To conduct the test, choose a location with a level, stable work surface on which to place the test station and where you can work undisturbed for 30 minutes.

3.4 During the test

1. Only use the test station components supplied.
2. Do not expose the test station to direct sunlight when using it.
3. Do not use the test station near a heat source.
4. Do not expose the test station to any direct air draughts when using it.
5. Never disconnect from the internet or the minoo app until the app indicates that the test is complete. A stable internet connection is required throughout the entire testing process.

3.5 During the analysis

1. Make sure that the outside of the test vial is free of liquids, stains or dust before inserting the test vial into the minoo Teststation.
2. After placing the sample in the test station and pressing the "Next" button, the analysis will start. DO NOT move the test station, open the test vial or move the smartphone away from the test station. Avoid vibrations.

3.6 Hygiene

1. It is recommended to wear nitrile gloves when handling samples. If gloves are not available, disinfect your hands with hand sanitiser or wash them with hand soap. Dry your hands thoroughly to avoid contaminating the samples.
2. Due to the high sensitivity of the minoo SARS-CoV-2 test, contamination of the workplace with previously examined positive samples can lead to a false-positive result. Clean the minoo Teststation and surrounding surfaces as described in the instructions for use.
3. Dispose of the test station in compliance with applicable local regulations.

3.7 minoo Teststation

1. Never attempt to open or disassemble the minoo Teststation.
2. Do not look directly into the optical LED port of the minoo Teststation, i.e. the opening into which the test vial is inserted. Prolonged exposure may cause burns to the eyes.
3. The minoo Teststation contains a LiPo battery. Please do not tamper with the battery, e.g. by burning, disassembling, short-circuiting or exposing it to high temperatures.
4. Avoid overheating the minoo Teststation by exposing it to high temperatures and/ or direct sunlight.
5. It must be disposed of in accordance with the local regulations for electronic devices.
6. Do not submerge the minoo Teststation in water or other liquids.
7. Follow the instructions in section 5.3 of this document to clean and disinfect the test station.
8. Protect the test station from dust.
9. When the device is not in use, please leave the protective cap on the device.
10. If the appliance and its accessories are used in a way that does not comply with the instructions for use, the protection provided by the appliance may be compromised.
11. Do not use a test station after the expiry date.
12. The minoo Teststation does not come with a power supply. Only use power supplies that comply with IEC 60950-1 or IEC 62368.
13. The power supply should be double insulated, with the double square symbol (IEC class II) and ”LPS“ (Limited Power Source) (IEC 60950-1).

3.8 minoo Testkit

Safety instructions regarding the minoo SARS-CoV-2 Testkit and sample collection can be found in the instructions for use that come with the minoo Testkit.

4 Limitations

1. The detection of SARS-CoV-2 RNA may be influenced by the method of sampling, personal factors (e.g. the presence of symptoms) and/or the stage of infection.
2. The test performance was not tested separately for symptomatic and asymptomatic individuals.
3. A false-negative result may occur if the sample is taken or handled improperly. False-negative results are also possible if the sample contains an insufficient number of virus particles.
4. False-negative results are likely to occur with high prevalence. False-positive results are more likely with low prevalence.
5. As with all molecular tests, mutations within the target region of SARS-CoV-2 can impair the binding of primers and/or probes and result in the presence of the virus not being detected.
6. This test cannot rule out diseases caused by other viruses or bacteria.
7. Since this is a qualitative test, it is not possible to determine the quantitative value of the organisms detected.
8. Clinical performance was not assessed for all circulating variants. However, it is expected to reflect the variants prevalent at the time and place of clinical evaluation. Performance at the time of the test may vary depending on the circulating variants, including emerging strains of SARS-CoV-2 and their prevalence, which changes over time.
9. The target analyte (viral nucleic acid) can be preserved in vivo, regardless of the infectivity of the virus. The detection of one or more target analytes does not mean that the corresponding viruses are infectious or cause the clinical symptoms.
10. If nasal spray or mouthwash has been used, at least 15 minutes should elapse before swabbing the throat.
11. At least 15 minutes should elapse after the last intake of food or liquids before swabbing the throat.

5 Test procedure and operation

5.1 Preparations

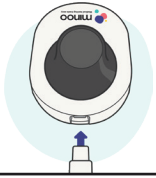
The minoo app guides you step by step through the entire testing process. The instructions below refer to the app‘s user interface.

Setting up your workspace

- Before using the minoo Teststation, please follow the instructions in section 3.3 ”Before conducting the test“
- Please refer to the instructions for handling the device in section 7 ”Storage and handling“.

Installation

- The minoo Teststation does not require any hardware installation. Once it‘s charged and placed on a stable, level surface, it‘s ready to go.
- To control the test station, however, you will require the minoo app, which can be downloaded from the Google Play Store.
- The supplied black protective cap must be located on the test station, otherwise the connection between the test station and the smartphone will fail.
- To use the minoo app, the device location and camera must be enabled in the settings of your smartphone. The minoo app will notify you of this while you are using it.



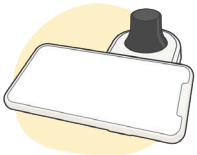
Preparing the test station

- The black protective cap supplied must be placed on the device, otherwise the connection attempt will fail. Only use the protective cap provided by the manufacturer. Other protective caps may lead to erroneous results.
- Make sure that the test station battery has been charged for at least 30 minutes. It may take 3 hours or more to fully charge. The test cannot be started until the battery is sufficiently charged. The test station battery is not charged during a test run.
- Your smartphone‘s device location, camera, NFC, Bluetooth and internet connections must be turned on and working.
- Once the connection between the smartphone and the test station is established, do not move your smartphone too far away from the test station (maximum 5 metres without obstacles). Otherwise, the Bluetooth connection may be lost.

Connecting the test station to your smartphone

- During a test, follow the on-screen instructions to connect your smartphone to the minoo Teststation.
- Use your smartphone to briefly touch the minoo logo on the test station.
- If this step has been carried out correctly, your smartphone will automatically connect to the minoo Teststation where the test is to be conducted.
- The LED on the device will illuminate with a steady green light when the connection has been successfully established.

- If the connection attempt fails, hold your smartphone in a different position against the test station and wait a few seconds.
- If it still does not connect, adjust the position and try again.



5.2 Conducting the test

The minoo app guides you step by step through the entire testing process.

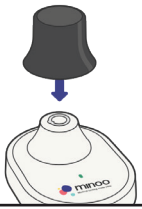
Conducting the minoo test with the swab samples

To take a throat swab sample, follow the guidance provided in the instructions for use of the minoo Testkit and in the minoo app.

NOTE: If the battery of your smartphone discharges during the analysis process, the minoo Teststation will still carry out the test to the end. The measurement data is stored at the test station. To view the results, the smartphone must be recharged, and the user must open the app and reconnect to the test station. It may take a few minutes to download the results.

Make sure that your smartphone is no more than 5 metres away from the test station after the analysis has been completed so that the result can be displayed in the minoo app.

At the end of the test



NOTE: Place the black protective cap supplied back on the minoo Teststation.

5.3 After use

Cleaning the minoo Testsystem

It is recommended to clean the minoo Teststation and sample station after each use with a lint-free cloth moistened with a 70% ethanol solution. Avoid allowing liquid to enter the opening of the test station. If this has happened, allow the liquid in the measuring area to evaporate by exposing it to dry air.

When not in use, leave the protective cap on the device.

Disposing of used vials and swabs

Follow the instructions for disposing of used test vials and swabs in the instructions for use of the minoo Testkit and in the minoo app.

Disposing of the minoo Teststation

A battery is installed in the minoo Teststation. Batteries must not be disposed of in normal household waste. They may contain heavy metals, which may pose a risk to human health or the environment at the end of their useful life if they are not disposed of properly.

Dispose of the minoo Teststation and its original accessories at a recycling centre for electronic and electrical equipment if you live in the EU or other European countries with a separate collection system for waste disposal.

Disposing of the packaging

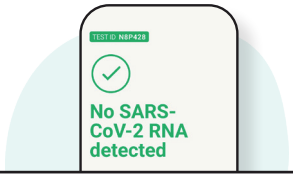
The packaging consists of various materials that can be disposed of at your local facilities.

Storage

Choose a storage location where the minoo Teststation cannot be dropped or contaminated. When not in use, the manufacturer recommends leaving the black protective cap on the test station. The protective cap protects the spectrometer‘s sensor from unwanted dust and liquids that can interfere with the fluorescence measurement.

Further detailed information on storing the minoo Teststation can be found in section 7 ”Storage and handling“.

6 Test results in the minoo app



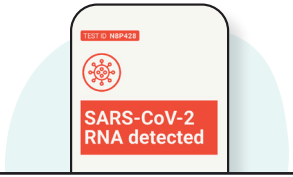
6.1 What does a negative test result mean?

A negative test result in green means that the minoo SARS-CoV-2 test did not detect any SARS-CoV-2 virus RNA in the sample.

A negative test result indicates that SARS-CoV-2 RNA was not present in the sample or was below the detection limit. However, a negative test result does not rule out COVID-19 and should not be used as the sole basis for decisions about treating or managing test persons. Negative test results should be considered to be presumptive and should be confirmed by another approved molecular test if clinical signs and symptoms suggest otherwise or if necessary for the management of the test persons.

If a diagnostic test is negative, the possibility of a false-negative result should be considered in light of the test person‘s recent contacts and the presence of clinical signs and symptoms suggestive of COVID-19. The possibility of a false-negative result should be considered in particular if the recent contacts or the clinical picture of the test person indicate that COVID-19 is likely and diagnostic tests to detect other causes of disease (e.g. other respiratory diseases) have been negative. If, based on the contact history and other clinical findings, COVID-19 is still suspected, retesting should be considered in consultation with the health authorities.

The risks of a false-negative result for the test person include: delayed or lack of supportive treatment; lack of monitoring exposure of infected persons, household members or other close contacts for symptoms that may lead to an increased risk of spreading COVID-19 within society; and other adverse events.



6.2 What does a positive test result mean?

A positive result against a red background means that the minoo SARS-CoV-2 test was able to detect SARS-CoV-2 virus RNA in the sample.

If a diagnostic test is positive, the possibility of a false-positive result should be considered. Pay particular attention to the test person's recent contacts and to the presence of clinical signs and symptoms suggestive of COVID-19.

The risks of a false-positive result for the test person include: an unnecessary recommendation to isolate the test person; monitoring of household members or other close contacts for symptoms; isolation of the test person that restricts their contact with family or friends and increases their contact with other potential COVID-19 patients; the test person is limited in their ability to carry out their work; delayed diagnosis and treatment of the actual infection responsible for the symptoms; unnecessary prescription of medication or treatment; and other adverse events.

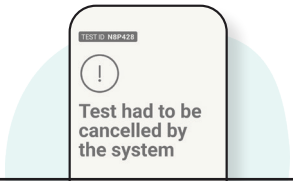
6.3 What does it mean if the test result is inconclusive?

This means that neither a positive nor negative result could be determined with certainty. The test must be repeated. The text is shown in orange.

Common causes of ambiguous results:

- Not enough sample material was taken.
- The sample was not prepared correctly.
- The sample was prepared and then left unattended for a long time.

If the result is inconclusive, you will need to conduct a new test. To do this, you will need to use a new minoo SARS-CoV-2 buffer vial, test vial and a new swab. The minoo app will take you from the "Result inconclusive" page to a page from which you can start a new test. Follow the instructions to retake the test in the minoo app.



6.4 Why was the test cancelled?

You will obtain a "Test cancelled" test result if the test had to be cancelled by the system, because you did not follow the test instructions correctly or because a system error has occurred.

Examples of cases when the system cancels the test:

- The sample was not prepared correctly.
- The test station was moved or tilted while the test was running.
- The test vial was removed or the protective cap was removed before the test could be completed.

7 Storage and handling

	Use	Storage
Temperature	21°C – 28°C	10° – 30°C
Air humidity	20-70% RH (non-condensing)	
Lighting conditions	< 2000 lux Avoid direct sunlight	Protect against sunlight
Heating	Keep at least 0,5 m away from any heat source	Keep at least 1 m away from any heat source
Operational environment	Do not store or freeze in a refrigerator.	
Water	Keep away from water and other liquids; Do not use test station outdoors	

8 Maintenance and service

8.1 General

Never attempt to open or disassemble the minoo Teststation. In the event of a malfunction or other problems with the minoo Teststation, Testkit or app, please contact the minoo customer service at support@minoo.de before starting further clinical testing with samples.

The manufacturer has not authorised third parties for maintenance and service purposes (service personnel). Please use the contact details provided above if you have any queries relating to this topic.

8.2 Cleaning the minoo Teststation

Follow the instructions in section 5.3 ”After use“ in this document.

9 Regulations for health-care providers and point-of-care facilities

To assist healthcare providers and point-of-care facilities using the minoo SARS-CoV-2 test, relevant regulations* are listed below:

A. All prescribing health service providers and point-of-care facilities are required to collect information on the performance of the minoo Teststation in the course of normal business operations and to report any suspected false-positive or false-negative results and significant deviations from the validated performance characteristics of the test kit to the German Federal Institute for Drugs and Medical Devices, BfArM (by email: medizinprodukte@ bfarm.de) and minoo (support@minoo.de).

B. All prescribing healthcare providers are required to report test results obtained from users of the test kit to the responsible public health authority in accordance with local, state and federal regulations. Healthcare providers must also provide minoo, upon request, with information on how many people have reported test results and how many tests have been prescribed by the healthcare provider in comparison.

C. Point-of-care facilities must use the testing station without deviations from the approved labelling.

D. Point-of-care facilities that purchase the product must notify the responsible public health authority about their intention to use the testing station before starting testing.

E. Point-of-care facilities using the testing station must have a procedure in place to report test results to healthcare providers and, if applicable, to the responsible public health authority.

* This list of regulations is for information purposes only and is based on the manufacturer's best knowledge at the time when the product was registered. It does not replace the obligation of organisations using this product as part of their business processes to apply the applicable regulatory framework. This is of particular importance as these vary from region to region and are subject to change at any time.

10 Performance characteristics

Extreme operating temperature and humidity

The study was conducted to evaluate the tolerance of the minoo SARS-CoV-2 test to both temperature and humidity extremes that may occur during normal operation of the station by end users. The performance of the test station was evaluated within extreme temperature and humidity combinations, where the temperature ranged from 21°C to 28°C and the humidity ranged from 20% and 70%.

All stations performed as expected under the ambient conditions tested.

11 Specifications

Category	Precise designation	Description / Value
Dimensions	Test station	92 x 67 x 37 mm
	Protective cap	45 x 45 x 33 mm
Weight	Test station	61 g
	Protective cap	9 g
Colour	Test station	white
	Protective cap	black
Duration of the test	Measurement duration	~18 min
	Preheating time	~2 min
Power supply	Cable	USB-C (male) to USB-A (male); white
	Battery type	LiPo battery
	Battery capacity	380 mAh
	Battery life	300 charging cycles ~80% of capacity

Category	Precise designation	Description / Value
Power supply	Device connection	USB-C
	Charging voltage	5.0 V DC, 0,7 W, 140 mA, Standard USB-2.0 A
	other	Power adapter not included with the device. WARNING: Only use double-insulated power supplies labelled ”LPS“ in accordance with IEC 60950-1 or IEC 62368.
Proben	Measurement volume	50 µl +/- 1µl
	Number of samples	1
	other	Use only with minoo Testkit components
Measurement technology		Fluorescence detection of isothermal amplification. Multi-channel detection
Data transfer	Bluetooth	Bluetooth Low Energy 5.0
	Tag technology	NFC

Category	Precise designation	Description / Value
Operational environment	Indoor / Outdoor	For indoor use
	Temperature	21 °C to 28 °C
	Air humidity	20% to 70% RH (non-condensing)
	Altitude	0 to 2000 m above sea level
	Degree of contamination	2
	Atmospheric pressure	0,77 to 1,01 bar
	Lighting conditions	Maximum illuminance of 2000Lux
Storage	Temperature	10 °C to 30 °C
	Air humidity	20% to 70% RH (non-condensing)
	Atmospheric pressure	0,77 bis 1,01 bar
	Altitude	0 to 2000 m above sea level
	Durability	Can be used for a maximum of 12 months if stored properly

Category	Precise designation	Description / Value
Cleaning	Process	Lint-free cloth, moistened with 70% ethanol solution CAUTION: Protect the device from free liquids and dust. When not in use, leave the protective cap on the device. If necessary, remove dust in the measuring area by slowly supplying clean, dry air.
Service life	Expected service life	1 year of operation or ~900 test runs, whichever comes first Note that the expected service life is measured from the time the packaging is opened.

12 Glossary of symbols

	Manufacturer
	Date of manufacture
	Use by date
	Catalogue number
	Batch code
	Serial number
	Product Identification Number (Unique Device Identifier)
	In vitro diagnostics
	Protect against sunlight
	Store in a dry place
	Lower temperature limit
	Upper temperature limit
	Temperature limitation
	Humidity limitation

	For single use, do not reuse
	Follow the instructions for use
	Fragile, handle with care
	Li-Ion-battery
	Recycle in accordance with regulations for electronic devices
	Do not use if packaging is damaged
	Content sufficient for <n> tests
	In vitro diagnostic (IVD) device for performance evaluation
	Double or reinforced insulation (IEC class II)
	Importer
	Direct current
	Attention!
	Warning!

13 Manufacturer information

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DE-12099 Berlin
Germany