

Rhonda SARS-CoV-2 disk

For all users SD003-02-I01-A02-EN

Instructions for Use

1 Information on this publication

Publication	Version	Changes
22 January 2021	SD003-02-I01-A02-EN	Initial publication in English.

1.1 Intended use

The Rhonda SARS-CoV-2 disks are consumable components in an *in-vitro* diagnostic system. The Rhonda SARS-CoV-2 disk is designed for use in combination with the Rhonda player.

Intended use

The Rhonda SARS-CoV-2 disk, processed on the Rhonda player is an automated, qualitative *in-vitro* diagnostic test intended for detection of SARS-CoV-2-specific nucleic acids. Rhonda SARS-CoV-2 disks are intended to analyze swab samples, taken from the upper respiratory tract (throat swab or throat swab combined with nasal swab) as SARS-CoV-2 RNA is generally detectable in swab samples, taken from the upper respiratory tract during infection.

The Rhonda SARS-CoV-2 disk together with the Rhonda player is intended for use in hospitals and decentralized settings (such as screening centers, nursing homes for the elderly) and is intended to be operated by health care professionals. The test utilizes reverse transcription followed by two-step *real-time* polymerase chain reaction (PCR) to amplify and detect the SARS-CoV-2-specific "E gene".

Positive results are indicative of active infection with SARS-CoV-2. Clinical correlation with patient history and other diagnostic information is necessary to determine the patient infection status. Positive results do not rule out bacterial co-infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Indication

Use of the Rhonda SARS-CoV-2 disk is indicated for screening for SARS-CoV-2 from swab samples taken from the upper respiratory tract.

Contraindication

The Rhonda SARS-CoV-2 disk cannot be used to distinguish between infectious (replication-capable) and non-infectious (replication-defective) viruses or free RNA.

A negative test result does not preclude a SARS-CoV-2 infection.

A positive test result does not rule out bacterial coinfection or co-infection with other viruses.

A positive test result may not be the definite cause of disease.

The Rhonda SARS-CoV-2 disk is intended to be used to detect the "E gene". Specific mutations in the binding sites of the primers and probes used in the assay may cause false-negative test results.

The Rhonda SARS-CoV-2 disk may detect SARS-CoV-2 below the limit of detection (LoD), but these test results may not be reproducible.

1.2 User information

Please read these Instructions for use before working with the Rhonda SARS-CoV-2 disk.

Keep the Instructions for Use in a safe, easily accessible place.

We would like our language to be as inclusive as possible. We have therefore used neutral formulations wherever possible.

The user information for the Rhonda player comprises:

- Rhonda player Instructions for Use
- Rhonda player Network and Service Documentation

The user information for the Rhonda SARS-CoV-2 disk comprises:

- Rhonda SARS-CoV-2 disk Instructions for Use Instructions for Use can be found on the side of every set of 20 Rhonda SARS-CoV-2 disks.
- Rhonda SARS-CoV-2 disk Analytical Principles

1.3 Obtaining electronic copies

You can obtain electronic copies of all the Instructions for Use from the Spindiag website. All electronic Instructions for Use are available in a number of different languages.

Tablets, smartphones, and the latest computers can display the electronic Instructions for Use directly in PDF format.

On older computers you will need a software program to display the PDF documents such as Adobe Acrobat Reader. You can obtain Adobe Acrobat Reader from the Adobe website.

Spindiag website: ifu.spindiag.de Adobe website: www.adobe.com

1.4 Reporting safety issues relating to the Spindiag system

If any difficulties occur while using the Rhonda player or the Rhonda disks, please report these by sending an e-mail to support@spindiag.de. If patients or users are harmed or their safety is affected you must comply with the statutory reporting obligations and deadlines. In such cases you can contact us by e-mail at support@spindiag.de or by telephoning +49 761 600 49 600.

1.5 Manufacturer information



Spindiag GmbH Engesserstr. 4a 79108 Freiburg, Germany Tel: +49 761 600 49 600 www.spindiag.de

If you need support on technical issues or training topics, please contact us by e-mail at support@spindiag.de or by telephoning +49 761 600 49 600.

For orders and other sales inquiries please contact us by e-mail at orders@spindiag.de or by telephoning +49 761 600 49 600.

- Please have the serial number of your Rhonda player to hand when contacting us. This is located on the nameplate (see Rhonda player - Instructions for Use Abb. 3.2 14).
- Additional sets of 20 Rhonda SARS-CoV-2 disks can be ordered under article number SD003-02-020-A01-EN.

1.6 Product names

These *Instructions for Use* refer to the following products.

Rhonda player

Processing device

Rhonda app

Optional app for tablets and the Rhonda player

Rhonda disk

Generic product name for all Rhonda disks

Rhonda SARS-CoV-2 disk

Product name for Rhonda disk for the SARS-CoV-2 analysis

For convenience, we use the following short form instead of the full name of the product: SARS-CoV-2 disk.

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Types of safety information

The colors below and the signal words *Warning*, *Caution* and *Notice* indicate the severity of a safety hazard or risk.



SEVERE HAZARDS

• Failure to follow these warnings can lead to *severe personal injury*.



HAZARDS

 Failure to follow these warnings can lead to mild or moderate personal injury.

NOTICE

IMPORTANT INFORMATION

• Failure to follow this information can lead to *damage to property*.

Safety information of "Warning" type

- **Risk of infection when handling samples** Spilt sample materials are potentially infectious.
 - Absorb spilt sample liquids with a disposable absorbent cloth and then wipe the sites down with a suitable disinfectant.
 - Follow the same procedure for contaminated surfaces.
 - If the external surface of a Rhonda disk is contaminated, refrain from using it and dispose of it.
 - You should wear gloves and further personal protective equipment such as gowns, face shields, masks, and eye protection in accordance with regional and lab-specific policies.
 - Follow the regional and lab-specific policies on handling biological samples, particularly those relating to general hygienic working practices, hand washing and disinfection, disposing of biological samples and removing spilt infections liquids.
 - Ensure that you do not touch or operate any system components with contaminated gloves.

Hazard due to improper use

SARS-CoV-2 disks are designed solely for use by properly instructed and trained professionals such as healthcare professionals and nursing care personnel or laboratory technicians. Improper use can cause a hazard to the user, incorrect test results or damage to the Rhonda player.

Ensure that only properly instructed and trained professionals work with the Rhonda player and the SARS-CoV-2 disks.

Hazards due to infectious material

After a swab sample is inserted, SARS-CoV-2 disks contain potentially infectious sample material. You should therefore handle the SARS-CoV-2 with due caution and dispose of the SARS-CoV-2 disk in accordance with regional and lab-specific policies on infectious material. Removal of the swab after preparing the SARS-CoV-2 disk poses the risk of becoming contaminated with infectious material. There is also a potential risk of uncontrolled carry-over of sample material and reagents and contamination of the working area with DNA amplificates.

- Do NOT throw or drop SARS-CoV-2 disks. If SARS-CoV-2 disks accidentally fall to the floor, dispose of the SARS-CoV-2 disk in accordance with regional and lab-specific policies and take a new SARS-CoV-2 disk.
- Handle the SARS-CoV-2 disk with care.
 Do NOT shake the SARS-CoV-2 disk.
- Dispose of any clearly damaged or soiled SARS-CoV-2 disks, or SARS-CoV-2 disks that you suspect of being damaged or soiled.
- You should wear gloves when inserting the swab, as well as further personal protective equipment such as gowns, face shields, masks, and eye protection in accordance with regional and labspecific policies.
- Do NOT open a SARS-CoV-2 disk if it already contains a swab.
- Do NOT remove a swab from the SARS-CoV-2 disk once it has been inserted.
- Dispose of all processed or invalid SARS-CoV-2 disks unopened.
- Do NOT damage SARS-CoV-2 disks when disposing of them.

Safety instructions in "Caution" class

Risk of contaminating working area

There is a risk that the working area will be contaminated with DNA amplificates when the swab is removed after preparing the SARS-CoV-2 disk. Carry-over of DNA amplificates from sample material and reagents may cause incorrect test results.

- Do NOT open SARS-CoV-2 disks if they already contain a swab.
- Do NOT remove a swab from the SARS-CoV-2 disk once it has been inserted.
- Dispose of all processed or invalid SARS-CoV-2 disks unopened.
- Do NOT damage SARS-CoV-2 disks when disposing of them.

Risk of injury

Risk of injury by trapping fingers in the disk slot of the Rhonda player.

Be careful not to place your fingers or hands inside the disk slot when you insert the SARS-CoV-2 disk in the Rhonda player. This could cause injuries.

Risk of incorrect test results

Using disks or cartridges made by other manufacturers may generate incorrect test results and damage the Rhonda player.

- ▶ Use original SARS-CoV-2 disks only.
- You should handle the SARS-CoV-2 with due caution and dispose of the SARS-CoV-2 disk in accordance with regional and lab-specific policies on infectious material.
- Do NOT throw or drop SARS-CoV-2 disks. If SARS-CoV-2 disks accidentally fall to the floor, dispose of the SARS-CoV-2 disk in accordance with regional and lab-specific policies and take a new SARS-CoV-2 disk.
- Handle the SARS-CoV-2 disk with care.
 Do NOT shake the SARS-CoV-2 disk.

List of symbols of the SARS-CoV-2 disk

CE mark in accordance with Directive 98/79/EC



Read the Instructions for Use



Manufacturer



Do NOT re-use a SARS-CoV-2 disk



LOT number



In-vitro diagnostic medical device



Use by date (date up to which SARS-CoV-2 disk can be used and is accepted by Rhonda player)



Temperature limit, indicating minimum and maximum storage temperatures for the SARS-CoV-2 disk



Do NOT use if packaging is damaged





Swab sample



Indicates the catalog number you can use to obtain more SARS-CoV-2 disks from Spindiag.



Number of SARS-CoV-2 disks per secondary packing unit



Number of SARS-CoV-2 disks per outer packing unit



Authorized sampling location. See 3.2 Suitable sample material 🛄 15



Direction in which to insert swab sample into SARS-CoV-2 disk.

Overview

3.1 SARS-CoV-2 disk

The SARS-CoV-2 disk is designed to detect SARS-CoV-2 in the upper respiratory tract during the acute stage of infection.



- **A** Application
- **B** Screw cap for swab insertion
- C Top
- **D** Bottom

- E SARS-CoV-2 disk data matrix code
- F Detection zone (do not touch without gloves or scratch!)
- ${\bf G} \ \ {\rm Direction} \ {\rm of} \ {\rm insertion}$

Abb. 3.1 SARS-CoV-2 disk



Abb. 3.2 Quick Reference Guide on each SARS-CoV-2 primary packing unit

To analyze samples using the SARS-CoV-2 disk you will need the Rhonda player.

C Rhonda player - Instructions for Use

3.2 Suitable sample material

Samples may only be collected for the SARS-CoV-2 disk using the swab kit below which can also be obtained directly from Spindiag:

 COPAN eSwab® Standard with 1 mL AMIES-Medium
 Manufacturer: COPAN Diagnostics
 Catalog numbers: #480CE and #490CE

The COPAN eSwab® Standard with 1 mL AMIES-Medium swab kit is suitable for swabs taken from various parts of the body.

However, swabs for the SARS-CoV-2 disk must only be taken from the following part of the body:

• throat swab

COPAN Diagnostics website: www.copanusa.com

3.3 Analysis principle

SARS-CoV-2 disks can be used for fully automated in-vitro diagnostic testings. SARS-CoV-2 disks are disposable plastic test carriers that contain all the reagents required to analyze a sample for SARS-CoV-2. Users do not come into contact with the reagents and do not have to handle them. The analysis principle using the SARS-CoV-2 disks is based on real-time polymerase chain reaction (PCR) following initial reverse transcription of the viral RNA. During the analysis the Rhonda player heats and spins the SARS-CoV-2 disks in a predefined sequence. No parts of the Rhonda player come into contact with reagents or the sample at any time. After the analysis the SARS-CoV-2 disk stays hermetically sealed at all times, allowing for easy disposal. During the analysis, the SARS-CoV-2 disk generates a fluorescence signal in the detection zone (Abb. 3.1 14 F) which the Rhonda player measures and assess at the end of a run.

For details of the analysis principle and data analysis, see Rhonda SARS-CoV-2 disk - *Analytical Principles*



4.1 Number of samples

You can process 1 or 2 Rhonda disks at the same time. Select 1 or 2 on the Rhonda player before the analysis. Once you have entered the selected number of Rhonda disks the analysis starts automatically. The duration of the analysis is independent of the number of Rhonda disks.

You can change the number of Rhonda disks by simply selecting 2 or 1 at any time until the analysis starts. Once the analysis has begun, however, you cannot add any more Rhonda disks. Wait until the analysis is complete before processing more Rhonda disks.

You can process a SARS-CoV-2 disk at the same time as one of the following Rhonda disks:

- A second SARS-CoV-2 disk
- Rhonda disks, if their *Instructions for Use* states that they are compatible with the SARS-CoV-2 disk.

The Spindiag website contains a complete list of compatible Rhonda disks.

📜 www.spindiag.de

4.2 Preparing the SARS-CoV-2 disk

RISK OF INFECTION IF SARS-COV-2 DISK IS PUNCTURED

Do NOT use scissors, knives, or other aids to open the SARS-CoV-2 disk primary packing unit. If the SARS-CoV-2 disk is damaged, dispose of it immediately in accordance with regional and laboratory-specific policies.

RISK OF INCORRECT TEST RESULTS

- Avoid exposure of the SARS-CoV-2 disk to direct sunlight over prolonged periods, high temperatures or high atmospheric humidity levels.
- Use the COPAN eSwab® Standard with 1 mL AMIES-Medium swab kit only.
- Only use sample material taken from a throat swab.



RISK OF INCORRECT TEST RESULTS

- Once the primary packaging unit is opened the sample must be inserted into the SARS-CoV-2 disk and processed in the Rhonda player as quickly as possible (within 2 hours).
- Once the primary packaging unit is opened the SARS-CoV-2 disk must not be stored on hot and/or soiled surfaces.
- Prepare each SARS-CoV-2 disk just before the analysis.
- Do NOT leave the SARS-CoV-2 disk opened for prolonged periods before use.
- Ensure that the swab in the swab test tube is immersed in the sample liquid before you open it.
- Do not fill or pipette ANY sample liquids into the SARS-CoV-2 disk.
- Do not introduce ANY other substances into the SARS-CoV-2 disk.
- The SARS-CoV-2 disk must NOT be stored and NOT shaken after the sample is inserted and must be inserted straight into the Rhonda player for processing.



RISK OF INFECTION FROM CONTACT WITH SAMPLE MATERIAL

Do NOT touch the outside of the SARS-CoV-2 disk with the swab sample. If this happens by accident, dispose of the swab sample and SARS-CoV-2 disk in accordance with regional and laboratory-specific policies.

RISK OF SAMPLE MIX-UPS WHERE 2 SAMPLES ARE INSERTED

Prepare the SARS-CoV-2 disk using sample 1 first and insert the SARS-CoV-2 disk with sample 1 first before starting on sample 2.

RISK OF DAMAGING THE RHONDA PLAYER AND RISK OF INFECTION AND CONTAMINATION

- If the SARS-CoV-2 disk is not screwed completely tight it may leak or tilt inside the Rhonda player.
- Do NOT stick barcodes onto the SARS-CoV-2 disk.

Are the required materials available?

1 or 2 SARS-CoV-2 disks

Preconditions met?

- You are wearing gloves and further personal protective equipment such as gowns, face shields, masks, and eye protection in accordance with regional and lab-specific policies.
- You have taken patient samples.

Patient samples that are unusually turbid and/or mucoid may cause invalid results.

Patient samples that contain inactivating substances or are inactive may cause invalid results.

See 3.2 Suitable sample material [1] 15 for suitable swab kits and sample material

- The swab test tube has a screw cap and contains one swab.
- **D** The sample is marked with a patient barcode.

Preparing the sample

- Before the analysis ensure that the swab has already been immersed in the transport medium for at least 5 minutes.
 - This can include transport times between taking the sample and placing it next to the Rhonda player.
- 2. WARNING! Risk of infection and contamination: Before you open the screw cap, shake down the sample tube to make sure all of the transport medium has settled at the bottom of the tube.

If not, any sample liquid left in the screw cap may leak when you unscrew it.

Before proceeding to shake down the sample liquid to the bottom of the tube, shake the sample tube vigorously back and forth for at least 10 seconds.



Preparing the Rhonda player

1. To prepare the Rhonda player, see Rhonda player - *Instructions for Use* and Rhonda player - *Quick Guide*.

Preparing the SARS-CoV-2 disk

- 1. Check the primary packaging unit:
 - Primary packaging unit NOT damaged?
 - Disk NOT past its use by date?
 - If anything is wrong, dispose of the SARS-CoV-2 disk in accordance with regional and lab-specific policies and take a new SARS-CoV-2 disk.
 - Do not use any SARS-CoV-2 disks that have passed their use by date. The use by date is located on the secondary and primary packaging units and the label of the SARS-CoV-2 disk.
- 2. CAUTION! Risk of invalid test results: Only touch the detection zone (see Abb. 3.1 [1] 14) with gloves, do not scratch it.

Open the primary packaging unit. Inspect the SARS-CoV-2 disk:

- NO damage?
- If anything is wrong, dispose of the SARS-CoV-2 disk in accordance with regional and lab-specific policies and take a new SARS-CoV-2 disk.

3. Hold the SARS-CoV-2 disk and the sample tube together in one hand.



- i Keep your other hand free.
- Transfer the swab into the SARS-CoV-2 disk
- 1. SARS-CoV-2 disk: Use your free hand to unscrew the screw cap.



2. WARNING! Risk of incorrect test results: The inside of the screw cap must NOT be contaminated.

Put the screw cap down with the **closed** side facing downwards.

3. Sample tube: Unfasten the *pink* screw cap.

4. WARNING! Risk of incorrect test results: Do NOT touch the inside of the pink screw cap. Do NOT touch other surfaces with the swab when transferring it. Do NOT let the swab dry out.

Transfer the swab with the *pink* screw cap from the sample tube into the SARS-CoV-2 disk.



5. **CAUTION!** Risk of infection and contamination Screw the *pink* screw cap completely tight on the SARS-CoV-2 disk.

You must transfer the swab together with the *pink* screw cap.

The SARS-CoV-2 disk must be properly screw shut as liquid may leak out otherwise.



6. Screw shut the sample tube using the screw cap that was originally on the SARS-CoV-2 disk.



- Once the sample has been inserted into the SARS-CoV-2 disk, the SARS-CoV-2 disk should be handled with care.
- Even with the swab removed, the sample tube still contains transport medium with sample material. Consideration is required before discarding it, since it could be used for further tests, for example in the laboratory. If it is no longer required, dispose of the sample tube in accordance with regional and lab-specific policies on infectious material.
- Treat material for quality controls in exactly the same way as sample material.
- 7. Check and ensure that the *pink* screw cap on the SARS-CoV-2 disk is locked tight into place.
- Starting the analysis
- 1. To start the Rhonda player, see Rhonda player *Instructions for Use* and Rhonda player *Quick Guide*.

4.3 Disposing of the SARS-CoV-2 disks

Dispose of any unused/expired SARS-CoV-2 disks

There are regional and lab-specific policies on non-infectious residual waste. Unused/expired SARS-CoV-2 disks must be disposed of in accordance with these policies.

Dispose of SARS-CoV-2 disks that contain sample material



RISK OF CONTAMINATION OF WORKPLACE WITH DNA AMPLIFICATES

Used SARS-CoV-2 disks contain potentially infectious sample material and DNA amplificates.

- Do NOT open SARS-CoV-2 disks that contain a swab.
- Do NOT reuse SARS-CoV-2 disks.

🔥 WARNING

RISK OF INFECTION

Used SARS-CoV-2 disks contain potentially infectious sample material and DNA amplificates.

- There are regional and lab-specific policies on infectious waste. Dispose of SARS-CoV-2 disks in accordance with these policies.
- It is NOT possible to reuse SARS-CoV-2 disks for analysis where the analysis was started but then canceled by the operator or due to an error.
- Used SARS-CoV-2 disks must be disposed of.

4.4 Analysis results

The display on the Spindiag Rhonda player shows analysis results in a compact format. The Rhonda player can pass analysis results to a POCT middleware or a hospital/laboratory information system (HIS/LIS) if preferred. Alternatively, you can view analysis results in the Rhonda app.

For SARS-CoV-2 disks, the Rhonda player shows qualitative analysis results (positive or negative).

- "Positive" means that SARS-CoV-2 has been detected in the sample.
- "Negative" means that SARS-CoV-2 was not detectable.

An analysis may also show the result *Invalid*, *Locked* or *Analyzing*. For the general root causes, see Rhonda player - *Instructions for Use*.

Invalid may also be due to the following causes where a SARS-CoV-2 disk is used:

 The patient sample contains interfering substances, in particular acetyl salicylic acid (Aspirin Plus C 500 mg, Bayer Vital GmbH) in very high concentrations (416.7 μg/mL or more). See Rhonda SARS-CoV-2 disk -*Analytical Principles*.

- 2) The patient sample was unusually mucoid and/or turbid.
- 3) The patient sample contains inactivating substances or was inactivated.

In such cases, analyze the patient sample again using a different method.

WARNING Only experts with the necessary qualifications and experience of interpreting data should draw conclusions on specific actions to take based on the test results. The notes and restrictions in chapter 1.1 Intended use 2 should be taken into account.

For details on test result displays see Rhonda player - *Instructions for Use* For the analytical process and data interpretation see Rhonda SARS-CoV-2 disk - *Analytical Principles* On connecting the Rhonda player to POCT middleware or a hospital/laboratory information system (HIS/LIS) see Rhonda player - *Network and Service Documentation*

4.5 Implementing quality controls

Spindiag explicitly recommends conducting regular measurements with external quality controls. The procedures to be followed for routine testing of patient samples and for quality controls are identical. It is only the sample material that is different.

Where quality controls are required under regional and laboratory-specific policies you should conduct regular quality control tests. These can be conducted either using patient samples where the test result is known because it was determined by a reference method, or using external quality control materials. If any unexpected test results occur, repeat the quality control with a different sample.

If a positive test result is obtained for a negative control the Rhonda player or the environment may be contaminated. If this is the case, refrain from using the Rhonda player and contact the Spindiag customer service. If positive controls are repeatedly tested with a negative test result, you should also contact the Spindiag customer service.

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5 Technical information

5.1 Storage conditions

RISK OF INFECTION AND CONTAMINATION

Potentially infectious sample material could leak out of the SARS-CoV-2 disk while it is being prepared for analysis or during the analysis itself if the SARS-CoV-2 disk is stored in conditions other than the permitted storage conditions.

- Ensure that the primary packaging units are stored continuously at the specified storage conditions.
- Do not open the primary packaging unit until just before you use it.

Store the SARS-CoV-2 disks in sealed primary packaging units at room temperature (15°C - 25°C) in a clean, dry room.

When kept under these conditions, SARS-CoV-2 disks can be stored until the use by date printed on the packing units. The use by date is also contained in the data matrix code printed directly on the SARS-CoV-2 disk. The code is automatically scanned and checked when the SARS-CoV-2 disk is inserted into the Rhonda player.

5.2 Obtaining SARS-CoV-2 disks

You can obtain SARS-CoV-2 disks directly from Spindiag or from authorized dealers. The Spindiag website contains ordering options and a list of authorized dealers.

Spindiag website: www.spindiag.de

5.3 Disposal of personal protective equipment

Dispose of personal protective equipment such as gloves, gowns, face shields, masks, and eye protection in accordance with regional and lab-specific policies on infectious material.

For your notes

