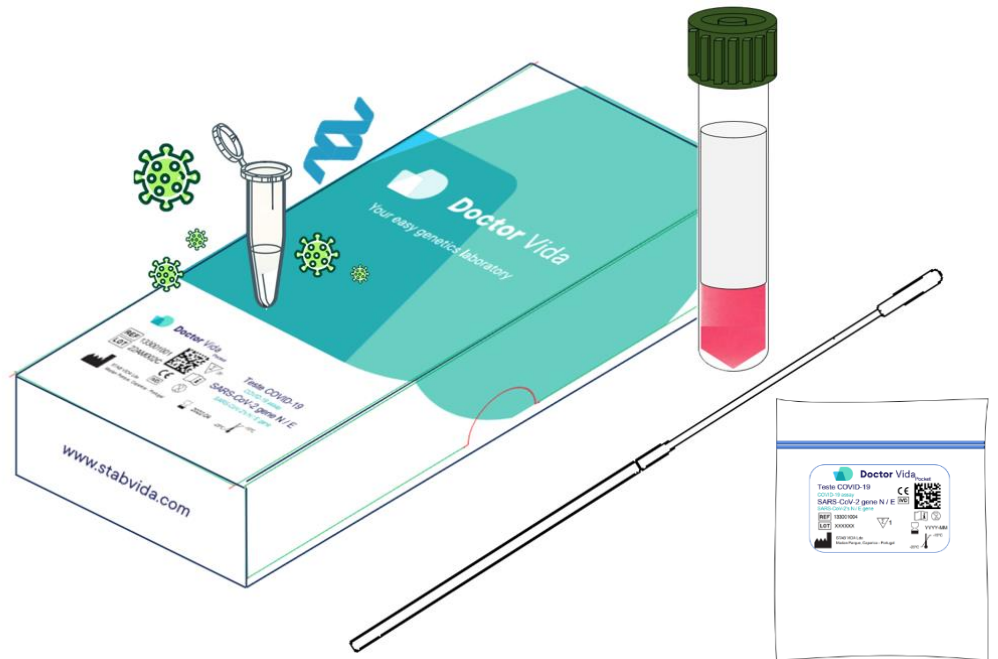


# Doctor Vida

Your pocket PCR



## COVID-19 test



## Instructions for use



Reference 1330010001,133001004

Version 15, October 2023

In Vitro diagnostic medical device

Stabvida.com

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Doctor Vida® is a trademark of STAB VIDA- Investigação e Serviços em Ciências Biológicas, Lda.

The manufacturer continues to improve its products and reserves the right to change the information at any time.

If the product is used differently than specified by the manufacturer, the device may be compromised. Please refer to the warnings, precautions, measures to be taken and limitations of use relating to the product.

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## Intended purpose

The COVID-19 Test is suitable for amplification and molecular detection of the SARS-CoV-2 virus in 40 minutes using a nasopharyngeal exudate preserved in viral preservation medium (VPM). This test should be used in combination with Doctor Life equipment and *Software*. The system is suitable for *near-patient-testing* and should only be used by healthcare professionals. The user is responsible for the analysis of the sample, compliance with the applicable biosecurity rules including the use of appropriate personal protective equipment, maintenance of the premises and the treatment of waste resulting from the analysis.

## Test Principles

The sample of nasopharyngeal exudate is collected by healthcare professionals following good practice procedures using the appropriate material and appropriate equipment not included in this product. 10uL of sample is added to the tube with the reagents (Covid-19 Test), following the instructions described in this document. The analysis performed by *Loop mediated isothermal amplification (rRT-LAMP)* is based on the reverse transcription and amplification at a constant temperature of the N and E genes specific to the SARS-CoV-2 virus. The detection of the amplification of the N and E genes is done by fluorescence. The detection system included in the Doctor Vida device and *Software* allows to detect the emitted fluorescence translating into the presence of RNA from the SARS-CoV-2 virus. On the other hand, if there is no emission of fluorescence or if it is residual, the viral RNA is absent or in quantity below the limit of detection of the technique and it is not possible to confirm the presence of the SARS-CoV-2 virus. The analysis of the sample in the Doctor Vida equipment, the results and report obtained are communicated to the user and user through the Dr Vida Pocket PCR application installed on the mobile phone.

## Quality control

**Human Control:** is recommended for use in all tests. This control ensures that there are no reaction inhibitors in the sample and that there is biological material in the sample. Human control reagent tubes are supplied with COVID-19 tests (ref. # 133001001/006). For more details, see the procedure described in the "Sample analysis" section.

**External controls** (optional, not provided in the product)

The recommended external controls are:

"White" Control – Add 10uL of VPM or nuclease-free water to the test tube. Mix well. Run the test as described in the "Sample Analysis" section using the Dr Vida Pocket PCR application and the Doctor Vida equipment.

Inactive viral particles or viral RNA: Mix 5uL of inactive viral particles (1) or viral RNA with 5uL of VPM medium or nuclease-free water. Add 10 uL of the mixture to the test tube. Mix well. Run the test as described in the section "Analysis of the sample using the Dr Vida Pocket PCR application and the Doctor Vida equipment" or,

Positive clinical sample (RNA extracted or direct sample if taken in VPM medium): Add 10uL of the sample to the test tube. Mix well. Run the test as described in the "Sample Analysis" section using the Dr Vida Pocket PCR application and the Doctor Vida equipment.

(1) It is recommended to use as positive control NATrol SARS-Related Coronavirus 2 (SARS-Cov-2), catalog number NATSARS(COV2)-ERC1, manufacturer ZeptoMetrix Corporation.

External controls are recommended in the following situations: 1) after the arrival of the tests, 2) before performing the tests, if they are not in regular use or 3) every 100 tests, if they are in regular use. Human control is recommended for each test.



## Applicable symbols



See instructions for use



Product Reference



Batch number



Manufacturer



Do not reuse



Use up to



CE marking



In vitro diagnostic medical device



Temperature limits



Contains enough to <n> tests



**Attention:**

Follow the instructions in this manual; Improper use may cause damage to the device or your health

# Warnings, precautions, safety measures and limitations of use

## Warnings, precautions and safety measures

For the safety of users, it is important to comply with and understand the information provided. If the product is used differently than specified by the manufacturer, the protection and performance of the product may be affected. See the product safety data sheet for more details.

▶ Do not use any component of the product if it is damaged or out of date or if the recall solution or reagent contains potential contaminants (turbidity). The use of damaged components may cause damage to health and/or compromise the performance of the product.

▶ Do not use components not included in the product, only those indicated by the manufacturer if necessary. The use of components not recommended by the manufacturer may compromise the performance of the test.

▶ The handling of this product should be limited to health professionals, following the use of good laboratory practices, allowing to prevent risks to the user and ensure the integrity of the reagents.

Avoid contamination of reagents and/or cross-contamination when performing each test:

▶ Wear appropriate personal protective equipment (gown, gloves, eye protection, mask, etc.) according to applicable regulatory guidelines;

▶ Keep the lid open only for the tube you are using. Do not change or reuse pipe covers.

▶ Change the gloves and always clean the device, the necessary materials and the surface before and after each test;

▶ Perform amplification in an isolated area of the sampling area and preparation of the reaction mixture (reagents + sample);

▶ Do not reopen the reaction tubes after the test, to avoid the release of amplified DNA fragments (amplicões) in significant quantities;

▶ Waste materials and reagents must be disposed of in a biological waste bag in accordance with applicable regulatory guidelines;

▶ Facilities should be cleaned daily with DNA-free products, and ventilated (natural aeration).

All users must be informed of the instructions for use of the test as well as the Doctor Vida equipment and *Software*. Failure to comply with the instructions may cause damage to the device and/or cause damage to health.



If the product is used in combination with another device, please refer to the information regarding warnings, precautions, safety measures and limitations of use of the Doctor Vida equipment and *Software* in the Instructions for Use, concerning:

- ▶ Handling of Fluids/Reagents near the device;
- ▶ The electrical current of the device;
- ▶ Device operating environment;
- ▶ Medium-physical where you place the device.

## Limitations of use

Failure to comply with proper procedures for transporting, storing, collecting, processing and analyzing the sample may invalidate or compromise the test result due to cross-contamination.

► Low sample quality can lead to inaccurate results. In the case of extracted RNA, aliquot and store the aliquots at -20°C or -80°C until analysis. MPV samples should be stored between 2-8°C and preferably used within 72 hours.

► Virus-inactivating harvesting media contain inhibitors that can affect the quality of the test. For inactivating harvesting media, RNA purification is recommended prior to analysis.

► Interferences present in the sample can lead to inhibition of the enzyme used in the test.

Substances	Concentration	Substances	Concentration
Kcl	150 mM	Hemoglobin	>4 µg/µL
Ethanol	7%	IgG	>2.4 µg/µL
Guanidine HCl	145mM	Humic acid	2 ng/µL
SDS	0.01%	Urea	1.5 M
Magnesium sulphate	22 mM	Calcium chloride	2. 5mM
Manganese sulphate	2 mM	Bile salts	0.6 µg/µL
DMSO	15%	BD Universal	>20%
DTT	>100 mM	Remel M4	>20%
<i>Whatman 903 Collection Paper</i>	>7.07 mm <sup>2</sup>	Amies	>20%
<i>Whatman FTA Collection Paper</i>	3.9 mm <sup>2</sup>	Stuart	>20%
<i>Whatman FTA Elute Collection Paper</i>	1.1 mm <sup>2</sup>	Collagen	>125 ng/µL
Hematin	4.5µM	Myoglobin	>2.4 µg/µL
Hemina	12µM	Melanin	2.5 ng/µL
Heparin	1.2 µg/µL	Mucin	0.66 µg/µL
Sodium citrate	15 mM	Tannic Acid	145 ng/µL
Sodium EDTA	4.5 mM	Indigo	300 µM

► A negative (undetected) result does not exclude COVID-19 disease. The analysed regions of the SARS-Cov-2 virus may not have been detected, for example, due to mutations in the primer hybridisation sites, amount of RNA below the detection limit of the technique or presence of inhibitors. In this case, diagnosis using the reference method, rRT-PCR can be used to confirm the result.

► In the event of an electrical current failure, the analysis is interrupted and the test is invalid. The reaction tube must be discarded and the test will have to be repeated with a new reaction tube.

► If the control fails, the test is invalid. The test tube should be discarded and the test should be repeated with a new test tube and a new control tube.



## Before starting the test

### Materials provided

The COVID-19 Test consists of the packaging of the test and the accessories provided for the execution of the test. Each component is single-use.

Components	Description	Quantity	Storage conditions
Product Packaging	COVID-19 testing	20 units or individual	-25°C to -15°C
	Disposable plastic pipettes	25 units or individual	--
Accessories	Harvesting tubes	20 units or individual	+4°C - 25°C
	Disposable nasopharyngeal swab	20 units or individual	+4°C - 25°C

### Materials needed but not provided

- ▶ Doctor Vida equipment (including power supply and micro-USB-B cable) – available with reference number 133001002;
- ▶ Dr Vida Pocket PCR app – available in Google play and iOS stores.
- ▶ Bluetooth enabled mobile phone – to install and use the Dr Vida Pocket PCR app
- ▶ Internet (wireless) – required for data transfer to the server.

To conduct a COVID-19 Test trial it is necessary to ensure that the Dr Vida Pocket PCR application is installed on your mobile phone and that the Doctor Vida equipment is connected to the electrical current and connected to it. For more details you should consult Instructions for use of Doctor Life equipment and *Software*.

### Product Transportation

For the transport of the product to be carried out accordingly, the test packaging is properly packed in Styrofoam boxes containing dry ice or ice sheets, to ensure the temperature conditions of the components (-25°C to -15°C). The Test accessories are packed and transported at room temperature.

### Product storage

The product and its components/accessories must be stored according to the temperature indicated on the labelling.

### Product handling

#### Considerations:

For each test, use only 1 test pack, which is single-use.

After thawing completely, the tubes are able to start the test.

⚠ Avoid freeze-thaw cycles, as it will decrease the efficiency of the product.

⚠ Minimize light exposure in the test tube as it will decrease the efficiency of the product.

### Product stability

This product maintains the stability of the reagents and the performance according to the expiration date imposed on the package label, provided that the conditions of transport, storage and handling are met.

### Classification of product reagents

Information available in the product safety data sheet.

## Performance characteristics

(Compared to the standard laboratory method of real-time rRT-PCR)

Nasopharyngeal exudate harvested with swab in virus preservation medium, VPM

		real-time rRT-PCR, Ct ≤35		Total
		Positive	Negative	
Doctor Life System for COVID-19	Positive	52(VP)	0(FP)	52
	Negative	2 (FN)	62(VN)	64
Total		54(VP+FN)	62(VN+FP)	116

PV=True positive; FN = False negative; VN= True negative; FP= False positive.

Parameters*	Formula	Result (CI95%)
Concordance rate of positives or sensitivity (%)	$VP/(VP+FN)*100\%$	96.30% (87.25% - 99.55%)
Negative agreement rate or specificity (%)	$VN/(VN+FP)*100\%$	100% (94.22% - 100.00%)
Total agreement rate BP (%)	$(VP+VN)/(VP+VN+FN+FP)*100\%$	98.28% (93.91% - 99.79%)
Theoretical agreement rate Pe	$[(VP+FP) (VP+FN)+(FN+VN)(FP+VN)]/(VP+VN+FN+FP)^2$	0.50
K-coefficient	$(PA-PE)/(1-PE)$	0.97

\*The analytical parameters presented correspond to Ct≤35 values when compared to the standard rRT-PCR technology. Ct (*threshod cycle, the intersection between an amplification curve and a threshold line*), is the number of the cycle in which the signal emitted during PCR intersects the fluorescence threshold line.

# Pre-sampling

Preparation of the site and all the equipment used in the test

Before starting the sampling and analysis of the test itself, you should prepare the entire place where the test is carried out and also all the equipment and material inherent in the analysis of the test.

The place should have an ambient temperature between 15°C to 30°C and humidity levels between 20 and 80%;

Keep the place clean and ventilated, daily natural aeration;

have well-defined spaces (with a minimum acceptable distance) for sampling, transfer of the sample to the test tube and analysis of the test;

Clean and disinfect work surfaces with 10% bleach and 70% ethanol to mitigate the risk of contamination;

Clean with paper moistened in 70% ethanol (do not spray) the outside of the Doctor Vida equipment and let it air dry;

Remove the lid of the Doctor Vida equipment and clean it with paper moistened in 70% ethanol and let it air dry;

**Note:** Be careful not to enter Ethanol in the hole where the test tube is placed

Keep the lid open until a new test;

Put on some new gloves at the beginning of each analysis.

# Installation

For more information see the Installation topic in the instructions for use of the Doctor Life and *Software* (<https://www.stabvida.com/drvida>)

Turn on the Doctor Vida equipment.

Connect the Doctor Vida equipment to the current or connect to a portable charger, output: 5VDC, 2A. The equipment may take a few minutes to stabilize the temperature.

## **Install the Dr Life Pocket PCR application.**

Install and configure the Dr Vida Pocket PCR application on your mobile phone (see instructions for using the Doctor Vida equipment and Software).

Select the Doctor Vida genetic test and Pair the Doctor Vida equipment.

On the main screen of the app, select the Doctor Vida genetic test you want to perform – "COVID-19 Test".

Then click "Select device" and turn on the device you want manually or scan the QRcode of the device to select. The equipment is ready to do the test.

Record the information of the reagents of the genetic test Doctor Vida.

The information of the reagents of the genetic test in question is recorded, or manually enter the test reference and batch number or read the QRcode on the test packaging.

Fill in the data relating to the sample.


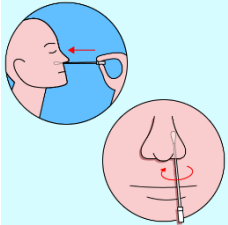


Click on "read the sample ID" to be able to fill in all the data related to the sample to be tested, such as the ID itself and the type of sample in question. Also, you have the option to select the "Test with certificate at the end" and for this you must go to "More details" fill in or check (if the filling has been done by reading the QRcode of the sample) the patient's data.

# Collection, handling, preparation and analysis of samples

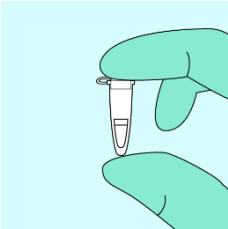

## Sampling – Nasopharyngeal exudate

The collection of the sample must be carried out by health professionals in accordance with the applicable regulatory guidelines, following the information present in this document. The illustrations are available in the Dr Vida Pocket PCR application.

### General instructions:

	<ol style="list-style-type: none"> <li>1. Remove the supplied nasopharyngeal swab from its sterile packaging.</li> </ol> <p> Do not touch the tip of the swab and avoid contact with any object or surface.</p>
	<ol style="list-style-type: none"> <li>2. Slowly introduce the swab into one of the nostrils to the pharynx by making 3 to 5 rotational movements. Repeat the same procedure in the other nostril.</li> </ol>
	<ol style="list-style-type: none"> <li>3. Insert the swab into the collection tube containing VPM medium (pink liquid) and bend the swab rod against the top of the tube until it breaks at the breaking point. Make sure the swab is inside the VPM medium, tighten the lid tightly to close the tube and mix vigorously for 15 seconds or vortex.</li> </ol> <p>Optional: Do a brief spin before proceeding.</p>
	<ol style="list-style-type: none"> <li>4. Let the sample incubate for at least 10 minutes at room temperature.</li> </ol>

## Sample handling, preparation and analysis

	<ol style="list-style-type: none"> <li>5. Meanwhile, remove a small test tube from the box and thaw it with the help of your fingers until the liquid is completely transparent.</li> </ol>
	<ol style="list-style-type: none"> <li>6. Transfer 10µL from the VPM sample to the test tube using the supplied pipette.</li> </ol>

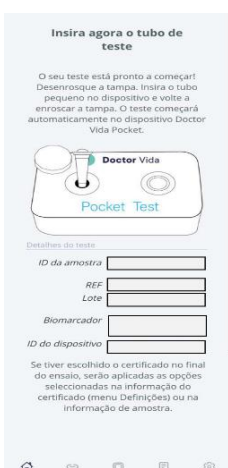
7. Close the test tube tightly and beat it on the bench 5 times to mix the sample well with the reagents.



⚠️ Check that the information that was entered earlier is correct in the 'Settings' menu and edit if necessary.



8. Click start test, the device will check the requirements needed to start the test.



9. When prompted, insert the test tube into the Doctor Vida equipment, unscrew the cap, place the tube, and screw the cap.

The test will start automatically and will take approximately 40 minutes.

⚠️ Do not touch or move the Doctor Vida equipment while the sample is being processed as it may compromise the reliability of the test.

 While the test is ongoing, do not disconnect the Doctor Vida equipment from the electrical current,

**Note:** If you lose internet or Bluetooth connection while the test is in progress, you do not lose the test. Just reopen the app and select the 'Pair available devices' screen to reconnect the device(s) that are in progress.

## After the test

See the result

As soon as the test is over, the Doctor Vida equipment transfers and stores the data in real time on the Doctor Vida API server, via the Dr Vida® Pocket PCR application.

**Note:** The transfer of the data until the result is obtained may take about 2 minutes.

After the data has been transferred, click on the 'Results' button of the application to be able to view the test result and/or consult the test result certificate in your email if you have selected and registered this option.

Cleaning of site and equipment and waste disposal

At the end of each test, ensure that the different sites are clean and ventilated as well as all the equipment used in the test, including the Doctor Vida equipment and ensure that the disposal of tubes A and B and all the inherent material is carried out in accordance with the rules of biological waste treatment and in accordance with regulatory guidelines.

After the analysis, open the lid of the Doctor Vida equipment, remove the tube and dispose of it in the biological waste;

Clean with paper dampened in 70% ethanol (do not spray) the outside of the Doctor Vida equipment as well as the lid and let it air dry;

**Note:** Be careful not to enter Ethanol in the hole where tube B is placed.

Clean and disinfect work surfaces with 10% bleach and 70% ethanol to mitigate the risk of contamination;

Keep the place clean and ventilated, daily natural aeration;

Keep the equipment cover open until a new test;

Dispose of the papers and gloves used in cleaning the space and equipment for the biological waste.

**Note:** Do not leave Doctor Vida equipment on if you are not using it.

# Troubleshooting

Problem noted	Possible solution
<ul style="list-style-type: none"> <li>-Failure detected after starting the scan</li> <li>-Electricity failure while the test is running</li> </ul>	<p>Turn off the machine and close the application. Open the Dr Vida app. Discard the reaction tube that was in use and restart the process using a new reaction tube.</p>
<ul style="list-style-type: none"> <li>- The application fails to give the result</li> <li>-The application takes too long to display the results or the test appears to be blocked</li> </ul>	<p>Close the App. Check your internet connection and Bluetooth. Open the App and in the "Devices" menu, reconnect the device. Press the device button again and click "continue".</p> <ul style="list-style-type: none"> <li>. If you continue to error, unpair the device and re-pair. It's important to make sure that the same device isn't connected to more than one phone.</li> <li>. If you are able to start a new test with this device, it means that a power failure has occurred or the device has restarted automatically. In this case, the test is invalid. Discard the reaction tube that was in use. Turn the device off and back on and start the process using a new reaction tube.</li> <li>. If the problem persists, please contact technical support.</li> </ul>
<ul style="list-style-type: none"> <li>- The device does not appear in the list of devices</li> <li>-The connection between the device and the phone has failed</li> </ul>	<ul style="list-style-type: none"> <li>. Check that the device is plugged in, that there is no electrical fault (for example the connection cable is damaged). If this is the case, you can for example use a cable from the Mobile Phone.</li> <li>. Check that the bluetooth is turned on and that in the settings of the phone, in the App gave permission to access the location of the device.</li> <li>. Refresh the screen by sliding your finger down.</li> </ul>
<p>The phone ran out of space</p>	<p>If your phone runs out of space before you start the test, you should free up space on your phone or use another phone.</p> <p>If the mobile phone runs out of space during the test, the test continues, however, the results will not be available. In this case do not turn off Doctor Vida since the data is stored on the device. Free up space on your phone and the connection will be re-established.</p> <p>Important note: If you turn off the device you lose all data and you must repeat the test with a new reaction tube.</p>
<p>Result with atypical graph</p>	<p>When the result is detected, however the growth of the curve is not of the exponential type, the analysis must be repeated with a new test. This type of result can occur when:</p> <ol style="list-style-type: none"> <li>1) There is current oscillation</li> <li>2)When the lid is opened during the test</li> <li>2)When moving sharply or tilting the device.</li> </ol>



## Warranty information

The product is covered by a warranty period equal to the validity period of the same. This warranty is intended to protect you from the costs associated with problems resulting from manufacturing defects. The warranty period starts on the date of receipt of the product at the desired location. For assistance during the warranty period, contact the manufacturer.

## Training

These instructions for use describe the correct use and operation of the device. Operators of the device shall familiarize themselves with the applicable sections in the document before carrying out tests to ensure safe and efficient use of the device. Make sure you follow the training requirements in accordance with applicable regulatory guidelines. If you need more information about training in the use of this product, please contact the manufacturer.

## Manufacturer Information

**Name:** STAB VIDA- Research and Services in Biological Sciences, Lda.

**Address:** Madan Parque, Rua dos Inventores, Sala 2.18, 2825-182 Caparica, Portugal.

**Website(s):** <https://www.stabvida.com/drvida>

**Technical assistance:**

In case of any problem please contact us by [drvida@stabvida.com](mailto:drvida@stabvida.com) email or phone (+351) 938 437 766.

Monday to Friday from 10:00 a.m. to 7:00 p.m. (GMT Time)

According to EU Regulation 2017/746, any serious incident that occurs in relation to the device must be reported to the manufacturer and the competent authority of the EU Member State where the user and/or patient is established.

## Revision history

Revision		Revised points	
No.	Date (dd/mm/yy)	No.	Revision description
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-
5	-	-	-
6	-	-	-
7	-	-	-
8	-	-	-
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10	-	-	-
11	-	-	-
12	-	-	-
13	-	-	-
14	-	-	-
15	04/10/2023	All	Document update and IVD isolation.