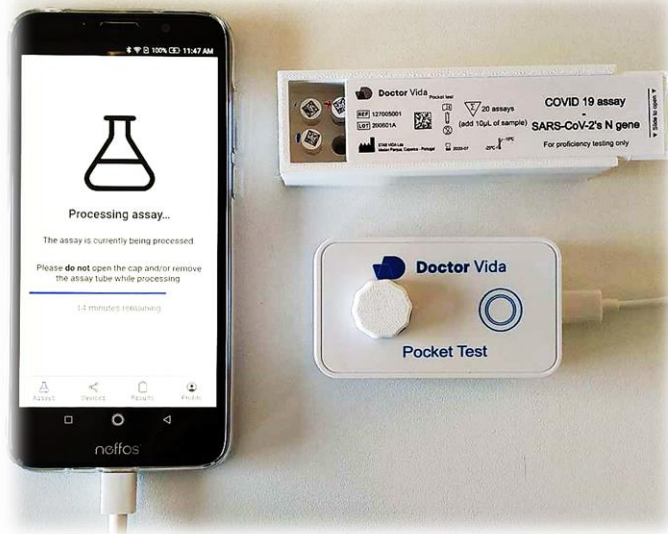


DOCTOR VIDA POCKET FOR MOLECULAR DETECTION OF SARS-CoV-2

Instructions for Use

Cat# 133001001, Cat# 133001002, Cat#133001003, Cat#133001004



Version 10.0, July 2021

For In Vitro Diagnostic Use



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INDICATIONS FOR USE

The Doctor Vida pocket system is suitable for molecular amplification and detection of SARS-Cov-2 virus in 40 minutes using swab nasopharyngeal, gargling or nasal sample collected in Viral Preservation Medium. The system is only to be used by healthcare professionals. The use is responsible for the sample analysis and compliance with the biosafety procedures, including the use of individual protection equipment required, facilities maintenance and waste management.

PRINCIPLE OF OPERATION

Nasopharyngeal swab are collected by healthcare professionals following the procedures of good practices using the appropriate material and equipment not included in this product. Gargling and nasal samples are self-collected with or without the supervision of a healthcare professional. 10uL of sample is added to the tube with reagents (Covid Test-19), following the instructions described in this document. The analysis performed by isothermal amplification mediated by fluorescent reverse transcription loop (RT-LAMP) was based on reverse transcription and amplification at a constant temperature of the SARS-CoV-2 virus-specific N and E genes. The detection of the amplification of the N and E genes is done by fluorescence. The detection system included in the Dr Vida pocket allows to detect the fluorescence translated into the presence of RNA from SARS-CoV-2 virus. On the other hand, if there is no fluorescence emission or if it is residual, the viral RNA is absent or in an amount below the detection limit of the technique, it is not possible to detect SARS-CoV-2 virus. The sample analysis in Dr Vida pocket and the produced results and report are communicated to the user and the patient through the Doctor VIDA application on the mobile phone.

WARNING

The health professionals that will use the equipment should validate their own tests using the appropriate controls.

SYMBOL TABLE

Dispositivo médico - Doctor Vida pocket Medical device - Doctor Vida pocket



Consultar instruções de utilização
Consult instructions for use



Marcação CE
CE mark



Referência do produto
Catalogue number



Dispositivo médico de diagnóstico *in vitro*
In vitro diagnostic medical device



Número de série
Serial number



Limites de temperatura
Temperature limits



Fabricante
Manufacturer



Atenção
Seguir as instruções apresentadas neste manual; um uso impróprio poderá provocar danos no dispositivo ou na sua saúde.



Conformidade RoHS
RoHS compliant



Corrente contínua (CC)
Direct current (DC)

Caution
Follow the instructions in this manual; improper use may cause damage to the device or health.



Resíduos equipamentos eléctricos e electrónicos (REEE)
(Diretiva 2012/19/EU)

Este símbolo no produto ou na sua embalagem indica que não deve ser descartado como os outros resíduos domésticos. É da sua responsabilidade descartar o dispositivo de forma adequada para a reciclagem de resíduos de equipamentos eléctricos e electrónicos. A recolha e a reciclagem selecionada destes equipamentos ajuda a conservar os recursos naturais e a proteger a saúde humana e o meio ambiente. Para mais informações sobre onde pode descartar o dispositivo, entre em contato com o fabricante ou a empresa distribuidora onde adquiriu o produto.

Waste Electrical and Electronic Equipment (WEEE)
(Directive 2012/19/EU)

This symbol on the product, or on its packaging, indicates that it should not be disposed like other household waste. It is your responsibility to properly dispose the device for recycling of waste electrical and electronic equipment. The selected collection and recycling of this equipment helps to conserve natural resources and protect human

health and the environment. For more information on where to dispose the device, please contact the manufacturer or distributor from which you purchased the product.

Doctor Vida pocket – Reagentes “Ready-to-use”

Doctor Vida pocket – “Ready-to-use” reagents



Consultar instruções de utilização
Consult instructions for use



Marcação CE
CE mark



Referência do producto
Catalogue number



Dispositivo médico de diagnóstico *in vitro*
In vitro diagnostic medical device



Número de lote
Batch code



Limites de temperatura
Temperature limits



Fabricante
Manufacturer



Contém suficiente para <n> testes
Contains sufficient for <n> tests



Não reutilizar
Do not reuse



Atenção
Seguir as instruções apresentadas neste manual; um uso impróprio poderá provocar danos no dispositivo ou na sua saúde.



Usar até
Use by

Caution
Follow the instructions in this manual; improper use may cause damage to the device or health.

BEFORE STARTING THE EXPERIMENT

1. Materials required

Materials provided	Cat. N°	Amount	Storage conditions
Doctor Vida pocket device	133001002	1 unit	Room temperature
Charger	--	1 unit	Room temperature
COVID-19 reaction tubes (box)	133001001	20 units	-20°C
COVID-19 reaction tubes (single package)	133001004	1 unit	-20°C
Instructions for Use	--	1 unit	Not applicable
Doctor Vida APP	133001003	1 unit	Not applicable

1.1 Materials not provided:

.Mobile phone with bluetooth – to install the Doctor Vida app

.Internet (wireless) – required for data transfer to the server

2. Doctor Vida pocket specifications

Feature	Specification
Excitation source	Two-dye specific LEDs: Green (570nm +/- 20nm) and blue (470nm +/- 35nm)
Detection	Standard CMOS silicon sensor with integrated Gaussian filters, 6-channel multispectral sensing in the visible wavelengths from approximately 430nm to 670nm with full-width half-max (FWHM) of 40nm
Spectral channels	450, 500, 550, 570, 600 and 650 nm (+/- 20nm)
Thermal system temperature range	Between + 5.0°C (above room temperature) and + 95°C Max. Heating: 0.22°C/sec
Dimensions (h x w x d)	33,11 mm x 75,80 mm x 44,45 mm
Weight	58 grams
Operating humidity	20% to 80%, non- condensing
Operating temperature	15°C to 30°C
Electrical power (input)	100- 240 VAC, 50/60 Hz
Output	5VDC, 2A
Bluetooth®	Bluetooth V4.2 BR/EDR and Bluetooth LE with GPS and camera activated
Wi-fi	IEEE 802.11b/g/n or mobile data
Warranty	One year warranty
Plastic consumables	Compatible only with the plastic consumables provided (COVID-19 reaction tubes)

3. Precautions and safety measures

- Do not use damaged components. The use of damaged components may cause hazard to health or affect the quality of the test. In that case please contact the technical support.
- COVID-19 reaction tubes: do not use it out of expiry date or if they present potential contaminants (the solution must be colorless).
- Prevent risks for the operator and prevent carry-over and other type of contaminations:
 - Use the appropriate individual protection equipment, according to the regulatory guidelines
 - After each experiment change gloves and clean the device, materials required and surface
 - Facilities should be ventilated in a daily basis.
- Doctor Vida pocket: All users must read and understand the Setup and User Guide and only operate the device in accordance with the provided instructions. Failure to follow instructions may cause damage to the device and/or cause a hazard to health. For your safety and to avoid damaging the device, it is important that the following safety precautions are read and understood before using the device.

Electrical

Standard electrical safety precautions should be applied, including the following:

- Always place the device in a location where, if needed, the power supply can be immediately disconnected.
- Use only the supplied power supply (Input: 100 – 240VAC, 50/60Hz | Output: 5VDC, 2A), or similar, with proper voltage to operate the device.
- Do not touch any switches or outlets with wet hands, nor operate the device in wet environments.

- Do not operate the device, in case you detect any anomaly in the device and/or the supplied power supply, such as deformations, fractures, exposed wires, liquid spills, etc.
- Unplug the device before you clean it or to wipe any major liquid spills.
- Do not service the electrical components unless you are qualified and authorized to do so.

Fluids and Reagents

- Always handle the liquid samples and transfer them to the reaction tube away from the device, to avoid any fluids to penetrate inside the device.
- Never incubate explosive, flammable and/or reactive substances in the device.
- You must comply with any relevant safety regulations, when handling pathogenic material, radioactive substances or any other substances hazardous to health.
- Do not submerge the device in any liquid, at any time.

Physical

- Do not use the device over any materials (plates, sealings, foils, mats, etc.) which are not sufficiently high temperature resistant. Please note that, during operation, it is normal that the device may get warm, especially underneath it.
- Never touch the inner side of the device, to avoid risk of burning.
- Do not use other materials (plates, foils, etc) rather than the reaction tubes designed to be operated with the device.

Electrostatic Discharge (ESD)

The device is static sensitive. Electrostatic discharges greater than 2000 volts may interfere with the normal operation of the USB ports on the

device. Handling precautions are required when working in high static environments. Wear a grounded wrist strap and take other antistatic precautions prior to making contact with the device in high static environments - ESD STM5.1- 1998 Class 1C.

Operating Environment

- Only operate the device indoors within an ambient temperature between 15°C and 30°C and humidity levels between 20% and 80% (non-condensing).
- Do not operate the device in a hazardous or potentially explosive environment.
- Do not attempt to remove the cap and/or the reaction tube, nor move the device when the device is running an assay.
- Only operate the device in a levelled-surface, with cap facing top.

DEVICE RATINGS

- Power input supply: 100- 240 VAC, 50/60 Hz
- Device input supply: 5VDC, 1A (min.)
- Pollution degree 2
- Installation category II
- Operating humidity: 20% to 80%, non- condensing
- Operating temperature: 15°C to 30°C
- Bluetooth®: Bluetooth V4.2 BR/EDR and Bluetooth LE with GPS and camera activated
- Wi-fi: IEEE 802.11 b/g/n
- For Indoor Use Only
- RoHS compliance

4. Analytical performance (when compared with the real-time PCR methodology)

4.1 Direct nasopharyngeal swab samples suspended in Virus Preservation Medium (VPM)

		Real-time rRT-PCR, Ct≤32		Total
		Positive	Negative	
Doctor Vida pocket for COVID-19	Positive	19 (TP)	1 (FP)	20
	Negative	1 (FN)	69 (TN)	70
Total		20 (TP+FN)	70 (TN+FP)	90

TP=True positive; FN = False negative; TN= True negative; FP= False positive.

Parameters	Formula	Results
Coincidence rate of positive or Sensitivity (%)	$TP/(TP+FN)*100\%$	95
Coincidence rate of negative or Specificity (%)	$TN/(TN+FP)*100\%$	99
Total coincidence rate PA or Accuracy (%)	$(TP+TN)/(TP+TN+FN+FP)*100\%$	98
Theoretical coincidence rate Pe	$\frac{[(TP+FP)(TP+FN)+(FN+TN)(FP+TN)]}{(TP+TN+FN+FP)^2}$	0.65
Kappa coefficient	$(PA-Pe)/(1-Pe)$	0.94

- The analytical parameters presented in the table are related to Ct≤32 when compared with the standard rRT-PCR, Ct (threshold cycle) is the intersection between an amplification curve and threshold line.

4.2 Self-collection of gargling and/or nostrils swab suspended in Virus Preservation Medium (VPM)

		Real-time rRT-PCR, Ct≤34		Total
		Positive	Negative	
Doctor Vida pocket for COVID-19	Positive	73 (TP)	0 (FP)	73
	Negative	6 (FN)	149 (TN)	155
Total		79 (TP+FN)	149 (TN+FP)	228

TP=True positive; FN = False negative; TN= True negative; FP= False positive.

Parameters	Formula	Results
Coincidence rate of positive or Sensitivity (%)	$TP/(TP+FN)*100\%$	92
Coincidence rate of negative or Specificity (%)	$TN/(TN+FP)*100\%$	100
Total coincidence rate PA or Accuracy (%)	$(TP+TN)/(TP+TN+FN+FP)*100\%$	97
Theoretical coincidence rate Pe	$\frac{[(TP+FP)(TP+FN)+(FN+TN)(FP+TN)]}{(TP+TN+FN+FP)^2}$	0.55
Kappa coefficient	$(PA-Pe)/(1-Pe)$	0.94

- The analytical parameters presented in the table are related to Ct≤34 when compared with the standard rRT-PCR, Ct (threshold cycle) is the intersection between an amplification curve and threshold line.

5. Limitations

- Low quality sample may lead to false results. Extracted RNA should be aliquoted and stored at -80°C up to analysis. VPM samples should be stored at 2-8°C and used up to 72 hours.

- Inactivated virus media contain nucleic acid amplification inhibitors which may affect the quality of the test. For this type of media please extract and purify the RNA before analysis.
- Interferences present in the sample may lead to inhibition of the enzyme used in the test.

KCl 150 mM
 Ethanol 7%
 Guanidine HCl 145mM
 SDS 0.01%
 Magnesium Sulfate 22 mM
 Manganese Sulfate 2 mM
 DMSO 15%
 DTT >100 mM
 Whatman 903 Collection Paper >7.07 mm²
 Whatman FTA Collection Paper 3.9 mm²
 Whatman FTA Elute Collection Paper 1.1 mm²
 Hematin 4.5µM
 Hemin 12µM
 Heparin 1.2 µg/µL
 Sodium Citrate 15 mM
 Sodium EDTA 4.5 mM
 Hemoglobin >4 µg/µL
 IgG >2.4 µg/µL
 Humic Acid 2 ng/µL
 Urea 1.5 M
 Calcium Chloride 2.5mM
 Bile Salts 0.6 µg/µL
 BD Universal >20%
 Remel M4 >20%
 Amies >20%
 Stuart >20%
 Collagen >125 ng/µL
 Myoglobin >2.4 µg/µL
 Melanin 2.5 ng/µL
 Mucin 0.66 µg/µL
 Tannic Acid 145 ng/µL
 Indigo 300 µM

- All users must follow the instructions provided, otherwise the quality of results could be affected.
- A negative result (not detected) does not exclude the COVID-19 disease. The regions analysed of virus SARS-Cov-2 may not be detected for instance due to mutations in primer sites or it was in

an amount below the detection limit of the technique. In that case diagnostic by gold standard rRT-PCR may be used to confirm the result.

- In case of a power failure, the analysis is interrupted. The reaction tube must be discarded and the test must be repeated using a new reaction tube.

6. Prepare the working area and Doctor Vida Pocket in the first use of the day

Important note: The device must be used in a flat surface, otherwise the test performance may be affected.

Important note: Do not let ethanol enter the hole where the test tube is placed.

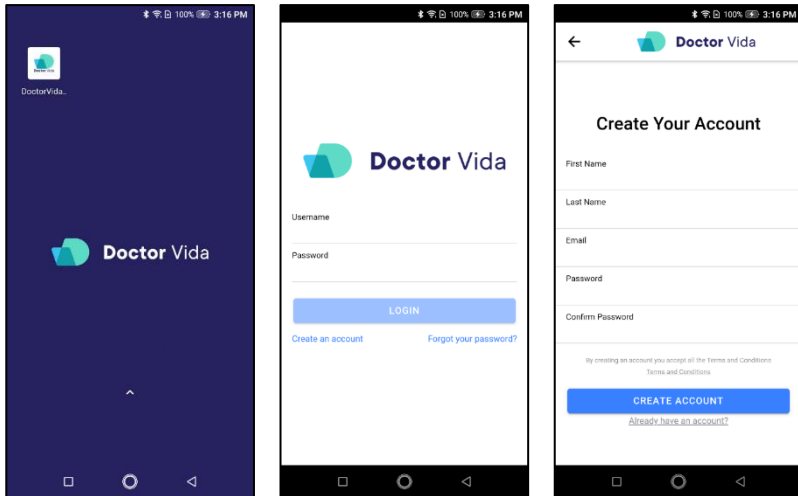
- Clean and disinfect the surface with bleach 10% and ethanol 70% to control infectious risks. Put the device in a flat surface.
- Remove the cap in the device and clean it with paper moistened with 70% ethanol. Let it dry.
- Screw the cap in the device and clean the device with paper moistened with 70% ethanol.
- Plug the device or connect it to a portable charger, output: 5VDC, 2A. The device may take few minutes to stabilize the temperature.
- Remove the cap and let the device plugged 1 hour before the first use of the day.

7. Open the Doctor Vida app

If you don't have an account,

a. Create an account

Select "Create an account". Fill the form and click "Create account".

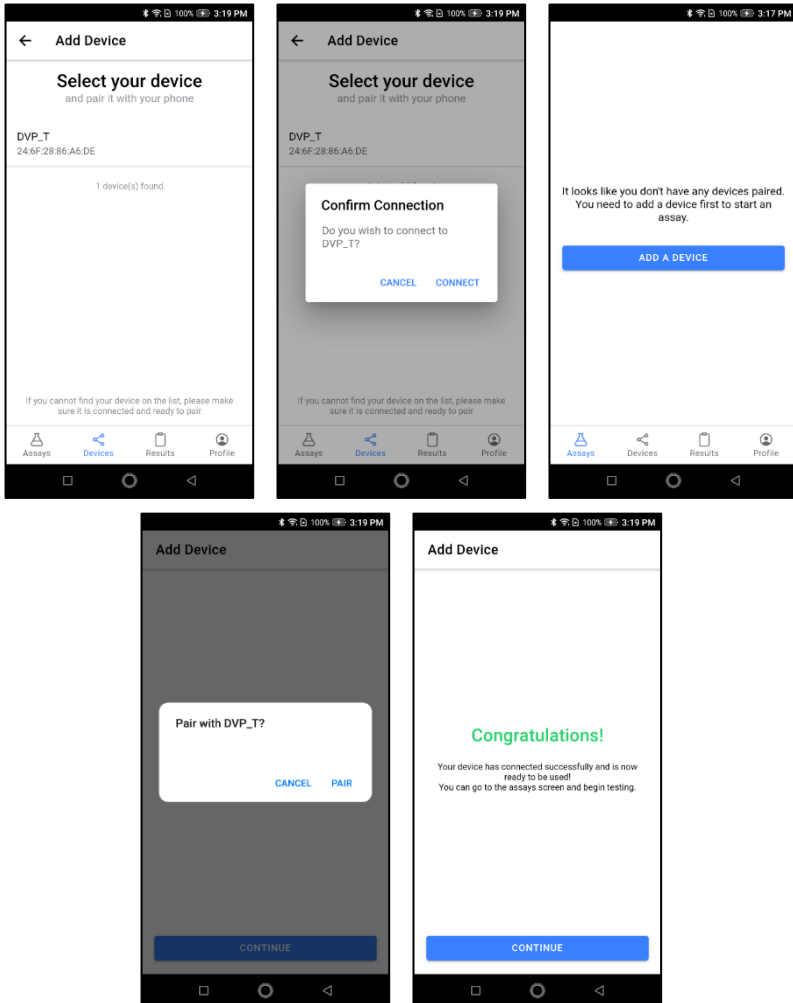


If you have an account please log in. Insert the username (registered email) and password and click "LOGIN".

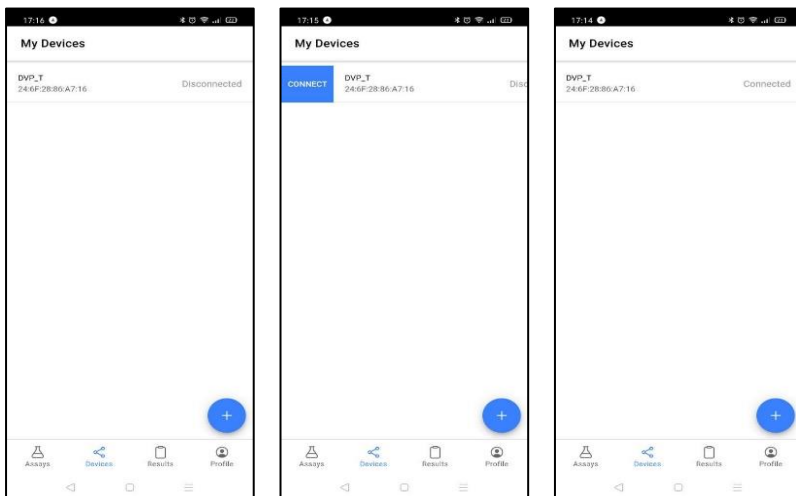
Open DoctorVida Pocket app in the Smartphone. In the "settings" menu, check informations about manufacturer and select the language.

8. Connect the Doctor Vida Pocket device with mobile phone

8.1 If you have not added a device before, click in "Add a device" and select your device (the device ID is shown on the label of the device located on bottom). Click in "Connect", "Pair" and "Continue".



8.2 If you have already paired a device before, click on “Devices” (on the bottom menu) and swipe the device to the right and click on connect. If successful the device should show as connected.



9. Prepare the COVID-19 test and sample

9.1 COVID-19 test

Remove the test from -20°C . Open the package and remove the tube and pipette and let it equilibrate at room temperature. Do a short spin if need it.



Important note: The solution must be completely defrosted (colorless). If not (e.g. different colour, turbid), do not use it and contact the technical support. The package shown in the image is blue, however the package may present a different colour.

9.2 Sample

9.2.1 Direct nasopharyngeal swab samples, gargling self-collection suspended in Virus Preservation Medium (VPM)

The collection of nasopharyngeal specimen in VPM medium is performed according to the national regulatory guidelines.

The instructions for self-collection of gargling and nostrils are provided with the COVID-19 test.

In case you do not proceed with sample analysis, store it at 2-8°C up to 72 hours. Seal the cap of the sample tube with parafilm.

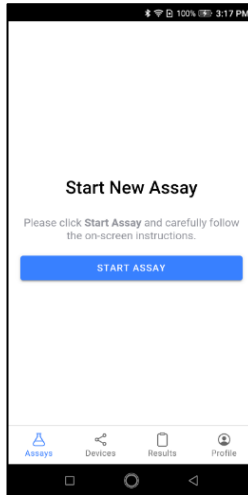
In case you want to proceed with the sample analysis, follow the procedure:

- 1) Make sure the collection tube is well closed. Mix vigorously by 10 to 15 seconds. Let the sample incubate at least 10 minutes at room temperature.
- 2) Make sure the COVID-19 test (reaction tube) is completely defrosted.
- 3) Proceed to the next section "Sample analysis".

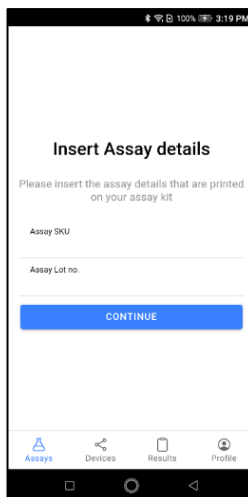
SAMPLE ANALYSIS

1. In Doctor Vida App, Start New Assay

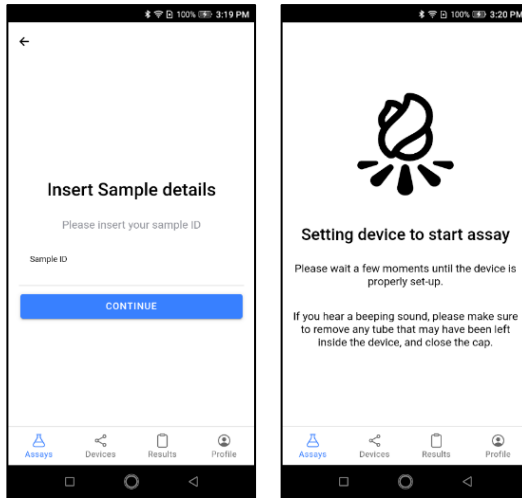
Click on “Start Assay”.



Type in the “Assay SKU” (REF) and “Assay Lot no.” (LOT) as indicated in the label of the reaction tube box. Click “Continue”.

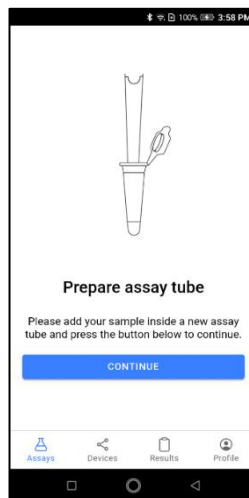


Insert your "Sample ID" and click "Continue". If needed, please wait a moment for the device to warm up a be properly set-up. In case you hear a beeping sound, please make sure to remove any tube that may have been left inside, and close the cap.



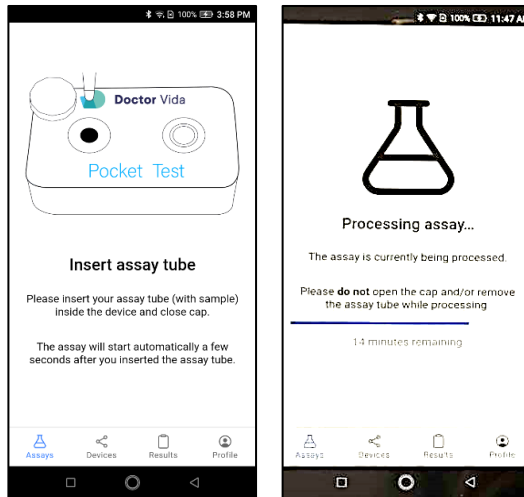
2. Load the sample

- a) Open the COVID-19 test tube and the sample collection tube.
- b) Press the pipette with the fingers (you may also pipette 10uL of sample with a micropipette) and introduce it in the VPM medium in the collection tube. Release the fingers and the sample will be aspirated up to the blue label of the pipette.
- c) Transfer the sample to the reaction tube by touching with the pipette in the liquid surface inside the COVID-19 test reaction tube and press again the pipette with the fingers until the sample is completely dispensed.
- d) Close well the reaction tube and spin it. As alternative you may shake slowly the tube from up to down avoiding bubbles. Incubate the tube 5 minutes at room temperature. Click "Continue".



3. Insert tube inside device

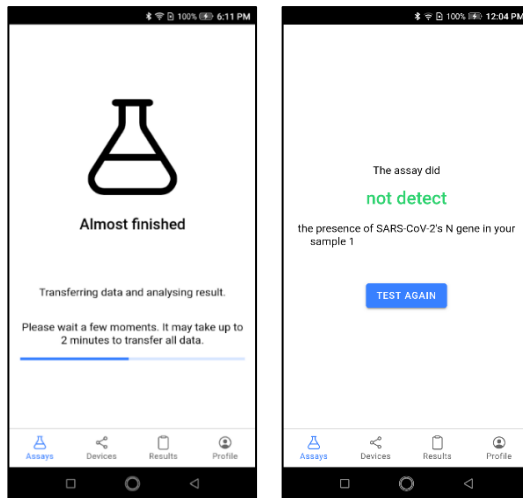
Open the device cap (twisting anti-clockwise), insert the reaction tube and close the device cap (twisting clockwise). The assay will start automatically in a few seconds.



Important note: Please do not touch or move the device while the assay is being processed, because this may affect the assay performance.

4. Final results

When the assay finishes the device will take up to 2 minutes to transfer all data to the App and the result will show as “Detect” or “Not detect”.



To view all information regarding the assay click on results menu.

The results will show a graphic as described:



Result: Detected



Result: Not detected

AFTER EXPERIMENT

1. Maintenance and cleaning the working area and Doctor Vida Pocket device

- At the end of each experiment, remove the test tube. Clean the cap with paper moistened with 70% ethanol (do not spray it). Let it dry. Do not let ethanol enter the hole where the test tube is placed.
- Keep the tube hole open (without cap) till next test.
- Do not let organic solvents or aggressive solutions come in contact with the instrument.
- Do not let any liquid enter the instrument.
- Keep the environment ventilated or provide natural ventilation at the end of the day.
- Avoid contaminations between tests: i) Keep the device and working area cleaned and ventilated and ii) change gloves between tests.

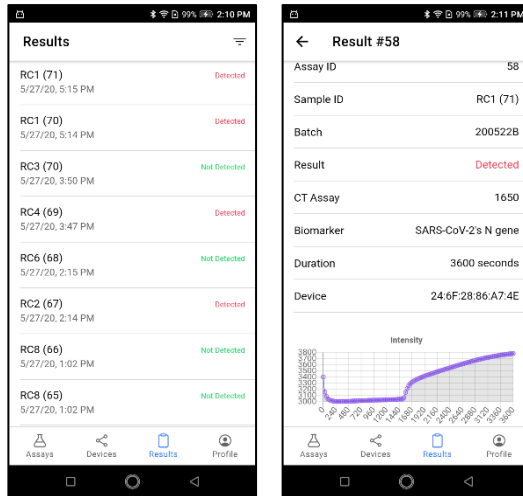
Important note: Do not leave the Pocket Doctor Vida ON if not using it.

2. Waste management

After analysis in Doctor Vida's pocket, keep the sample at 2-8°C (in case you need to repeat the test) or discard the sample collection tube and reaction tube, including the individual protection equipment in compliance with the biological waste management guidelines.

3. How to access to previous assay results

To access to the previous results click on “Results” on the bottom menu and select your assay by clicking on it. More details will be shown about it.



If you want to select a specific assay or a type of assays you can apply a filter by clicking on top right side (red circle).

Results

RC1 (71)	5/27/20, 5:15 PM	Detected
RC1 (70)	5/27/20, 5:14 PM	Detected
RC3 (70)	5/27/20, 3:50 PM	Not Detected
RC4 (69)	5/27/20, 3:47 PM	Detected
RC6 (68)	5/27/20, 2:15 PM	Not Detected
RC2 (67)	5/27/20, 2:14 PM	Detected
RCB (66)	5/27/20, 1:02 PM	Not Detected
RCB (65)	5/27/20, 1:02 PM	Not Detected

Assays Devices Results Profile

Filter Results

CLOSE

Result

Detected

Not Detected

Blank

Since Start Date

Until End Date

Sample ID


Assay ID

Sort Results None

APPLY

TROUBLE SHOOTING

Observed Problem	Solution
<p>-An assay as started and cannot abort (e.g. because you realise you did something wrong, such as, missing the sample)</p> <p>-Electrical failure</p>	<p>Unplug the device and close the app. Discard the reaction tube that you may have used and re-start the process using a new reaction tube.</p>
<p>- Fails to give result</p> <p>-The app shows that the assay is almost finished but is taking more than 3 minutes to show the result.</p>	<p>.Make sure you have an internet connection and that the device is still connected (under Devices menu). If not, reconnect to the internet and/or the bluetooth, go to Assays (in the bottom menu) and press "continue". It should resume the ongoing assay.</p> <p>. If the error persists, remove the device from the app and reconnect it again. It is important to check if the same device is not connected with more than one mobile phone.</p> <p>.If "Start analysis" message appears on the screen (as if happens for a new assay), this means a power failure has occurred. In this case, discard the reaction tube in use and restart the process using a new reaction tube.</p> <p>.If the problem persists please contact the technical support.</p>
<p>The remaining time indicated in the processing screen is not advancing and seems to have stopped.</p>	<p>Go to Devices (bottom menu), check if your device is still connected. If not, try to connect it again by swiping the device DVP_T to the right and press</p>

	<p>connect (or disconnect and connect again). Go back to Assays (bottom menu) and it should resume the ongoing assay.</p>
<p>Connection failed between Doctor Vida pocket and mobile phone</p>	<p>.Make sure the device is plugged without power supply failure (for instance, if the cable is not damage).</p> <p>.Check if you give permission to access the device´s location.</p>
<p>The mobile phone has no available space</p>	<p>If the phone has no space to start the assay you must free up space on the phone or use other phone</p> <p>If the phone runs out of space during assay, the results will not be available but the results will be saved, only if you keep the Dr Vida pocket connected. If you disconnect the Dr Vida pocket the results will be lost.</p> <p>If you free up space, the connection will be re-established automatically.</p>
<p>Result with non-standard curve</p>  <p>The screenshot shows assay details: ID do Ensaio: 2691, Data do Ensaio: 2/27/21, 12:10 PM, ID da Amostra: 6, Lote: 21AM005, Resultado: Detectado, CT Ensaio: 2910, Biomarcador: SARS-CoV-2's N gene, Duração: 3600 segundos. Below the text is a graph titled 'Intensidade' vs 'Tempo' showing a non-standard curve with a small peak followed by a larger peak.</p>	<p>When the result is detected but the curve is not exponential as expected, the test must be repeated with new reaction tube. This type of profile may occur when the current is not stable.</p>

STAB VIDA manufacturer contacts

Manufacturer name: STAB VIDA

Address: Madan Parque, rua dos inventores, s/n, sala 2.18, 2825-182
Caparica, Portugal

Technical support: In case of any problem please contact us by email
info@doctorvida.com or phone 00351210438606.