

Instructions for Use

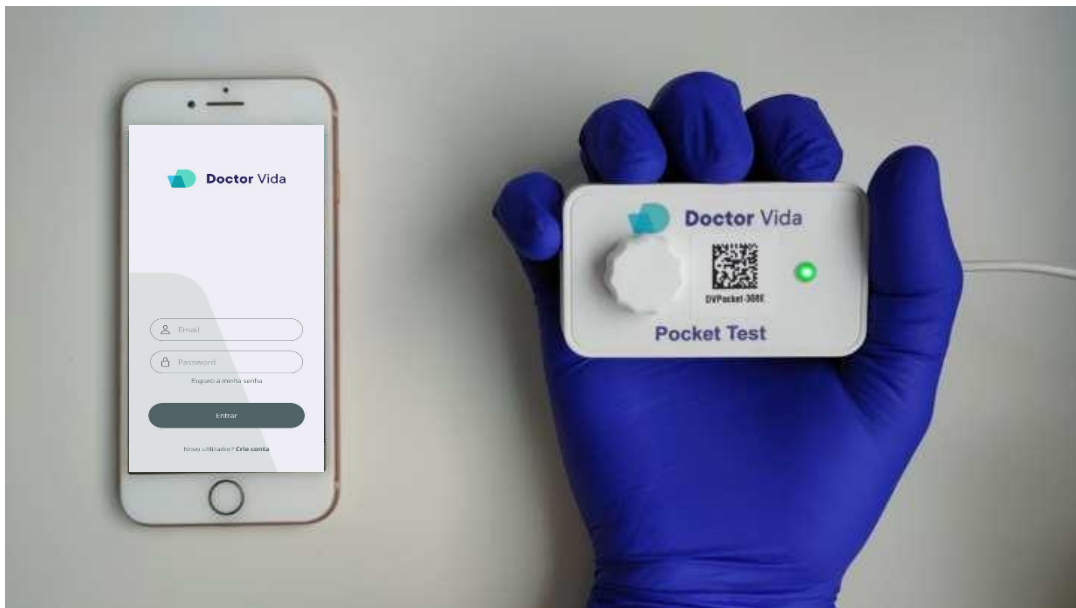
DOCTOR VIDA DEVICE AND SOFTWARE

Hardware version: 2.4.1

Firmware version: 6.1.0

Software Version: 3.0.0

Reference 133001002, 133001003



Version 5, April 2023

Medical Device for In Vitro Diagnostics



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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 in a manner not specified by the manufacturer, the device may be damaged. Refer to the product's warnings, precautions, measures to be taken and limitations for use.

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INTENDED PURPOSE OF THE DEVICE

The Doctor Vida device (reference 133001002) is a semi-automatic instrument for the isothermal amplification and qualitative molecular detection of nucleic acids by fluorescence. If no fluorescence or residual fluorescence is emitted, the target nucleic acids (e.g., RNA or DNA) are not detected or are below the detection limit of the technique. The device is fully controlled by a mobile phone application (Dr Vida Pocket PCR app, cat. 133001003) intended for near-patient testing and is intended for use by healthcare professionals. The user is responsible for compliance with safety procedures, including the use of necessary personal protective equipment, maintenance of equipment and facilities, and waste management.

OPERATING PRINCIPLES

The Doctor Vida device should be used in combination with compatible reagents (Dr Vida tests) and the Dr Vida Pocket PCR app (ref. 133001003) (available on the iOS and Google shops) following the instructions for use described in this document.

Biological samples are collected by healthcare professionals following good practice procedures using appropriate equipment and supplies not included with this product. The biological sample is added to the test tube and placed into the Doctor Vida device for analysis. The device is controlled by the mobile phone Dr Vida Pocket PCR app and at the end of the sample processing, the results are issued to the user.

QUALITY CONTROL

The device is submitted to a Quality Control called TestJig which consists of the functional testing of the hardware, photometric, and temperature sensors.















The TestJig is designed to program the microcontrollers in the device, carry out functional tests on the device's sensors and actuators, and issue reports on the test results

TestJig is separated into two work areas.

The first area prepares the device and performs validations of each hardware element according to the parameters provided. After validation of the correct operation of the electronic hardware, the firmware required to control the device is uploaded.

The second area uses the BLE (Bluetooth Low Energy) communication protocol to perform a temperature test that is validated with a temperature probe that is introduced in the device. This round of tests allows the correct final operation of the device to be evaluated. The final product Quality Report is available whenever required by the client.

TABLE OF SYMBOLS APPLICABLE

| | | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
|  | Consult instructions for use |  | CE mark |
|  | Product reference |  | In-vitro diagnostic medical device |
|  | Serial Number |  | Temperature limits |
|  | Manufacturer |  | Attention Follow the instructions given in this manual; improper use may cause damage to the device or your health. |
|  | RoHS Compliance | | |
|  | Direct Current (DC) | | |
|  | Indoor use only |  | The device is not intended for self-diagnosis |
|  | Near-patient testing device | | |
|  | 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 of like other household waste. It is your responsibility to dispose of the device appropriately for the recycling of waste electrical and electronic equipment. The separate collection and recycling of this device help to conserve natural resources and protect human health and the environment. For more information about where you can dispose of the device, please contact the manufacturer or the distributor where you purchased the product.

TECHNICAL SPECIFICATIONS OF DOCTOR VIDA DEVICE (v6)

| Parameter | Specification |
|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Power supply | LEDs: Green (570nm +/- 20nm). Blue (470nm +/- 35nm) |
| Detection system | CMOS silicon sensor with integrated Gaussian filters, 6 channels for multispectral detection in the visible wavelength range of approximately: 430nm - 670nm with a half-height width (FWHM) of 40nm / |
| Spectrum channels | 450, 500, 550, 570, 600 and 650 nm (+/-20nm) |
| Thermal system | 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 |
| Humidity Conditions | 20% to 80%, non-condensing |
| Safety environmental temperature conditions | +5°C to +40°C The device is safe within normal safety conditions (IEC/EN 61010-1) |
| Environmental temperature conditions during the use of the device | +15°C a +30°C |
| Transport temperature | Room temperature |
| Electrical characteristics of the power supply (input / output) | Input: 100- 240 VAC, 50/60 Hz Output: 5VDC, 2A |
| Doctor Vida Pocket Device Electrical Characteristics (Input) | 5VDC, 1A |
| Maximum altitude of use | 2 000 m |
| Bluetooth® | Bluetooth V4.2 BR/EDR, Bluetooth LE GPS/camera enabled |
| Internet connection | IEEE 802.11b/g/n or mobile data |
| Warranty | Two years |
| Consumables | Compatible only with plastics supplied |

WARNINGS, PRECAUTIONS, SAFETY MEASURES, AND LIMITATIONS OF USE CONCERNING THE DEVICE

All users must read and follow the instructions for use of the device provided.

Failure to follow the instructions may cause damage to the device and/or cause harm to health. For your safety and to avoid damage to the device, it is important that the following safety precautions are read and understood before using the device.

Do not use damaged components. The use of damaged components can cause damage to health or compromise the reliability of the device. In this case, contact technical support.

Prevent risks for the operator and avoid other types of contamination:

- Wear the appropriate personal protective equipment in accordance with regulatory guidelines.
- After each experiment, change gloves and clean the device, the necessary materials, and the surface.
- The premises should be ventilated daily.

Electricity

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

- Always place the equipment in a location where, if necessary, the power supply can be immediately disconnected.
- Use only the supplied power supply (Input: 100 - 240VAC, 50/60Hz | Output: 5VDC, 2A), or a similar certified power supply with the same specifications to operate the device.
- The maximum fluctuation for the main supply voltage is +/- 10%.
- Do not touch switches or sockets with wet hands or operate the device in wet environments.
- Do not operate the device if you detect any anomaly in the device and/or in the supplied power supply, such as deformations, fractures, exposed wires, liquid spills, etc.
- Unplug the device before cleaning it or cleaning up any important liquid spills.

- Do not service electrical components unless you are qualified and authorized to do so.
- In case of a power failure, the analysis is interrupted, and the test is invalid. The reaction tube must be discarded, and the test must be repeated with a new reaction tube.

Fluids and reagents

Always handle liquid samples and transfer them to the reaction tube away from the device to prevent any fluids from entering the device.

Never incubate explosive, flammable, and/or reactive substances in the device.

Never immerse the device in any liquid at any time.

Physical medium

Do not use the device on materials (plates, fences, sheets, mats, etc.) that are not sufficiently resistant to high temperatures. Note that during operation, it is normal for the device to heat up slightly, especially underneath it.

Never touch the internal part of the device to avoid the risk of burns.

Do not use other materials (plates, blades, etc.) instead of 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. In high-static environments, wear an anti-static wrist strap and take other anti-static precautions before handling the device (ESD STM5.1-1, 1998, Class 1C).

Operational environment

Only operate the device indoors, at 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 or move the device while it is running a test.

Operate the device only on a level surface with the lid facing up.

DEVICE CLASSIFICATIONS

-Power supply: 100-240 VAC, 50/60 Hz

-Device input source: 5VDC, 1A (min.)

-Pollution degree: 2

-Installation category: II

-Operating humidity: 20% to 80%, no condensation

-Operating temperature: 15°C to 30°C

-Bluetooth®: Bluetooth V4.2 BR/EDR and Bluetooth LE specification with GPS and camera support

-Wi-Fi: IEEE 802.11b/g/n and mobile data

-For indoor use only

-RoHS compliant

BEFORE STARTING THE TEST

Materials supplied

| Description | Reference N° | Quantity | Storage conditions |
|-------------------------------------------------------------------------|---------------------|-----------------|---------------------------|
| Doctor Vida device (Including power supply and micro-USB-B cable) | 133001002 | 1 unit | +15°C a + 30°C |
| Dr Vida Pocket PCR app (available on Google play and iOS store) | 133001003 | 1 unit | Not applicable |

Table 1 Material supplied, description, quantities and applicate conditions

Materials required but not provided:

- Bluetooth mobile phone - to install and use the Dr Vida Pocket PCR application.
- Internet (wireless) - required for data transfer to the server.
- Reagents - reaction tubes. Ask for the list of tests available and compatible with the Doctor Vida device and Software.

PERFORMANCE CHARACTERISTICS

Please refer to the performance characteristics in the Instructions for Use supplied with the reagents used in combination with the Doctor Vida device and software.

SAMPLE COLLECTION, HANDLING, PREPARATION, AND ANALYSIS

Please refer to the Instructions for Use supplied with the reagents used in combination with Doctor Vida device and software for information about sample collection, handling, preparation, and analysis procedures.

INSTALATION

DOCTOR VIDA DEVICE

Daily preparation of the workplace and the Doctor Vida device before starting the tests

Important note 1: If the device is not on a flat surface, the test performance may be affected.

Important note 2: Do not allow ethanol to enter the hole where the reaction tube is placed.

- Clean and disinfect the work surface with 10% bleach and 70% ethanol to control infectious risks. Place the device on a flat surface.
- Remove the device lid and clean the device with paper dampened in 70% ethanol (do not spray). Allow airing dry.
- Screw the lid back on the device and wipe the entire outside with paper moistened with 70% ethanol (do not spray).
- Plug the device into the electrical outlet 5VDC, 2A. The device may take a few minutes to stabilize the temperature.
- Remove the cover and leave the device on for approximately 30 minutes before the first use of the day.

SOFTWARE

Minimum hardware requirements for the software to function as intended

Android phones: Operating system > 5.0

iOS phones: Operating System > 11.0

It is recommended to have a Bluetooth > 5.0 version and stable WiFi connection.

Check your device's compatibility requirements with the software in the compatibility section within each store (Android/iOS).

Characteristics of computer networks and computer security measures

The design and maintenance of the software follows the standards of ISO 62304-Software **Requirements Testing**.

The information security system generated by the software follows the standards of the **ISO27001-Information Security Management standard**.

DESCRIPTION, INSTALLATION, AND CONFIGURATION OF THE SOFTWARE

Install and configure the software (Dr Vida Pocket PCR app) (v3)

The Dr Vida Pocket PCR app (v3) can be downloaded to the mobile phone from the App store (Google Play store or iOS store).

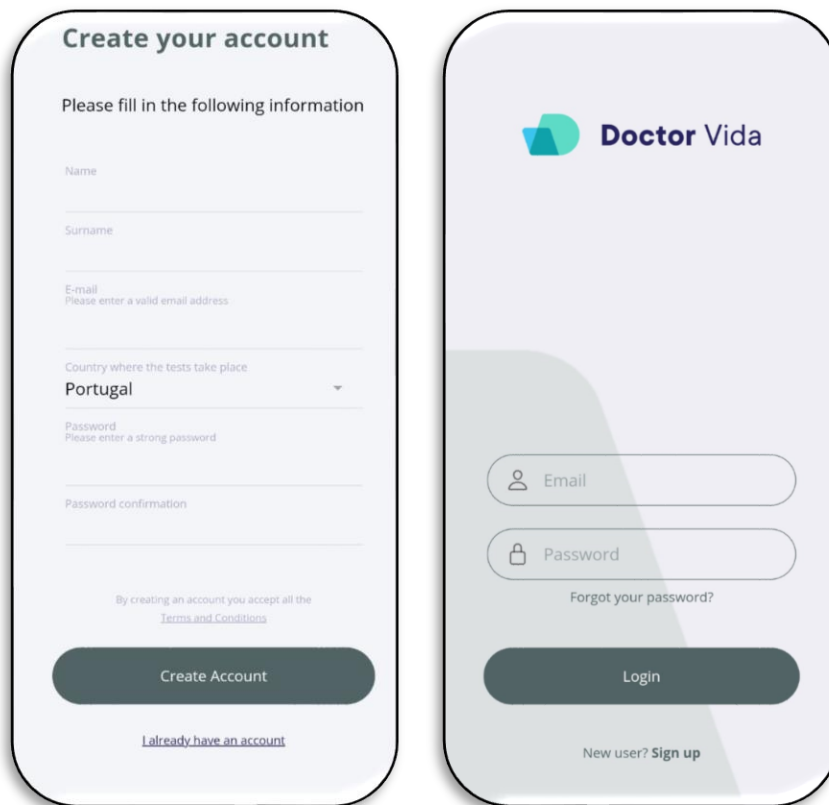
Permissions

To use the App, you must give permission to store data, Camera, and Location for the Dr Vida Pocket PCR app. Please see more details in the Privacy Policy (<https://www.doctorvida.com/privacy.html>).

Account

If you do not have an account, please create one.

Select "New user? Create account", fill in the form, and select "Create account".



The image shows two mobile app screens. The left screen is titled "Create your account" and contains a registration form with fields for Name, Surname, E-mail (with a note "Please enter a valid email address"), Country where the tests take place (set to Portugal), Password (with a note "Please enter a strong password"), and Password confirmation. At the bottom, there is a "Create Account" button and a link for "I already have an account". The right screen is the login screen, featuring the "Doctor Vida" logo at the top, followed by input fields for "Email" and "Password", a "Forgot your password?" link, and a "Login" button. At the bottom, there is a link for "New user? Sign up".

If you have an account.

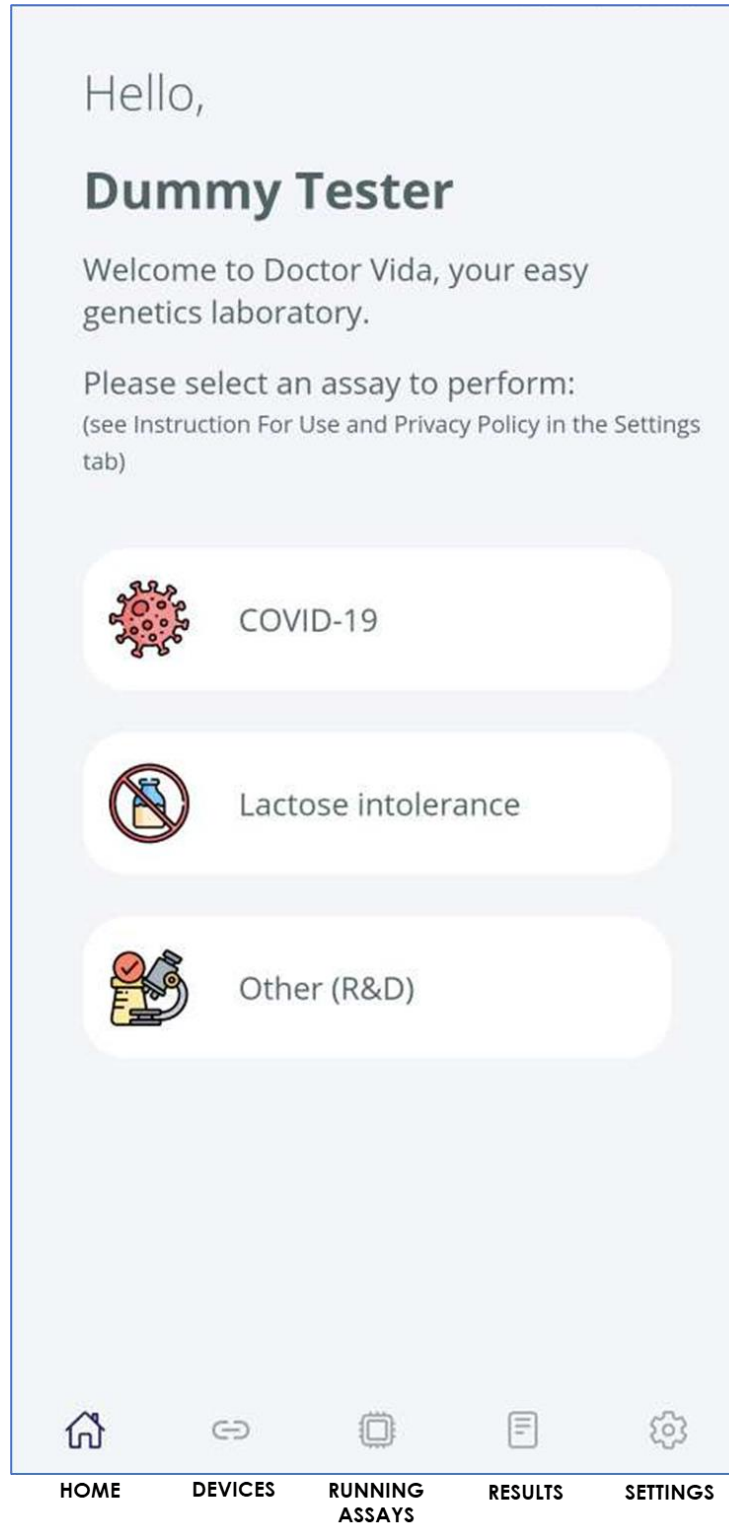
Enter the registered email and password and click on "Login".

Note: Make sure the e-mail is valid, otherwise you will not receive the test results.

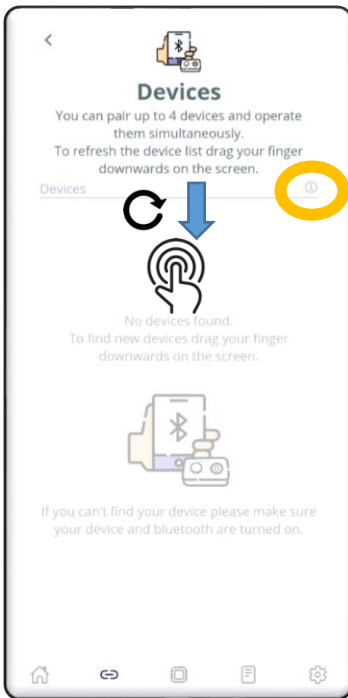
Menus

Open the Dr Vida Pocket PCR app on your mobile phone. Check the menu description at the bottom of the screen:

Home



Devices

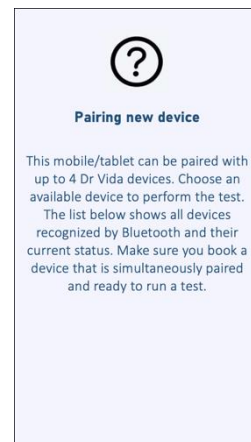
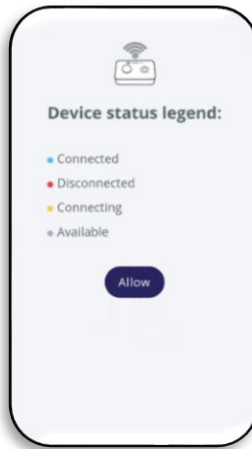


In this menu, you can check and select the devices available to perform tests. Only the devices recognized by Bluetooth and their current status will be shown.

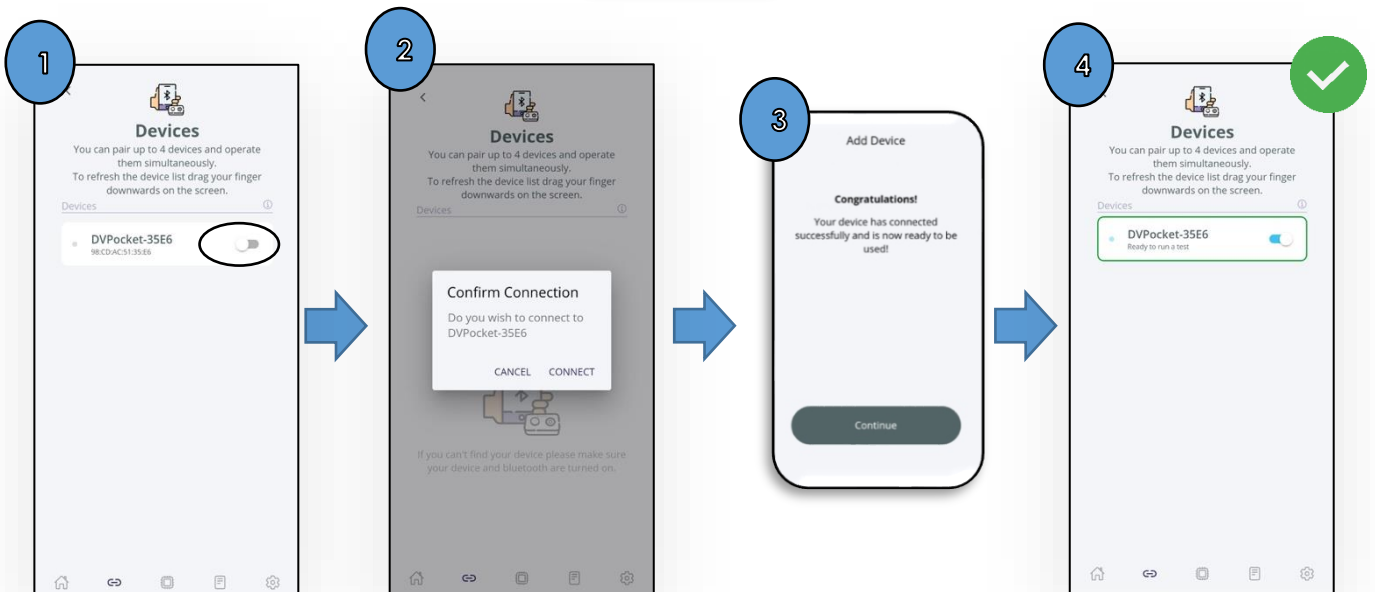
Slide the button on the devices you want to pair. Click on "Connect" and "Continue". The devices will be ready to make a test.

You can connect up to 4 devices and operate them simultaneously.

Pay attention to the device status legend (click on the icon?):



Steps to be followed:



If one or more devices do not appear in the list, simply refresh the list by swiping downwards with your finger on the screen.

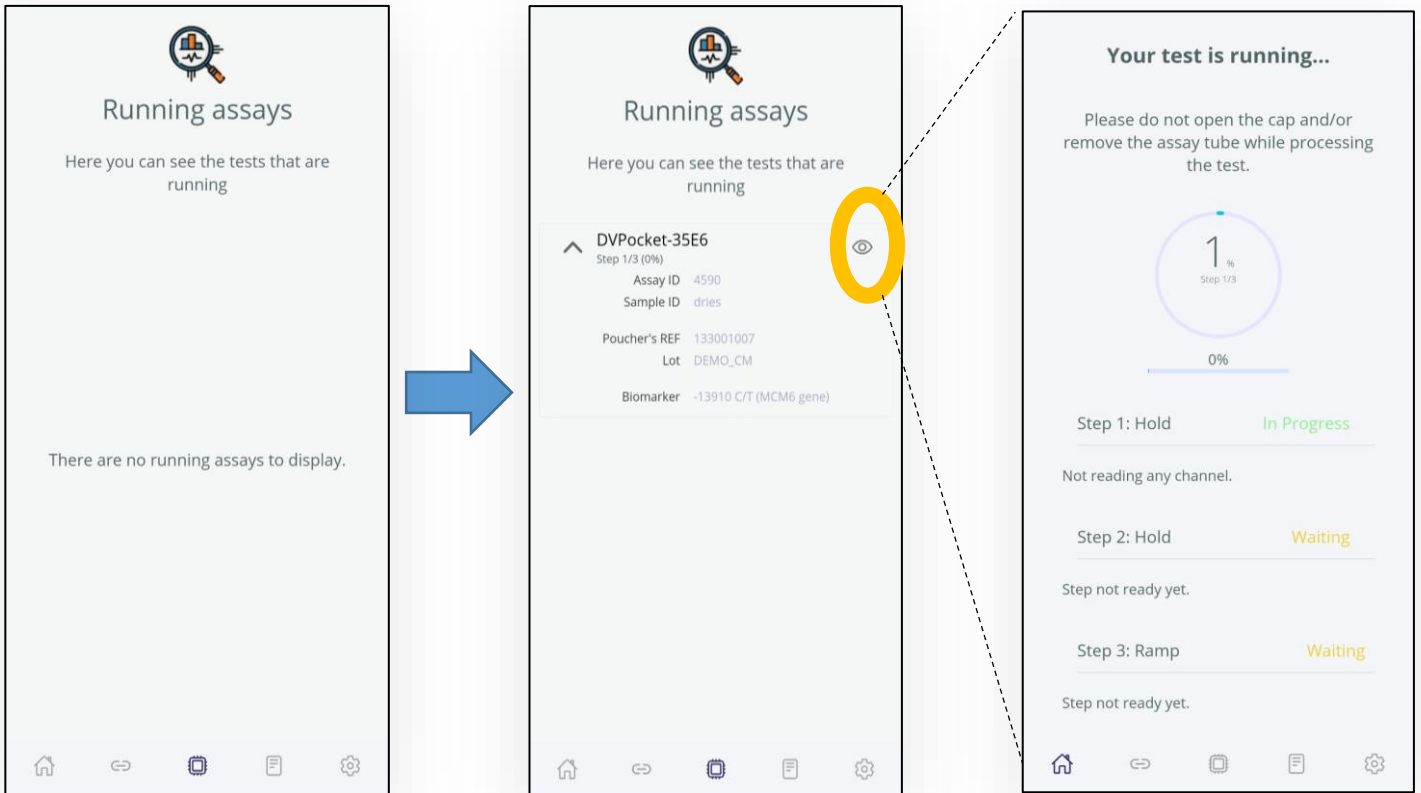
If not, make sure that:

The desired device is switched on and not connected to another mobile phone, Bluetooth is activated on the mobile phone.

If not, see the troubleshooting table.

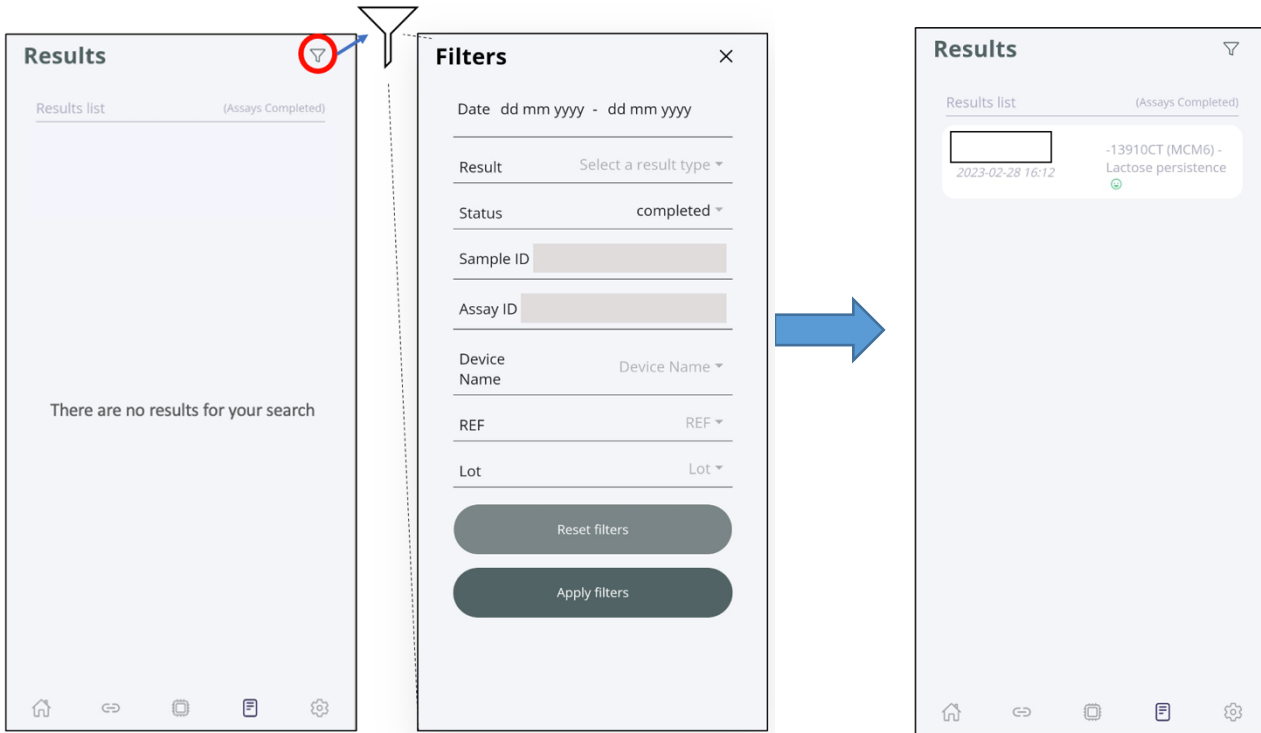
Running assays

In this menu, you can check and consult the information about the tests that are in progress. You can operate and view the progress of up to 4 devices (at maximum) at the same time for each mobile phone. In this menu, you can filter by device and check the details of each test individually.



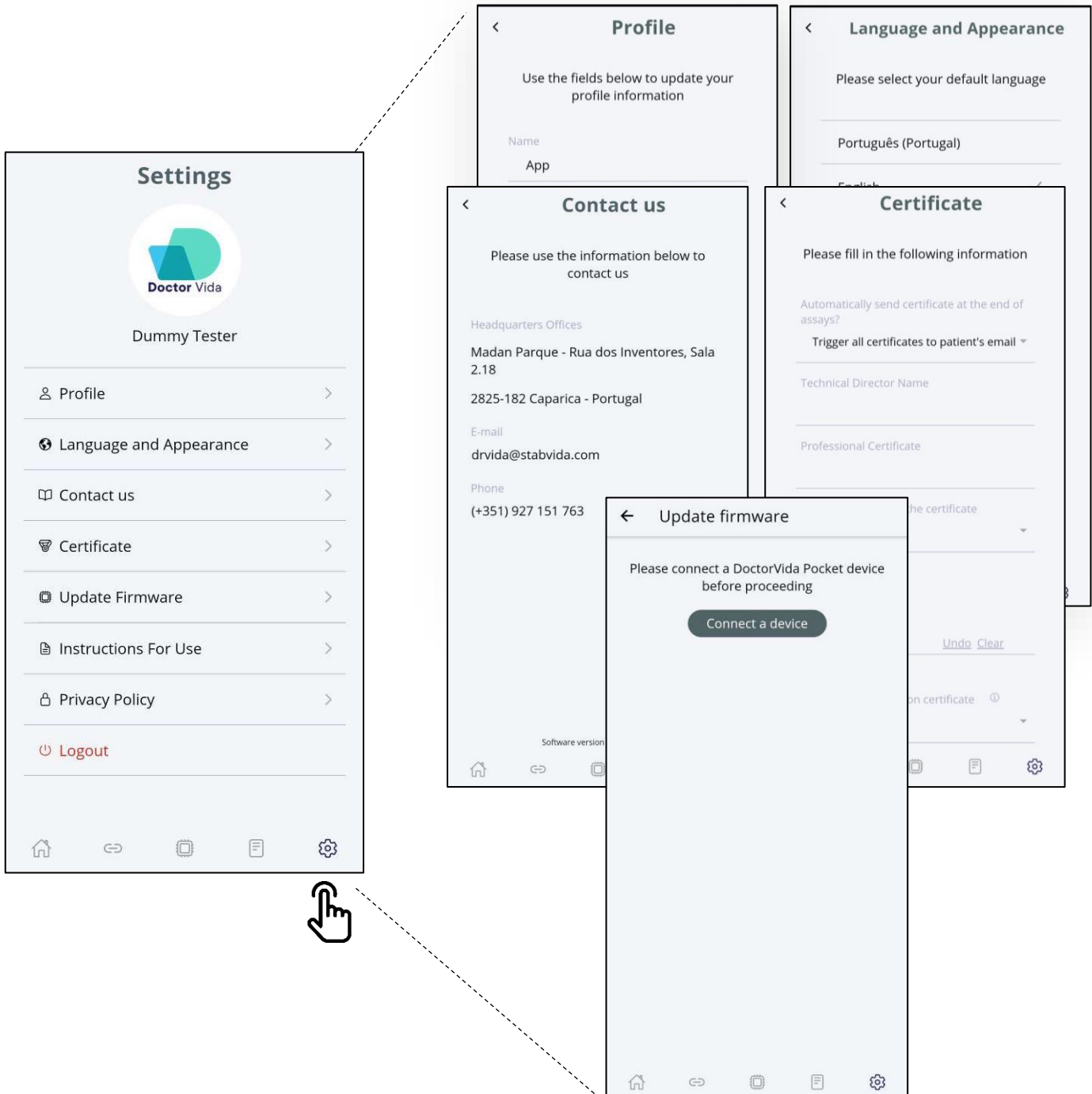
Results

In this menu, you can check and consult information about the results of the selected tests.



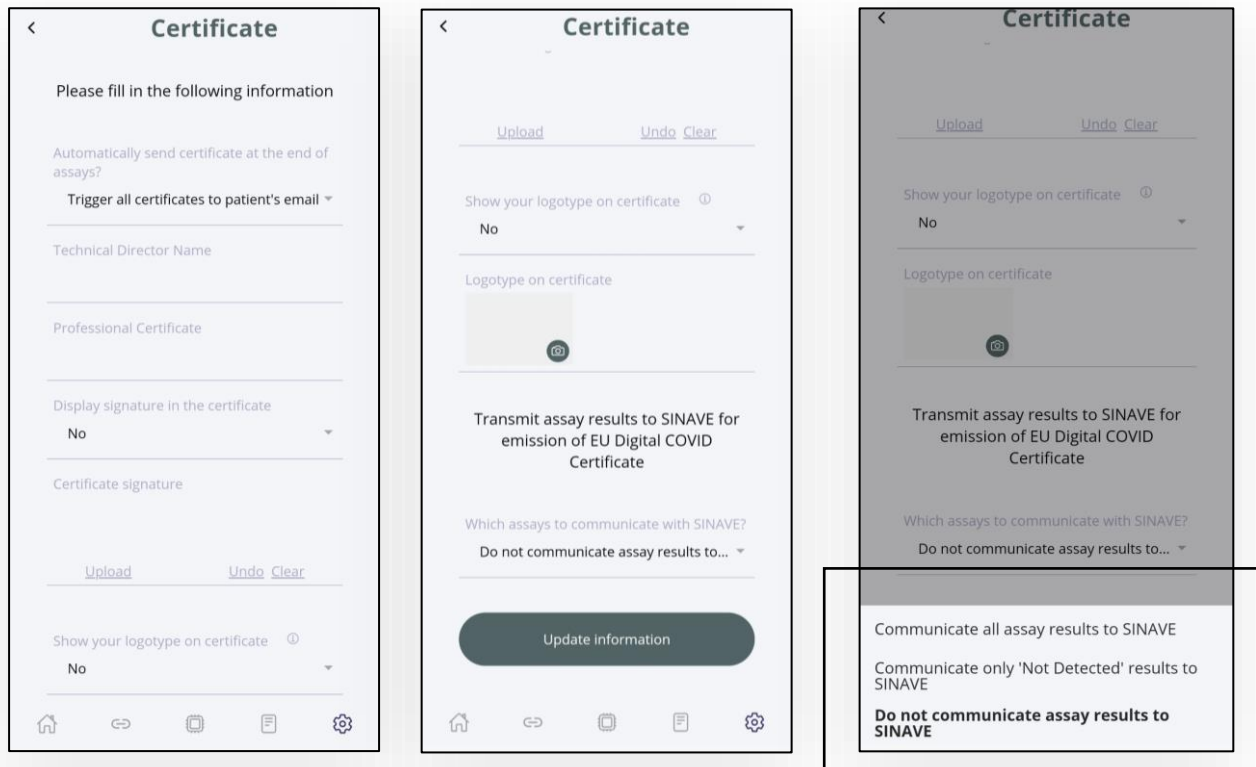
Definitions

In this menu, you can check profile information, select language and colour, manufacturer contacts, set Certificate options (test results report), and Instructions for use (full IFU are shown in PDF format. IFU is also available at and Privacy Policy (available at www.stabvida.com/drvida).



Certificate

Before starting a trial, you should define the information that will be included in the report of results (Certificate).



Automatically send the certificate at the end of the tests?

There are three options available:

- ⇒ Send all certificates to the patient's email - Results will be automatically sent to the Account User (Operator) and patient's email after the trial is completed.
- ⇒ Send only "Not Detected" certificates to the patient's email address - Only negative results will be automatically sent to the patient's email address. Positive results must be validated at the end of the test by the Operator. After validation of the results, the Operator can decide whether to send the certificate to the patient's e-mail address.
- ⇒ Never send the certificates directly to the patient's email - The results will be sent only to the Operator. Then the Operator will decide at the end of the trial and after validation of the results to send or not to send the results to the patient's email.

Technical Director's Name - Full or first name and surname of the Technical Director of the organization conducting the trial.

Professional Certificate - Certificate or Licence number of the Health Professional and of the Association in which the Health Professional is a member (e.g., 1234, Order of Biologists).

Display Signature on Certificate - Yes, it means that the signature of the Technical Director (responsible for validating the trial and submitting the report results) will be displayed on the Certificate.

Signature of the certificate - Signature of the Technical Director. It can be done directly on the mobile phone or submitted. The "Delete" option will allow to delete the signature and replace it with another one.

Logo on the certificate - You can upload the logo of the organization to be displayed on the Certificate.

Show the logo on the certificate - If you select the option **YES**, the logo will be shown on the certificate. If the option is **NO**, the logo will not be shown.

Transmit the test results to SINAVE for issuing the EU DIGITAL COVID Certificate - Only valid for Portuguese operators. SINAVE is the Portuguese health system reporting COVID-19 tests. Results performed in other countries should be manually reported to the health system of the appropriate country.

What tests can you communicate with SINAVE?

There are three options available:

- Communicate all test results - All results will be automatically communicated to SINAVE.
- Report only "Not Detected" results - Only negative results will be automatically reported to SINAVE. The operator must manually report positive results to SINAVE after internal validation.
- Do not communicate any test results - No results will be automatically communicated to SINAVE. The operator must manually communicate the results to SINAVE after internal validation.

After selecting the correct information to be displayed on the Certificate, select the "Update Information" button.

It is possible that the user may decide **not to submit the Certificate** or **to change the SINAVE communication options** when starting a new trial.

Update Firmware

This feature allows you to check and update the latest firmware version of the machine, follow the steps:

1. Turn on the equipment, perform the pairing in the "Devices" menu.
2. Go to the "Settings" menu and click on the "Update firmware" option and check if it requires updating.
3. If you require it, click on the update firmware option, you can update one at a time. The application interphase indicates the state of the update.

Only available for Android devices.

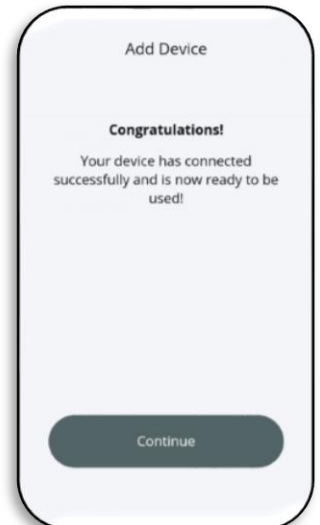
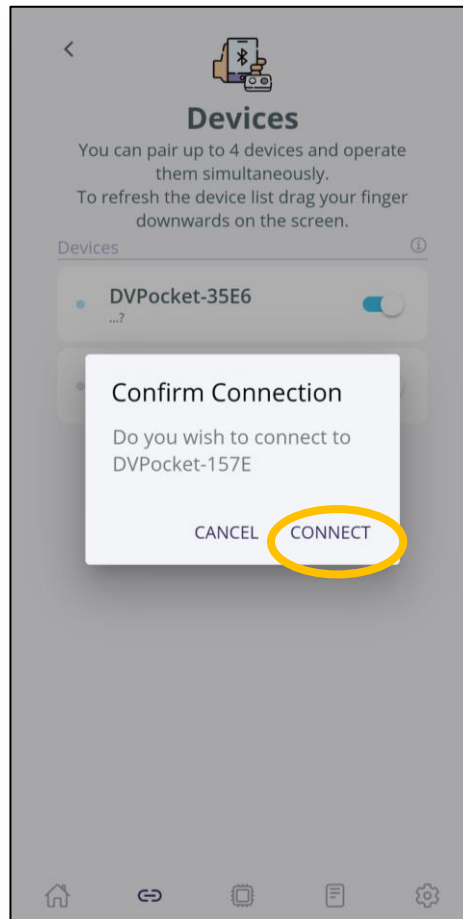
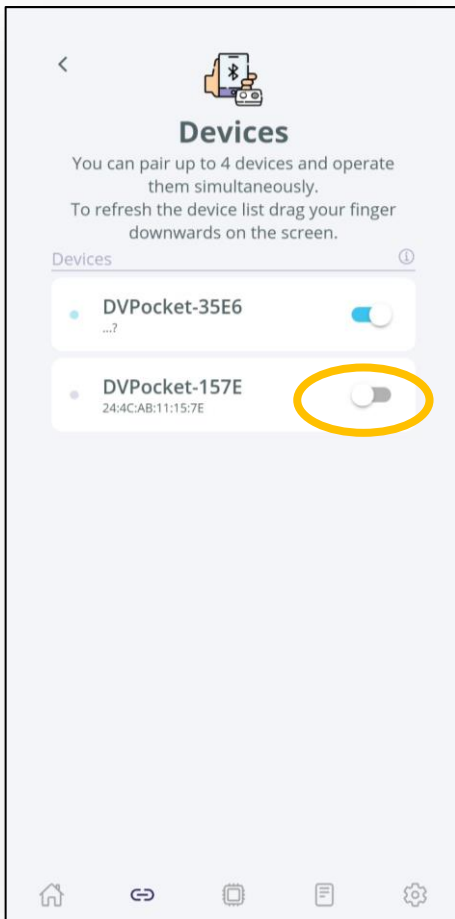
Doctor Life devices compatible with MAC ID prefix: AC:67:B2, E8:DB:84.

SOFTWARE OPERATION

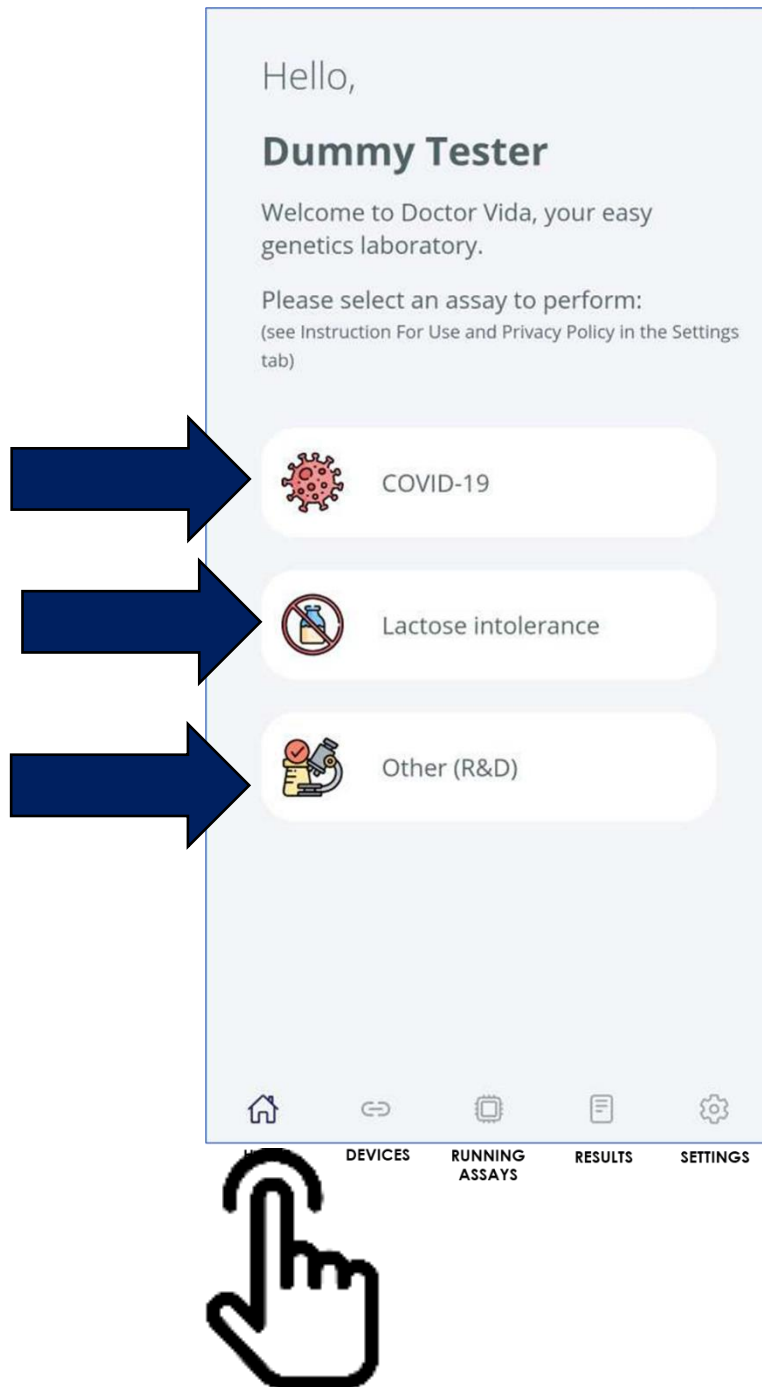
With the reagents

- ⇒ Reference # 133001001/133001004 (COVID-19 Test)
- ⇒ Reference # 133001006 (Human Control)
- ⇒ Reference # 133001007 (Lactose Intolerance Test)

- a. For each test, turn on the Doctor Vida device.
- b. Connect the device to power, output: 5VDC, 2A. The devices may take a few minutes to stabilize the temperature.
- c. In the app, connect the device. On the main screen, click on "Devices" and slide the button on the devices you want to pair. Click "Connect" and "Continue". The devices will be ready to run a test.



Select the "HOME" screen and **choose the test you want to perform:**



Follow the steps described and pay attention to the colour code indicated.

Manual option

Lactose Intolerance

Please fill in the following steps to start a **new assay**:
(see Instruction For Use and Privacy Policy in the Settings tab)


- 1
Select device
- 2
Insert reagents info
- 3
Read sample's ID
First insert the reagents info
- 4
Proceed
First complete the three steps above

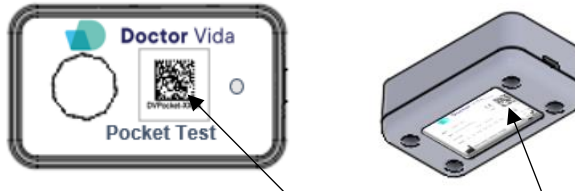


QR Code scan option

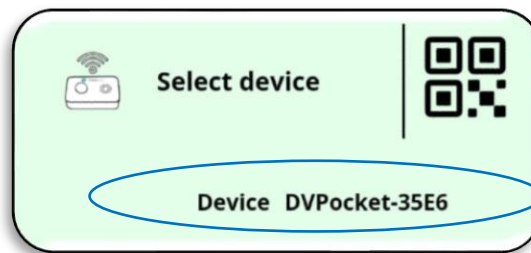
Orange menu - information required.

Menu in purple - cannot be selected until the information above is filled in.

- 1) **Click the "Select device" option or the QR code icon of the device**  **of the device**
Select the device that is ready to perform a test by clicking on the device box or by scanning the device QR code present on the device labeling.
– The QR code of the device is on the label at the top or bottom of the device.



Once step 1 is done, the box turns green and the device ID will be shown in the green box.



2) Click the option to enter the information or read the QR code of the reagents

Enter the reagent reference number (REF) and lot number (LOT) or scan the QR code on the package labelling.

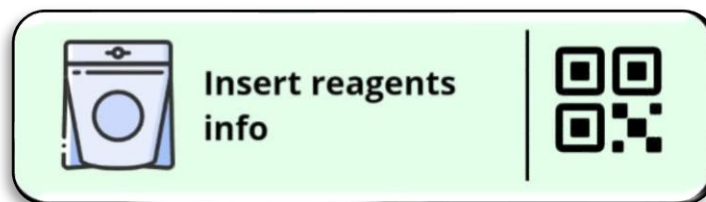
This will make it possible to identify the trial protocol and choose the analysis algorithm for the data collected while the new trial is running.

The QR code of the reagents should have a standard format as referred to in the app.

The image shown is purely illustrative.



Once step 2 is completed, the box turns green.



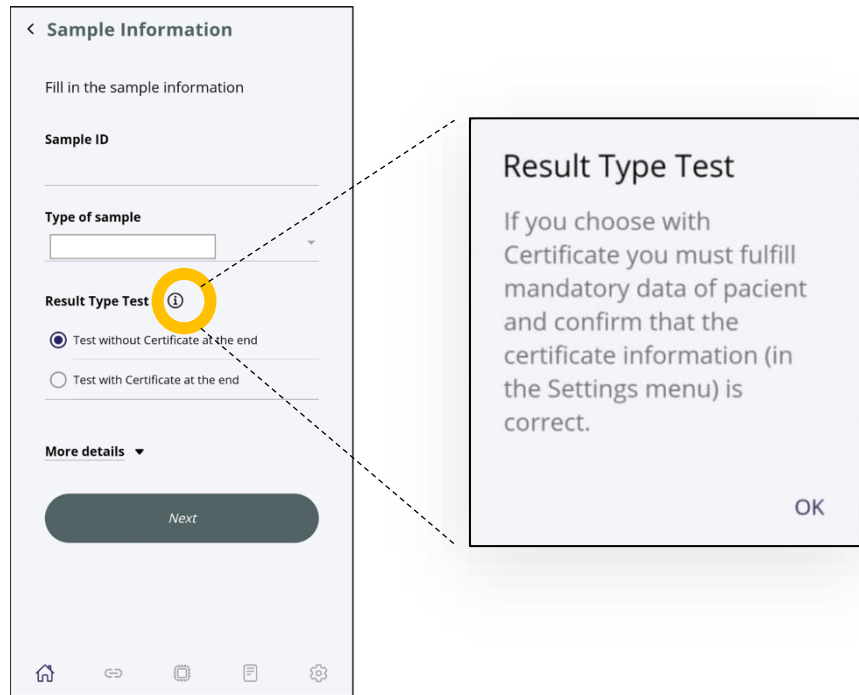
3) Click to enter the information or read the QR code of the sample

Fill in the information or scan the QR code on the sample.

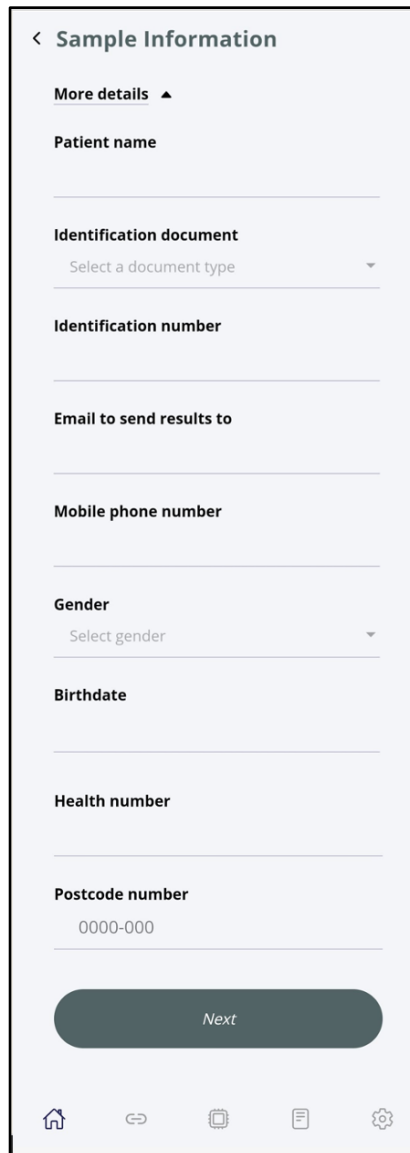
An anonymous alphanumeric code is **recommended** for sample identification.

The QR code of the sample should have a standard format, as referred to in the App.

The image shown is purely illustrative.



- If you select the test with certificate and/or to submit to SINAVE - there is mandatory information to fill in and confirm that the certificate information (in the **Settings** menu) is correct.

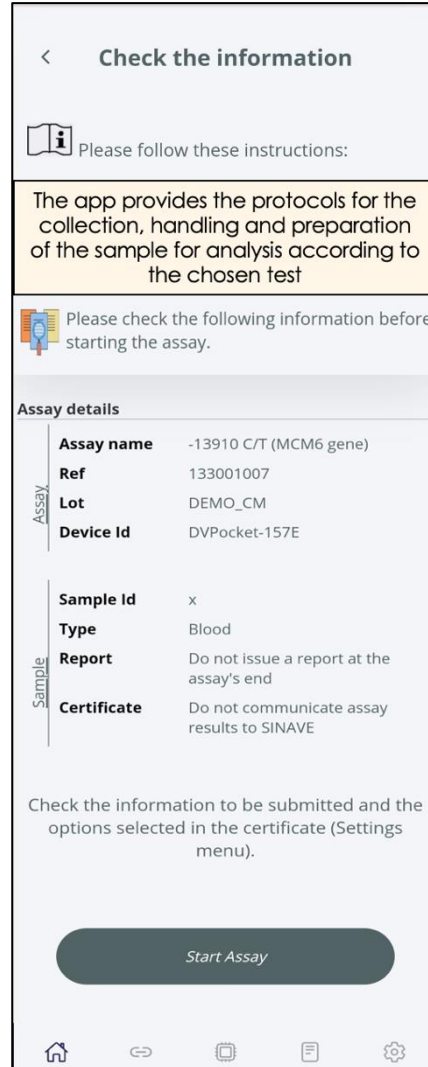
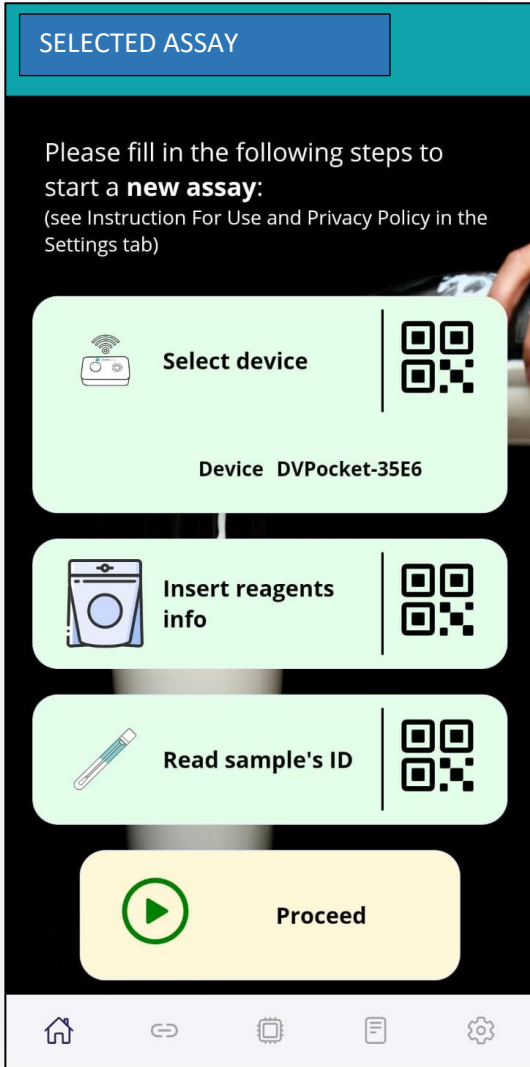


- If you select the test without a certificate - only the sample ID is required.

After filling out the form, click "Next" and the box "Read sample ID" turns green: Assim que o passo 3 for cumprido, a caixa fica verde.



- 4) Click "Continue" and follow the instructions provided in the Doctor Vida Pocket PCR app regarding the protocol for collecting, handling, and preparing the sample for analysis depending on the assay chosen.

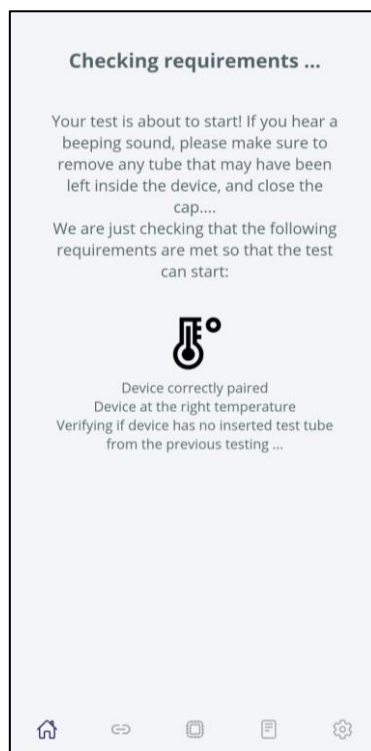


At the end **check the information required before starting the test**, if the information needs to be corrected, click on the arrow at the top left of the screen and return to the previous screen.

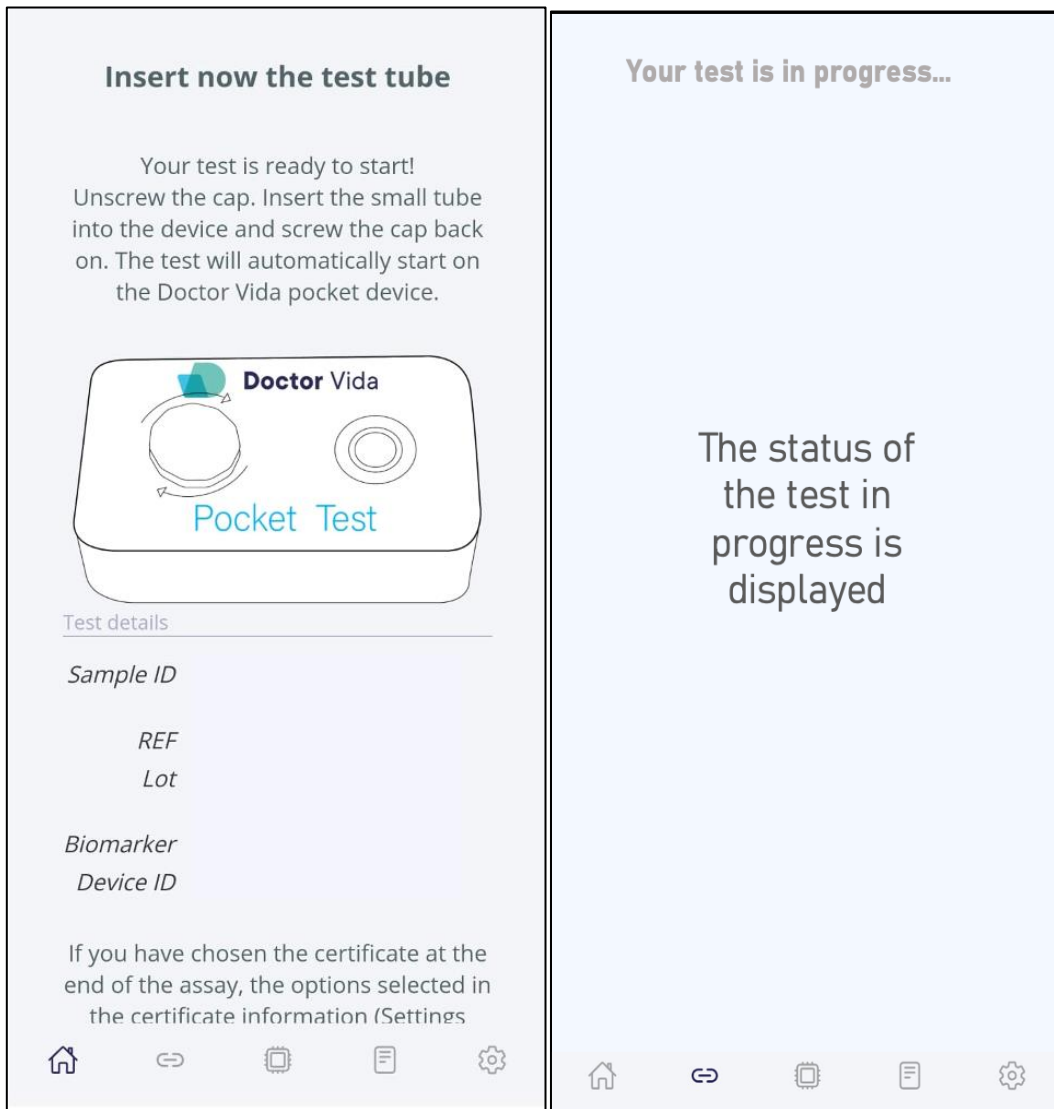
After selecting the "**Start test**" button, the system will verify that the requirements necessary to start the test are met. Make sure that the device does not have any tubes from the previous test. If yes, you will hear a beep. Please remove it to continue.

Important Note: Do not touch or move the device while the assay is being processed, as this may affect the performance of the assay.

Important note: You will not lose the information if you lose your Bluetooth or Internet connection during rehearsals. **Never** unplug your device. Close the app, open the app again, and select the "Devices" screen to re-connect the devices that are in progress. Then click on the device(s) again and click on "resume rehearsals" to resume rehearsals.



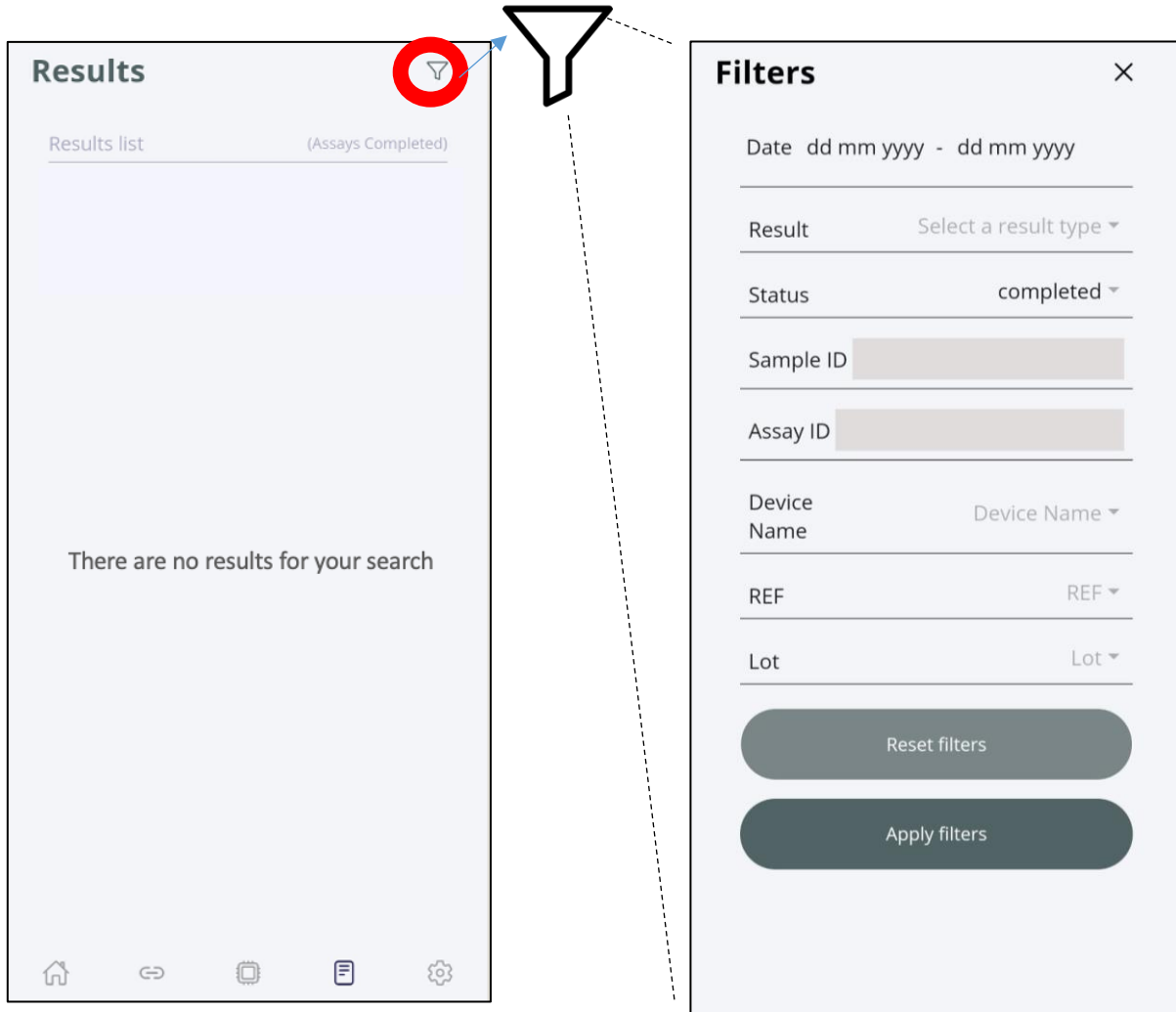
Now insert the test tube - Make sure that the tube is tightly closed. Unscrew the cap (counter clockwise), insert the tube into the device, and screw the cap on (clockwise). The test will start automatically.



Important note: Please do not move the device while the sample is being processed as this may compromise the reliability of the result.

Results

Click on "Results". When the test is finished, the device may take up to 2 minutes to transfer all data to the app. If you want to select a specific test or type of test, you can apply a filter by clicking on the upper right side (red circle).



Click on each test and the result summary will be displayed.

Refer to the Instructions for Use supplied with the reagents used in combination with the Doctor Vida device and software for information on the interpretation of results.

"Invalid Result" - An "Invalid" result means that the test was not performed successfully, and the test needs to be repeated or a new sample collected.

You can resend the certificate by reselecting the user and/or the patient and clicking on "Resend Certificate".

Issuing of certificates

The Certificate will be sent to the User and the patient if selected.

**Teste Molecular Rápido de Amplificação de Ácidos Nucleicos (TAAN) LAMP
PCR: Detecção de SARS-CoV-2**

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Director técnico: Cédula profissional: Referência da amostra: Tipo de amostra: Nome do utente: E-mail: Documento de identificação: : Cartão de Cidadão Número de utente de saúde: Data do ensaio: Data da Emissão Relatório:</p> | <p>QA Tester 92929292 SVT_280423 Exsudado da Nasofaringe em VPM Carol Lewis dummysfesterjr@gmail.com 82939292 929292 28-04-2023 11:15 28-04-2023 11:56</p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Descrição do estudo
Detecção de ARN do SARS-CoV-2 por amplificação de ácidos nucleicos através da metodologia RT-LAMP, com pesquisa de dois genes que codificam para a nucleoproteína (gene N) e para o invólucro (gene E).⁽¹⁾

Resultado:

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Um resultado "não detetado" significa que não foi detetado ARN do SARS-CoV-2 na amostra analisada. Se a amostra tiver sido colhida durante o período de incubação, é possível que o vírus não seja detetado. No caso de aparecimento de sintomas, deverá ser efetuada nova colheita. | Gene N/E _____ Não detetado |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|

(1) Laboratory testing for coronavirus disease (COVID-19) in suspected human cases. Interim guidance: 16 March 2020 (World Health Organization). Orientação nº 16/2020. 23/03/2020 atualizado 24/Março/2020 (BOC) e versão nº 016/2020 atualizado 16/03/2020 (BOC).

Director Técnico:

Ensaio desenvolvido pela tecnologia Doctor Vida

Teste Molecular de Amplificação de Ácidos Nucleicos (TAAN) LAMP PCR: Detecção de SARS-CoV-2 © STABVIDA, Lda. reprodução não autorizada. Em caso de dúvidas contactar o e-mail: info@doctorvida.com.

**TESTE GENÉTICO MOLECULAR
DETEÇÃO DE INTOLERÂNCIA À LACTOSE PRIMÁRIA**

Nome do utente:
Erica Wayne
Número de utente de saúde:
939392
E-mail:
fernando.dominguez@stabvida.com

Referência da amostra: SVT_280423
Tipo de amostra: Exsudado oral
Documento de identificação: 270403030
Data do ensaio: 28-04-2023 10:13
Data da Emissão Relatório: 28-04-2023 11:36
Técnico responsável: Fernando Egas

Descrição do estudo
Detecção do polimorfismo -13910 C/T no gene MCM6 associado à persistência da lactase.

Indicação clínica
Suspeita de intolerância à lactose.

Genótipo
-

Conclusão
Um resultado "inválido" significa que o teste não foi realizado com sucesso e é necessário repetir o teste ou fazer nova colheita de amostra.

Comentários
1) A intolerância à lactose em adultos não é uma doença genética, mas sim uma característica ancestral.
2) Este teste não é um diagnóstico *in vitro*.
3) O teste é válido apenas para a população caucasiana.
4) Em crianças (em particular até aos 11 anos) a análise do polimorfismo LCT-13910 C/T produz um resultado preditivo, contudo o teste pode ser usado como método de rastreio para a intolerância à lactose na fase adulta.

Método

1. Amplificação por LAMP da região do gene MCM6 que contém a variante LCT-13910 C/T.
2. Hibridação de sondas específicas para a mutação com o fragmento amplificado.
3. Medição das alterações de fluorescência em tempo real durante a análise da curva de melting.

Bibliografia:
Enattah NS et al. 2002. Identification of a variant associated with adult-type hypolactasia. Nature Genetics, vol.30

Director técnico: Technical Dummy
Cédula profissional: 28423

Assinatura

Teste Molecular Rápido de Amplificação de Ácidos Nucleicos (TAAN) LAMP PCR: Detecção de Intolerância à Lactose Primária © STABVIDA, Lda. reprodução não autorizada. Em caso de dúvidas contactar o e-mail: info@doctorvida.com.

AFTER THE TEST

Maintenance and cleaning of the workplace and device

- At the end of each test, remove the reaction tube. Wipe the outside with paper moistened with 70% ethanol (do not spray), without letting ethanol enter the hole where the reaction tube is placed. Keep the cap open until further testing.
- Do not allow organic solvents or aggressive solutions to come into contact with the device.
- Do not allow liquids to enter the device.
- Keep the space ventilated or provide natural ventilation at the end of each day.
- Avoid potential contamination between analyses by (i) keeping the workplace clean and ventilated and the device clean, and (ii) changing gloves after each analysis.

Important Note: Do not leave Doctor Vida device on if you are not using it.

Waste disposal

Waste electrical and electronic device (WEEE) (Directive 2012/19/EU)

This symbol on the product or on its packaging indicates that it should not be disposed of like other household waste. It is your responsibility to dispose of the device appropriately for the recycling of waste electrical and electronic device. This device's separate collection and recycling help conserve natural resources and protect human health and the environment. For more information about where you can dispose of the device, please contact the manufacturer or the distributor where you purchased the product.

PROBLEM SOLVING

| Problem observed | Possible Solution |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> - Fault detected after starting analysis - Power failure while the test is running | <p>Switch off the device and close the app. Open the Dr Vida Pocket PCR app. Discard the used reaction tube and restart the process using a new reaction tube.</p> |
| <ul style="list-style-type: none"> - The application fails to give the result -The application takes too long to display the results, or the test appears to be locked | <p>Close the app. Check the internet connection and Bluetooth. Open the app and in the "Devices" menu, reconnect the device. Press the device button again and click "Continue".</p> <p>If it still gives an error, unpair the device and pair it again. It is important to check that the same device is not connected to more than one mobile phone.</p> <p>If you manage to start a new test with this device, it means that there has been a power failure, or the device has restarted automatically. In this case, the test becomes invalid. Discard the reaction tube that was in use. Switch the device off and on again and start the process using a new reaction tube.</p> <p>If the problem persists, please contact technical support.</p> |
| <ul style="list-style-type: none"> -The device does not appear in the device list - The connection between the device and the mobile phone has failed | <p>Check that the device is connected to the mains, that there is no power failure (e.g., the connection cable is damaged). If this is the case, you can for instance use a cable from the mobile phone.</p> |

| Problem observed | Possible Solution |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <p>Check that Bluetooth is switched on and that in the phone settings, in the app you have given permission to access the location of the device.</p> <p>Refresh the screen by swiping downwards.</p> |
| <p>The phone has run out of space</p> | <p>If the phone runs out of space before starting the test, you should free up space on the 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 disconnect Doctor Vida pocket as the data is stored on the device. Free up space on the phone and the connection will be restored.</p> <p>Important note: If you disconnect the device, you will lose all data and will have to repeat the test with a new reaction tube.</p> |
| <p>Result with atypical graph</p> | <p>When the result is detected, but the growth of the curve is not exponential, the analysis must be repeated with a new test. This type of result can occur when:</p> <ol style="list-style-type: none"> 1) There is current fluctuation 2) When the lid is opened during the test 2) When the device is moved abruptly or tilted. |

WARRANTY INFORMATION

The product is covered by a two-year warranty period. This guarantee is to protect you against the costs associated with problems arising from manufacturing defects. The guarantee period begins on the date of receipt of the product at your chosen location. For support during the warranty period, please contact the manufacturer.

TRAINING

Whenever required the customer may request:

These operating instructions describe the correct use and operation of the device.

Operators of the device must familiarise themselves with the applicable sections in the document before carrying out tests to ensure safe and efficient use of the device. Ensure that you follow the training requirements in accordance with applicable regulatory guidelines. If you need more information about training in the use of this product, contact the manufacturer.

MANUFACTURER INFORMATION

Name: STAB VIDA- Investigação e Serviços em Ciências Biológicas, Lda.

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

Website: <https://www.stabvida.com/drvida>

In case of any problems please contact us by email drvida@stabvida.com or telephone 00351927151763.

Monday to Friday from 10am to 7pm (GMT Time)

In accordance with EU regulation 2017/746, any serious incident occurring in connection with the device must be reported to the manufacturer and the competent authority of the EU Member State where the user and/or patient are established.

REVISION HISTORY

| Review | | Revised points | |
|--------|--------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------|
| N. ° | Date (dd/mm/aa) | N. ° | Description of the revision |
| 1 | 04/11/2022 | All | Issuance of the document considering the set Equipment and Software. |
| 2 | 18/01/2023 | All | Issuance of the document considering the set Equipment and Software. |
| 3 | 18/01/2023 | All | Issuance of the document considering the set Equipment and Software. |
| 4 | 31/03/2023 | All | Adaptation of the document according to the requirements of EU regulation 2017/746 and relevant harmonized standards. |
| 5 | 28/04/2023 | ALL | Added functionality and limitations of the firmware update. Adding new certificate examples |