Doctor Vida

Your pocket PCR

STAB vida

Your easy genetics laboratory

Lactose Intolerance Test

Instructions for use

CE IVD

Reference 133001007

Document version (v3): 28, August 2024

In vitro *diagnostic medical device*

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 other than that specified by the manufacturer, the device may be compromised. Refer to the warnings, precautions, measures to be taken, and limitations of use for the product.

The images, screenshots present in the document are for illustrative purposes only.

Content

Introduction

The Doctor Vida Genetic Test - Lactose Intolerance Test is a CE-IVD marked kit designed to determine primary lactose intolerance in the Caucasian population.

This kit is an *in vitro diagnostic assay* that allows the qualitative detection of polymorphisms in a specific region in intron 13 of the MCM6 gene, namely -13910 C/T (rs4988235) by *Loop-mediated isothermal amplification* (LAMP) from a human biological sample (smear of the buccal mucosa). These tests allow the identification of each individual's phenotype regarding the persistence or non-persistence of lactase (enzyme that degrades lactose) in adults and in turn determine the degree of lactose tolerance. Lactose intolerant individuals (CC genotype) have difficulty digesting lactase, individuals with lactase persistence can digest it (TT genotype) and heterozygous individuals (CT genotype) generally have varying degrees of lactase persistence and therefore varying levels of lactose intolerance.

The LAMP technique is a technique of isothermal amplification of nucleic acids, where the target sequence is amplified at a constant temperature (around 65ºC). This technique needs 3 pairs of specific *primers* that serve to identify 8 distinct regions of the target gene, thus increasing specificity. The genotype detection of each sample is done by the analysis of the *melting* curve after amplification.

Intended purpose

The Lactose Intolerance Test is suitable for the detection of the genetic variant -13910 C/T in the MCM6 gene associated with lactase persistence among adults of the Caucasian population from a human biological sample, namely smear of the buccal mucosa. The result of the test helps in the diagnosis of patients with suspected primary lactose intolerance. Although typical symptoms are abdominal pain, diarrhea, nausea and meteorism after consuming lactose products, lactose intolerance in adults is not considered a genetic disease, but rather an ancestral characteristic.

This test should be used in combination with the Doctor Vida equipment for amplification and molecular detection of DNA in 60-90 minutes. 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.

Principles of the test

The mouth swab sample is placed in lysis buffer, in the collection tube (Tube A) by a healthcare professional following good practice procedures using the appropriate material included in this product and appropriate personal protective equipment not included. After 10-minute incubation at room temperature, approximately 10 µL of sample is added with the aid of component C (disposable dispenser) to the test tube (Tube B), following the instructions described in this document. The analysis is carried out by *Loop-mediated isothermal amplification (LAMP*) which requires 6 types of *primers* designed to hybridize distinct regions around the polymorphism (FIP and F3 primers at the 3' end and BIP and B3 primers at the 5' end and the loop, LF and LB primers) and is based on the amplification at a constant temperature of the MCM6 gene region containing the -13910 C/T variant. MCM6 is made with specific probes for mutation through fluorescence quenching detection. After amplification, the temperature drops to 40°C allowing the probe to hybridize with the amplified fragment, which brings the fluorophore and *the quencher* closer together, resulting in *quenching* of the fluorescence. During the analysis of the *melting curve*, the temperature gradually increases to 70ºC, allowing the detection system included in the Doctor Vida equipment (Ref. 133001002) to detect the emitted fluorescence. As the probe is specific for the mutation (T), it does not perfectly hybrid with DNA fragments that do not contain the genetic variant (C) and therefore in these cases fluorescence emission occurs at lower temperatures than for DNA fragments that contain the genetic variant (T). Changes in fluorescence at different temperatures are detected by the Doctor Vida equipment, allowing the distinction between the different nucleotides in the region of the -13910C/T variant. On the other hand, if there is no fluorescence emission or if it is residual, it means that the amount of biological material is below the detection limit of the technique or there are inhibitors in the sample causing an invalid result. 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

The quality control procedure is intended to monitor the performance of the test. The components of this product are manufactured in accordance with ISO 13485 and applicable regulatory requirements.

Each batch produced is properly tested along with Doctor Vida equipment and the Certificate of Analysis (CoA) for each batch is available on request. For each batch, tests are carried out with a negative control to verify whether the reagents in the kit have any contamination with nucleic acids and with a positive control essential to evaluate the efficiency of the procedure. This quality control test also allows you to check the quality of the reagents (integrity of the probes, *primers* and enzyme activity).

Applicable symbols

	See instructions for use		CE Marking
	Product Reference		In vitro diagnostic medical device
	Lot number		Temperature limits
	Manufacturer		Contains enough to <n> tests
	Do not reuse		*Near-patient testing*
	Use Up to		The device is not intended for self-diagnosis

Attention:

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

Abbreviations

Abbreviation	Meaning
CE	European Compliance
CQ	Quality Control
EN	European standard
IVD	*in vitro* diagnostic
IVDR	In vitro diagnostic regulation
N/A	Not applicable
PDF	Portable document format

Warnings, precautions, safety measures and limitations of use

All users must read and comply with the instructions for use provided.

Failure to follow the instructions may cause damage to the product and/or cause damage to health. For your safety and to prevent damage to the product, it is important that the following safety precautions are read and understood before using the product. Refer to the product safety data sheet for details.

Being a product used in combination with another device, read the warnings, precautions, safety measures and limitations on the use of Doctor Vida equipment and *software*, relating to:

Electricity | Fluids & Reagents | Physical Medium | Electrostatic Discharge (ESD) | Operating Environment |Equipment Ratings

Warnings, precautions and safety measures

►Do not use any component of the kit if it is damaged or out of date or if the collection solution or reagents have potential contaminants (turbidity). The use of unsuitable components may cause damage to health and/or compromise the performance of the test. In this case, contact technical support.

►Do not use components from different kits (batches) or components that are not included in the kit in the same test. The use of components other than those provided in the kit may compromise the performance of the test result.

►Handling of this product should be limited to healthcare professionals, taking into account the use of good laboratory practices and applicable guidelines, reducing risks to the operator and the integrity of the reagents.

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

—Wear appropriate personal protective equipment (gown, gloves, eye protection and mask) in accordance with applicable regulatory guidelines;

—Keep the lid open only on the tube you are using. Do not change or reuse tube caps.

—Change gloves and always clean equipment, necessary materials and surface before and after each test;

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

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

—Waste materials and reagents must be properly disposed of in the biological waste bag, in accordance with the applicable legislation;

—The facilities must be cleaned daily with DNA-free products, and ventilated (natural ventilation).

Limitations of use

Failure to comply with proper procedures for transport, storage, collection, processing and analysis of the sample may invalidate or compromise the test result due to cross-contamination.

The possibility of additional rare mutations that could generate false genotyping results. Thus, the manufacturer must evaluate possible genetic alterations that compromise the result and report them as a limitation, if applicable.

If the amount of sample in the test is below the detection limit (LoD=5 cells per reaction), the result may be invalid and you will need to repeat the sample collection and you will need to use a new test kit.

Before starting the trial

Materials provided

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

Kit Components	Description	Quantidade	Storage conditions
Test Packaging	Tube A (Collection Tube)	200µL Collection Solution	-25ºC to -15ºC
	Tube B (Assay tube)	90µL Reaction solution	
	Component C (Disposable dispenser)	1 unit	
Accessories	Component D (Disposable swab)	1 unit	4ºC to 25ºC
	Biological waste bag	1 unit	Room Temperature

Materials required but not provided

►Doctor Vida equipment (including power supply and micro-USB-B cable) – available with reference no. 133001002;

►Dr Vida Pocket PCR application – available on Google play and iOS stores.

►Mobile phone with Bluetooth – to install and use the Dr Vida Pocket PCR application

►Internet (*wireless*) – required to process the sample in the Dr Vida Pocket PCR and transfer data to the server.

To carry out a test, 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, please refer to the instructions for use of the Doctor Vida equipment and *software*.

Product Transportation

For the transport of the product to be carried out accordingly, the test packaging is properly packed in boxes containing thermal accumulators, to ensure the temperature conditions of the components (<8ºC). The product's accessories, on the other hand, are packaged and transported at room temperature.

Product Storage

The components of the product should be stored according to the temperature indicated on the labeling of each component, as described in the section: Materials supplied, preserving the performance of the product until the expiration date indicated on the labeling.

Product handling

When handling the product, you should take into account that:

►For each assay, use only 1 test pack, which is for single use.

►After taking the sample, if you wish to proceed immediately with the analysis, place the collection tube (tube A) and the test tube (tube B) in the holder provided in the package and allow them to thaw at room temperature;

►After completely thawing, the tubes are ready to start the test.

 **Danger sign, warning sign, attention sign. Danger warning attention icon on transparent background PNG - Similar PNG**

 **Danger sign, warning sign, attention sign. Danger warning attention icon on transparent background PNG - Similar PNG**

Product stability

The product maintains its performance until the expiry date indicated on the labelling of the packaging and accessories, provided that the conditions of transport, storage and handling are met.

Classification of product reagents

The classification of substances and/or mixtures of substances present in the product is carried out in accordance with Regulation (EC) No 1272/2008. Refer to the safety data sheet of the product.

Performance characteristics

Analytical performance

The analytical performance was evaluated in combination with the Doctor Vida® equipment and the Dr Vida Pocket PCR application. Considering the following parameters:

Intra-batch reproducibility

Intra-lot reproducibility was evaluated in 2 types of triplicate samples within the same lot. The data collected show that the replicated results corresponded to 100% of the expected qualitative results.

Sample	% Correct results (Expected/Replicated Result)	% Total Correct Results
NTC (Sample collection buffer)	Expected Result: Invalid 100% (3/3)	100% (6/6)
POS (Cells A549)	Expected Result: TT 100% (3/3)	

Inter-batch reproducibility

Inter-lot reproducibility was evaluated in the same 2 types of samples in triplicate with 3 different lots. The data collected indicate that in the 3 batches tested, all results corresponded to 100% of the expected qualitative results.

Sample	% Correct results (Expected/Replicated Result)	% Total Correct Results
NTC (Sample collection buffer)	Expected Result: Invalid 100% (3/3)	100% (6/6)
POS (Cells A549)	Expected Result: TT 100% (3/3)	

Analytical sensitivity (detection limit)

To determine the limit of detection (LoD) of the test, triplicate assays were performed using different concentrations of a sample with known concentration and known genotype. The data collected denote that for a detection rate > 95% the lowest level of concentration is 5 cells per reaction (i.e. 100 cells/mL), thus defining the analytical sensitivity of the test.

	Sample Level (No. of cells A549/reaction)	% Correct results (Detected/Replicated)
	1	33% (1/3)
LoD →	5	100% (3/3)
	10	100% (3/3)
	50	100% (3/3)
	75	100% (3/3)
	100	100% (3/3)

Table 4 – Analytical sensitivity of the test (LoD)

Product stability in storage

See the expiration date on the product packaging.

Clinical performance of the product

The clinical performance of the Lactose Intolerance Test – isothermal method was performed in comparison with the laboratory reference laboratory method – Sequencing by the Sanger method (using DNA purified from FTA cards). The clinical validation study was carried out following a non-probabilistic sample with a total of 63 mouthpiece exudate samples from volunteers in Portugal (N=63).

All data were analyzed using the 3x3 confusion matrix method, after exclusion of invalid results. Overall statistics and statistics by genotype classes were calculated using the R statistical computing software (R Foundation, version 4.2.2).

The results obtained by the Doctor Vida method showed an overall accuracy of 98.41% (with a 95% confidence interval between 91.47% and 99.96%) compared to the reference method. Of a total of 63 assays performed, only 1 had an invalid result (1.59%) and another had a genotyping not in accordance with the reference method – Sanger sequencing.

In the clinical validation, statistical analysis by genotype class was also performed. The result of the relative sensitivity per class is 96.67%, 100% and 100%, for the genotypes CC, CT and TT respectively. The result of relative specificity by classes is 100%, 97.44% and 100%, for the genotypes CC, CT and TT respectively. In the same study, the positive predictive value for each of the genotypes, CC (100%), TC (96%) and TT (100%) and negative predictive value for each of the genotypes, CC (97.06%), TC (100%) and TT (100%) were also calculated. Parameters such as prevalence, detection rate, detection prevalence and accuracy were also calculated for each genotype.

Buccal swab samples

Number of invalid assays: 1/63 (1.59%)

		Reference method – Sanger sequencing			
		-13910 CC	-13910 CT	-13910 TT	**Total**
Isothermal lab-on-phone - Lactose Intolerance	-13910 CC	28	0	0	**28**
	-13910 CT	1	24	0	**25**
	-13910 TT	0	0	9	**9**
	Total	**29**	**24**	**9**	**62**

Overall statistics

Accuracy: 98.41%
95% CI: (91.47% - 99.96%)
No Information Rate: 47.62%
P-Value [Acc > NIR]: < 2.2e-16
Kappa: 0.9739

Class statistics by Genotype:	-13910 CC	-13910 CT	-13910 TT
Sensitivity	96.67%	100%	100%
Specificity	100%	97.44%	100%
Pos Pred Value	100%	96.00%	100%
Neg Pred Value	97.06%	100%	100%
Prevalence	47.62	38.10%	14.29%
Detection Rate	46.03	38.10%	14.29%
Detection Prevalence	46.03	39.68%	14.29%
Balanced Accuracy	98.33%	98.72%	100%

Statistical analysis of the clinical performance of the lactose intolerance test - Doctor Vida method vs. reference method - *Sanger sequencing*.

Sample Pre-Collection

Site preparation and equipment used in the test

Before starting the collection of samples and the analysis of the test, you must prepare the place where the test is carried out and also the equipment and material inherent to the analysis of the same.

►The place must have an ambient temperature between 15ºC and 30ºC and humidity levels between 20 and 80%;

►Keep the place clean and ventilated with daily natural ventilation, preferably after the tests;

►Have well-defined spaces (with a minimum acceptable distance) for sample collection, transfer of the sample to the test tube (test B) and analysis;

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

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

►Remove the cover of the Doctor Vida equipment and clean it with paper dampened in 70% ethanol and let it air dry;

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

►Keep the lid open until a new test;

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

Installation of Doctor Vida equipment for sample analysis

For more information, please refer to the "Installation" section referred to in the instructions for use of the Doctor Vida equipment and *software*.

Turning on the Doctor Vida equipment

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

Install the Dr Vida Pocket PCR app

Install and configure the Dr Vida Pocket PCR application on your mobile phone (see instructions for use of the Doctor Vida equipment and *software*).

Select the Doctor Life genetic test and Pair the Doctor Life equipment

On the main screen of the app, select the Doctor Vida test you want to perform - "Lactose intolerance". 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.

Register the information of the Doctor Life test reagents

The information of the genetic test reagents in question is recorded, either you manually enter the test reference and batch number or scan the QRcode of the test kit.

Fill in the sample data

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. 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 verify (if the filling has been done by reading the sample QRcode) the patient's data.

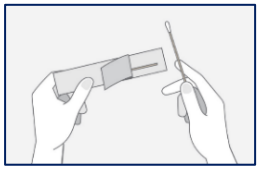
Sample collection, handling, preparation and analysis

Sample collection – Oral swab

The sample collection must be carried out by health professionals in accordance with good practices and applicable national regulations, following the instructions in this document and the diagrams available in the Dr Vida Pocket PCR application.

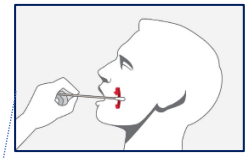
Avoid eating, drinking or smoking 30 min before collection.

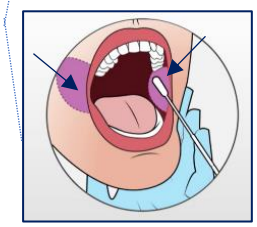
General Instructions



1. Remove the swab provided from its sterile packaging, taking care to avoid contact with any object or surface.

Hold the swab by the plastic end, not bringing your fingers close to the cotton area.

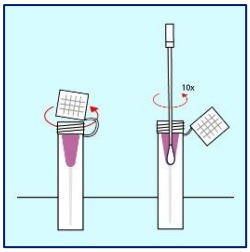




2. Insert the swab into your mouth and vigorously rub the inside of both cheeks, in a circular motion, for at least 30 seconds.

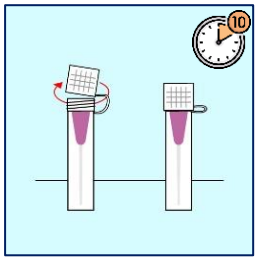
The goal is to collect a swab on the inner wall of the cheek(s). An insufficient sample may lead to a new collection.

3. Remove the swab carefully so that it does not touch your teeth, lips, or other surface.



4. Unscrew the cap of the tube A (collection) containing the pink liquid, place the swab inside and turn it repeatedly about 10 times.

5. Remove the swab to ensure maximum sample transfer and dispose of it in the biowaste bag.

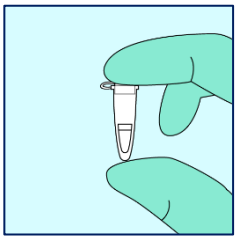


6. Close tube A with its screw cap and allow it to incubate at room temperature for 10 minutes.

   If you wish to analyse the sample, follow the procedure described in the "Sample analysis".

   If you do not want to analyze the sample immediately, store it between 2-8ºC for up to 24 hours.

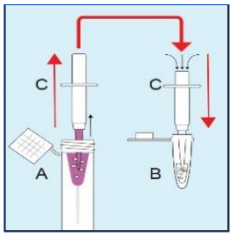
Sample handling, preparation and analysis



Before starting sample preparation, make sure you have the Dr Vida App installed, with Bluetooth and the camera activated, and a stable internet connection.

7. Remove the B (test) tube and thaw it with the help of your fingers until the liquid is completely transparent.

8. After 10 minutes of sample incubation, unscrew the cap of tube A and collect 10µL of sample with the aid of component C (disposable sample dispenser) provided.



Make sure you do not obstruct the hole at the top of component C when it is taking the sample.

If the sample volume is not raised to the mark of component C, remove and replace the tip of the dispenser several times so that the pressure differential can more easily increase the total sample volume.

9. Dispense the collected sample into the tube B by placing the tip of component C inside the tube and plugging the hole at the top and pressing the plunger lightly.

After sample dispensing, a pink middle layer should be visible inside the B tube.

Re-close tube A and dispose of it in the biowaste bag provided.

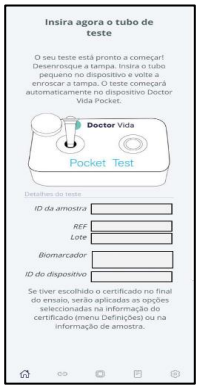
10. Close tube B tightly and tap the tube on the bench 5 times to mix the sample well with the reagents.

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

12. Click Start Test, and wait for the device to verify that the requirements needed to start are being met.

13. When prompted, insert tube B into the Doctor Vida equipment, unscrew the cap of the same, place the tube and screw the cap on.

14. The rehearsal will start automatically and take approximately 90 minutes.



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

⚠ While the test is in progress, do not disconnect the Doctor Vida equipment from the mains.

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

After the Analysis of the sample

Consult the result obtained

►When the test ends, 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: Under normal internet connection conditions, it may take about 2 minutes to transfer the data to obtain the result.

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

►The test result indicates the nucleotide(s) present in the region of the -13910 C/T polymorphism (rs4988235), based on the temperature at which the peak(s) is observed.

►The lactose intolerance test may have three possible outcomes. If the result is invalid, the test must be repeated including a new collection.

Interpretation of the result

Chart				
Chart description and interpretation	1 peak at 48-54ºC – Indicates presence of Nucleotide C.	1 Peak at 48-54ºC and 1 Peak at 56-64ºC – Indicates the presence of Nucleotide C and T simultaneously.	1 peak at 56-64ºC – Indicates presence of T Nucleotide.	0 Peaks – indicates failure of the test. Repeat.
Genótipo	CC	CT	TT	Invalid
Fenótipo	Primary lactose intolerance – Lactase deficiency in adults.	Different degrees of primary lactose intolerance.	Lactose tolerance – Lactase persistence in adults	--

Site cleaning and equipment including bio-waste disposal

At the end of each test, ensure that the site is clean and ventilated as well as all the material used in the test, including the Doctor Vida equipment and ensure that the disposal of reagent tubes, accessories and consumables is carried out in accordance with the rules for treatment and disposal of biological waste according to the applicable legislation.

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

►Dispose of tube A, as well as component C, consumables and accessories supplied in the biological waste;

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

Note: Be careful not to get ethanol into the hole where the reagent tube 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 ventilation;

►Keep the lid of the equipment open until a new test;

►Dispose of the papers and gloves used to clean the space and equipment for biological waste.

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

Troubleshooting

Observed problem	Possible solution
—Electricity failure while the test is running. In this case it is not possible to complete the test.	►Turn off the machine and close the app. ►Open the Dr Vida Pocket PCR app. ►Discard the test tube that was in use and restart the process using a new test tube.
—Failed to start the test.	►Make sure you have an internet connection and that Bluetooth is working. ►Check the hardware compatibility requirements of your device with the Dr Vida software in the compatibility section within each store (Android/iOS). ►Turn off the app and reconnect to the device. ►Turn off the device and pair again in the App, in the "Devices" menu.
—The test starts, but does not end.	► During the reaction, there is a step in which the temperature needs to drop to 40ºC for the test to continue. If the temperature does not reach 40ºC, the test does not continue. In this case, place the equipment on a cooler surface (e.g. the aluminium cover of the equipment housing).
—Data transfer failed. **—The application takes too long to display results or the test appears to be stuck.**	►Close the Dr Vida Pocket PCR app. ►Check your internet connection and Bluetooth. ►Open the app in the "Devices" menu, reconnect the device. Press the device button again and click "continue". ►If it continues to fail, unpair the machine and pair again. It is important to check that the same device is not connected to more than one mobile phone. ►If you are able to start a new test with this machine, it means that a power failure has occurred or the machine has automatically restarted. In this case, the test becomes invalid. Discard the test tube that was in use. Turn the equipment off and on again and start the process using a new test tube. ►If the problem persists, please contact technical support. See the "Manufacturer Information" section.
—Failure to send the report with the results of the App to the customer's email.	► Contact technical support. See the "Manufacturer Information" section.
—The machine does not appear in the list of devices. **—The connection between the device and the mobile phone failed.**	►Check that the equipment is connected to the mains, that there is no electrical fault (e.g. the connection cable is damaged). ►In the phone's settings, check if Bluetooth is turned on, and if in the app you have given permission to access the device's location. ►Refresh the screen by swiping down.

Observed problem	Possible solution
—The phone ran out of space to store the data.	►If your phone runs out of space before starting the test, you should free up space on your phone or use another phone. ►If your 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 the equipment as the data is stored on the device. Free up space on your phone and the connection will be re-established. **Important note:** If you turn off the equipment, you lose all data and you must repeat the test with a new test tube.
—Result with atypical/invalid graph.	►The result is issued, but the growth of the curve is not as expected, the analysis must be repeated with a new test. This type of result can occur when: 1) There is current oscillation 2) When the lid is opened during the test. 3) When the equipment moves sharply or tilts. **Note:** This type of result can occur when there is an inhibitor present in the sample or a lack of biological material.

Bibliography

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

—Rasinpera et al, 2004. A genetic test which can be used to diagnose adult-type hypolactasia in children, Gut; 53: 1571-1576

Warranty Information

The product is covered by a warranty period equal to the expiry date indicated on the package labelling. This warranty is intended to protect you from the costs associated with problems resulting from manufacturing defects. The warranty period begins 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 should familiarise themselves with the applicable sections in the document before testing to ensure safe and efficient use of the document. Make sure you follow the training requirements in accordance with the 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.

Sítio(s) web: https://www.stabvida.com

Technical assistance:

+351 938 437 766

In case of any problem, please contact us by email drvida@stabvida.com or phone 00351 938 437 766 (Call to national mobile network)

Monday to Friday from 8:30 am to 5:30 pm. (GMT time)

According to EU regulation 2017/746, any serious incident that occurs 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 is established.

Revision history

Revision		Revised points	
N.º	**Date (dd/mm/yy)**	**N.º**	**Review Description**
0	25/05/2022	-	Issuance of the document
1	31/03/2023	-	Compliance with Regulation (EU) 2017/746 IVDR
2	30/10/2023	-	Change in the description of the conditions of transport of the product. Change in the description related to product stability.
3	28/08/2024		Change of technical support contact number. Updated the troubleshooting list.