

SYSTEM MANUAL 1.0

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1. Introduction

ABOUT INNE

When we see the female reproductive system, we see beauty and we see logic.

Our mission is to help women see the same and provide a way to get reliable information about their personal hormone levels. Our MINILAB system combines science, technology and design to help women understand the rhythms of their bodies, how they change during the menopausal transition, and what those changes mean for her.

The rhythms of a woman's body are controlled by hormones. These hormones, estrogen and progesterone in particular, regulate the menstrual cycle and trigger ovulation. By measuring progesterone levels at different times in the cycle, the inne MINILAB can provide insights into the natural fluctuations and changes that occur during perimenopause.

ABOUT THIS DOCUMENT

This SYSTEM MANUAL contains important information about how to use the inne MINILAB system, which consists of the inne READER and the inne STRIPS. Read it carefully prior to using the inne MINILAB for the first time and keep it for future reference. This manual describes the proper procedures for operation and maintenance. The inne MINILAB must not be used for any purpose other than that which is specified in this document.

INTENDED USE

The inne MINILAB is a hormone monitoring device that measures progesterone in saliva throughout the menstrual cycle. It is designed for self-testing by female laypersons at home.

SUMMARY AND EXPLANATION OF THE TEST

In order to use the inne MINILAB, you need to carry out a saliva collection using an inne STRIP, perform a measurement using the inne READER, and finally review the results in the Phenology APP. Progesterone levels in saliva are measured by the inne STRIPs, which are read by the inne READER. The inne algorithm processes the data and calculates your progesterone level, which is displayed in the Phenology APP. Because of normal daily fluctuations in progesterone levels, testing more frequently will provide better insights.

THE SCIENCE BEHIND THE INNE MINILAB

Lateral flow immunoassays represent a well-established and appropriate technology when applied to a wide variety of point-of-care (POC) or field use applications. The Lateral Flow (LF) format is so versatile that manufacturers have developed LF tests for almost any situation where a rapid test is required [1]. They can be used to test just about any biological samples, including urine, tears, sweat, saliva, serum, plasma, whole blood, and biopsied tissue and fluids [1, 2]. Urinary lateral flow assays are already used in the field of fertility monitoring. Strips are available in the market for the monitoring of different fertility hormones or hormones metabolites (Luteinizing hormone - LH, estrone-3-glucuronide, pregnanediol-3-glucuronide).

The inne MINILAB system enables women to understand their hormones, specifically progesterone, which is secreted following ovulation (see Figure 1 on p.7). Progesterone influences many aspects of the body in a cyclic pattern. Along with informing the body about when to ovulate and when to menstruate, progesterone can also affect other aspects of health during the menopausal transition.

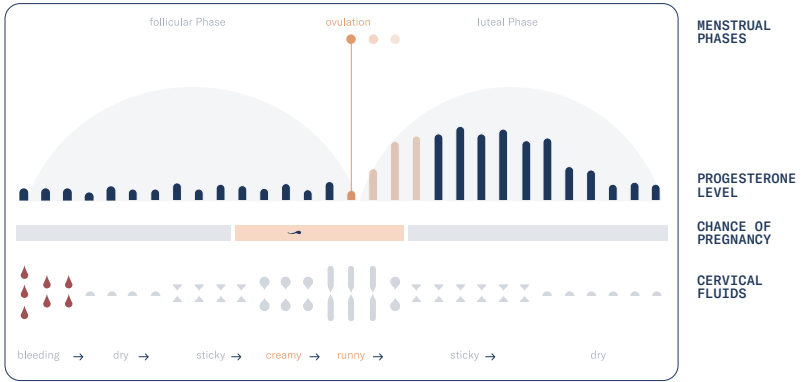


FIGURE 1

CONTRAINDICATIONS: WHEN THE INNE MINILAB SYSTEM SHOULD NOT BE USED

Before using the inne MINILAB system, make sure none of the following statements apply:

You are younger than 18 years of age

You are undergoing hormone treatment such as hormonal contraception, fertility treatments or hormone replacement therapy

You are in or have recently undergone a treatment which may affect your menstrual cycle (this would be mentioned in the patient information leaflet of the treatment)

You suffer from polycystic ovarian syndrome or endometriosis

You are currently or have recently been pregnant (until after the third consecutive period, even if the pregnancy was not carried to term)

You are breastfeeding or have recently breastfed

CAUTIONS

If the pouch is damaged, the inne STRIP cannot be used. Please use another one.

Make sure to not bite or suck the collector.

Make sure there is no blood on the collector pad.

Make sure not to touch the collector pad with your fingers during the activation process.

The inne STRIP needs to be inserted into the inne READER immediately after activation. See p.24.

Do not take the inne STRIP out of the inne READER while the measurement is in progress.

Do not consume caffeine or alcohol for 30 minutes prior to taking a test.

PRECAUTIONS

For in vitro diagnostic use

Not for internal use

For self-testing at home

Keep out of the reach of children

Read the SYSTEM MANUAL carefully before performing the test

Do not use the inne STRIP after the expiration date printed on the pouch

Do not use the inne STRIP if the pouch is punctured or damaged

Use the inne STRIP immediately after removing it from the pouch

Pay attention to collection time and procedure of activation of the inne STRIP

The inne STRIP cannot be used if blood is detected on the inne STRIP as it interferes with the result

The inne STRIP is for single-use only and cannot be reused

The inne STRIPs can only be read by the inne READER

The inne READER only works with original inne STRIPs

Test results may vary for different individuals

Use the test only for the purpose described in the SYSTEM MANUAL

Do not make any decision of medical relevance without first consulting the appropriate healthcare professional

2. The inne MINILAB – Principles of the test

The inne MINILAB is based on measuring progesterone in saliva samples with a lateral flow assay (the inne STRIP) which is further analyzed by the inne READER.

The rise of progesterone always occurs after ovulation has happened and characterizes the beginning of the luteal phase of the menstrual cycle. A sustained elevation in the salivary progesterone is measurable for at least three consecutive days.

TEST PROCEDURE

For the saliva sample collection, please refer to p.20 Upon sample collection and strip activation, the saliva fluid migrates through the capillary bed and initiates the reaction. The test result is displayed by a Test Line and a Control Line. For a competitive assay, the Test Line (TL) will show as a full colored line when the progesterone in the saliva sample is below the limit of detection. A colored line for the Control Line (CL) will demonstrate the test's validity.

CONTROL PROCEDURE

The inne MINILAB does not require the user to do any additional controls or use calibrators to assure the accuracy of the test. Therefore, no controls and calibrators are provided.

BIOLOGICAL REFERENCE RANGE

Not applicable as no quantitative results are provided to the user.

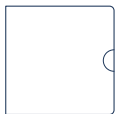
PRINCIPLES OF PROCEDURE

The inne STRIP is based on the lateral flow immunoassay technology. A sample is added to the sample pad, and the treated sample migrates to the conjugate pad, where dried mobile conjugate particles are present. The particle can typically be colloidal gold, or colored, or fluorescent latex particles. This particle has been conjugated to one of the specific biological components of the assay, usually an antibody specifically directed towards the analyte. The sample re-mobilizes the dried conjugate, and the analyte in the sample interacts with the conjugate as both migrate into the next section of the strip, which is the reaction matrix. This control line typically comprises a species-specific anti-immunoglobulin antibody, specific for the antibody in the particulate conjugate [1].

3. Components of the inne MINILAB system

COMPONENTS OF 'THE READER' BOX

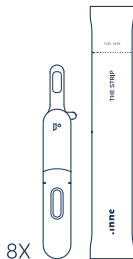
The inne READER box includes the following components. If something is missing, please contact support@myphenology.com.



- Quick Guide
- inne READER
- USB-C Cable

COMPONENTS OF 'THE STRIPS' BOX

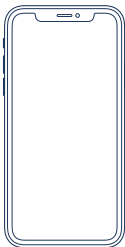
The inne STRIP box includes the following components. If something is missing, please contact support@myphenology.com.



- 8 inne STRIPs in single pouches

ADDITIONAL EQUIPMENT REQUIRED

A mobile device is required to install the Phenology APP and connect to the inne READER.



Mobile device operating system requirements

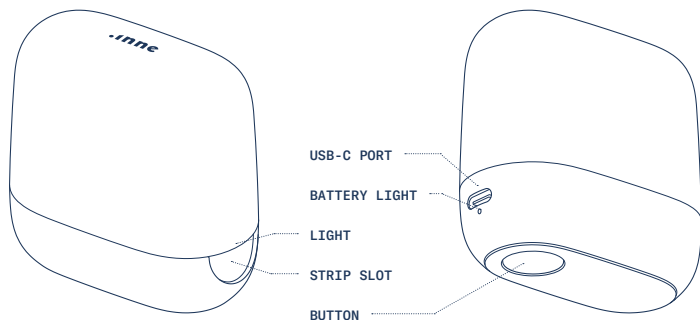
→ iOS 14 or later

→ Android 9.0 or later










Please download the free Phenology APP from the Apple App Store or Google Play Store.

INNE READER

The inne READER is designed to be a perfect travel companion with its compact form and the ability to connect to your mobile device via Bluetooth.



USER INTERFACE (UI) LIGHT

White pulsing		Reading in progress - do not take out the inne STRIP!
White solid		Reading completed successfully
Red solid		Measurement error: the inne READER has encountered an error while analysing your reading or the battery is too low. For more information, see p.31.
Green blinking		Unable to send the reading to the Phenology APP - caused by a connection error. Make sure the inne READER is connected via Bluetooth and then open the Phenology APP to retrieve data. See how to retrieve data from the inne READER on p.32
Blue blinking		Searching for Bluetooth connection The inne READER is searching for an available Bluetooth connection.
Blue solid		Bluetooth connected The inne READER has established a Bluetooth connection to the Phenology APP.
Yellow blinking		Setup mode: searching for connection The inne READER is trying to establish a connection to the Phenology APP.
Yellow solid		Setup mode: connected The inne READER has established a connection to the Phenology APP. To exit from this mode, wait until the light has turned off.
Yellow pulsing		Setup mode: inne READER software update in progress. Do not press the inne READER button or insert an inne STRIP during this process.






STRIP SLOT

Slot for inne STRIP	Insert the activated inne STRIP (p.22) by placing the window side (p.17) inside the STRIP SLOT until you hear it click into place.
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BUTTON

Short Press	Wake up: inne READER attempts to send data
3-Second press	Setup mode: start the following actions from the Phenology APP → unlink the inne READER from the account by following the on-screen instructions in the Phenology APP → update the inne READER firmware by following the on-screen instructions in the Phenology APP
10-Second press	Reset: inne READER will revert to factory default settings

BATTERY LIGHT

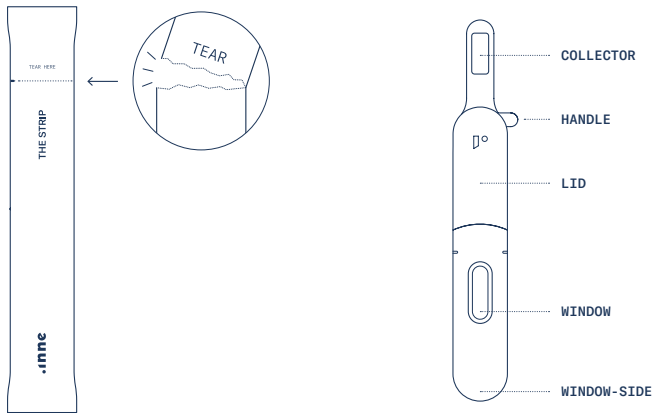
Green Solid		On - battery sufficiently charged
Yellow Solid		On - battery status low (below 20%)
Red Solid		On - battery status critically low (below 10%). The inne READER cannot measure an inne STRIP due to insufficient battery level
Red blinking		Charging - battery level critically low (below 10%). Wait until battery light turns yellow (above 10%) to measure an inne STRIP
Yellow blinking		Charging - battery level above 10%

USB-C PORT

Battery charging port	Connect a USB-C cable to this USB-C-port, and connect the other end of the cable to a power adapter or computer.
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INNE STRIP

The inne STRIP is designed for single-use only. Each inne STRIP is packaged in a pouch.



NAME	DESCRIPTION	INSTRUCTION
Collector	The collector holds a collector pad to retrieve a saliva sample.	Use the collector to collect a saliva sample by holding it in your mouth for 30 seconds. See more details p.20 (Collect).
Handle	The handle is used to fold the collector before activating the inne STRIP.	Use the handle to fold in the collector after you have collected a sample. See more details on p.22 (Activate).
Lid	The lid starts the activation of the inne STRIP by releasing the saliva.	Open the lid before folding in the collector and close it back afterwards to activate the inne STRIP. See more details on p.22 (Activate).
Window	The window is used by the inne READER to analyze the progesterone concentration in your saliva and verify it against the control line.	Make sure the inne STRIP window is clean and is never covered by anything.
Window side	This side of the inne STRIP marks the side which goes into the inne READER.	Only insert activated inne STRIP inside the inne READER. See more details on p.24 (Measure).

4. Preparing for and Running the Test

Follow the instructions in the Phenology APP to connect your inne READER via Bluetooth.

RULES FOR TAKING THE TEST

In order to record accurate progesterone levels, it is important to ensure two key things:

- take the test inside your set daily 4-hour testing window
- no foreign substances have been in your mouth for 30 minutes prior to testing

OR

- rinse your mouth thoroughly with water and wait 10 minutes before taking the test

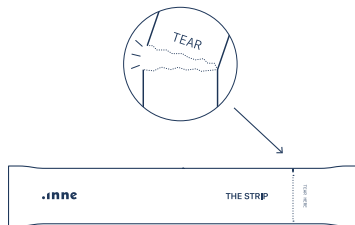
NOTE If you taste blood in your mouth, you can rinse your mouth with clean water and wait for another 10 minutes before doing the test.

COLLECTION OF YOUR SALIVA SAMPLE

In order to collect a saliva sample accurately with an inne STRIP, please follow these steps:

Take a new inne STRIP

Make sure the pouch is intact before using the inne STRIP, then tear the pouch by pinching and pulling to open it.



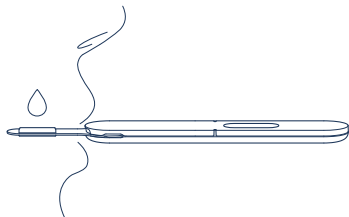
Start the timer

Use the timer in the Phenology APP to collect saliva for 30 seconds or more if needed.

CAUTION If the pouch is damaged, the inne STRIP cannot be used. Please use another one.

Collect saliva

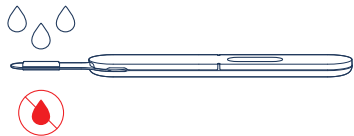
Place the collector in your mouth and move it freely over your tongue until the pad is fully soaked.



CAUTION Make sure to not bite or suck the collector.

Check collected sample

Make sure the collector pad is fully soaked after taking it out of the mouth.



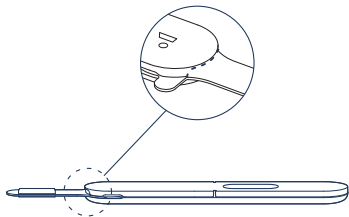
CAUTION Make sure there is no blood on the collector pad.

ACTIVATE

The inne STRIP must be activated after saliva collection in order to develop a test result.

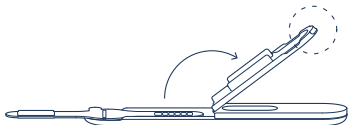
Start here

To open the lid locate the inne symbol on the STRIP.



Open Lid

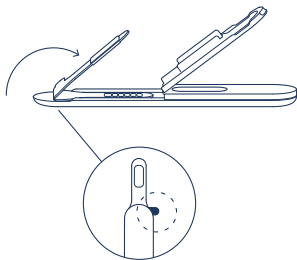
Grab the front of the lid to pull it open as shown below:



CAUTION Make sure not to touch the collector pad with your fingers during the activation process.

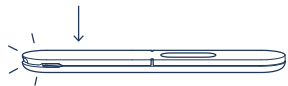
Fold

Use the handle to fold in the collector as seen below:



Activate

Close the lid again and press until it 'clicks', indicating that the inne STRIP is activated.



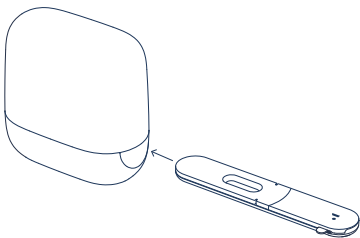
CAUTION The inne STRIP needs to be inserted into the inne READER immediately after activation. See p.24.

MEASUREMENT OF THE INNE STRIP WITH THE INNE READER

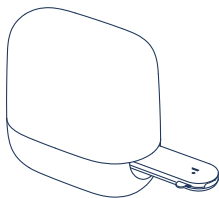
Insert the activated inne STRIP into the inne READER to start measurement of the collected sample.

Start Reading

Reading automatically starts when an inne STRIP is inserted into the inne READER as shown below



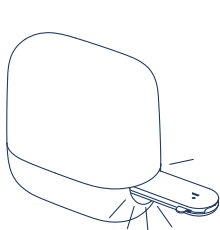
Make sure to insert the window side of the inne STRIP first as shown and check that nothing is covering the strip window.



The inne STRIP needs to be inserted into the inne READER right after it has been activated to ensure accurate results.

Reading in progress

The white pulsating light indicates the reading is in process.



CAUTION Do not take the inne STRIP out of the inne READER while the measurement is in progress.

Reading successful

When the measurement is done, the light should turn solid white. If you encounter any other color light, please see p.15. The result is automatically sent to the Phenology APP when the reader is connected via Bluetooth. After a measurement, the inne READER will go to deep sleep, which is indicated by the light turning off.



TIP To transfer data to the Phenology APP, the inne READER must be connected via Bluetooth and within 30 feet of your mobile phone.

RESULTS

Receive Results

Launch the Phenology APP and follow on-screen instructions to see your results.

Review the results on home screen

- ① Today's progesterone reading shown on the graph.
- ② Today's progesterone trend in context of past days.

DISCARD USED INNE STRIP

The inne STRIPS are made for single-use only. After the measurement has been done, the inne STRIP can be removed from the inne READER and discarded.

5. The inne MINILAB – Performance Characteristics & Technical Specifications

DYNAMIC RANGE

The range of the assay is 100.5 – 1450 pg/mL.

PERFORMANCE CHARACTERISTICS

ANALYTICAL SPECIFICITY

From the different substances evaluated for cross-reactivity and interference, caffeine and alcohol have been identified as possible interferents.

Respecting the saliva collection guidelines as explained in the section RULES (p.19) mitigates the possible interference of caffeine and alcohol.

REPRODUCIBILITY

The variability between production lots is estimated above 20%, so it is important to use inne STRIPS from the same lot throughout a menstrual cycle.

EXPECTED VALUES

The inne MINILAB does not return quantitative progesterone values to the user.

IMPORTANT INFORMATION ABOUT THE INNE READER

→ The inne READER is for indoor use only

→ The equipment is supplied by protected and limited USB-C in compliance to IEC 61010-1 Limited-Energy- Circuit (LEC) or IEC 60950-1 Limited Power Supply (LPS)

Rated 3.5 V  4.4 V max.

Inout 4.75 V  5.25 V max.

4w

→ inne READER dimensions:

Height: 67mm (2.637in)

Width: 38mm (1.46in)

Length: 68mm (2.67in)

Weight: 86g (3.03oz)

STORAGE AND STABILITY OF THE INNE STRIP

Store at 60°-85°F

Stable in the sealed pouch up to the expiration date printed on the pouch

Keep away from direct sunlight, moisture and heat and do not freeze.

6. Maintenance – Troubleshooting

The troubleshooting guide in this chapter is applicable to both the inne READER and the Phenology APP.

The described troubleshooting is only for problems which can be solved by you, the user. If any other problems or defects occur with the inne READER, you should immediately contact customer care (see p.33) and ship the inne READER to the manufacturer for servicing.

There is no maintenance or service procedure to be performed by you, the user.

CLEANING

Cleaning of the inne READER is not recommended - if you want to clean the outer shell, you must use a dry cloth and no chemical detergents. If you have any questions reach out to support@myphenology.com.

I HAVE MISSED MY 4-HOUR TESTING WINDOW

If you have missed taking your reading within the 4-hour testing window, you cannot take a measurement for that day.

I FORGOT TO ACTIVATE THE INNE STRIP BEFORE STARTING A READING

If you started your reading before activating your inne STRIP, please follow the steps below.

- Take out the inne STRIP from the inne READER.
- Open a new inne STRIP and follow all the steps under Collect (p.20) and Activate (p.22) to take a new measurement.

MY INNE READER IS SHOWING A RED STATIC LIGHT

If the inne READER shows a solid red light, it means the device has encountered an error. The error could either be a too low battery level or an error when analyzing your saliva sample. In order to identify the error type, please follow the steps below.

1. Check the inne READER's battery level: short press the button on the inne READER and check the battery light of the inne READER.

→ RED BATTERY LIGHT or NO BATTERY LIGHT: Battery level is too low to take a measurement.

STEPS: Connect the inne READER to a charger and wait until the battery light changes from red to yellow. Then take a new inne STRIP and repeat the progesterone measurement.

→ YELLOW / GREEN BATTERY LIGHT:

Battery level is sufficient to do a reading. There is a problem with the collected sample or the inne STRIP.

STEPS: Repeat the test with a new inne STRIP to get the progesterone reading. Follow all the steps under Collect (p.20) and Activate (p.22) to take a new measurement.

RED BLINKING LIGHT

If the inne READER shows you a blinking red light and goes off afterwards, it means that the inne READER has encountered a system error. Please contact customer service by sending an email to support@myphenology.com.

MY READINGS HAVE NOT SYNCHRONIZED WITH MY PHENOLOGY APP

If you have done your daily saliva test and the Phenology APP does not display your readings, short-press the inne READER button. If the inne READER shows a green light, it means that it has stored unsynchronized measurements due to a lack of connection to your mobile device. If this happens, make sure the inne READER is connected via Bluetooth and then open the Phenology APP to retrieve data.

DATA

To transfer unsynchronized results make sure the mobile device is within reach, that Bluetooth connection is enabled and the Phenology APP is launched when pressing the button on the inne READER.

The inne READER sends the results automatically via Bluetooth to the Phenology APP. The inne READER has the capacity to store the 10 most recent measurements.

When the inne READER has over 10 unsynchronized measurements in memory, it will overwrite the oldest with the latest when a new measurement is taken.

6. Maintenance – General Information

READER REPAIR

Your inne READER contains no user-serviceable parts. Do not attempt to open or disassemble your inne READER or remove, crush, or puncture the battery in your inne READER, expose it to high temperatures or liquids. Disassembling your inne READER may damage it or cause injury to you.

WARRANTY INFORMATION

Feral GmbH warrants the inne READER, and only the inne READER, against defects in materials and workmanship under normal use for a period of three years from the date of purchase by the original purchaser. Defects discovered within the warranty period should be reported to Feral GmbH. Feral GmbH reserves the right to a period of investigation to establish the cause of the defect and may exercise its discretion in determining whether or not to replace free of charge. This warranty does not cover cosmetic deterioration or damage caused by general wear and tear, physical or natural destruction, accident, misuse, neglect or other external causes. Any attempt to take the READER apart will invalidate this warranty. Any warranty claims must be supported with reasonable evidence, including proof of date of purchase, alongside these warranty

conditions. In the event that Feral decides to provide a replacement, any replacement will not extend the life of this warranty.

CUSTOMER CARE

If you have any questions or require assistance with your inne READER or STRIPS, or if you want to share feedback or complaints about these devices, please contact:

→ Via email
support@myphenology.com

→ Via post
Hologram Sciences, Inc.
c/o Feral GmbH
177 Huntington Avenue
Suite 1703, PMB 71158
Boston, MA 02115

Return authorization: All returns must be pre-approved by Feral GmbH before sending the device.

REGIONAL DISPOSAL AND RECYCLING INFORMATION



The symbol above indicates that the inne READER and/or its battery should not be disposed of with household waste. When you decide to dispose of the inne READER and/or its battery, do so in accordance with local environmental laws and guidelines.

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REGULATORY COMPLIANCE INFORMATION

This system was developed in compliance with the following standards:

ISO 13485:2016
IVD Directive 98/79/EC (IVDD)
ISO 14971:2019
IEC 62366-1:2015
IEC 62304:2006+A1:2015
IEC 61010-1:2010
IEC 61010-1-2010/AMD1:2016
IEC 61010-2-101:2018
ISO 18113-1:2009
ISO 18113-4:2009
ISO 18113-5:2009

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LEGEND



Consult the SYSTEM MANUAL for important information such as warnings and precautions



Do not use if package is damaged



Batch code



Do not reuse



Temperature limit to which the inner STRIP can be safely exposed



In vitro diagnostic medical device

MANUFACTURER DETAILS

Designed & manufactured by
Feral GmbH
Skalitzerstrasse 85-86, TR B
10997, Berlin
GERMANY

Distributed by
Hologram Sciences, Inc.
177 Huntington Avenue
Suite 1703, PMB 71158
Boston, MA 02115



