

PROGESTERONE STRIPS MANUAL 1.0

Table of Contents

4 1. INTRODUCTION

- 4 → About inne
- 4 → About this document
- 5 → Intended use
- 6 → Summary and explanation of the test
- 6 → The science behind the inne MINILAB
- 7 → Contraindications
- 8 → Cautions
- 9 → Precautions

10 2. PRINCIPLES OF THE TEST

- 10 → Test procedure
- 10 → Control procedure
- 10 → Biological reference range
- 11 → Principles of procedure

12 3. COMPONENTS OF THE INNE MINILAB SYSTEM

- 12 → Components of the strip box
- 12 → Components of the reader box
- 13 → Additional equipment required
- 14 → inne READER
- 15 → inne STRIP

17 4. PREPARING FOR AND RUNNING THE TEST

- 17 → Rules for taking the test
- 18 → Collection of your saliva sample
- 20 → Activate
- 22 → Measurement of the inne STRIP with the inne READER
- 24 → Results
- 25 → Discard used inne STRIP

26 5. PERFORMANCE CHARACTERISTICS AND TECHNICAL SPECIFICATIONS

- 26 → Dynamic range
- 26 → Analytical specificity
- 26 → Reproducibility
- 26 → Expected values
- 27 → Storage and stability of the inne STRIP

28 6. GENERAL INFORMATION

- 28 → Customer care
- 29 → Regulatory compliance information
- 30 → Bibliographical reference
- 31 → Legend
- 31 → Manufacturer details

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 MANUAL contains important information about how to use the inne progesterone STRIPS with the inne MINILAB system. Read it carefully prior to using the inne MINILAB for the first time and keep it for future reference. The inne progesterone STRIPS must not be used for any purpose other than that which is specified in this document.

INTENDED USE

The inne progesterone STRIPS are intended to be used with the inne READER as part of the inne MINILAB system. 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. 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.

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.22.

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.18. 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.

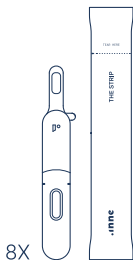
PRINCIPLES OF PROCEDURE

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 STRIPS' BOX

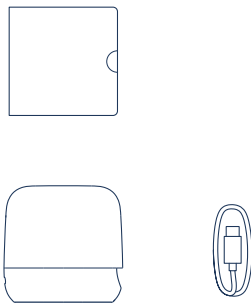
The inne STRIP box includes the following components. If something is missing, please contact support@myphenology.com.



→ 8 inne STRIPs in single pouches

COMPONENTS OF 'THE READER' BOX

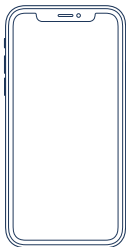
The inne READER box includes the following components. If something is missing, please contact support@myphenology.com.



→ Quick Guide
→ inne READER
→ USB-C Cable

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

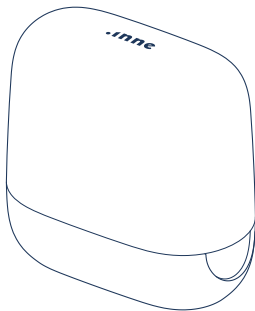
Please download the free Phenology APP from the Apple App Store or Google Play Store.

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.

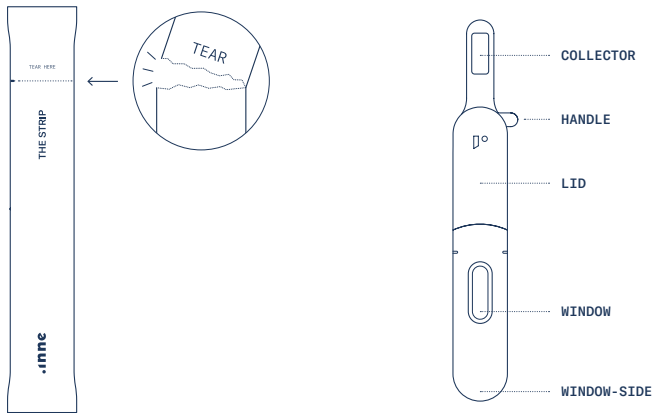
The inne STRIPS can only be used with and read by the inne READER. Refer to the inne SYSTEM MANUAL for detailed information on the operation, maintenance and troubleshooting of the inne READER, and instructions for connecting it to the Phenology APP.

The SYSTEM MANUAL can be downloaded from:
<https://www.myphenology.com/manuals>



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.18 (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.20 (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.20 (Activate).
Window	The window is used by the inne READER to analyze the progesterone concentration in your saliva. 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.22 (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

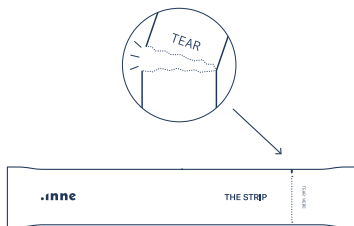
NOTE If you taste blood in your mouth, you can rinse your mouth with clean water and wait for another 10 minutes before doing the test.

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.



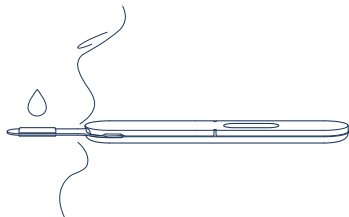
Start the timer

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

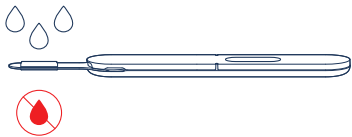
Place the collector in your mouth and move it freely over your tongue until the pad is fully soaked.



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.



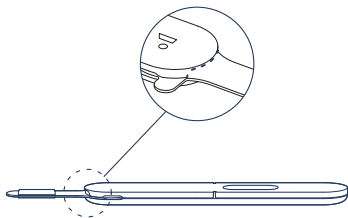
CAUTION Make sure there is no blood on the collector pad.

ACTIVATE

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

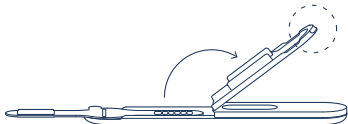
Start here

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



Open Lid

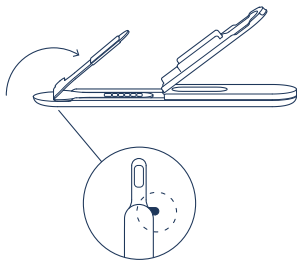
Grab the front of the lid to pull it open as shown below:



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

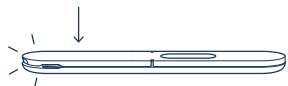
Fold

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.



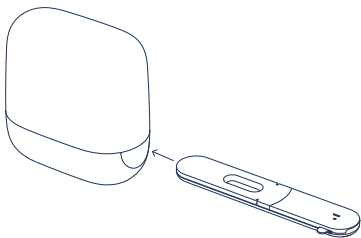
CAUTION The inne STRIP needs to be inserted into the inne READER immediately after activation. See p.22.

MEASUREMENT OF THE INNE STRIP WITH THE INNE READER

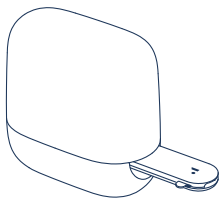
Insert the activated inne STRIP into the inne READER to start measurement of the collected sample.

Start Reading

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



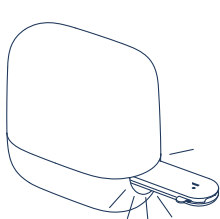
Make sure to insert the window side of the inne STRIP first as shown and check that nothing is covering the strip window.



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 the light is another color, consult p 15. of the SYSTEM MANUAL. 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 STRIPS – 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.17) 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.

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. General Information

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

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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

BIBLIOGRAPHICAL REFERENCE

1. Wong, Raphael, and Harley Tse, eds. Lateral flow immunoassay. Springer Science & Business Media, 2008.
2. Lateral flow (immuno)assay: its strengths, weaknesses, opportunities and threats. A literature survey. Posthuma-Trumpie GA, Korf J, van Amerongen A. Anal Bioanal Chem. 2009 Jan;393(2):569-82. doi: 10.1007/s00216-008-2287-2. Epub 2008 Aug 13.
3. Regulation of the human menstrual cycle. Chabbert Buffet N, Djakoure C, Maitre SC, Bouchard P, Front Neuroendocrinol. 1998 Jul;19(3):151-86. Review.
4. The Effect of Steroid Hormones on Ovarian Follicle Development. Chou CH, Chen MJ., Vitam Horm. 2018;107:155-175. doi: 10.1016/bs.vh.2018.01.013. Epub 2018 Feb 9. Review.
5. Saliva as a medium for investigating intra- and interindividual differences in sex hormone levels in premenopausal women. Gann PH, Giovanazzi S, Van Horn L, Branning A, Chatterton RT Jr., Cancer Epidemiol Biomarkers Prev. 2001 Jan;10(1):59-64.
6. Salivary measurement of episodic progesterone release. O'Rourke MT, Ellison PT., Am J Phys Anthropol. 1990 Mar;81(3):423-8.
7. Salivary steroids and natural variation in human ovarian function. Ellison PT., Ann N Y Acad Sci. 1994 Feb 18;709:287-98. Review. No abstract available.
8. Characteristics of salivary profiles of oestradiol and progesterone in premenopausal women. Chatterton RT Jr, Mateo ET, Hou N, Rademaker AW, Acharya S, Jordan VC, Morrow M., J Endocrinol. 2005 Jul;186(1):77-84.

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.
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