







F-2.2-17 Instructions for Use - HCP USA

Label and Symbols

| | | |
|--|--|---|
| Serial Number = LFC202109  Serial Number = LFC202109 | Manufacturing Date = 2021- 09  Manufacturing Date = 2021-09 | Electronic Instruction for Use  Electronical- IFU |
| Caution / Safety  Caution/ Safety | Information  Information | Producer  Producer |

Levy Health GmbH



Producer

LEVY Health GmbH

Torstraße 223

10115 Berlin



For support and technical advice, please contact the LEVY Care Team at support@levy.health.

Email: support@levy.health

Please include a detailed description of any problems encountered and your contact details.

LEVY Fertility Code - System Requirements



Product Name: LEVY Fertility Code

To use the LEVY Fertility Code, you must be 20 to 51 years old and speak English or Spanish. You need a personal email address and a device with internet access (computer, laptop, smartphone or tablet). Our application is compatible with versions of the following web browsers:

Desktop

1. Google Chrome (latest version)
2. Microsoft Edge (latest two versions)
3. Firefox (latest version and Extended Support Release (ESR))
4. Safari (latest two versions)

The LEVY Fertility Code should be used on a desktop/notebook.

Legal Notices



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Levy Health GmbH reserves the right to change its products and services at any time. These instructions for use may be changed without prior notice. Although the Instructions for Use have been prepared to ensure accurate application of the LEVY Fertility Code, Levy Health GmbH accepts no liability for errors or for any damage arising from the use of this information.

Safety and Regulatory Compliance

The LEVY Fertility Code is a non-Device clinical decision support software (CDSS), exempt from FDA approval under [FDA-2017-D-6569](#).

LEVY Fertility Code - System Warnings and Precautions



- Always make sure that the electronic device you are using is password protected to keep your data safe and that your password cannot fall into unauthorized hands.
- When answering the Medical Questionnaire, it is important that you are in an environment that does not distract you. The blood test you will be recommended by a healthcare practitioner (HCP) in the next step will depend on the answers you give. Incorrect answers can therefore lead to incorrect recommendations and thus to results that do not apply to you.
- Please also follow all instructions when preparing for the blood test, as this may affect the diagnostic results.

Intended Use



LFC is a standalone clinical decision support software intended for the purpose of displaying and analyzing medical and patient information to both health care professionals (HCPs) and their patients. It aggregates a patient's reported medical history to algorithmically present biomarkers to the HCP that are relevant for a diagnosis. Once in vitro diagnostic results are provided to the software, the LFC displays patient data alongside guideline-based reference information for consideration by HCPs.

LFC provides information derived from published clinical guidelines and reference data. The software does not provide a definitive diagnosis, preventive action, or treatment directive. All outputs are intended solely as guideline-based considerations to support clinical decision-making. The final interpretation of the data and any clinical decisions remain the full responsibility of the treating health care professional.

LFC cannot be used to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system.

Intended Users

The LEVY Fertility Code is intended for women aged 20 to 51 who are trying to conceive. Using the LFC medical questionnaire, they can invite their female and male partners to the process.

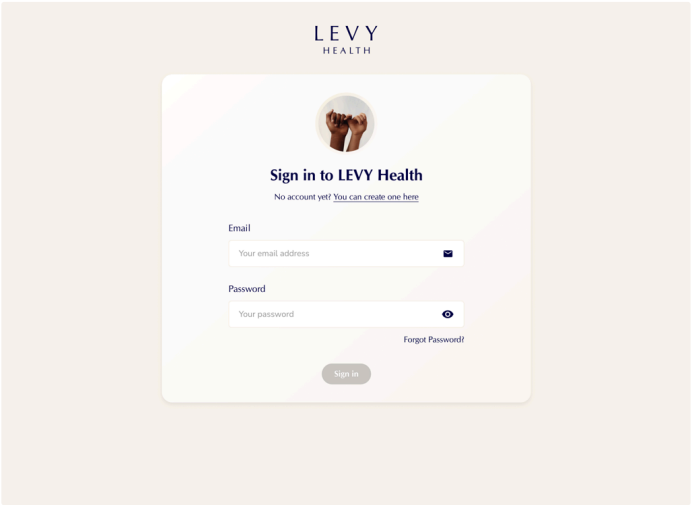
The LEVY Fertility Code is intended for health care professionals with at least a basic education in women's health and endocrinology to support their decision finding.

Device's Performance Characteristics (How to Use LEVY Fertility Code)



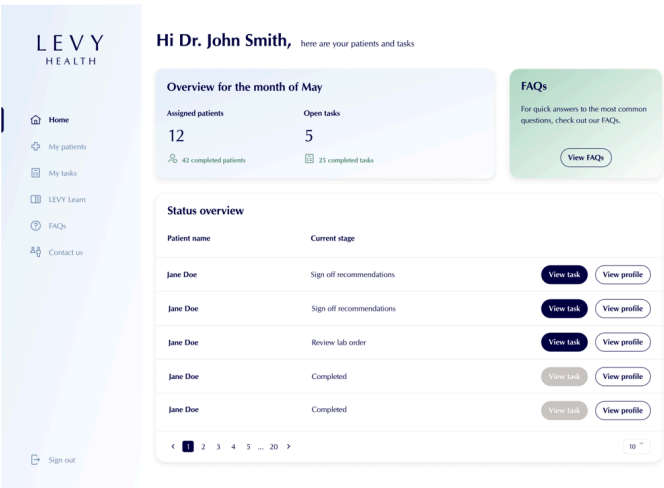
Step 1 - Log-in

Use your email address and password to log in.



Step 2 - Landing page

This page shows a summary of your tasks as well as which stage your patients are currently in.



Step 3 - Patient profile

You can access all the patient data through clicking on “View Profile” in the previous step from “My Patients” on the sidebar. Here you can view all the patient data and their history, Reproductive Health Assessment (RHA) answers, as well as uploaded documents and notes.

LEVY
HEALTH

Home

My patients

My tasks

LEVY Learn

FAQs

Contact Us

Sign out

← My patients / Jane Doe

OverviewPatient timelineHistoryLab resultsRecommendationsDocuments and notes

Jane Doe

+1 (333) 769-4231 | jane.doe@gmail.com | 456 Elm Avenue, Suite 12, Austin, Texas

AGE

BMI

DATE OF BIRTH

USER TYPE

PARTNER

STATUS

36

21

08/22/1988

TTC

John Doe

Results and Recommendations

INSURANCE PROVIDER: [Placeholder]
Member ID: [Placeholder] ; Group ID: [Placeholder]

GENERAL HISTORY

GENERAL

| HEIGHT | WEIGHT | NICOTINE | NUTRITION | IMMUNITY STATUS | LAST DENTAL CHECK | MEDICATION |
|-------------|--------|-------------|-----------|----------------------------|-------------------|------------|
| 5ft 7inches | 131lbs | Not anymore | Vegan | Varicella immunity present | 7/1/2022 | Amlodipin |

MEDICAL HISTORY

| PRE-EXISTING CONDITIONS | OPERATIONS | CURRENT COMPLAINTS |
|---------------------------------|--------------------------------------|---|
| Endometriosis; Internal disease | 1 D&C; Laparoscopy for endometriosis | Acne; Hirsutism; Hair loss/thin hair; Depressive mood |

| INCHUSIOUS DISEASES | FAMILY HISTORY | FOLIC ACID SUPPLEMENTATION |
|---------------------|----------------|----------------------------|
| No | Endometriosis | 1/1/2023 |

GYNECOLOGICAL HISTORY

PREGNANCIES

| TRYING TO CONCEPT | PREGNANCIES | DELIVERY METHOD | PREVIOUS IUT |
|-------------------|----------------------------|-----------------|---|
| 1/1/2023 | 1 Gravidia: 2021 0 Para | N/A | Cycle 1: 8/1/2021, 2 blastocysts, 1 gravida |

| PREVIOUS TREATMENTS | HORMONAL CONTRACEPTION | HOME OVIULATION TESTS |
|---------------------|---------------------------------------|-----------------------|
| Spermegg duration | Yes; 5 - 10 years; Stopped 1 year ago | Performed; 12 months |

CYCLE

LENGTH

Typical cycle length: 30 days; Typical period length: 6-7 days; Intermittent vaginal bleeding present; Irregular; Length: 25-40

| MENTRUAL FLOW | LAST PERIOD | AGE AT MENARCHE |
|------------------|-------------|-----------------|
| Heaviness: Heavy | N/A | 12 |

PERFORMED TESTS

| TUBAL PATENCY TEST | LAST PAP SMEAR | CARRIER SCREENING | PARTNER SEMEN ANALYSIS |
|---------------------------------------|-------------------|---|-------------------------|
| Laparoscopic chromopertubation; (+/-) | 10/1/2023, Normal | Performed; Patient and partner negative | Performed; Not abnormal |

Recommendations

Options supported by evidence-based literature to consider

Diagnosis

Vitamin B12 deficiency

Suspected polycystic ovary syndrome (PCOS)

Ovarian insufficiency with normal FSH, LH, and AMH

Suspected insulin resistance

Further diagnostics

Screening for metabolic syndrome

Vaginal ultrasound

Semen analysis

Advanced Thyroid panel

Glucose metabolism testing

Luteal Phase (Screening for Luteal Phase Deficiency)

Treatment

Folic acid

Nutritional counseling

Vaccination counseling

Biomarkers out of range

Extended Fertility Hormones

Cortisol

20.00 µg/ml

Basic Vitamins

Vitamin B12

120.00 pg/l

Glucose metabolism

HOMA index

3.639 index

Patient files

Lab results

File uploaded: 01/09/2025

Lab order form

File uploaded: 02/05/2024

Patient authorization form

File uploaded: 12/28/2024

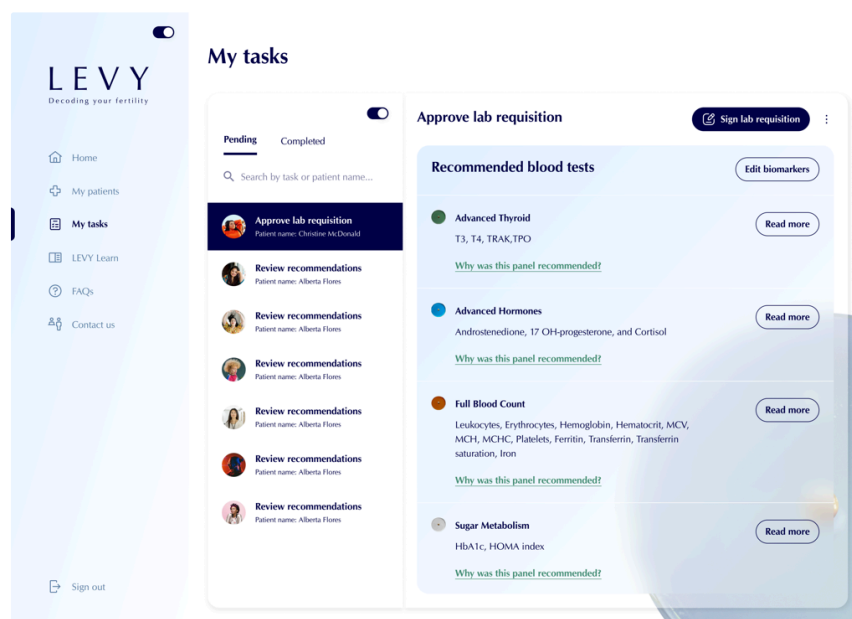
Carrier screening

File uploaded: 11/19/2024

Step 4 - Lab Requisition

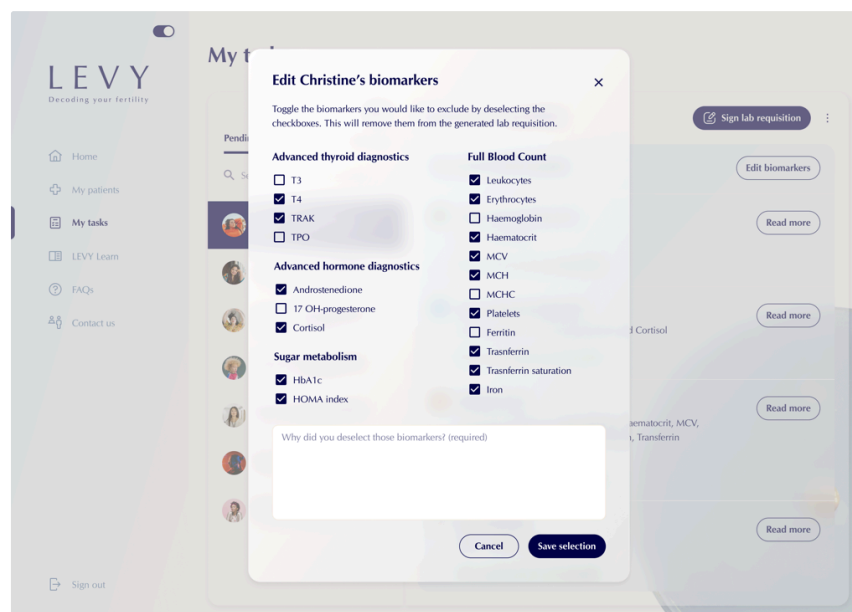
Once the patient completes the Reproductive Health Assessment, you will receive an e-mail informing you about the task of approving the biomarkers that LEVY Fertility Code recommends for the patient. Make sure to review the logic and literature supporting this list of biomarkers.

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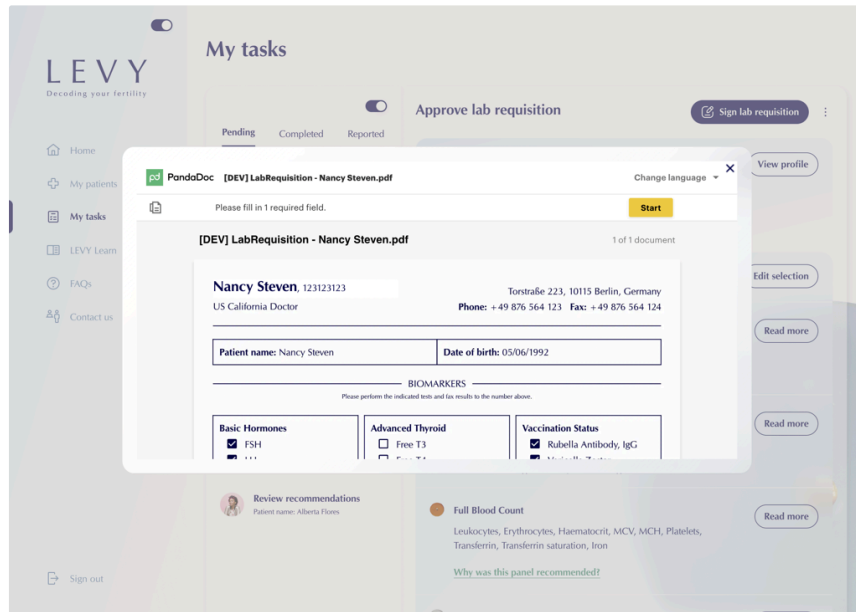
Step 5 - De-select and Add Biomarkers

If you deem a suggested biomarker irrelevant, you are able to delete it. If you think a biomarker should be added, you are able to add it.



Step 6 - Sign Lab Order

Once you have the final list of biomarkers to be tested, please click on sign lab requisition. A process of signature will be triggered. Once signed, the patient receives the lab requisition in their dashboard and will be notified about this via e-mail.

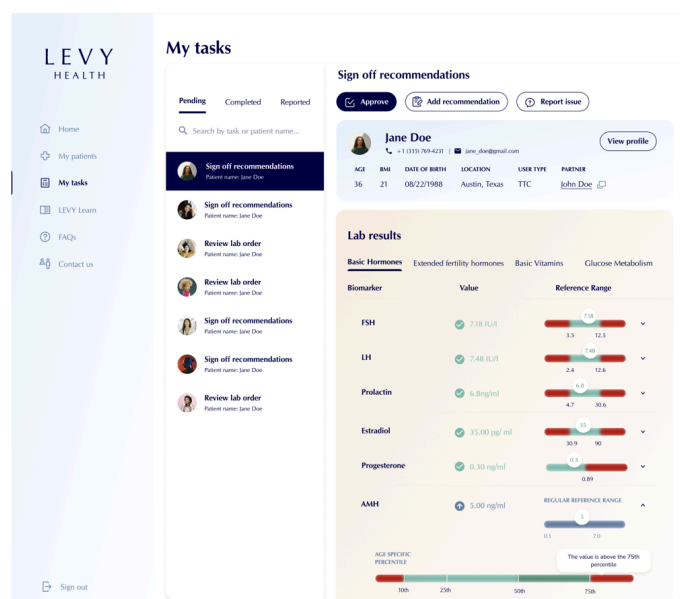


Step 7 - Approve Recommendations

After the lab results are received, the algorithm is automatically triggered. Once the recommendations are ready, you will receive a task of reviewing and approving the recommendations. Often times, several choices are given for you to choose from, e.g. intrauterine insemination vs in-vitro fertilization. Add your choice by clicking “Add recommendation”.

Within the ‘My Patient’ view, under the ‘Recommendations’ tab, each recommendation contains a section titled ‘View the logic based on peer-reviewed literature that supports this recommendation’. This section outlines the specific biomarker results and Reproductive Health Assessment responses that informed the recommendation. In addition, an ‘Evidence & Sources’ icon provides direct access to the peer-reviewed literature supporting the clinical rationale.

Important: The options/recommendations provided by the LFC algorithms are evidence-based and can not be deleted or changed. However, it is your choice if you want to approve of them, choose a certain path over another, or disapprove. Once approved, recommendations will be released for the patient.



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Search by task or patient name...

Sign off recommendations

Patient name: Jane Doe

Sign off recommendations

Patient name: Jane Doe

Review lab order

Patient name: Jane Doe

Review lab order

Patient name: Jane Doe

Sign off recommendations

Patient name: Jane Doe

Sign off recommendations

Patient name: Jane Doe

Review lab order

Patient name: Jane Doe

Sign off recommendations

ApproveAdd recommendationReport issue

Jane Doe

+1 (351) 769-4231 | jane_doe@gmail.com

View profile

| AGE | BMI | DATE OF BIRTH | LOCATION | USER TYPE | PARTNER |
|-----|-----|---------------|---------------|-----------|----------|
| 36 | 21 | 08/22/1988 | Austin, Texas | TTC | John Doe |

Recommendations

Options supported by evidence-based literature to consider

DiagnosisFurther diagnosticsTreatmentDoctor's Recommendation

Suspected polycystic ovary syndrome (PCOS)

PCOS, according to the Rotterdam criteria 2003 (ESHRE/ASRM), is present if 2 of the following 3 criteria are fulfilled: 1. Chronic anovulation (oligo- or amenorrhea) 2. Polycystic ovaries 3. Clinical and/or chemical hyperandrogenism Exclusion of other diseases of the ovary, pituitary gland and adrenal gland If other diseases have been ruled out and 2/3 of the criteria have not been fulfilled (chronic anovulation and

Leave a recommendation for [patient first name]

Start typing here...

Save note

Recommendations

Options supported by evidence-based literature to consider

DiagnosisFurther diagnosticsTreatmentDoctor's Recommendation

Suspected polycystic ovary syndrome (PCOS)

Lack of varicella immunity (chickenpox)

Suspected insulin resistance

Insulin is a hormone that plays an important role in the body's metabolism of sugar. When insulin doesn't work properly, it's called insulin resistance, which can lead to type 2 diabetes.

View the logic based on peer-reviewed literature that supports this recommendation

Related Biomarkers

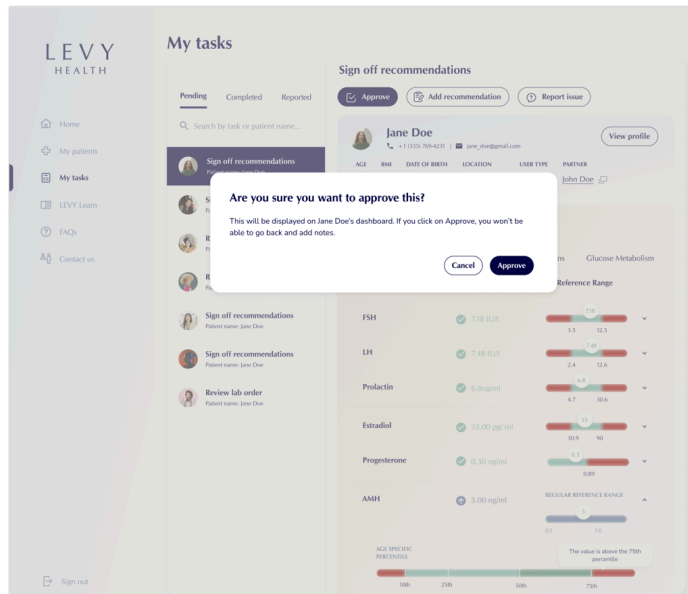
HOMA index3.951 Index

Evidence & Sources

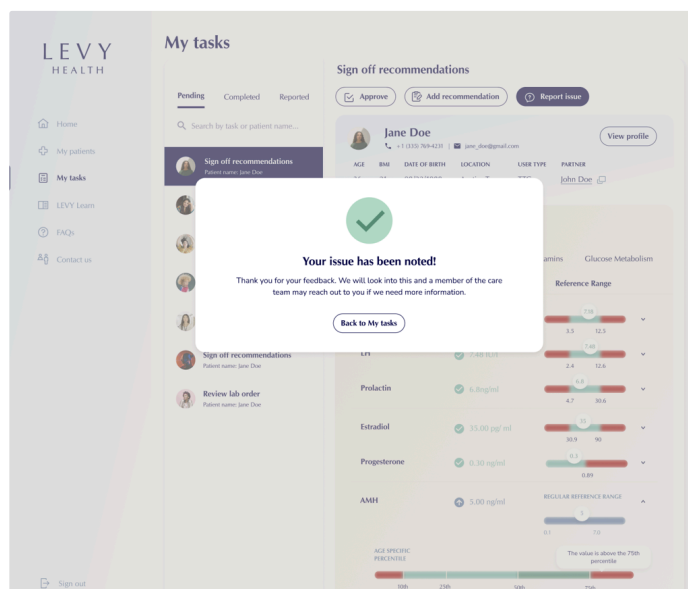
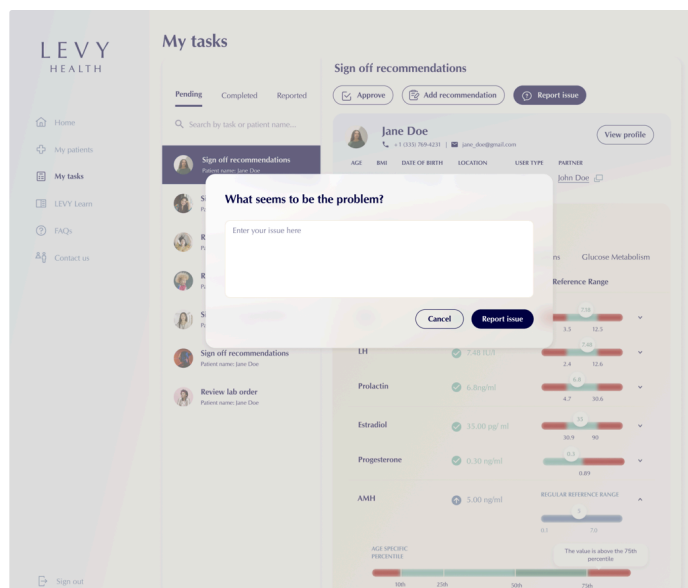
Evidence & Sources

DeFronzo, R. A., et al. Insulin Resistance and Type 2 Diabetes. Endocrine Reviews. 2012 May 1.

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If you have any concerns with the generated recommendations, you can use the 'Report issue' option at the top of the screen. This will notify our support team, who will contact you to discuss further.



LEVY Learn

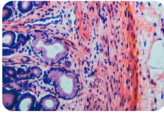
Here we have compiled articles that explain terms that appear in the LEVY Fertility Code. It is divided into three sections:

- Biomarkers
- Diagnoses & Diseases
- Therapy

Diagnoses & Biomarker Lexicon

Search lexicon...

123A B C D E F G H I L M N O P R S T U V




Diagnosis

Adrenal insufficiency

Adrenal insufficiency happens when the adrenal glands don't produce enough steroid hormones. One...

Medically VerifiedLearn More




Diagnosis

Amenorrhea (not getting your period) and fertility

Not getting your period is a condition called amenorrhea. It's important for fertility...

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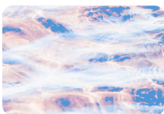


Biomarker

Androstenedione

Androstenedione is a sex hormone that has "masculinising" (androgenic) effects. It belongs to...

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Diagnosis

Anorexia

Anorexia is a type of eating disorder where you severely limit what you...

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Biomarker

Anti-Müllerian hormone (AMH)

The anti-Müllerian hormone (AMH) is produced by the growing eggs in the ovaries...


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For PatientsFor Providers

Search terms, diagnoses etc.

All articlesEgg DonationEgg FreezingFertility 101Fertility StoriesGuideIVF/IVU JourneyLGBTQ+ Family Building


Latest News



Egg Donation


Egg Retrieval Day: What Really Happens, Step by Step

July 14th, 2025 | 5 Minutes




Guide

How to Find the Fertility Clinic That's Right for You



IVF/IVU Journey

11 Ways to Finance IVF: Fertility Loans and Benefits to Explore



Fertility 101

9 Tips on How to Talk to Your Partner About Fertility Treatment

Complaints and Feedback

In case you have any complaint, suggestion or other feedback regarding LEVY Fertility Code, please feel free to let us know. You can find our contact details by clicking on the "Contact" button.

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Phone
(415) 969-1373

Email
support@levy.health

Timing
Monday - Friday | 9AM - 7PM

We'd love to hear from you!

Do you have any questions? Or perhaps ideas for improvement, feedback or compliments? Yes, we'd like to hear them too. Then do not hesitate in reaching out to us. The LEVY Care Team is awaiting you!

Name

Your name

Email

Your email address

Your message

How can we help you?

Send message

Effective Date: 2023-02-20

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