F-2.2-17 Instructions for Use - Patient EN

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Label and Symbols





Levy Health GmbH



LEVY Health GmbH Torstraße 223 10115 Berlin

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

Please include a detailed description of any questions you have and your contact details.

LEVY Fertility Code - System Requirements

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You need to be between the ages of 25-51 and speak English or German to be able to use the LEVY Fertility Code. You also need a personal email address and a device with internet access. Our application is compatible with versions of the following web browsers:

Desktop

- Chrome: Version 100 or later
- Firefox: Version 99 or later
- Edge: Version 100 or later
- Safari: Version 15 or later

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

Legal Notices

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No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording or any information storage or retrieval system, without the written permission of Levy Health GmbH.

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 has been extensively tested and meets all of the following applicable regulatory requirements:

CE

The CE mark indicates that the manufacturer ensures that the product complies with the essential requirements of the European Directive on in vitro diagnostic medical devices 98/79/EC.

LEVY Fertility Code - System Warnings and Precautions



- For use in in vitro diagnostics
- Always make sure that the electronic device you are using is password protected to keep your data safe and that your password remains private and secure.
- Make sure to fill out the Reproductive Health Assessment in an environment where you have no distractions. The answers you give determine which blood tests you are recommended in the next step, so incorrect answers can lead to recommendations and results that don't apply to you.
- There's a small chance that software errors in the LEVY Fertility Code can lead to an incorrect result. All results are checked by our doctors and will be discussed with you.
- Please follow all of the instructions we provide when preparing for the blood test, as this may affect the results. We have no control over how quickly your chosen laboratory evaluates your blood test results and sends them back to us, so there may be a slight delay in you receiving your results. In any case, we make every effort to avoid delays and are in close contact with our partner laboratories.

IVDR (In Vitro Diagnostic Device)

Product Name: LEVY Fertility Code

Intended Use



LEVY Fertility Code is a standalone clinical decision support software that uses input from in vitro diagnostic devices and patient medical history to aid physicians with the diagnosis of female sterility medical conditions.

Contraindications



The LFC should not be used if the user has been using hormonal contraception within the past three months, has started or stopped using hormonal contraception within the past three months, has had a miscarriage in the past eight weeks, or has given birth in the last eight weeks.

Intended User

The LEVY Fertility Code is intended for women with infertility conditions from 25 years to 51 years of age.

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

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Step 1 - Registration

The first step is to create an account with a strong password (at least 8 characters) and personal email address. Make sure that no one else can access your login information.

	L E	ng your fertility			DE EN
1. What's your name!					
	Hi, I'm Silvia f Before we can start decc Let's get started! Tell me, rest was War for name LACARI TO THE INSIANO, Con back Unit of the Instance.	from LEVY Health uding your fertility, we need som what's your name and where an 'Worrlast name Coordinate of the State of the State 'Worrlast name 'Sign: In now!	e contact information from yo e you from? counter Your country	X.	

Step 2 - Login

Use your email address and password to log in to your LEVY account.



Step 3 - Reproductive Health Assessment

After setting up your account, you'll be invited to begin the medical questionnaire.

- To begin the questionnaire, press the "Start" button.
- To view the FAQ, press the "View" button.
- To view the instructions for use, press the "View" button.



While filling out the Reproductive Health Assessment, you will be asked to upload any relevant medical documents from blood tests, operations, etc. that can help us make a diagnosis. Your answers will be saved automatically and you can return to the questionnaire later if you need to.

Step 4 - LEVY Care Team Call

After finishing the questionnaire, you'll be invited to schedule an optional call with someone from the LEVY Care Team. Available days and times are shown in blue, and the appointment you have chosen will be in dark blue.

Please log into your LEVY account in time for the call.

oding your fertility	Reproductive health assessment Check-in call	Blood diagnostics	Nagnostic recommendations
Home	Any questions? We're here to he	lp!	📞 +49 1567 8393 502 🛛 🖂 care@levy.h
My health profile	Now we know which tests you need for us to	make a diagnosis on why you haven't been	able to
LEVY Lounge	conceive. Book a free care team call and we'l	walk you through everything you need to	know! Book a call now
LEVY Learn			
FAQs	← Go back		
Contact us	Time to get tested!		
	Based on what you've told us, we created a custo and choose how you'd like to move forward.	m list of biomarkers you should test. Now y	rou can learn more about the blood panels
	(L) Purchase the LEVY Fertility Code		€ 399.0
	To continue your fertility analysis, it's required	to buy access to the LEVY Fertility Code. 1	With your purchase,
	you'll have care support, the Basic Hormone results, plus aa personalized treatment plan to	Panel test, and a 1:1 doctor's consultation to improve your chances of a healthy pregna	o understand your ncy.
	Here are the blood tests we reco	ommend for you	
	These are the biomarkers we suggest for you to te you don't wish to test these, click on Keep Going	st so that our doctors can make a complete	fertility diagnosis. This is optional, but recommended.
Sign out	✓		
	Advanced thyroid diagnostics	Advanced hormone diagnostic	s 😑 Full Blood Count
	Advanced thyroid diagnostics One or more of your answers in the Reproductive Health Assessment	Advanced hormone diagnostic One or more of your answers in the Reproductive Health Assessment	s Full Blood Count Your symptoms may indicate an infection or bleeding disorder. This
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Step 5 - Lab Recommendation

A LEVY Care Team member will explain the biomarkers that the LEVY Fertility Code recommends for you. He/she will help you choose a laboratory and the right time for a blood draw (usually this is on cycle day 2-5).

Additional information on the biomarkers recommended for testing can be found by clicking on the drop-down arrows in the lab panels.

	Hi Pia, let's check your progress
LEVY Decoding your fertility	tegin Fulli Cles Quenarane Chelar Cal Digense transmistras
ம் Home	Need to re-join your call: for call now Please jun the call sia desktap only!
My Health Profile	Do you want to test more biomarkers?
LEVY Learn	The LPV Fertily Code has and/yed your answers and customised your personal recommended set of biomarkers. Bio-what? Biomarkers are indicators of biological processes and help us getting a proper view on your fertile health.
⑦ FAQs	So what's next? View your recommended blood panel, click and read through the individual biomarkers and understand what needs to be tested. We give you full transparency and involve you in our diagnostic process, so
My Account	Like the chance and learn'
යිලී Contact Us	Basic Hormone Basic Vitamin Vaccination
	Bask Hormone 60.00
	A woman's hormonal balance is a complex system that is controlled by various organs in the body. The function of the organs and the interaction of the hormones they produce is the perequisite for a normally functioning mestitual cycle and thus for pregnancy. If one part of the system is out of balance, the entire system can be disturbed. The Rod more
	Included Homarkers FSH, LH, Anti-Mulletain-Hormone, TSH, Prolactin, Estituidol, Progesterone, Testosterone, DHEAS, SHBG, FAI (Bree: Androgen index)
	5 Ande Vitania Subtotal: €87.09 (51.40
⇒ Sign out	Vitamis being to the so-called micronartients and are essential nutrients. This means that they are vitamis by any vitamis by the body totel (exception is vitamis D) and must be supplied through ford. Utening have a variable of different functions in the body Totel (exception is vitamis D) and must be supplied through

Step 6 - Choosing a Lab

Now you can pick a lab for your blood test. We have identified several laboratories which meet our requirements that you can choose for your blood draw. A member of the LEVY Care team will help you find the nearest laboratory during the call (see step 4).

If you know of a laboratory that is even closer for you, you can go to that laboratory to have your blood sample taken and analyzed. The requirements for the lab are:

- All biomarkers personally recommended for you in the LEVY Fertility Code can be analyzed.
- You will receive the lab results in the form of an electronic PDF, with all results displayed with numbers, units and the associated normal ranges.

Important: For most of the laboratories we recommend, it's not necessary to make an appointment.

LEVY Decoding your fortility	Hi Pia, lets check your progress	Dagwate tecommediate Charack Lab
Home My Health Profile LEVY Learn FAQs	Find a lab near you New V1 time to via table ug try out blood drawn. Because the LEVY Ferrily Code is a confider metadorkey, we need whather likular isouits to make diagrosers. And it isou only be guaranteed when a qualified healthcare professional draws your blood.	
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Sign out		e fi

Step 6.1 - Blood Sample - LEVY Partnerlab

If you go to a LEVY partner lab, make sure to download your lab referral, print it out, and bring it with you on the day of your blood test.

You'll get an email informing you as soon as your results are available.



Step 7 - LEVY Doctor's Call

Once your blood test results are available, you can schedule a doctor's appointment. Click on the "Book appointment" button to select a date and time that works for you.



You will see the screen when it's time to join the call. Remember to be on time, otherwise your appointment will be cut short. If you can't make the scheduled time, please let us know at least 24 hours before the appointment is supposed to begin. You can reschedule your appointment free of charge up to 24 hours before your appointment. If you don't show up or change the appointment within the 24 hour period, further charges will apply. You can find these under LEVY Services.

	Hi Pia, let's check your progress	DE EN
LEVY Decoding your fortility	ing it Frails Clerk Gurstanane. Oncler Cal Disprove Reconvendence Choose A.(ch. Dector Constitution	
Home My Health Profile LEVY Learn FAQs	Join your video consultation Your doctor is anating you. Your doctor will go brough your results is deal and dabarate on any questions you may have. Is and just about what we found, but particularly showing your your options & not any questions Khody note, you will get access to the results and recommended ratis taps with further elaboration and in deeph information after your consultation 5 minutes before the starting time. You will be able to join the consultation 5 minutes before the starting time.	
දල my Account	Starling time: 1400, 09.06.1022 Image: 1400, 09.06.1022 John now Please join the call via disktop only! My recommendations In this section you will that the individual results of your blood work per panel and per biomarker. Come result alone is not meesarily meaning/id, much more important is the combination of them al. View my recommendations	
G≁ Sign out		•

Step 8 - Your Results

After your doctor's appointment, you will get to view your lab results. These are divided into two sections:

Your results:

• This shows your blood test results and whether the values are within or outside the normal range.

Your recommendations:

- Here you can see what further steps are recommended for you to continue your fertility journey. The recommendations are divided into three categories:
 - Recommendation to see a medical specialist
 - Further diagnostics
 - Online counseling



Navigation Bars

	Hi Pia, let's check your progress						DE
LEVY Decoding your feetility	Log in	Health Check Questionnaire	Checkin Call	Diagnostic Recommendation	Choose A Lab	Doctor Consultation	

Home: Takes you to where you were last in the LEVY Fertility Code.

My Health Profile

When all the steps in the horizontal display have been completed, you can view your health profile here. You have access to the following:

- Reproductive Health Assessment
- My documents
- My results

Reproductive Health Assessment

Here you can check your answers to the questionnaire and make changes if necessary. It's only possible to change your answers before your call with the LEVY Care Team.

My Documents

Here you can view the documents you uploaded while answering the questionnaire. If you forgot to upload a document, you can do so here.

Important note: All documents must be uploaded at least 24 hours before your doctor's appointment.

My Results

You can see your test results by clicking on the menu item My Labwork and My Recommendations. These are first available for you to view when your doctor approved everything.

LEVY Lounge

LEVY Lounge includes additional services that LEVY Health GmbH offers you after completing the LEVY Fertility Code. These include fertility coaching, nutritional counseling, preparation for artificial insemination and other doctor's appointments.

Please note that these services are not included in the LEVY Fertility Code and are charged separately.

LEVY Learn

Here you can find further information and definitions of terms that appear in the LEVY Fertility Code. It's divided into three sections:

- Biomarkers
- Diagnoses & Diseases

• Therapy



Complaints and Feedback



If you'd like to share any feedback, suggestions, or complaints about your experience with the LEVY Fertility Code, we're all ears! Feel free to reach out to us by clicking the "Contact" button.



Effective Date: 2023-02-20