



ALIFERT
science for the next generation

ALIFERT TEST USER GUIDE

1.	General information.....	2
2.	Users, indications and contraindications.....	2
2.1.	users.....	2
2.2.	Patients.....	2
2.3.	Indications	2
2.4.	Contra-indications.....	2
3.	Precautions for use - Requirements.....	2
4.	Instructions for use.....	3
5.	Clinical benefits	3
6.	Performances.....	3
7.	Side effets	3
8.	Warnings	4
9.	Update and maintenance	4
10.	Cybersecurity	4
11.	Storage precautions	4
12.	Conservation precautions	4
13.	Disposal of the Medical Device	4
14.	Contact.....	5
15.	Identification.....	5



1. General information

The ALIFERT Test is a diagnostic tool for assessing the impact of metabolic and nutritional factors on infertility risk for couples.

It is intended for all types of patients wishing to have children.

The tool is based on an algorithm that produces a score according to clinical data and biomarker values obtained from patient blood tests.

It features an interface for patients to help them manage and track the evolution of their health data and scores. The interface is intuitive, easy to use and easy to read.

2. Users, indications and contraindications

2.1. users

- Adults

2.2. Patients

- Adults wishing to have children

2.3. Indications

- Evaluation and follow-up of interventions addressing metabolic and/or nutritional risk factors for fertility
- Support for diagnosis and therapeutic decisions by healthcare professionals

2.4. Contra-indications

- No contra-indications

3. Precautions for use - Requirements

In order to use the ALIFERT Test, you need to connect to the ALIFERT web application (<https://alifert.com/en/app/login>), with the following requirements:

- A secure Internet connection (mobile network, private wifi network, private Internet network),
- Internet browsers: Chrome 113+, Firefox 113+, Edge 113+ and Safari 16+,
- An authentic medical profile: the completeness and accuracy of the medical profile impacts the device's performance.

4. Instructions for use

- Create a user account on the online platform: <https://alifert.com/en/app/login>
- Select the ALIFERT Test corresponding to your situation (couple, man, woman...)
- Download the blood test request form
- Take your blood test in the laboratory of your choice
- Enter your blood test results and anthropometric parameters
- Get your score

You can download your test results from the "My Results" menu: <https://alifert.com/en/app/results>

5. Clinical benefits

The ALIFERT Test is a Medical Device software designed to:

- Assess the impact of metabolic and nutritional factors on patients' risk of infertility,
- Improve patients' understanding of this impact,
- Assist healthcare professionals in diagnosing, advising, prescribing and monitoring appropriate treatments for specific cases.

6. Performances

In order to meet the expected benefits, the ALIFERT Test is based on:

- Accuracy of clinical data provided by the user,
- Accuracy in calculating the blood concentration of the biomarkers required to calculate the score.

7. Side effects

The ALIFERT Test does not generate any side effects, given the informative nature of the solution.

However, any serious incident occurring in connection with the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

France: ANSM.

For further information: <https://ansm.sante.fr/documents/reference/declarer-un-effet-indesirable>

Caution: Medicines can have side effects. These effects are the responsibility of the manufacturer responsible for the medication.

For any complaints or malfunctions, please contact us via our customer service portal at the following address: <https://alifert.com/en/contact-us>

8. Warnings



The ALIFERT Test does not substitute for a medical consultation with a doctor or any other healthcare professional.

The device must not be used by minors (under 18).

To avoid any data entry errors, we recommend using the device in a quiet environment away from any source of distraction.

The device should be used with a stable internet connection to avoid unexpected downtime, and an up-to-date internet browser.

The ALIFERT Test is an indicator; under no circumstances does it recommend the treatment to be adopted.

Failure to comply with these warnings and indications constitutes a misuse of the Medical Device.

9. Update and maintenance

To ensure the correct operation and performance of the ALIFERT Test, please update your web browser as soon as a new version is available.

The expiration date of the medical device is 1 year from the date of purchase.

10. Cybersecurity

Please use a unique alphanumeric password of at least eight characters and including at least one special character when registering.

Sharing your login information is at your discretion.

Please do not use the device on unsecured public wifi.

11. Storage precautions

No particular storage precautions

12. Conservation precautions

No particular conservation precautions

13. Disposal of the Medical Device

To delete the account from the web application, please follow these steps:

1. Log in to the application
2. Go to your profile by clicking on the user icon
3. Click on Delete my user account

14. Contact

For further information or inquiries, please contact us via our customer support portal at the following address : <https://alifert.com/en/contact-us>

15. Identification



Name or company name: ALIFERT SAS
Head office address: 51, rue du Rocher
Postal Code: 75008
City: Paris
Country: France



Classe I Medical Device
CE Marking on 13.07.2023
Medical Device Version: v1.0.0