

LabTest Checker

by Labplus®

Medical software supporting diagnostics and preventive
healthcare using artificial intelligence solutions

User Manual

version 3.1



Program LabTest Checker®

Version 2.15.0

Medical device class IIa

Basic UDI-DI: 5904815650LTCII9V

SRN: PL-MF-000048940



(01)05904815650014(8012)2.12.X/1.7.X

Manual Version 3.1

Release date 18.06.2026 r.



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2443



Software LabTest Checker by Labplus® is a medical device that meets the requirements of Regulation (EU) 2017/745 of 5 April 2017 on medical devices.



Please read the user manual before using this product.



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Introduction

LabTest Checker by Labplus® (LTC) is a class IIa medical device standalone software that analyzes laboratory test data and medical history interview using advanced artificial intelligence algorithms, allowing it to predict the risk of disease or condition. Patients access the software through the website or the mobile application of a medical partner (e.g., clinic, laboratory). LTC provides patients who have voluntarily decided to use the software functionality with clinically validated information supporting them in making diagnostic and prophylactic decisions.

How it works?

LabTest Checker by Labplus® works in three simple steps:

1. Analyzes your laboratory test results
2. Conducts a personalized medical interview by asking questions tailored to your results
3. Provides a clear interpretation along with specific recommendations

Our solution was created by a team of Polish specialist physicians and scientists in collaboration with a leading medical university in Poland.

Clinical Benefits

Our software was created to:

- Help you understand the significance of results before visiting a doctor
- Indicate which abnormalities require urgent consultation
- Provide personalized recommendations for next steps

Clinical Reliability

The safety and performance of the LabTest Checker® system are monitored through a continuous clinical validation process. To maintain high clinical standards, our knowledge base is regularly updated in accordance with the latest medical practices and guidelines from recognized scientific societies, ensuring ongoing compliance with the current state of medical knowledge.

Clinical Safety

Safety is our highest priority. This area measures how effectively the system protects the patient from underestimating the urgency of their health condition.

- Patient Triage Safety: We maintain a level of $\geq 95.0\%$. This index confirms that the system correctly identifies cases that require intervention.
- Sensitivity in detecting life-threatening conditions: We maintain a threshold of $\geq 95.0\%$
- Sensitivity in detecting urgent conditions: We maintain a threshold of $\geq 95.0\%$.

Clinical Performance

This area measures the accuracy of the system's recommendations and how well the information is communicated to the user.

- Patient Triage Accuracy: The system aims for an accuracy level of $\geq 90.0\%$ in matching its recommendations with the assessment of medical experts.

Usability metrics

- Intelligibility of Interpretation: We ensure that at least 78.0% of users find the generated interpretations clear and easy to understand.
- Usefulness of Recommendations: We maintain a threshold of $\geq 78.0\%$ for the practical utility of the advice provided to the patient.

Labplus Scientific Council

The highest medical and scientific level of the Labplus system is ensured by our Scientific Council, composed of leading experts in their respective fields. The Council's core responsibility is to ensure the clinical methodologies used in the system align with current, globally accepted medical standards and practices.

Composition of the Scientific Council:

- Prof. dr. Grzegorz Mazur
- Prof. dr. Aleksandra Butrym
- Prof. dr. Rafał Poręba

Intended Purpose

The LTC system is intended for patients who have undergone laboratory tests and who, independently, prior to a doctor's visit, wish to familiarize themselves with their results. The system aims to help patients understand the significance of these results and support them in making further diagnostic and prophylactic decisions.

The system analyzes laboratory test data and medical history using advanced artificial intelligence algorithms to perform its key medical functions. These functions are:

- Analysis and interpretation of laboratory test results (according to the list of supported tests) in the context of the patient's medical history.
- Identification of clinically significant deviations requiring medical consultation
- Screening or identification of early symptoms of a disease or condition.
- Assistance in guiding further diagnostics based on the analysis of results.
- Support for the diagnostic and prophylactic process.

Through these functions, the system provides the patient with clinically validated information, including:

- Assessment of the urgency for contacting a doctor
- Recommendations for performing supplementary tests.
- Recommendations concerning further diagnostic and prophylactic management.

The LTC system is a **supportive tool**. As stated in the device warnings, the system does not replace a medical consultation and cannot be used as the sole diagnostic tool.

Intended Patient Population

The LTC system is intended for the following patient population:

- Adults (18+ years of age),
- Patients who have undergone laboratory tests,
- The product can be used without restrictions regarding gender or ethnic groups.

This device is **not** intended for the following populations:

- Age below 18 years
- Pregnancy (due to the specifics of interpreting results during this period and the lack of clinical validation for this group)



Intended User

The intended user of the LTC system is the patient themselves (a lay person) whose laboratory test results are being interpreted.

The user interacts directly with the software via the web or mobile interface. The user must be able to read, understand, and provide answers to the medical history interview.

The limitations defined for vulnerable groups apply, and these individuals may require support from another person (e.g., a caregiver).

Medical conditions to be diagnosed, treated, or monitored

LTC is not intended to diagnose or treat any specific condition. Its function is to:

- It monitors laboratory data to identify clinically significant deviations.
- It supports the diagnostic process by providing urgency stratification(immediate, urgent, planned, no contact necessary) and recommendations .

System and hardware requirements

LabTest Checker by Labplus® is available via:

- Web browser (computer, tablet, phone)

Requirements for the browser version

- ✓ Internet connection with a minimum bandwidth of 1 Mbps
- ✓ One of the following web browsers with JavaScript enabled (ES2020 standard or newer)
 - Google Chrome v130 or newer
 - FireFox v132 or newer
 - Edge v130 or newer
 - Opera v115 or newer
 - Safari v18.5 or newer
- ✓ Screen larger than 4 inches (minimum resolution of 640 x 1136 px recommended)

eIFU Access: Requires internet & a modern browser or mobile device (IOS 18.5+/Android 13+).

Recommended Security Measures

- Install and maintain up-to-date antivirus software with real-time protection enabled

- Regularly update your operating system, web browser / mobile app to the latest versions
- Do not share application access with others — your account is for your use only
- Log out of the application after completing your work
- Avoid connecting to public Wi-Fi networks while using the application
- Do not leave your device unattended when logged into the application
- Enable automatic device lock after a short period of inactivity

Warning and Precautions

Before using LabTest Checker by Labplus®, you must read and understand the following safety information.

When not to use LTC?

Contraindications: do not use LabTest Checker by Labplus® in case of:

- Suspicion of a life-threatening or health-threatening condition
- Emergency / acute conditions requiring immediate medical attention (e.g., trauma, poisoning)
- Hospitalized patients

In such situations, you should:

- Contact a physician
- Go to the Hospital Emergency Department (ED)
- Or call the Emergency Medical Services (tel. 112 or 999)

Key Safety Warnings

- LabTest Checker by Labplus® results are for informational purposes only and are not medical advice, consultation, or diagnosis. The system does not replace a medical consultation and cannot be used as the sole diagnostic tool.
- If you are concerned about your health, contact a doctor immediately. Interpretation of results should be discussed with the attending physician during the next visit
- Recommendations are not medical referrals.

Limitations

- The effectiveness of the interpretation depends on the quality, completeness, and validity of all input data. This includes both the laboratory test results pulled from the laboratory system and the patient's answers provided in the mandatory medical history interview.

- In the event of an excessive number of "I don't know" responses in the medical history interview, the system will be unable to provide a reliable interpretation.
- The system requires one or more "interpretable" laboratory test results that LTC interprets to perform an analysis. Please note that certain laboratory tests individually may not be sufficient to generate a report.

A result is considered "interpretable" only if it is recent (not expired) and contains sufficient data for analysis (e.g., necessary parameters and units). This information is specific to each test. The system automatically checks the validity for each test. There are no general limitations such as 'every patient must have a complete blood count'.

- In case the system does not have at least one interpretable test result (e.g., the result is incomplete, too old, or missing key information), or in the event of too many "I don't know" responses, the system will not provide an interpretation and will inform the user accordingly.

Precautions for Use

- Particularly vulnerable groups - it is recommended that these individuals are supported by another person (e.g., a caregiver).
 - Individuals with severe cognitive impairments may have difficulty understanding the system's limitations and correctly interpreting the recommendations.
 - Individuals with language barriers may misunderstand questions or recommendations, leading to a risk of incorrect use.
 - Individuals with limited visual acuity may have difficulty correctly reading warnings and recommendations, which increases the risk of misinterpretation.
- In case of incorrect interface display (missing buttons, text), stop using the software. Ensure that your device meets the system and hardware requirements described in these instructions. For further problems, please contact us by email at: kontakt@labplus.pl

Certain images presented in this User Manual are for illustrative purposes only. The appearance of the interface presented in the manual may differ from the appearance of the interface implemented by one of our business partners.

Product Support

The LabTest Checker by Labplus® program is available to laboratory patients via:

- The laboratory's website (in the results panel)
- The laboratory's mobile application (selected laboratories)

Depending on the laboratory, the service may be:

- Free of charge
- Require an online purchase before starting the interpretation

It does not require additional installation or special training. Laboratory test results are automatically downloaded from your profile in the laboratory system – you do not need to enter them yourself.

If the system is not working (e.g., due to power outage, internet access issues), wait a moment and reload the website or application.

Lifetime: 5 years

Beginning of interpretation

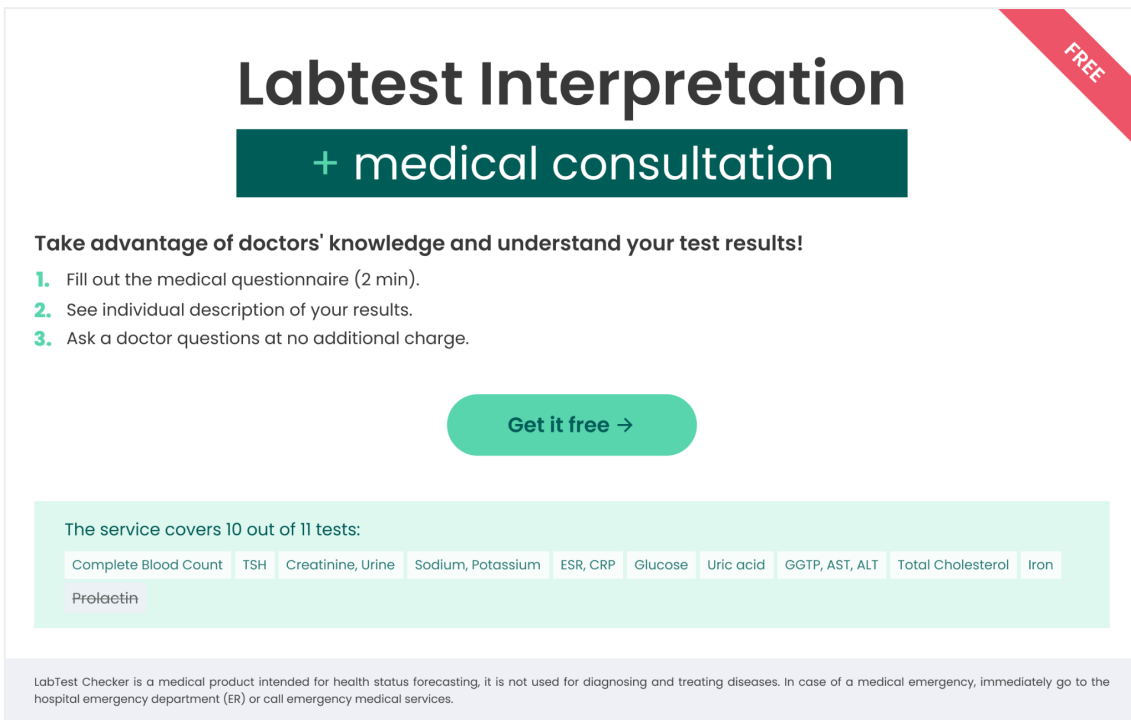
1. Log in to your laboratory system account
2. Navigate to the section with test results
3. Click the "Receive for free" or "Buy interpretation" button (depending on the laboratory)
4. For paid services, complete the online payment
5. The software is ready to use when the "I go to the survey" button is visible. Fill out the medical survey

Medical questionnaire

Medical questionnaire / medical interview is a stage during which we ask you to answer questions related to your health status. The system adapts the questions to your laboratory test results and the answers you provide, thereby shortening the length of the interview.

How to fill out the questionnaire?

1. Click "Receive for free"
2. Mark the necessary consents related to the service
3. Answer questions according to your current knowledge about your health
4. If you are uncertain, choose the "I don't know" option
5. After clicking an answer, you will automatically move to the next question. Using the "Back" button, you can return to previous questions and change your answer



The landing page for Labtest Interpretation features a large title 'Labtest Interpretation' with a subtitle '+ medical consultation' in a dark green box. A red diagonal banner in the top right corner says 'FREE'. Below the title, a section titled 'Take advantage of doctors' knowledge and understand your test results!' lists three steps: 1. Fill out the medical questionnaire (2 min), 2. See individual description of your results, and 3. Ask a doctor questions at no additional charge. A green button labeled 'Get it free →' is centered below the list. A light green box contains the text 'The service covers 10 out of 11 tests:' followed by a list of tests: Complete Blood Count, TSH, Creatinine, Urine, Sodium, Potassium, ESR, CRP, Glucose, Uric acid, GGTP, AST, ALT, Total Cholesterol, Iron, and Prolactin. At the bottom, a small disclaimer states: 'LabTest Checker is a medical product intended for health status forecasting, it is not used for diagnosing and treating diseases. In case of a medical emergency, immediately go to the hospital emergency department (ER) or call emergency medical services.'

Labtest Interpretation

+ medical consultation

Take advantage of doctors' knowledge and understand your test results!

1. Fill out the medical questionnaire (2 min).
2. See individual description of your results.
3. Ask a doctor questions at no additional charge.

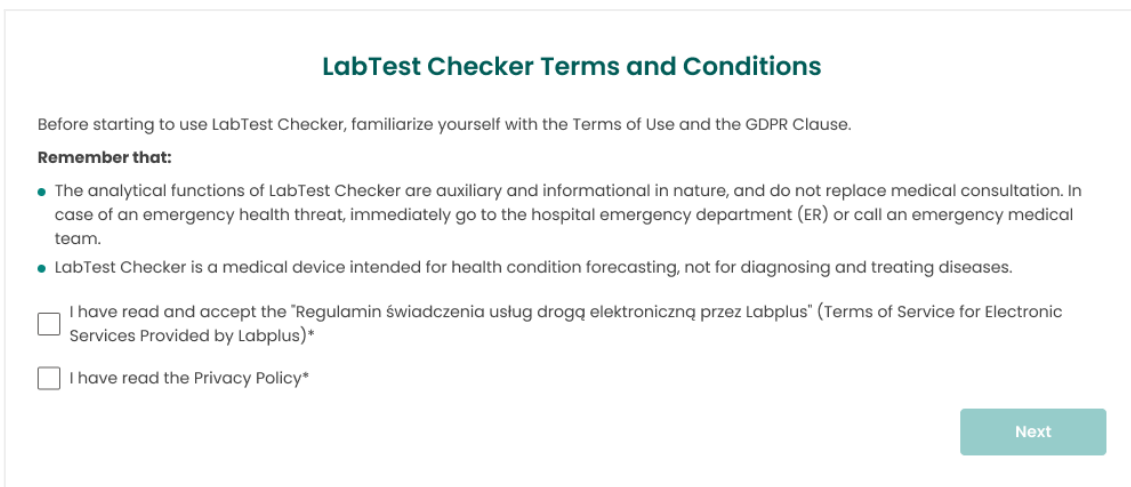
[Get it free →](#)

The service covers 10 out of 11 tests:

Complete Blood Count TSH Creatinine, Urine Sodium, Potassium ESR, CRP Glucose Uric acid GGTP, AST, ALT Total Cholesterol Iron Prolactin

LabTest Checker is a medical product intended for health status forecasting, it is not used for diagnosing and treating diseases. In case of a medical emergency, immediately go to the hospital emergency department (ER) or call emergency medical services.

Fig. 1. Landing page, preceding the stage of consents and medical questionnaire*



The 'LabTest Checker Terms and Conditions' page has a title 'LabTest Checker Terms and Conditions'. Below it, a paragraph states: 'Before starting to use LabTest Checker, familiarize yourself with the Terms of Use and the GDPR Clause.' A section titled 'Remember that:' contains two bullet points: 'The analytical functions of LabTest Checker are auxiliary and informational in nature, and do not replace medical consultation. In case of an emergency health threat, immediately go to the hospital emergency department (ER) or call an emergency medical team.' and 'LabTest Checker is a medical device intended for health condition forecasting, not for diagnosing and treating diseases.' Below the bullets are two checkboxes: 'I have read and accept the "Regulamin świadczenia usług drogą elektroniczną przez Labplus" (Terms of Service for Electronic Services Provided by Labplus)*' and 'I have read the Privacy Policy*'. A green 'Next' button is at the bottom right.

LabTest Checker Terms and Conditions

Before starting to use LabTest Checker, familiarize yourself with the Terms of Use and the GDPR Clause.

Remember that:

- The analytical functions of LabTest Checker are auxiliary and informational in nature, and do not replace medical consultation. In case of an emergency health threat, immediately go to the hospital emergency department (ER) or call an emergency medical team.
- LabTest Checker is a medical device intended for health condition forecasting, not for diagnosing and treating diseases.

☐ I have read and accept the "Regulamin świadczenia usług drogą elektroniczną przez Labplus" (Terms of Service for Electronic Services Provided by Labplus)*

☐ I have read the Privacy Policy*

[Next](#)

Fig. 2. Page with consents preceding the medical questionnaire

Results interpretation: medical survey

31%

Medical history Health Report

Do you smoke cigarettes?
Include cigarettes, e-cigarettes, and other tobacco products.

✓ Yes

✗ No

? I don't know

[Why are we asking about this?](#) ▼

↶ Previous question

Fig. 3. Fragment of medical questionnaire

Information

- Estimated time to complete is approximately 2 minutes, depending on the complexity of your situation
- You can return to previous questions at any time
- For laboratories offering paid services:
 - Payment can be made online before starting the interpretation
 - Popular payment methods are available (card, BLIK, bank transfer)
 - After paying for the service, you will receive a purchase confirmation to the email address provided

Results

After completing the medical questionnaire, you will be informed by a message on the screen that the interview has been completed.

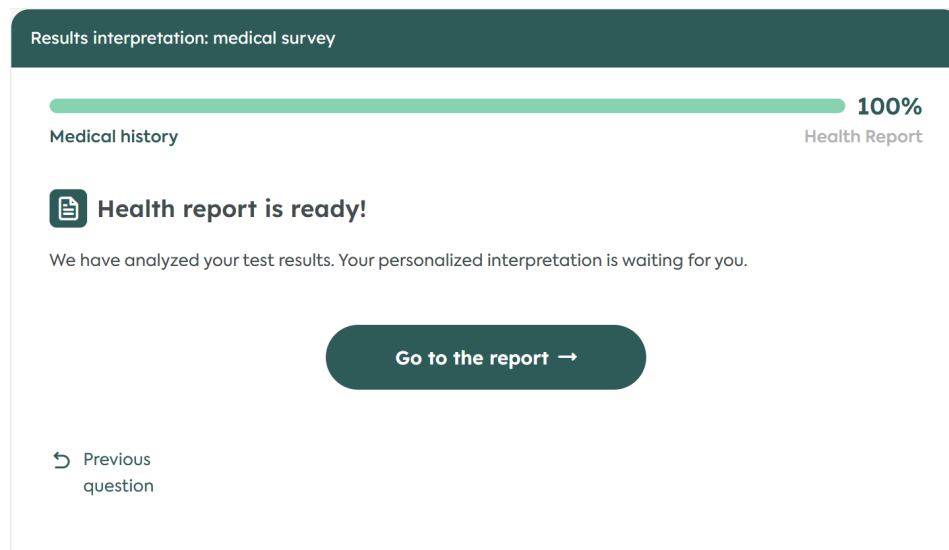


Fig. 4. Message informing about the completion of the medical questionnaire.

You will receive:

1. A report with interpretation of results — available immediately after completing the questionnaire
2. Ability to ask additional questions to Labplus doctors (details in the "Result Consultations" section)
3. Recommendations for additional tests, in medically justified cases (details in the "Additional Test Requests" section)

Report interpretation includes:

- The final urgency categorization
- Detailed justification and interpretation of deviations in the patient's context.
- Recommendations for further actions
- Recommendations for performing supplementary tests (if applicable).
- Personalized diagnostic and prophylactic advice.

If the system detects symptoms or test results that indicate a threat to your health, LTC will direct you to a doctor or hospital. In such a situation, in the report you will receive after completing the analysis, an appropriate message will be displayed to guide you to the right place.

Prevention and biological age

In the „Prevention“ section of your report you will find additional information supporting health prevention, including your biological-age tile.

Biological age is an indicative measure of your body's condition, calculated from your laboratory results. It serves prevention and educational purposes only — it is not a diagnosis.

To calculate your biological age we need 6 current results (from the last 30 days): alkaline phosphatase (ALP), CRP, creatinine, complete blood count (CBC), albumin, glucose.

How it works:

- If you have all 6 required results (from the last 30 days) and you provided your age in the questionnaire, the tile shows your estimated biological age, a comparison with your chronological age, and a validity date (1 year).
- If any result is missing, the tile stays locked and shows how many tests are missing. Missing tests are also listed in the „Health Plan“ section, under „Complete your prevention“.
- An elevated CRP result (above 10 mg/l) may indicate a transient inflammation and is not used in the calculation — in that case we recommend repeating the test.

Important: Biological age is informational and preventive only. It does not constitute medical advice or a diagnosis and does not replace a consultation with a physician.

Result Consultations

LabTest Checker by Labplus® allows you to ask additional questions to qualified Labplus doctors. The service is available at no extra cost.

How to ask a question?

1. In the interpretation report, find the "Consult the result" section
2. Type your question in the dedicated field
3. Provide an email address to receive a notification about the response
4. Click "Send question"

Receiving answers

- You will usually receive a response the same day, no later than 48 hours after asking the question (excluding Saturdays, Sundays, and statutory holidays)
- You will be notified about the available response:
- By email to the provided address
- By notification in the laboratory's mobile app (if you use it)

How to read the response?

1. Log in to the results portal or app

2. Open the interpretation report
3. Go to the consultation section
4. Find the answer under your question

After receiving the answer, you can rate how helpful it was (5-star scale) and optionally leave a short comment.

Additional Test Requests

In medically justified cases, along with the interpretation, you will receive a recommendation for additional tests:

- The recommendation is available directly in the interpretation report
- You can save it on your device and use it at the collection point
- You will receive a reminder about deferred tests

Important information

- Recommendations are not medical referrals
- Tests are not reimbursed by the National Health Fund (NFZ)
- The patient bears the cost of performing the tests

Ending the Session

You do not need to take additional steps to finish working with the LTC program:

- In the browser version: simply close the website or go to other tabs
- In the app: you can exit the interpretation module using the "Return" button or close the application

In both cases, the system will automatically save your results and they will be available after logging in again.

Validity period of tests

Test parameter		Validity of results
• APTT • Beta human chorionic gonadotropin (beta-hCG) • chloride • CRP • D-dimer • hs CRP	• magnesium • potassium • PT (INR) • sodium • total calcium • ESR • Zinc in serum, quantitative	7 days

- Inorganic phosphorus - Insulin after glucose load after 60 min and after 120 min.	Histamine	
- amylase - lipase	- Lipoprotein Lp(a) - Urinalysis with sediment	14 days
Pertussis (Bordetella pertussis) IgM		21 days
- Adiponectin - AMH - Androstenedione - AST - ALT - ALP - complete Blood Count (CBC) - Cortisol - creatinine + eGFR - Creatinine 24h excretion - DHEA-SO₄ - estradiol - Folate - Free testosterone - FSH - GGTP - Inhibin B - Insulin - Leptin - LH	- progesterone - prolactin - Selenium - SHBG - testosterone - total bilirubin - Urea - Albumin - DAO (Diamine Oxidase) - Iodine (quantitative) - IGF-1 (Insulin-like Growth Factor 1) - Anti-Ascaris lumbricoides IgG - Dihydrotestosterone (DHT) - Fecal Occult Blood (FOB) - Total IgE - vitamin D - 25(OH) metabolite (or 25-hydroxyvitamin D) - Vitamin H (biotin)	30 days
HIV Ag/Ab (Combo) (screening test)		42 days

- Borrelia burgdorferi IgG antibodies - Borrelia burgdorferi IgM antibodies - Ferritin - Hepatitis C virus antibody test (anti-HCV test)	- iron - Soluble transferrin receptor - Syphilis screening test - TIBC - TSAT (Transferrin saturation) - Vitamin B6	60 days
- AFP - antibodies against TSH receptors (TRAb) - CA 125 - CA 15-3 - CA 19-9 - CA 72-4 - CEA - CYFRA 21-1 - ft3 - ft4 - glucose - glycated hemoglobin (HbA1c) - HE4 - HOMA-IR	- lipid profile (LDL, HDL, non-HDL, TG, TC) - ROMA (Risk of Ovarian Malignancy Algorithm) - Thyroxine TT4 - total cholesterol (without other lipid profile parameters) - Triiodothyronine TT3 - TSH - uric acid - Toxoplasma gondii IgM - Toxoplasma gondii IgG - Parvovirus B19 IgM - Parvovirus B19 IgG - Lupus Anticoagulant (LA)	90 days
- Anti-HBc IgM (Hepatitis B core IgM antibodies) - Anti-HBe (Hepatitis B antibodies)	- HBeAg (Hepatitis B e antigen) - HBsAg (Hepatitis B surface antigen)	150 days
- Antistreptolysin O ASO - Homocysteine	Vitamin B12	180 days
total PSA		365 days

Contact

Reporting Problems and Complaints



e-mail: pomoc@labplus.pl

- Subject: [Your data]
- Content:
 - Session ID number (e.g., 23590834)
 - Problem description
 - Application version

Serious medical incidents related to the product must be reported to the manufacturer and the appropriate authority – the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products.

Opinions and Ideas

If you want to share your opinion or ideas with us, write to kontakt@labplus.pl. We're waiting!

User Manual in Paper

If you want to receive this User Manual in paper form, contact us at pomoc@labplus.pl. At a mutually agreed meeting time (within 7 calendar days of receiving a request), we will provide you with the Instructions free of charge at our company headquarters.

Compliance with Regulations and Standards

LabTest Checker® is an active medical device of class IIa. We have completed conformity assessment and obtained medical device certification in accordance with the requirements of Regulation (EU) 2017/745. Certificate of conformity issued by Notified Body No. XXXX. Certificate No: XXXXXX. The full EU Declaration of Conformity is available at www.labplus.ai

Data protection and Privacy

- We process personal and medical data in accordance with the GDPR Regulation and the Act on Patient Rights
- We apply safeguards compliant with requirements for medical devices (MDR)



- You have the right to access your data, rectify, delete or limit processing in accordance with applicable regulations

References and Citations

Szumilas D, Ochmann A, Zięba K, Bartoszewicz B, Kubrak A, Makuch S, Agrawal S, Mazur G, Chudek J. Evaluation of AI-Driven LabTest Checker for Diagnostic Accuracy and Safety: Prospective Cohort Study. JMIR Med Inform 2024;12. doi: 10.2196/57162