SMART REPORT

INSTRUCTIONS FOR USE

- FOR PATIENTS

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MANUFACTURER

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PRODUCT

Type: English version

Name	Unique device identifier UDI-DI
AILife SMART REPORT Basic	5999577910018
AILife SMART REPORT Normal	5999577910025
AILife SMART REPORT Premium	5999577910056

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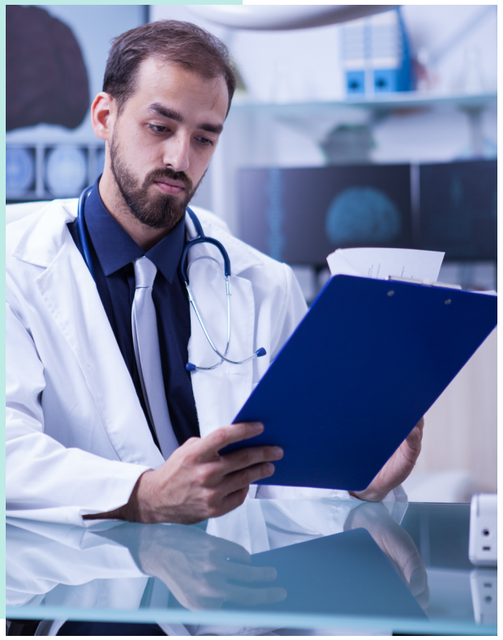
Intended use



AILife SMART REPORT is an artificial intelligence-based diagnostic software system that processes blood test results exclusively. The system aims to present blood test data in a format that is easy to understand for both healthcare professionals and patients, and to assist in interpreting the data by providing additional information. AILife uses advanced machine learning algorithms to analyze available medical data, perform risk assessments for different disease groups, and draw attention to any abnormalities.

The software displays blood test results in a way that is understandable and visually transparent for patients, provides additional information on individual laboratory parameters, and offers insight into the risk assessment of disease groups. For doctors, it presents blood test data in a structured and transparent manner and provides predictive analyses and risk assessments for individual disease groups.

The input data for AILife SMART REPORT is blood test data (various hormones, ions, blood count) in HL7 format. The SMART REPORT software compares this data for a given patient with hundreds of thousands of other patients' validated data, as well as patterns between the data, and performs risk assessment based on this.

The disease groups examined: thyroid diseases (thyroiditis, thyrotoxicosis, iodine deficiency thyroid diseases, thyroid cancer); various forms of diabetes; liver diseases; inflammatory bowel diseases; nutritional anaemias; non-nutritional anaemias; immunological defects; systemic autoimmune diseases; lipid metabolism disorders; bile and pancreatic diseases; kidney diseases; cardiovascular diseases; malignant neoplastic diseases; rare diseases. The **output is a document called OKOSLELET, which is a blood test result in password-protected PDF format.**

SMART REPORT serves as a supplement to the interpretation of the patient's own laboratory results.

SMART REPORT assists specialists in drawing attention to possible risks, thereby potentially shortening the time required for diagnosis.

SMART REPORT does not replace medical examination and diagnosis, but serves as a supplementary source of information.

Limitations on use

1. SMART REPORT cannot be used to make an independent diagnosis or start treatment.
2. A doctor must always be consulted to interpret the results.
3. SMART REPORT is based solely on the laboratory test data provided and does not take other clinical factors (e.g., symptoms, medical history) into account..
4. If the patient has a known and treated disease in a certain disease group, this may influence the interpretation of the results (e.g., false negative results).

Prerequisites for using SMART REPORT

The document will be sent by email, so the patient must have their own email address.

To open the document:

- We recommend using a PDF reader (available free of charge at: https://get.adobe.com/reader/) or
- one of the internet browsers. It may be necessary to update your software.

System requirements for opening PDF files correctly:

- Windows 10 or newer operating system for Windows users,
- MacOS 10.13 or newer for MacOS users.

Target groups for use

AILife SMART REPORT is designed for two main user groups:

Patients who want to understand their own laboratory test results in a clear, structured format and learn about their possible clinical significance..

Healthcare professionals (doctors) who can obtain faster and more informed decision support during the diagnostic process based on the structured presentation of blood test data, predictive analyses, and risk assessments.

Other target users may include companies or institutions that want to obtain a comprehensive picture of the health status of their employees and wish to receive the information provided by OKOSLELET for this purpose.

The function of SMART REPORT

One of the functions of AILife SMART REPORT is to assist patients in interpreting their findings. In addition, it provides diagnostic assistance to specialists by estimating the risks associated with the disease groups examined. The output is an interval expressed as a percentage and a qualitative (**categorical**) classification for the given disease group. For example: the probability of kidney disease can be determined to be between 24-38% - the probability of heart disease is “unlikely.”

The risk assessment is based on automated comparative analysis by AILife software products, which compare the known, validated health data of hundreds of thousands of real patients with data from the patient’s blood sample. The comparison is intended for medical specialists and is for informational purposes only and, as such, does not replace the opinion of a medical specialist.

The specialist may use, accept, and review all or part of the SMART REPORT. The disease risks and probabilities described in the analysis do not indicate the presence of the disease itself, but only provide an estimate of the proportion of a given disease found in a **control group of adult outpatients** with similar laboratory tests.

Although the IT analysis that forms the backbone of the system is based on the latest IT results and methods and makes predictions based on real diagnostic data in order to provide the user with the most accurate information possible, it is still purely informative in nature and the issuer of the analysis does not take responsibility for the data contained in the document or for the completeness of the data (and therefore for the analysis as a whole).

Diseases examined per package

	Basic package	Normal package	Premium package
Thyroid disorders	✓	✓	✓
Various forms of diabetes	✓	✓	✓
Liver disorders	✓	✓	✓
Kidney disorders	✓	✓	✓
Biliary and pancreatic disorders	✓	✓	✓
Lipid metabolism disorders	✓	✓	✓
Nutritional anaemia	✓	✓	✓
Other types of anaemia		✓	✓
Immunological defects		✓	✓
Systemic autoimmune disorders		✓	✓
Inflammatory bowel diseases		✓	✓
Cardiovascular diseases		✓	✓
Rare diseases			✓
Certain types of cancer			✓

Risks associated with rare and cancerous diseases are not included in SMART REPORT. If a risk related to these disease groups arises, the manufacturer will notify the patient separately. In this regard, the manufacturer provides the patient with a free online consultation with a specialist, but this does not preclude the possibility of the patient consulting another doctor.

Description of operating principle

SMART REPORT is an artificial intelligence-based decision support software that analyzes patients' laboratory test results. The system's operation can be described in the following main steps:

1. Input data

SMART REPORT works with data from blood tests performed by partner laboratories. The data is sent to the system in HL7 format, which is an international standard for the exchange of healthcare data. The data includes test results and anonymized patient data (e.g., age, gender).

2. Data processing

The system compares the received laboratory data with hundreds of thousands of previous laboratory results and known diagnoses from real patients. During data processing, machine learning algorithms developed specifically for this purpose use artificial intelligence to search for patterns that may indicate the presence of certain disease groups.

These patterns help determine how similar the patient's results are to those of patients who had a particular disease. This method ensures that the system can provide statistically reliable risk predictions.

3. Risk assessment

Based on the information obtained during data processing, the system uses predictive models to calculate the estimated probability of the diseases under investigation. The SMART REPORT system examines the probability of 14 disease groups. The risk level is a value between 0 and 1 (where 0 indicates no risk and 1 indicates certain presence).

4. Visual representation

The results are presented in the form of numerical probability values, which are associated with color-coded risk categories (green: unlikely – red: likely). The color codes are determined based on the statistical distribution of the values calculated by the models, so there is no direct, one-to-one correspondence between the percentage values and the colors. The risk assessment result is also categorized into one of the following categories:

- improbable,
- rather improbable,
- conceivable,
- rather probable,
- probable.

Necessary samples

The output of SMART REPORT is based on the patient's blood test results. Blood tests are widely available, inexpensive, and essential in diagnostic processes. In addition, their high reliability provides an ideal basis for the application of machine learning algorithms to improve diagnostic accuracy.

The software processes data from the following laboratory test samples during operation:

Blood count	WBC (white blood cell count), RBC (red blood cell count), HGB (hemoglobin), HCT (hematocrit), MCV (mean corpuscular volume), MCH (mean corpuscular hemoglobin), MCHC (mean corpuscular hemoglobin concentration), PLT (platelet count), RDW (red blood cell distribution width), MPV (mean platelet volume), PDW (platelet distribution width), NEU (neutrophils), LYM (lymphocytes), MONO (monocytes), EO (eosinophils), BASO (basophils)
Carbohydrate metabolism	GLUC (glucose), FRUC (fructosamine)
Kidney function	UREA (urea), CREA (creatinine), eGFR (estimated glomerular filtration rate)
Metabolic product	UA (uric acid), tBIL (total bilirubin), dBIL (direct bilirubin)
Ions	Na (sodium), K (potassium), Cl (chloride), Ca (calcium), Mg (magnesium), P (phosphorus)
Protein parameters	TP (total protein), ALB (albumin)
Inflammatory markers	hsCRP (high sensitivity C-reactive protein), ESR (erythrocyte sedimentation rate), MPXI (myeloperoxidase index)
Iron metabolism	Fe (iron), TRF (transferrin), FER (ferritin)
Lipid profile	CHOL (total cholesterol), TG (triglycerides), HDL-C (high-density lipoprotein cholesterol), LDL-C (low-density lipoprotein cholesterol)
Enzymes	AST (aspartate aminotransferase), ALT (alanine aminotransferase), GGT (gamma-glutamyl transferase), ALP (alkaline phosphatase), LDH (lactate dehydrogenase), CK (creatine kinase), LIP (lipase), AMY (amylase)
Hormons	sTSH (thyroid-stimulating hormone)

Clinical performance

During the development and validation of SMART REPORT softwares, we paid special attention to ensuring that the system's results are reliable not only in a theoretical environment, but also in everyday medical practice. To this end, we tested the program's performance in a real clinical environment with more than 8,000 outpatients, in collaboration with various healthcare institutions.

During the trials, predictions based on patients' routine laboratory blood test results were reviewed and evaluated by independent specialists, comparing them with actual diagnoses and clinical observations. The aim of the analyses was to determine the diagnostic sensitivity and specificity of the system, as well as its positive and negative predictive values.

Clinical trials have confirmed that SMART REPORT is capable of early disease detection and more accurate risk assessment, thus contributing to supporting doctors' diagnostic decisions.

However, it is important to note that the final diagnosis is always made by the attending physician, and the software serves as a decision support tool.

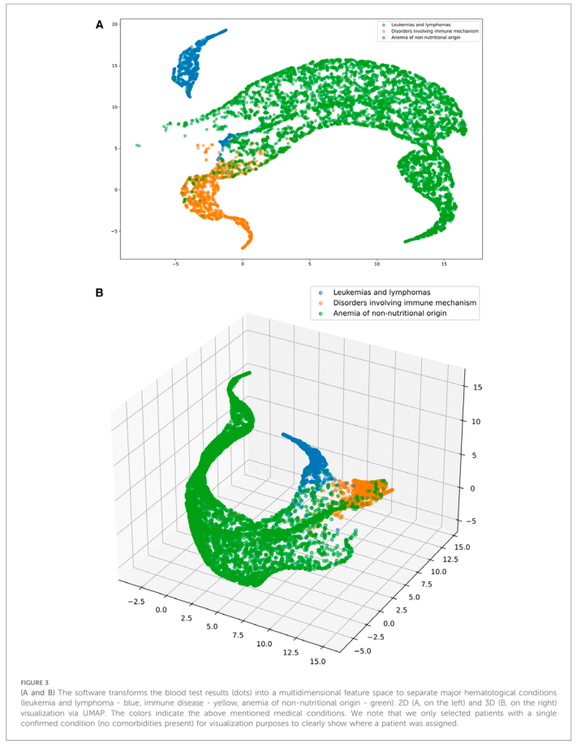


FIGURE 3
(A and B) The software transforms the blood test results (dots) into a multidimensional feature space to separate major hematological conditions (leukemia and lymphoma – blue, immune disease – yellow, anemia of non-nutritional origin – green). 2D (A, on the left) and 3D (B, on the right) visualization via UMAP. The colors indicate the above mentioned medical conditions. We note that we only selected patients with a single confirmed condition (no comorbidities present) for visualization purposes to clearly show where a patient was assigned.

The SMART REPORT prediction software classifies the findings of patients belonging to different disease groups. Image source: https://doi.org/10.3389/fdgth.2024.1505483

The study confirms that SMART REPORT's risk assessment can indicate the risk of disease 30-270 days before clinical diagnosis, especially when a wider range of blood test results are available. With the exception of non-inflammatory bowel diseases and cardiovascular diseases, more than 95% of validating physicians fully agreed with the diagnostic recommendations of artificial intelligence for each disease group. Furthermore, the results of the study show that with the help of SMART REPORT, doctors' report validation time was significantly reduced by 50.7% (from an average of 645 seconds to 318 seconds).

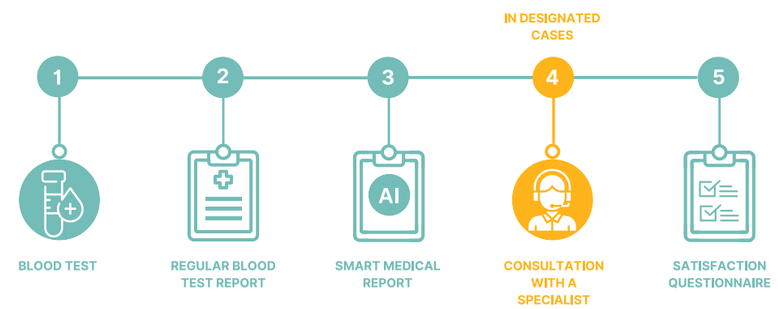
The full study describing and summarizing the research is available on the Frontiers in Digital Health website: **Dr. Ákos Németh, Bálint Daróczy et al. (2024)**: Smart medical report: efficient detection of common and rare diseases on common blood tests. Front. Digit. Health Volume 6 - 2024 | https://doi.org/10.3389/fdgth.2024.1505483

Conditions of use

The AILife SMART REPORT service process consists of the following steps for the patient:

1. The first step of the examination is to take a blood sample at the location chosen by the patient. The sample is processed at the partner laboratory, and the results are recorded in standard HL7 format.
2. Traditional laboratory results are also available in the Electronic Health Service Space (EESZT), but these only contain the measured laboratory parameters and do not include the results of the risk assessment performed by AILife SMART REPORT.
3. The HL7 data is processed for risk assessment by the AILife OKOSLELET software package, which performs personalized, artificial intelligence-based analysis. The result reflects the risk profile of the condition at the time of blood sampling. OKOSLELET is issued within 1-7 working days, depending on the package selected, and is sent to the email address provided during registration at a later date than traditional findings.
4. If the patient's lab results indicate a risk of a rare or cancerous disease, the patient is entitled to a free online medical consultation. DiagnostIQ Kft. staff will contact the patient directly regarding the free specialist consultation: first, they will send an email to the patient about the possibility of a consultation. If the patient accepts the offer and provides a telephone number for contact, the manufacturer's staff will also contact them by phone. If the patient accepts the opportunity and provides a telephone number for contact, the manufacturer's staff will also contact the patient by telephone to arrange an appointment. Although rare and cancerous diseases may seem frightening at first, it is important for patients to remain calm, because it may be that:
   - based on the patient's medical history, it becomes clear that the software has incorrectly predicted something,
   - there is a risk of a disease that does not affect quality of life, or
   - the risky disease has been detected early, so the patient has a good chance of recovery. In all cases, our specialists will help you plan the next steps after a careful assessment, whether it be further targeted testing or referral to a specialist, lifestyle advice, or a follow-up consultation.
5. At the end of the process, patients can participate in a questionnaire-based satisfaction survey, which we use to help us improve our services..

If you have any questions during the process, please feel free to contact DiagnostIQ Kft. Customer Service at **support@diagnostiq.hu**.



Data protection and security

During the AILife SMART REPORT service, the manufacturer pays special attention to the protection of the patient's personal and health data. Data processing is carried out solely for the purpose of preparing and validating SMART REPORT and providing related customer service activities. The scope of the data processed is limited to information that is essential for the provision of healthcare services. The data controller processes personal and health data until the service is provided or until the patient requests its deletion.

During data processing, it is ensured that only authorized persons have access to the data, i.e., the specialists performing the validation, the data protection officer, and the designated customer service staff. The employees performing the development only encounter the data in anonymized form and only have access to personal data to the extent necessary in justified error correction or incident management situations.

By using the service, the patient consents to the processing of their personal and health data in full compliance with the relevant data protection rules (GDPR) and legislation. The patient has the right to access their data, request its correction or deletion, and request information about how it is processed.

Since SMART REPORT and related notifications are sent electronically via email, there is a risk of data theft or unauthorized access. To mitigate this risk, the manufacturer sends all findings as password-protected PDF documents that can only be opened with information known to the patient. Patients are provided with detailed information about the risks of email transmission in the declaration they sign when using the service at the time of blood collection.

All employees and subcontractors participating in the AILife SMART REPORT service are bound by medical confidentiality, which is valid indefinitely, regardless of whether the data comes directly from the patient, from laboratory tests, or from other medical documentation.

Data is processed and transmitted in accordance with the strictest security regulations, as specified in detail in the privacy policy and information notice. The detailed Data Processing Notice is available at www.diagnostiq.hu.

Interpretation guide

AILife SMART REPORT consists of five parts, which are as follows:

1. general and personal data,
2. summary of traditional laboratory test results,
3. artificial intelligence-supported evaluation,
4. explanation of risky disease groups and
5. explanation of values that deviate from the reference range.

1. General and personal data

This section contains the patient's personal data, the most important data from the laboratory test on which SMART REPORT is based, and, for quality assurance reasons, the SMART REPORT ID and the version number of the software used.

General and personal data

Name	
Social security number	
Date of birth	
Age	
Sex	
Time of phlebotomy	
Laboratory provider	SYNLAB MAGYARORSZÁG KFT.
Smart report package	Okoslelet PREMIUM
Number of laboratory tests	59
Software version	AE.PT.HTHP-beta.0.6.5
Report identifier	
Time of report generation	

2. Summary of traditional laboratory test results

Here you will find all laboratory tests grouped together, which OKOSLELET uses to estimate the patient's disease risks. These tests are transferred to OKOSLELET from the patient's ordered laboratory test package and are primarily used for quality assurance purposes and to ensure that all test-related information is available in one place. In this section, you can view your completed laboratory tests and easily see if a test is above (marked in red) or below (marked in blue) the reference range. From left to right, the columns represent: test name, test classification type, test value, test unit of measurement, lower value of the test reference range, upper value of the test reference range, position of the test value relative to the reference range (A - below, F - above, N - normal).

Name	Type	Value	Unit	Reference range		
White Blood Cell Count (WBC)	Blood Count	6.2	Giga/L	4.4	11.3	N
Red Blood Cell Count (RBC)	Blood Count	4.8	Tera/L	4.5	5.9	N
Hemoglobin (Hgb)	Blood Count	149	g/L	140	175	N
Hematocrit (Hct)	Blood Count	0.45	L/L	0.4	0.52	N
Mean Corpuscular Volume (MCV)	Blood Count	93	fL	80	96	N
Mean Corpuscular Hemoglobin	Blood Count	31	pg	28	33	N
MCHC	Blood Count	331	g/L	310	370	N
Platelet Count (PLT)	Blood Count	260	Giga/L	150	450	N

3. Summary of artificial intelligence

The main part of OKOSLELET, which shows which of the 14 disease groups the patient's laboratory results may indicate the presence or possible risk of developing, based on the evaluation of artificial intelligence. The summary table consists of three main elements (columns): disease group, estimated probability, and presence of disease.

Disease group	Probability	Estimated presence of the disease
Thyroid diseases	between 59-70%	
Immunological defects	below 0.8%	
Different forms of diabetes	below 4.3%	
Liver diseases	below 1.5%	
Nutritional anaemia	between 1.5-9%	
Other anaemia	below 4.1%	
Inflammatory bowel diseases	below 0.5%	
Lipid metabolism disorders	below 4.3%	
Biliary and pancreatic diseases	below 1.5%	
Kidney diseases	below 2.7%	
Systemic autoimmune diseases	between 2.7-30%	
Cardiovascular diseases	between 9.5-27%	

Disease group
Thyroid diseases
Immunological defects
Different forms of diabetes
Liver diseases
Nutritional anaemia
Other anaemia
Inflammatory bowel diseases
Lipid metabolism disorders
Biliary and pancreatic diseases
Kidney diseases
Systemic autoimmune diseases
Cardiovascular diseases

Disease groups

The 14 disease groups for which OKOSLELET provides risk estimates

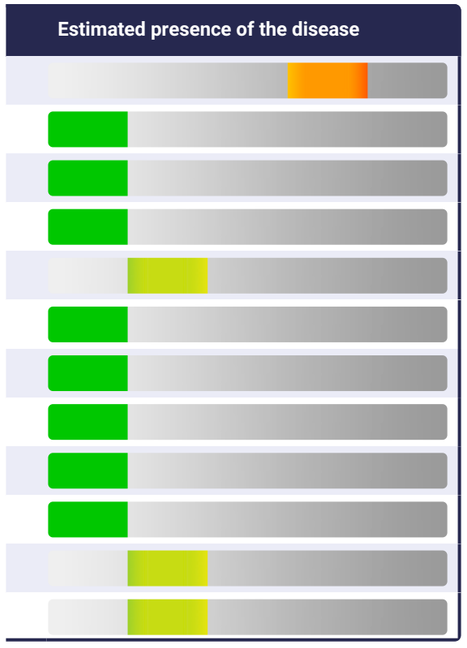
Risk estimates for rare and cancerous disease groups are not included in the summary. If a risk arises for such a disease group, the patient concerned will be notified separately by email. Following the email notification, the manufacturer's staff will contact the patient by phone to arrange a free consultation with the designated specialist.

Estimated probability

The estimated probability of the presence of a given disease group. Its value shows the average percentage of patients with laboratory results similar to those of the patient and included in statistical studies who were found to have one of the diseases in the disease group under investigation. The probability is a value calculated by mathematical models, which depends on the models included in the study, their reliability, the prevalence of the disease, the number of tests performed, and the color category of the disease (1-5).

Even if a patient has the same disease color category (e.g., red) for two different diseases, they may experience different estimated probability values for the two diseases. This means that although the relative risk of the two diseases is similar in the two categories of the same color, the actual numerical risk differs due to different statistical models and different frequencies of the diseases. The actual risks for the patient are determined by the family doctor or specialist based on their precise knowledge of the patient's medical history..

Probability
between 59-70%
below 0.8%
below 4.3%
below 1.5%
between 1.5-9%
below 4.1%
below 0.5%
below 4.3%
below 1.5%
below 2.7%
between 2.7-30%
between 9.5-27%



Presence of disease

The presence of disease is represented by a color scale ranging from 1 to 5 (from green to yellow to red), with increasing values indicating an increased risk of the presence of the given disease group.

1 and 2 (green-yellow-green):

Basically means a negative finding. If the patient's estimated disease risk falls into these categories, the probability of the disease group being present in the patient's case is unlikely (1) or less likely (2).

3 (yellow):

The patient's result is in the uncertain range; the presence of the disease is conceivable, but mathematical models are unable to either confirm or rule it out with any greater certainty..

4 and 5 (orange-red):

This basically means a positive finding. If the patient's estimated disease risk falls into these categories, the probability of the disease group being present in the patient's case is more likely (4) or likely (5).

The exact probabilities for each category can be found in the Probability column.

It is important to note that mathematical models make decisions based solely on the patient's current laboratory results and do not take into account the patient's medical history, physical status, other test results, and lifestyle/ environmental factors, which are essential for making an accurate diagnosis. Blood tests are an important but not exclusive element of diagnosis, so patients should always consult their general practitioner or specialist about the accuracy of SMART REPORT results for their individual case.

4. Explanation of high-risk disease groups

If there is a risk for a particular disease group, a description of the disease group follows. The description includes the specific possible clinical pictures belonging to it, as well as recommendations on which specialist to consult and what further diagnostic tests may be necessary in case of involvement.

The border of the disease group description corresponds to the risk:

- yellow - conceivable,
- orange - rather probable,
- red - probable existence of the disease according to the comparative analysis of SMART REPORT's artificial intelligence..

Thyroid diseases

RISK: **RATHER PROBABLE**

Thyroid diseases include a wide variety of disorders affecting the thyroid gland, including congenital (familial) defects, iodine deficiency conditions, hypo and hyperthyroidism, thyrotoxicosis, thyroiditis, and other thyroid disorders. In case of involvement, consultation with an endocrinologist and further specific thyroid testing is recommended.

5. Explanation of values deviating from the reference range

Deviations from the reference range show the patient which tests show deviations from the limits defined for the healthy reference population, and indicate the direction and extent of the deviation. For each deviation, you can find out what clinical conditions these deviations are likely to indicate based on decades of laboratory medicine literature, and what other values tend to deviate for these conditions.

Name: White Blood Cell Count (WBC)

Difference: -9%

Description: White blood cells are components of the immune system that are produced in the bone marrow and protect the body against infections. During an infection, white blood cells attack and destroy the pathogens causing the infection.

Common causes if difference is lower: Viral and certain bacterial infections; Autoimmune diseases; Deficiency disorders; Liver and spleen diseases; Bone marrow disorders; Tumors; Poisonings; Side effects of medication

Related important laboratory tests, in regard of the anamnesis and other test results:

Other components and parameters of blood count; C-reactive protein; Liver function tests; Autoimmune testing; B12, folic acid; LDH (lactate dehydrogenase); Viral serology tests

Name: Hemoglobin (Hgb)

Difference: -9%

Description: Hemoglobin is a protein (metalloprotein) found in red blood cells and is responsible for the transport of oxygen in the blood.

Common causes if difference is lower: Disturbance in red blood cell production: iron deficiency, B12 or folate deficiency, kidney disease, hypothyroidism, genetic causes;-Increased destruction or loss: blood loss (gynecological, gastrointestinal, surgical, etc.), autoimmune disease (hemolysis), liver and spleen diseases, bone marrow disorders, tumors, toxins, etc.

Related important laboratory tests, in regard of the anamnesis and other test results:

Other components and parameters of blood count; Reticulocyte; Iron, ferritin, transferrin; B12, folic acid; Kidney function tests; Thyroid function tests; Liver function tests; Stool occult blood test; LDH

Frame: red or blue, depending on whether the tested value deviates upward (red) or downward (blue) from the reference range.

Test name: name of the test that deviates from the reference range

Test description: brief description of the test that deviates from the reference range (what it measures, why its value is important).

Most common reasons for higher (lower) values: according to clinical laboratory literature, the direction of the deviation from the reference range is most commonly observed in the following clinical conditions or states.

Related important laboratory tests, taking into account medical history, clinical findings, and other test results: shows what other tests usually differ in the case of a deviation in a given direction, and what tests can contribute to a more accurate understanding of the underlying causes.

It is important to note that artificial intelligence does not use clinical chemistry literature and does not make decisions based on deviations from reference ranges. Artificial intelligence bases its decisions on similarity patterns between the patient's laboratory results and the laboratory results of tens of thousands/hundreds of thousands of patients in each group. Although there are often similarities between the two (no deviation results in a negative result, while many deviations result in a positive result according to the clinical literature on the given deviations), which is not surprising, given that laboratory medicine literature also uses knowledge and statistics accumulated over many decades, it is not uncommon for the picture presented based on a summary of deviations from the reference ranges to differ from the findings of artificial intelligence. In all cases, the specialist is entitled and responsible for making an accurate diagnosis, taking into account (or ignoring) the information provided.

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