

AKREDITEERIMISTUNNISTUS
ACCREDITATION CERTIFICATE

Eesti Akrediteerimiskeskus kinnitab käesolevaga, et
The Estonian Accreditation Centre hereby confirms that

laboratory of diagnostic centre of
JSC “SK Impeks Medical diagnostic centre”

vastab ISO 15189:2007 nõuetele kui meditsiinilabor
conforms to the requirements of ISO 15189:2007 as a medical laboratory

kliinilise keemia valdkonnas
in the field of clinical chemistry

Akrediteerimise ulatus ja tingimused on esitatud tunnistuse lisas
The scope and conditions of accreditation are specified in the annex

Registreerimisnumber: **L241**
Registration number.

Akrediteeritus kehtib kuni: **30.11.2016**
Accreditation is valid until:

Tallinnas, 1.12.2011.


Viktor Krutob
Juhataja *Director*





EESTI AKREDITEERIMISKESKUS

LISA JSC“SK Impeks Medical diagnostic centre” laboratooriumi akrediteerimistunnistusele nr L241
 ANNEX to the accreditation certificate no L241 of the Laboratory diagnostic centre of JSC “SK Impeks Medical diagnostic centre”

1. Akrediteerimisulatus on toodud järgnevas tabelis: Accreditation scope is given in the following table:

Nr	Määratavad näitajad <i>Analysed parameters</i>	Maatriks <i>Matrix</i>	Mõõtemetod <i>Technique</i>	Metoodika <i>Procedure</i>	Mõõteulatus <i>Measurement range</i>	Laiendmääramatus <i>(k=2)</i> <i>Expanded uncertainty</i>
Clinical biochemistry lab						
1.	Creatinine	Serum	Enzymatic colorimetric	LM-LB12	(5.00-2700.0) µmol/L	3.4 %/3.8 %
2.	Glucose	Serum	GOD/POD (enzymatic colorimetric)	LM-LB09	(0.11-41.60) mmol/L	0.4 %/0.24 %
3.	Triglycerides	Serum	GPO-PAP (enzymatic colorimetric)	LM-LB16	(0.10-10.0) mmol/L	3.6 %/7.6 %
4.	Cholesterol	Serum	CHOD/PAP (enzymatic colorimetric)	LM-LB17	(0.10-20.70) mmol/L	2.5 %/1.4 %
5.	High density lipoproteins cholesterol	Serum	Homogenic enzymatic colorimetric (direct)	LM-LB39	(0.08-3.12) mmol/L	5.7 %/1.1 %
6.	Low density lipoproteins cholesterol	Serum	Homogenic enzymatic colorimetric	LM-LB40	(0.10-14.20) mmol/L	6.8 %/4.7 %
7.	Total bilirubin	Serum	Diaz reaction	LM-LB14	(1.70-650.00) µmol/L	4.0 %/8.2 %
8.	Iron	Serum	Ferrozine	LM-LB05	(0.90-179.00) µmol/L	9.1 %/6.5 %



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Nr	Määratavad näitajad <i>Analysed parameters</i>	Maatriks <i>Matrix</i>	Mõõtemetod <i>Technique</i>	Metoodika <i>Procedure</i>	Mõõteulatus <i>Measurement range</i>	Laiendmääramatus (k=2) <i>Expanded uncertainty</i>
20.	Automatic urine test SG pH Leu Nit Pro Glu Ket UBG Bil Ery	Urine	Photometry	LM-LK09	(1-1030) 5-9 (0-500) / μ L (0.25-5) g/L (3-56) mmol/L (0.5-15) mmol/L (17-203) μ mol/L (17-100) μ mol/L (10-250)/ μ L	

2. Katseprotokollidele vastutava isikuna allkirjutamise õigusega isikud:

Next persons are authorized for signing the test reports and certificates:

Ina Šapranauskienė, Ona Petruškienė, Vida Baronienė, Rita Ališauskaitė, Jūrate Patricija Civinskaitė, Kristina Barauskienė, Indrė Daukantienė, Vilnelė Lipnickienė

3. Firma juridiline aadress

Legal address of firm: V. Grybo str. 32, Vilnius Lithuania

Laborite asukohad

Laboratories addresses: V. Grybo str. 32, Vilnius Lithuania



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Nr	Määratavad näitajad <i>Analyzed parameters</i>	Maatriks <i>Matrix</i>	Mõõtemetod <i>Technique</i>	Metoodika <i>Procedure</i>	Mõõteulatus <i>Measurement range</i>	Laiendmääramatus (k=2) <i>Expanded uncertainty</i>
Clinical research lab						
19.	Hemogram with 5-part leucocyte differential count WBC RBC HB HCT MCV MCH MCHC PLT RDW-SD RDW-CV PDW PCT MPW P-LCR NEUT# LYMPH# MONO# EO# BASO# DIFF-X DIFF-Y	blood	Flow cytometry Impedance Sodium lauryl sulphate Cumulative pulse height measurement Calculation Calculation Calculation Impedance Calculation Calculation Calculation Calculation Calculation Calculation Calculation Fluorescence flow cytometry Fluorescence flow cytometry Fluorescence flow cytometry Fluorescence flow cytometry Flow cytometry Fluorescence flow cytometry Fluorescence flow cytometry	LM-LK01	(0.00-999.99)x10 ⁹ /L (0.00-99.99)x10 ¹² /L (0.00-300) g/L (0-100) % (0-9999)x10 ⁹ /L	2.4 %/4.8 % 1.0 %/1.4 % 1.6 %/2.4 % 1.4 %/2.8 % 7.4 %/8.4 %



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Nr	Määratavad näitajad <i>Analysed parameters</i>	Maatriks <i>Matrix</i>	Mõõtemetod <i>Technique</i>	Metoodika <i>Procedure</i>	Mõõteulatus <i>Measurement range</i>	Laiendmääramatus ($k=2$) <i>Expanded uncertainty</i>
9.	Aspartat Aminotransferase (AST/GOT)	Serum	IFCC without pyridoxal phosphate, 37 °C	LM-LB18	(5.00-700.0) U/L	1.9 %/3.0 %
10.	Alanine Aminotransferase (ALT/GPT)	Serum	IFCC without pyridoxal phosphate, 37 °C	LM-LB19	(5.00-700.0) U/L	2.4 %/5.2 %
11.	C-Reactive Protein	Serum	Immunoturbidimetric	LM-LB29	(1.0-250.0) mg/L	0.2 %/6.0 %
12.	Pancreatic amylase	Serum	IFCC (glucosidase/p-nitrophenol), 37 °C	LM-LB25	(3.00-1500.00) U/L	0.45 %
EIA Laboratory						
13.	Thyroid stimulanting hormone (TSH)	Serum	ECLIA	LM-LF01	(0.005-100.00) mIU/L	6.7 %/6.8 %
14.	Free Thyroxin (FT4)	Serum	ECLIA	LM-LF03	(0.30-100.00) pmol/L	2.2 %/1.5 %
15.	Free Triioditronin (FT3)	Serum	ECLIA	LM-LF042	(0.400-50.00) pmol/L	16.8 %/9.0
16.	Prolactin	Serum	ECLIA	LM-LF11	(1.00-10000.00) IU/L	2.7 %/4.2 %
17.	Prostate-specific antigen (PSA)	Serum	ECLIA	LM-LF12	(0.002-100) µg/L	2.1 %/4.0 %
18.	Human immunodeficiency antibodies of 1,2 types viruses (HIV 1/2) and HIV Ag	Serum	ECLIA	LM-LF66		



4. Katselabor on kohustatud:

Testing laboratory has responsibility to:

- teatama viivitamatult akrediteerimisasutusele kõigist akrediteerimise suhtes olulistest muudatustest (organisatsiooni struktuur, juhtimine, personal, juhtimissüsteemi struktuur, olulised seadmed, akrediteerimisulatus, alltöövõtjad, protseduurid);
inform immediately the body granting accreditation of any changes bearing on its compliance with the accreditation requirements (organisation, management, personnel, management system structure, relevant equipment, scope of accreditation, subcontracting, procedures);
- järgima pidevalt standardi ISO 15189 nõudeid;
comply at all times with the requirements of standard ISO 15189;
- olema akrediteerimisasutuse järelevalve all ning vastu võtma ettenähtud sagedusega hindamisgruppi;
be under surveillance of the accreditation body and regularly enable the work of the surveillance visit team;
- viitama oma akrediteeritusele EAK J9 (EA-3/01) nõuete kohaselt.
refer to its accreditation according to the requirements of EAK J9 (EA-3/01).



Viktor Krutob
EAK juhataja
Director of EAK

Tallinnas, 1.12.2011.



Kaire Tõugu
Peaassessor
Lead Assessor