



EA MLA Signatory
Czech Accreditation Institute, Public Service Company
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. 475 / 2013

Všeobecná fakultní nemocnice v Praze
with registered office Ke Karlovu 2, 128 08 Praha 2

to Medical laboratory No.8097
Diagnostické laboratoře Ústavu dědičných metabolických poruch

Scope of accreditation:

Laboratory examination and diagnostics of hereditary metabolic disorders in the field of clinical biochemistry and molecular genetics to the extent as specified in the appendix to this Certificate which is attached.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO 15189:2007

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

The Certificate of Accreditation is valid until: **21 August 2018**

The Certificate of Accreditation becomes effective on the date of its delivery to the Conformity Assessment Body.

Prague: 21 August 2013



Jiří Růžička
Director
Czech Accreditation Institute
Public Service Company



Accredited entity according to ČSN EN ISO 15189:2007:

Všeobecná fakultní nemocnice v Praze
Diagnostické laboratoře Ústavu dědičných metabolických poruch
Ke Karlovu 2, 128 08 Praha 2

Testing laboratory working site:

1. **Biochemistry Laboratory** Ke Karlovu 2, 128 02 Praha 2
2. **DNS Diagnostics Laboratory** Ke Karlovu 2, 128 02 Praha 2

1. **Biochemistry Laboratory**

Examination:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
1	Determination of the concentration of lactate in urine by enzymatic photometric method on analyzer Hitachi 902 [U-Lactate]	SOP-UDMP-B-10	Urine
2	Determination of mucopolysaccharides in urine by screening method [U-Mucopolysaccharides Screening]	SOP-UDMP-B-14	Urine
3	Determination of the concentration of mucopolysaccharides in urine by photometric method [U-Mucopolysaccharides]	SOP-UDMP-B-15	Urine
4	Determination of creatinine in urine by Jaffé photometric method without deproteinization on analyzer Hitachi 902 [U-Creatinine]	SOP-UDMP-B-18	Urine
5	Determination of the concentration of uric acid in serum, plasma and urine by uricase/peroxidase enzymatic photometric method on analyzer Hitachi 902 [S,P,U-Uric Acid]	SOP-UDMP-B-19	Serum, plasma, urine
6	Determination of the concentration of creatinine in serum and plasma by enzymatic photometric method on analyzer Hitachi 902 [S,P-Creatinine]	SOP-UDMP-B-20	Serum, plasma
7	Determination of the concentration of lactate in deproteinized blood and CSF by enzymatic photometric method on analyzer Hitachi 902 [B,L-Lactate]	SOP-UDMP-B-23	Deproteinized blood, CSF
8	Determination of the concentration of pyruvate in deproteinized blood by enzymatic photometric method on analyzer Hitachi 902 [B-Pyruvate]	SOP-UDMP-B-24	Deproteinized blood



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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
9	Determination of the concentration of 3-hydroxybutyrate in deproteinized blood by enzymatic photometric method on analyzer Hitachi 902 [B-3-hydroxybutyrate]	SOP-UDMP-B-25	Deproteinized blood
10	Determination of the concentration of orotic acid in urine by spectrophotometric method [U-Orotic Acid]	SOP-UDMP-B-26	Urine
11	Determination of the concentration of total homocysteine in plasma, and serum by enzymatic photometric method on analyzer Hitachi 902 [P,S-Total Homocysteine, Enzymatic Method]	SOP-UDMP-B-28	Plasma, serum
12	Reserved		
13	Profiling examination of amino acids in serum, plasma and CSF on amino acid analyzer by ion exchange chromatography method with ninhydrin detection ¹⁾ [S,P,L-Amino Acids]	SOP-UDMP-B-30	Plasma, serum, CSF
14	Profiling examination of amino acids in urine on amino acid analyzer by ion exchange chromatography method with ninhydrin detection ²⁾ [U-Amino Acids]	SOP-UDMP-B-31	Urine
15	Determination of amino acids and acylcarnitines on dry blood spot using tandem mass spectrometry for the purpose of newborn screening ³⁾ [KP-AMK, AC Newborn Screening]	SOP-UDMP-B-33	Dry blood spot
16	Determination of amino acids and acylcarnitines on dry blood spot using tandem mass spectrometry for the purpose of selective screening ⁴⁾ [KP-AMK, Acylcarnitines MS/MS, Pregnancy Screening MS/MS, Compensation of PKU/HPA MS/MS]	SOP-UDMP-B-34	Dry blood spot
30	Determination of the concentration of orotic acid in urine by capillary electrophoresis [U-Orotic Acid CE]	SOP-UDMP-B-57	Urine



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Explanations:

Names in parentheses [] are the names of examinations shown in the reports.

1) S, P, L – Amino Acids: Taurin, Phosphoethanolamine, Aspartic acid, Hydroxyproline, Threonine, Serine, Asparagine, Glutamic acid, Glutamine, Glu+Gln, α -aminoadipic acid, Proline, Glycine, Alanine, Citrulline, α -aminobutyric acid, Valine, Cystien, Methionine, Allo-isoleucine, Cystathionine, Isoleucine, Leucine, Tyrosine, Phenylalanine, Free homocystine, β -alanine, β -aminoisobutyric acid, γ -aminobutyric acid, δ -aminolevulinic acid, Free hydroxylysine, Ethanolamine, Ornithine, Lysine, Histidine, Homocarnosine (in CSF only), 1-Methylhistidine, 3-Methylhistidine, Arginine.

2) U - Amino Acids: Taurin, Phosphoethanolamine, Aspartic acid, Hydroxyproline, Threonine, Serine, Asparagine, Glutamic acid, Glutamine, Glu+Gln, α -aminoadipic acid, Proline, Glycine, Alanine, Citrulline, α -aminobutyric acid, Valine, Cystien, Methionine, Allo-isoleucine, Cystathionine, Isoleucine, Leucine, Tyrosine, Phenylalanine, Free homocystine, β -alanine, β -aminoisobutyric acid, γ -aminobutyric acid, δ -aminolevulinic acid, Free hydroxylysine, Ethanolamine, Ornithine, Lysine, Histidine, 1-Methylhistidine, Arginine, Cystine-lithogeneity.

3) KP - AMK, AC Newborn Screening: Ala, Phe, Tyr, Val, Xle, C2, C5, C5DC, C6, C8, C10, C10:1, C12, C14, C14:1, C14:2, C14OH, C16, C16OH, C16:1, C18, C18:1, C18:1OH, C18OH, C0 and ratios: Phe/Tyr, Xle/Ala, C5DC/C8, C5/C0, C8/C2, C14:1/C2, (C16+C18)/C0, (C16+C18:1)/C2

4) KP - AMK Acylcarnitines MS/MS, Pregnancy Screening MS/MS, Compensation of PKU/HPA MS/MS : Ala, Phe, Tyr, Val, Xle, Cit, C2, C3, C3DC, C4, C4DC, C5, C5:1, C5DC, C5OH, C6, C8, C10, C10:1, C12, C14, C14:1, C14:2, C14OH, C16, C16:OH, C16:1, C18, C18:1, C18:1OH, C18OH, C0 and ratios: Phe/Tyr, Xle/Ala, C3/C2, C4/C3, C5DC/C8, C5/C0, C8/C2, C14:1/C2, (C16+C18)/C0, (C16+C18:1)/C2.

2. DNA Diagnostics Laboratory

Examination:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
17.	Examination of the <i>NOTCH3</i> gene from genomic DNA by Sanger sequencing method [<i>NOTCH3</i>]	SOP-UDMP-G-006	Uncoagulable blood, isolated DNA
18.	Examination of the <i>ASPA</i> gene from genomic DNA by Sanger sequencing method [<i>ASPA</i>]	SOP-UDMP-G-007	Uncoagulable blood, isolated DNA
19.	Examination of the <i>ASADM</i> gene from genomic DNA by Sanger sequencing method [<i>ACADM</i>]	SOP-UDMP-G-011	Uncoagulable blood, isolated DNA
20.	Examination of the <i>BTD</i> gene from genomic DNA by Sanger sequencing method [<i>BTD</i>]	SOP-UDMP-G-014	Uncoagulable blood, isolated DNA
21.	Examination of the <i>HADHA</i> gene from genomic DNA by Sanger sequencing method [<i>HADHA</i>]	SOP-UDMP-G-017	Uncoagulable blood, isolated DNA
22.	Examination of the <i>OTC</i> gene from genomic and complementary DNA by Sanger sequencing method [<i>OTC</i>]	SOP-UDMP-G-022	Uncoagulable blood, isolated DNA
23.	Examination of the <i>GLA</i> gene from genomic and complementary DNA by Sanger sequencing method [<i>GLA</i>]	SOP-UDMP-G-024	Uncoagulable blood, isolated DNA



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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
24.	Examination of the <i>GBA</i> gene from genomic DNA by Sanger sequencing method [<i>GBA</i>]	SOP-UDMP-G-026	Uncoagulable blood, isolated DNA
25.	Examination of the <i>GALC</i> gene from genomic DNA by Sanger sequencing method [<i>GALC</i>]	SOP-UDMP-G-033	Uncoagulable blood, isolated DNA
26.	Examination of the <i>CLN2 (TPP1)</i> gene from genomic and complementary DNA by Sanger sequencing method [<i>CLN2 (TPP1)</i>]	SOP-UDMP-G-044	Uncoagulable blood, isolated DNA
27.	Examination of the <i>CLN3</i> gene from genomic DNA by Sanger sequencing method [<i>CLN3</i>]	SOP-UDMP-G-045	Uncoagulable blood, isolated DNA
28.	Examination of the <i>CLN7 (MFSD8)</i> gene from genomic DNA by Sanger sequencing method [<i>(CLN7 (MFSD8))</i>]	SOP-UDMP-G-048	Uncoagulable blood, isolated DNA
29.	Examination of <i>NPC1</i> and <i>NPC2</i> genes from genomic DNA by Sanger sequencing method [<i>NPC1, NPC2</i>]	SOP-UDMP-G-051	Uncoagulable blood, isolated DNA
31	Microscopic evaluation (detection) of cell growth in tissue culture	SOP-UDMP-T-01	skin biopsy

Explanations:

Names in parentheses [] are the names of examinations shown in the reports.

