EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Hájkova 2747/22, Žižkov, 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. **532/2024**

Všeobecná fakultní nemocnice v Praze
with registered office U Nemocnice 499/2, 128 08 Praha 2,
Company Registration No. 00064165

for the Medical Laboratory No. **8097**
Department of Pediatrics and Inherited Metabolic Disorders (KPDPM) of General University Hospital in Prague and 1 st Medical Faculty of Charles University, Diagnostic Laboratories for Inherited Metabolic Disorders (DPM)

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.

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 ed. 3:2023

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

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 255/2023 of 29/05/2023, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **29/05/2028**

Prague: 10/10/2024

Český institut pro akreditaci, o.p.s.
-7-

Milena Lochmanová
Director of the Department
of Medical Laboratories
Czech Accreditation Institute

The Appendix is an integral part of
Certificate of Accreditation No.: 532/2024 of 10/10/2024

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

Všeobecná fakultní nemocnice v Praze
CAB Number 8097, Department of Pediatrics and Inherited Metabolic Disorders (KPDPM) of the General University Hospital in Prague and 1st Medical Faculty of Charles University, Diagnostic Laboratories for Inherited Metabolic Disorders (DPM)
Ke Karlovu 455/2, 128 08 Praha 2

Medical laboratory locations:

1. **DPM Biochemistry Laboratory** Ke Karlovu 455/2, Praha 2
2. **DPM Molecular Genetics Laboratory** Ke Karlovu 455/2, Praha 2
3. **Laboratory for the study of mitochondrial disorders** Ke Karlovu 455/2, Praha 2

The laboratory applies a flexible approach to the scope of accreditation.
The current "List of activities within the flexible scope" is available on the website www.vfn.cz/pacienti/kliniky-ustavy/klinika-detskeho-a-dorostoveho-lekarstvi/laborator/ .

1. **DPM Biochemistry Laboratory**

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom[1]
801 – Clinical Biochemistry					
1.	Amino acids and acylcarnitines	Tandem Mass Spectrometry	Commercial procedure	Dry blood spot	A, B, C
2.	Biotinidase	Fluorimetry	Commercial procedure	Dry blood spot	A, B
3.	Amino acid profile	Ion-exchange chromatography	In-house method	Serum, plasma, cerebrospinal fluid, urine	A, B, C
4.	Orotic acid	Capillary electrophoresis	In-house method	Urine	A, B
5.	Galactitol	Gas chromatography	In-house method	Urine	A, B
6.	Profile of purines and pyrimidines	Liquid chromatography	In-house method	Urine	A, B, C
7.	Mucopolysaccharides	Spectrophotometry	In-house method	Urine	A, B
8.	Lactate	Spectrophotometry	In-house method	Urine, blood deproteinate, cerebrospinal fluid deproteinate	A, B
9.	Vacant				

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom[1]
10.	Homocysteine	Spectrophotometry	Commercial procedure	Plasma, serum	A, B
11.	Creatinine	Spectrophotometry	Commercial procedure	Serum, plasma, urine	A, B
12.	Uric acid	Spectrophotometry	Commercial procedure	Serum, plasma, urine	A, B
13.	Enzymes	Fluorimetry	In-house method	Biological material	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Newborn screening for SCID and SMA	Real-time PCR	Commercial procedure	Dry blood spot	A, B

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2. **DPM Molecular Genetics Laboratory**

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Examination of germline genome variants	Massive parallel sequencing	Commercial procedure, In-house method	Biological material containing genomic DNA	A, B, C
2.	Examination of germline genome variants	Sanger sequencing	In-house method	Biological material containing genomic DNA	A, B, C

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

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Ke Karlovu 455/2, 128 08 Praha 2

3. **Laboratory for the study of mitochondrial disorders**

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom[1]
801 – Clinical Biochemistry					
1.	Determination of the profile of sialic forms of transferrin	Isoelectric focusing	In-house method	Biological material	A, B, D
816 – Medical Genetics Laboratory					
1.	Examination of germline genome variants	Massive parallel sequencing	In-house method	Biological material containing genomic DNA	A, B, C
2.	Examination of germline genome variants	Sanger sequencing	In-house method	Biological material containing genomic DNA	A, B, C
3.	Investigation of mtDNA mutations associated with LHON syndrome	RFLP	In-house method	Biological material containing genomic DNA	A, B, C
4.	Examination of germline genome variants	HRM	In-house method	Biological material containing genomic DNA	A, B, C

Explanatory notes:

[1] Established degrees of freedom according to MPA 00-09-..:

A – Flexibility concerning the documented examination / sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

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SCID – Severe Combined Immunodeficiency
SMA – Spinal Muscular Atrophy
mtDNA – Mitochondrial Deoxyribonucleic Acid
LHON – Leber Hereditary Optic Neuropathy
RFLP – Restriction Fragment Length Polymorphism
HRM – High Resolution Melting

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself. "