NÁRODNÍ AKREDITAČNÍ ORGÁN

EA MLA Signatory
Český institut pro akreditaci, o.p.s.
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. **21/2021**

Fakultní nemocnice Hradec Králové
with registered office Sokolská 581, 500 05 Hradec Králové - Nový Hradec Králové,
Company Registration No. 00179906

to the Medical laboratory No. **8234**
Laboratory of the Institute for Clinical Biochemistry and Diagnostics and the Department of Medical Genetics – Germinal Genome

Scope of accreditation:

Molecular genetic examinations of the human genome 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 15189:2013

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.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 608/2019 of 21. 11. 2019, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **6. 1. 2026**

Prague: 6. 1. 2021

Český institut pro akreditaci, o.p.s.
NÁRODNÍ AKREDITAČNÍ ORGÁN
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Milena Lochmanová
Director of the Department of Medical Laboratories
Czech Accreditation Institute
Public Service Company

The Appendix is an integral part of
Certificate of Accreditation No. 21/2021 of 07/01/2021

Accredited entity according to ČSN EN ISO 15189:2013:

Fakultní nemocnice Hradec Králové
Laboratory of the Institute for Clinical Biochemistry and Diagnostics and the Department of Medical Genetics – Germinal Genomé
Sokolská 581, 500 05 Hradec Králové - Nový Hradec Králové

The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex. Updated list of activities provided within the flexible scope of accreditation is available on the laboratory website http://ukbd.fnhk.cz/zamereni-laboratore.html and at the Quality Management Department.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
	816 - Medical Genetics Laboratory		
1.	Analysis of congenital genetic CNV variants by ARRAY – CGH method [Array - CGH] [Array – CGH - prenatal]	4-36-0038 A	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow, native amniotic fluid
2.	Analysis of DNA by PCR method with electrophoretic detection of product [1)]	4-36-0060 F	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow
3.	Detection of methylation status of gene by methylation specific MLPA[2)]	4-36-0061 F	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow
4.	Detection of sequential variants in genes by real-time PCR method [3)]	4-36-0062 F	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, buccal smear, tissue, bone marrow
5.	Analysis of fluorescently labelled DNA fragments by capillary electrophoresis method [4)]	4-36-0063 F	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow, amniotic fluid
6.	Determination of genomic alterations by MLPA method [5)]	4-36-0064 F	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, tissue, bone marrow
7.	Detection of sequential variants in genes by Sanger sequencing [6)]	4-36-0065 F	Incoagulable blood - peripheral, cultured amniocytes, CVS cells, buccal smear, tissue, bone marrow
8.	Gene mutation analysis by massive parallel sequencing method [7)]	4-36-0066 F	Incoagulable blood - peripheral, Buccal smear, tissue, bone marrow

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

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Annex:
Flexible scope of accreditation

Examination procedure ordinal numbers
2, 3, 4, 5, 6, 7, 8

The Laboratory is allowed to modify the examination procedures listed in the Annex within the specified scope of accreditation provided the measuring principle is observed.

The flexible approach to the scope of accreditation cannot be applied to the examinations not included in the Annex.

Explanatory notes:

1)

Examination of polymorphism in apolipoprotein E gene, codons 112 and 158;
Procedure 4-36-0007 A; [ApoE]

Examination of genetic predisposition to coeliac disease; Procedure 4-36-0052 A; [Genetic predisposition to coeliac disease]

Molecular genetic analysis of the trinucleotide expansion – expansion of CGG repeats in *FMR1* gene 5´ area; Procedure 4-36-0018 A; [FRAXA-screening]

2)

Prader Willi/Angelman sy;
Procedure 4-36-0044 A; [PWS-AS-UPD 14]

3)

Examination of HFE gene C282Y, H63D and S65C mutations; Procedure 4-36-0005 A; [HFE]

Examination of Thiopurine Methyltransferase (TPMT) gene mutations, alleles *2, *3A, *3B and *3C;
Procedure 4-36-0017 A; [Mutation TPMT]

Examination of blood coagulation Factor V gene Leiden mutation (G1691A);
Procedure 4-36-0028 A; [FV Leiden]

Examination of blood coagulation Factor II gene G20210A mutation (Prothrombin)
Procedure 4-36-0029 A; [G20210A FII]

Examination of C677T mutation in Methylenetetrahydrofolate Reductase (MTHFR) gene;
Procedure 4-36-0003 A; [C677T MTHFR]

Examination of alpha-1 antitrypsin gene defect, mutations Z and S;
Procedure 4-36-0006 A; [Alpha1-AT]

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Examination of variants in CYP2C9 and VKORC1 genes; Procedure 4-36-0014 A;
[Exam. polymorph. of CYP/VKOR gene]

HRM analysis of c.1138 in *FGFR3* gene; Procedure 4-36-0055 A; [Achondroplasia_HRM]

4)

FRAXA – examination of sy. Fragile X FMR1 gene; Procedure 4-36-0023A; [FRAXA FA]

Examination of CFTR gene mutations; Procedure 4-36-0004 A; [CFTR]
F508del, G542X, N1303K, W1282X, G551D, 1717-1G>A, R553X, CFTRdele2,3(21kb), I507del, 711+1G>T, 3272-26A>G, R560T, 1898+1G>A, 3120+1G>A, 621+1G>T, 3849+10kbC>T, 2183AA>G, 2789+5G>A, R1162X, 3659delC, R117H, R117C, R1066C, R334W, R347P, R347H, G85E, 1078delT, 2143delT, Y1092X, L1077P, L1065P, T338I, I336K, 1677delTA; polymorphism 5T/7T/9T
Procedure 4-36-0004 A; [CFTR]

Examination of post transplant chimerism using STR loci and amelogenin gene;
List of genetic loci used:
CSF1PO, D2S1338, D18S51, D5S818, D7S820, D3S1358, D19S433, FGA, D8S1179, D13S317, TPOX, D21S11, D16S539, vWA, TH01, Amelogenin
Procedure 4-36-0012 A; [Chimerism]

Molecular genetic analysis - CTG trinucleotides in *3' UTR DMPK* gene;
Procedure 4-36-0031 A; [Myotonic dystrophy-basic]

Molecular genetic analysis - CTG trinucleotides in *3' UTR DMPK* gene;
Procedure 4-36-0031 A; [Myotonic dystrophy-full]

5)

Microdeletion sy, CMT1A1
genes *SHOX, TP53, NF1, CHEK2, MLH1, MSH2, MSH6, BRCA2; STK11* Procedure 4-36-0049 A
[MLPA GM]

MLPA BRCA1; Procedure 4-36-0033 A; [MLPA BRCA]

Spinal muscular atrophy; Procedure 4-36-0059 A; [SMA I]

6)

Sanger sequencing analysis
genes *DHCR7, PHOX2B, SHOX, SPRED1, PMP22, TTN*;

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genes included in NGS - oncopanel: *PALB2, CHEK2, MLH1, MSH2, ATM, NBN*
genes included in NGS - NF panel: *NF1*
Procedure 4-36-0048 A; [Seq. analysis of gene exon Y], Y = number of amplicons

Predictive diagnostics of BRCA1/2 genes, exon amplicons of BRCA1/2 genes;
Procedure 4-36-0025 A; [Prediction BRCA 1/2]

Examination of connexin 26 gene (GJB2) mutations;
Procedure 4-36-0039 A; [Mutations-GJB2]

7)

Molecular diagnostics of 22 genes associated with the risk of hereditary tumours;
genes *ATM, APC, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53*
Procedure 4-36-0051 A; [NGS]

Examination of mutations in NF1 and NF2; Procedure 4-36-0053 A; [Neurofibromatosis -NGS]

Molecular diagnostics of 34 genes associated with the risk of hereditary tumours – genes *ATM, APC, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, SMAD4, STK11, TP53+BAP1, BLM, CDK4, CDKN2A, FH, GREM, POLD1, POLE, PTCH1 and SUFU*
Procedure 4-36-0056 A; [SSEL_34G]

Examination of minimal residual disease in IGVH alterations;
Procedure 4-36-0057 A; [NGS SM]