List of activities within the flexible scope of accreditation

Accredited Body: Unilabs Diagnostics k. s.

CAB Name: Laboratoř forenzní a lékařské genetiky

CAB Number: 8141

Certificate of Accreditation No. 501/2024

Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023

Updated: 26.9.2024

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Examination of germline genome variants	Real-Time PCR	SOP č. 0, v4, SOP-A, v5; CFX 96, CFX Connect	Biological material containing human nuclear DNA	A, B, C
2.	Examination of somatic genome variants	Real-Time PCR	SOP č. 0, v4, SOP-A, v5; CFX 96	Biological material containing human nuclear RNA	A, B, C
3.	Examination of germline genome variants	PCR – fragment analysis, gel	SOP č. 0, v4, SOP-B, v4	Biological material containing human nuclear DNA	A, B, C
4.	Examination of germline genome variants	PCR – fragment analysis, capillary	SOP č. 0, v4, SOP-C, v5; ABI PRISM 3100 Avant; SeqStudio Genetic Analyzer	Biological material containing human nuclear DNA	A, B, C
5.	Examination of germline genome variants	PCR – reverse hybridization	SOP č. 0, v4, SOP-D, v4;	Biological material containing human nuclear DNA	A, B, C
6.	Examination of germline genome variants	Direct sequencing	SOP č. 0, v4, SOP-E, v6; ABI PRISM 3100 Avant; SeqStudio Genetic Analyzer	Biological material containing human nuclear DNA	A, B, C
7.	Examination of germline genome variants	MLPA	SOP č. 0, v4, SOP-F, v6; ABI PRISM 3100 Avant; SeqStudio Genetic Analyzer	Biological material containing human nuclear DNA	A, B, C
8.	Examination of germline genome variants	NGS-MPS	SOP č. 0, v4, SOP-G, v5; Genexus Integrated Sequencer System	Biological material containing human nuclear DNA	A, B, C

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Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816 /1	Factor V - Leiden mutation (G1691A); Factor II Prothrombin (G20210A); Factor XIII (V34L); Factor V R2 (H1299R); *PAI-1* (4G/5G); *MTHFR* (C677T, A1298C); HLA-B*27 – Morbus Bechterew; Lactose intolerance (*LCT* -13910C>T, -22018G>A); Fructose intolerance (*ALDOB*: mutations A149P, A174D, N334K, del4E4); α-1 antitrypsin deficiency (*SERPINA1*: mutations PI*S = E264V, PI*Z = E342K); β-fibrinogen (-455G>A); *ApoB* (R3500Q); *ApoE* (E2/E3/E4); *GpIIIa* (L33P); Metabolism of thiopurine drugs (*TPMT*: mutations TPMT*2 = G238C, TPTMT*3A = G460A/A719G, TPMT*3B = G460A, TPMT*3C = A719G); Metabolism of warfarin (*VKORC1*: mutations G1639A, *CYP2C9*: CYP2C9*2 = C430T, CYP2C9*3 = A1075C); Gilbert syndrome (*UGT1A1*); Predisposition to celiac sprue (loci *DQA1* and *DQB1*; serological equivalents DQ2.5, DQ2.2, DQ8); Hereditary hemochromatosis (*HFE*: mutations C282Y, H63D, S65C); *GpIa* (C807T); Determination of predisposition to psoriasis (HLA-C*06 alleles) Metabolism of anticoagulants, antidepressants, antiepileptics, proton pump inhibitors, anticonvulsants, hypnotics, sedatives, antimalarials, antiretrovirics, antifungals and (*CYP2C19* gene *1, *2, *3, *17 alleles); Metabolism of myorelaxans, e.g. suxamethonium, mivacurium (*BCHE* gene A, K, F1, F2, S1 alleles); *ACE* (ins/del)
816/2	Determination of *BCR-ABL* fusion gene and determination of rearrangement type (M-bcr, m-bcr, μ-bcr)
816/3	Determination of predisposition to celiac sprue (loci *DQA1* and *DQB1*; serological equivalents DQ2.5, DQ2.2, DQ8); Determination of predisposition to narcolepsy (allele DQB1*0602)
816/4	Cystic fibrosis (mutation in *CFTR* gene); Fragile X syndrome – determination of CGG repeats number in *FMR1* gene Determination of *AZF* locus microdeletions on Y chromosome (AZFa, AZFb, AZFc);

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816/5	Examination of predisposition to rheumatoid arthritis (shared HLA-DRB1 epitope)
816/6.	Copper metabolism (*ATP7B* - exons 3, 8, 14, 15 and 17); Prelingual hearing loss, non-syndromic (*GJB2* gene)
816/7	Spinal muscular atrophy (deletion/duplication of exons 7 and 8 in *SMN1* and *SMN2*genes); Detection of deletions and duplications in *BRCA1* gene; Detection of deletions and duplications in *BRCA2/CHEK2* genes Detection of deletions and duplications in *EPCAM*, *MSH2*, *MLH1*, *PMS2*, *MUTYH* a *MSH6* genes by MLPA method
816/8	Hereditary breast and ovarian cancer (*BRCA1 and BRCA2*) genes; Hereditary breast and ovarian cancer - NGS panel of 21 genes (*ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CDK12, FAM175A, FANCD2, CHEK2, MRE11, MSH6, NBN, PALB2, PMS2, RAD51B, RAD54L, TP53, RAD50, RAD51C, RAD51D*); Hereditary prostate cancer - NGS panel of 26 genes (*AKT1, APC, AR, ATM, BRAF, BRCA1, BRCA2, CDH1, CDK12, CTNNB1, HOXB13, CHEK2, IDH1, KRAS, MED12, MLH1, MSH2, MSH6, MYC, PIK3CA, PIK3R1, PMS2, PTEN, RB1, SPOP, TP53*); Colorectal and pancreatic cancer - NGS panel of 13 genes (*APC, BRAF, CTNNB1, KRAS, MLH1, MSH2, MSH6, MYC, PIK3CA, PMS2, PTEN, STK11, TP53*); NGS panel of hereditary cancer syndromes - 50 genes (*AKT1, APC, AR, ATM, ATR, BARD1, BLM, BRAF, BRCA1, BRCA2, BRIP1, CDH1, CDK12, CTNNB1, EPCAM, FAM175A, FANCD2, GATA3, GEN1, HOXB13, CHEK2, IDH1, KRAS, MED12, MLH1, MRE11, MSH2, MSH6, MUTYH, MYC, NBN, NF1, PALB2, PIK3CA, PIK3R1, PMS2, PTEN, RAD50, RAD51B, RAD51C, RAD51D, RAD54L, RB1, RET, SPOP, STK11, TP53, VHL, WT1, XRCC2*)

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.

Real-Time PCR	Real-Time Polymerase Chain Reaction
MLPA	Multiplex ligation-dependent probe amplification
NGS-MPS	Next Generation Sequencing – Massively Parallel Sequencing
PCR	Polymerase Chain Reaction