List of activities within the flexible scope of accreditation

Accredited Body: Fakultní nemocnice v Motole

CAB Name: IBMG Laboratories

CAB Number: 8058

Certificate of Accreditation No.: 123/2025

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

Updated: 11. 8. 2025

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	Fragment analysis	IISOP_UBLG_6/2013, version 9; IISOP_UBLG_9/2013, version 11; IISOP_UBLG_12/2013, annex 1, 2 version 08; IISOP_UBLG_01/2015, version 5; IISOP_UBLG_02/2018, version 3_amendment_250116; ABI 3130XL; 3500 Genetic Analyzer; SeqStudio 8 Flex	Biological material containing genomic DNA	A, B, C
2.	Examination of germline genome variants	Direct sequencing (acc. to Sanger)	IISOP_UBLG_19/2013, annex 1, version 11; IISOP_UBLG_02/2015, version 06; IH_IVD_2_2025, version 1; ABI 3130XL; 3500 Genetic Analyzer; SeqStudio 8 Flex	Biological material containing genomic DNA	A, B, C
3.	Examination of germline genome variants	MLPA	IISOP_UBLG_01/2017, version 4_amendment_241129; ABI 3130XL; 3500 Genetic Analyzer	Biological material containing genomic DNA	A, B, C

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4.	Examination of germline genome variants	NGS-MPS	IISOP_UBLG_02/2017, annex 1, 2 a 3, version 5; Illumina MiSeq, Sophia DDM	Peripheral blood	A, B, C, D
5.	Examination of unbalanced chromosomal aberrations	array CGH	IISOP_UBLG_03/2015, annex 1 and 2, version 8; Microarray Scanner Agilent Dx–G5761A; GenetiSure Cyto 8x60K CGH; GenetiSure Cyto 4x180K CGH; SurePrint G3 human CGH array 4x180K; SurePrint G3 ISCA V2 CGH 8x60K; SurePrint G3 CGH+SNP Array 4x180K; GenetiSure Cyto 4x180K CGH+SNP; SurePrint G3 Custom CGH Microarray 8x60K; SurePrint G3 Custom CGH+SNP 4x180K	Peripheral blood, umbilical cord blood, amniotic fluid, chorionic villi, aborted tissues	A, B, D
6.	Examination of constitutional karyotype	Conventional cytogenetic analysis	IISOP_UBLG_16/2013, annexes 1, 2 and 5, version 11; IIOP_UBLG_11/2013, annex 1, version 13	Peripheral blood, fetal blood, umbilical cord blood, amniotic fluid, chorionic villi, aborted tissues and skin biopsy	A, B, D
7.	Examination of acquired chromosomal aberrations	Microscopy	IISOP_UBLG_16/2013, version 11; IIOP_UBLG_11/2013, annex 1, version 13	Peripheral blood	A, B

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8.	Examination chromosomal aberrations	FISH	IISOP_UBLG_17/2013, annex 1 a 2, version 13; IIOP_UBLG_11/2013, annex 1, version 13	Peripheral blood, fetal blood, umbilical cord blood amniotic fluid, chorionic villi, aborted tissue, buccal mucosa and skin biopsy	A, B
Laboratory examinations for IVF					
1.	Semen evaluation	Macroscopy; Microscopy	IISOP_UBLG_30/2013, annex 1, 2 and 3, version 9	Semen	A, B

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/1	Primers for detection of mutant and wt alleles: R347H, R347P, 2789+5G>A, 3120+1G>A, 711+1G>T, R334W, I507del, F508del, 3849+10kbC>T, 1677delTA, 1078delT, V520F, L206W, W1282X, R560T, 2347delG, Q890X, R553X, G551D, S549R(T>G), S549N, M1101K, G542X, 3905insT, Y1092X(C>A), S1251N, 444delA, 1811+1.6kbA>G, 1717-1G>A, R117H, R117C, N1303K, Y122X, 394delTT, G85E, R1066C, 1898+1G>A, W846X, 2184delA, D1152H, CFTRdele2,3, P67L, 2143delT, E60X, 3659delC, 3272-26A>G, 621+1G>T, A455E, R1162X a R1158X, IVS8-5T, IVS8-7T, IVS8-9T Primers for identification of 2 hypervariable STR markers. Leiden mutation in the factor V gene, 20210G>A mutation in the 3' untranslated region of the coagulation factor II gene, and C677T polymorphism in the Methylenetetrahydrofolate reductase (MTHFR) gene. 13q12.12 (D13S742), 13q21.32-q21.33 (D13S634), 13q31.1 (D13S628), 13q13.3 (D13S305), 13q22.1 (D13S800), 13q12.2 (D13S252), 13q21.1 (D13S1492), 18q12.3 (D18S978), 18q12.3 (D18S535), 18q22.1 (D18S386), 18q22.1 (D18S386), 18q11.2 (D18S1002), 18p11.31 (D18S976), 18p11.32 (GATA178F11), 18q22.1 (D18S1364), 21q21.3 (D21S1435), 21q21.1 (D21S11), 21q22.3 (D21S1411), 21q22.13 (D21S1444), 21q21.3 (D21S1442), 21q22.2 (D21S2055), Xq21.31/Yp11.31 (DXYS267), Xp22.33/Yp11.31 (DXYS218), Xq26.2 (DXS1187), Xq13.1 (DXS981), Xq26.2-26.3 (XHPRT), Xq27.1-q27.2 (DXS2390), Xp22.2 (AMELX), Yp11.2 (AMELY), Yp11.31/Xp22.1 (ZFY, ZFX), Yp11.31 (SRY), 7q34/Xq13, 3p24.2/Xq21.1 Gene FMR1 (region Xq27.3, locus FRAXA) Repetitive GAA triplet sequence in the first intron of the FXN gene

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Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/2	Exon 10 of the FGFR3 gene in achondroplasia, exons 13 and 15 of the FGFR3 gene in hypochondroplasia, exons 7, 10, 15, and 19 of the FGFR3 gene in thanatophoric dysplasia, exon 7 of the FGFR3 gene in Muenke craniosynostosis, exon 8 of the FGFR2 gene in Apert syndrome, exons 8 and 10 of the FGFR2 gene in Crouzon syndrome, Pfeiffer syndrome, and non-syndromic craniosynostosis, VHL gene in von Hippel-Lindau disease, PANK2 gene in pantothenate kinase-associated neurodegeneration (PKAN), GCH1 gene in dopa-responsive dystonia, AR gene in androgen insensitivity syndrome, SRY gene in disorders of sex development, GJB2 gene in non-syndromic deafness. *CFTR, BRCA1, BRCA2*
816/3	*CFTR, BRCA1, BRCA2*
816/4	*APC, BRCA1, BRCA2, PALB2, TP53, ATM, CDH1, CHEK2, NBN, RAD51C, RAD51D, BARD1, BRIP1, MLH1, MRE11A, MSH2, MSH6, MUTYH, PMS2, PMS2CL, PTEN, RAD50, STK11, EPCAM, FAM175A, PIK3CA a 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.

NGS-MPS	massively parallel sequencing
array CGH	oligonucleotide array comparative genomic hybridization on chip
MLPA	hybridization and ligation of probes followed by multiplex polymerase reaction
FISH	fluorescence *in situ* hybridization