The Appendix is an integral part of
Certificate of Accreditation No. 154/2022 of 25/03/2022

Accredited entity according to ČSN EN ISO 15189:2013:

Fakultní nemocnice Brno
Internal Hematology and Oncology Clinic, Center of Molecular Biology and Gene Therapy
Černopolní 212/9, 613 00 Brno

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 at the Laboratory from the Quality Manager.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
802 - Medical Microbiology Laboratory			
1.	Detection of CMV DNA by CMV HHV6,7,8 R-gene (Argene) diagnostic kit	SA/CMBG/V0002	Biological material containing human nuclear DNA
2.	Examination of EBV DNA using EBV R-gene (Argene) diagnostic kit	SA/CMBG/V0003	Biological material containing human nuclear DNA
813 - Allergology and Immunology Laboratory			
1.	Detection of PNH clone characterized by the occurrence of combinations of $GlyA^{+}CD59^{-}$ or $CD64^{++}14^{-}Flaer^{-}$ or $CD15^{+}24^{-}Flaer^{-}$ surface antigens on peripheral blood cells by flow cytometry	SA/CMBG/F0001	Peripheral blood
2.	Detection of CLL residual clone by flow cytometry according to modified Rawstron protocol[8]	SA/CMBG/F0003	Peripheral blood, bone marrow
816 - Medical Genetics Laboratory			
1.	Examination of karyotype of tumor cells by banding method	SA/CMBG/C0001	Bone marrow, solid tumor tissue, peripheral blood, node
2.	Examination of constitutional karyotype by banding method	SA/CMBG/C0003	Peripheral/umbilical cord blood, amniotic fluid, chorionic villi, fetal tissue
3.	Examination of acquired chromosomal aberrations by cytogenetic analysis of peripheral lymphocytes [ZCA, CAPL]	SA/CMBG/C0004	Peripheral blood

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
4.	Examination of chromosomal aberrations by fluorescent in-situ hybridization method [FISH]	SA/CMBG/C0002	Peripheral/umbilical cord blood, amniotic fluid, chorionic villi, fetal tissue, buccal smear, bone marrow, solid tumor tissue, node
5.	Examination of chromosomal aberrations by comparative genomic hybridization on oligonucleotide microarrays [array-CGH]	SA/CMBG/C0005	Peripheral/umbilical cord blood, amniotic fluid, chorionic villi, tissue, buccal smear, bone marrow, solid tumor tissue, node
6.	Analysis of DNA by PCR method with electrophoretic detection of product[1]	SA/CMBG/M1	Biological material containing human nuclear DNA
7.	Detection of sequential variants in genes by Sanger sequencing[2]	SA/CMBG/M2	Biological material containing human nuclear NA
8.	Investigation of mutations in genes by massively parallel sequencing (NGS)[3]	SA/CMBG/M3	Biological material containing human nuclear DNA
9.	Detection of sequential variants in genes by real-time PCR method[4]	SA/CMBG/M4	Biological material containing human nuclear NA
10.	Determination of genetic alterations by MLPA method[5]	SA/CMBG/M5	Biological material containing human nuclear DNA
11.	Analysis of fluorescently labelled DNA fragments by capillary electrophoresis method [6]	SA/CMBG/M6	Biological material containing human nuclear NA
12.	Detection of sequential variants in genes by PCR method with reverse hybridization (strip-assay)[7]	SA/CMBG/M7	Biological material containing human nuclear NA

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
13.	Examination of cellular chimerism after allogeneic HSCT by fragment analysis method and RQ-PCR	SA/CMBG/MO003	Biological material containing human nuclear DNA
14.	Examination of BCR-ABL1 fusion gene by Xpert BCR-ABL Ultra Kit (Cepheid) diagnostic kit[9]	SA/CMBG/MO006	Peripheral blood, bone marrow
15.	Examination of gene fusions and transcript variants with the AMLplexQS (Mentype) diagnostic kit	SA/CMBG/MO007	Peripheral blood, bone marrow, RNA

Annex:
Flexible scope of accreditation

Examination procedure ordinal numbers:
6, 7, 8, 9, 10, 11, 12

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] Analysis of DNA by PCR method with electrophoretic detection of product:

SA/CMBG/M1001	Determination of sex [SRY]
SA/CMBG/M1002	Celiac disease – genes DQB1, DQA1, DRB1 [HLA typing]
SA/CMBG/M1003	Detection of fusion gene BCR:: BLL1

[2] Detection of sequential variants in genes by Sanger sequencing:

SA/CMBG/M2001	Retinoblastom [Rb1]
SA/CMBG/M2002	Non syndromic hearing loss [GJB2]
SA/CMBG/M2003	Phenylketonuria [PKU]
SA/CMBG/M2004	Wilson disease [ATP7B]
SA/CMBG/M2005	Determination of mutation state of IGVH gene
SA/CMBG/M2006	Detection of mutations in the kinase domain of the fusion gene BCR::ABL1

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[3] Analysis of germinal mutations of genes:

LDLRAP1, ANGPTL3, APOB, ABCG5, ABCG8, MTTP, SAR1B, LPL, GPIHBP1, ABCA1, LIPA, APOA5, APOC3, APOA1, GPD1, SCARB1, LIPC, LMF1, CETP, LCAT, APOC2, AARS, ACTA1, ALG13, ALG2, ALS2, ANO5, AR, ATP1A2, BAG3, BICD2, BIN1, CACNA1S, CAPN3, CAV3, CFL2, CFTR, CLCN1, CNTN1, COL6A1, COL6A2, COL6A3, COLQ, CRYAB, CYP2CD, DAG1, DES, DMD, DNAJB6, DNM2, DOK7, DPM3, DYSF, EMD, EXOSC3, EXOSC8, FKRP, FKTN, FLNC, F8, GAA, GARS, GMPPB, GNE, CHKB, CHRNE, ISCU, ISPD, ITGA2B, ITGA7, KCNA1, KLHL40, KLHL41, KLHL9, LAMA2, LAMP2, LARGE, LBD3, LDB3, LMNA, LMOD3, MATR3, MSTN, MTM1, MYH2, MYH8, MYOT, NRAP, PABPN1, PIEZO2, PLEC, POLG, POLG2, POMGNT1, POMK, POMT1, POMT2, PTRF, RAPSN, RRM2B, SCN4A, SEPN1, SERPINE1, SGCA, SGCB, SGCD, SGCE, SGCG, SMCHD1, SPEG, SUCLA2, SYNE1, SYNE2, TCAP, TK2, TMEM43, TMEM5, TNNT1, TNPO3, TPM2, TPM3, TRAPPC11, TRIM32, TRIM63, TRPV4, TUBB3, UBA1, VAPB, VCP, VMA21, VKORC1, VRK1

[4] Detection of sequential variants in genes by real-time PCR method:

SA/CMBG/M4001	Factor V-Leiden – p.Arg506Gln
SA/CMBG/M4002	Factor II – Prothrombin – c.20210G>A
SA/CMBG/M4003	Lactose intolerance (LI) – LCT gene variants: -13910T/C a -22018A/G
SA/CMBG/M4004	Examination of fusion gene BCR-ABL from RNA[a]
SA/CMBG/M4006	Determination of mutations in *TPMT* gene
SA/CMBG/M4007	Determination of mutations in *DPYD* gene

[5] Determination of genetic alterations by MLPA method:

SA/CMBG/M5001	Duchenne muscular dystrophy [DMD]
SA/CMBG/M5002	Spinal muscular atrophy [SMN1, SMN2]
SA/CMBG/M5003	Léri–Weill dyschondrosteosis [SHOX]
SA/CMBG/M5004	Retinoblastom [RB1]
SA/CMBG/M5005	Detection of chromosomal aberrations (microdeletion/microduplication)
SA/CMBG/M5006	Phenylketonuria [PKU]

[6] Analysis of fluorescently labelled DNA fragments by capillary electrophoresis method:

SA/CMBG/M6001	Cystic fibrosis by ARMS method [CF EU 50 mt]. Variants R347P, 2789+5G>A, 3120+1G>A, 711+1G>T, R334W, I507del, F508del, 849+10kbC>T, 1078delT, W1282X, R560T, R553X, G551D, S 549RT>G,M1101K, G542X, 3905insT, S1251N, 1717-1G>A, R117H, N1303K, G85E,1898+1G>A, 2184delA, D1152H, CFTRdele2,3, P67L, E60X, 3659delC, 621+1G>T, A455E, R1162X, 394delTT, 444delA, R117C, Y122X, L206W, R347H, 677delTA, V520F, S549N, 1811+1.6kbA>G, 2143delT, 2347delG, W846X, Q890X, 3272-26A>G, R1066C, 1092X(C>A) a R1158X, IVS8-5T, IVS8-7T, IVS8-9T
SA/CMBG/M6002	13, 15, 16, 18, 21, 22, X, Y chromosome aneuploidies by QF PCR method

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	SA/CMBG/M6003	Determination of azoospermatic factor deletions by multiplex PCR method [AZF]
	SA/CMBG/M6004	Hereditary hemochromatosis – detection of HFE gene variants p.C282Y, p.H63D, S65C
	SA/CMBG/M6005	Fragile X syndrome – determination of the length of the CGG tract in 5'UTR of FMR1 gene
	SA/CMBG/M6006	Myotonic dystrophy 1
	SA/CMBG/M6007	Examination of NPM1 gene

[7] Detection of sequential variants in genes by PCR method with reverse hybridization (strip-assay):

SA/CMBG/M7002	Congenital adrenal hyperplasia (CAH) – gene variants CYP21A2 P30L, I2 splice (I2 G), Del 8 bp E3 (G110del8nt), I172N, Cluster E6 (I236N, V237E, M239K), V281L, L307 frameshift (F306 + T), Q318X, R356W, P453S, R483P
SA/CMBG/M7003	α-thalassemia variants of the α-globin locus: -3.7 kb, -4.2kb, -20.5kb, -MED, -THAI, -FIL, α1 codon 14 G>A, α1 codon 59 G>A, anti – 3.7 triplication, α2 initiation codon T>C, α2 codon 59 G>A, α2 codon 125 T>C, α2 codon 142 T>C, α2 codon 142 T>A, α2 codon 142 A>T, α2 codon 142 A>C, α2 polyA-1 AATAAA>AATAAG, α2 polyA-2 AATAAA>AATGAA β–thalassemia variants of the β-globin locus: sequence variants in position: -101 C>T, -87 C>G, -30 T>A, codon 5 -CT, codon 6 G>A, codon 6 A>T, codon 6 –A, codon8 –AA, codon 8,9 +G, codon 15 TGG>TGA, codon 27 G>T, codon 39 C>T, codon 44 –C, IVS 1.1 G>A, IVS 1.5 G>C, IVS 1.6 T>C, IVS 1.110 G>A, IVS 1.116 T>G, IVS 1.130 G>C, IVS 2.1 G>A, IVS 2.745 C>G, IVS 2.848 C>A.

[8]	SA/CMBG/F0003	Examined markers: CD3, CD5, CD19, CD20, CD22, CD43, CD45, CD79b, CD81
[9]	SA/CMBG/MO006	Detected alterations: b2a2 (e13a2), b3a2 (e14a2)
[a]	SA/CMBG/M4004	Detected alterations: b2a2 (e13a2), b3a2 (e14a2), e1a2, e19a2, b3a3 (e14a3) + rare alterations

Abbreviations:

HSCT	- Hematopoietic stem cell transplantation
NGS	- Next generation sequencing
NA	- Nucleic acid
PNH	- Paroxysmal nocturnal hemoglobinuria
RP PCR	- Repeat Primed PCR
RQ-PCR	- Real-Time Quantitative PCR
RT	- Reverse Transcription