The Appendix is an integral part of
Certificate of Accreditation No. 346/2023 of 27/06/2023

Accredited entity according to ČSN EN ISO 15189:2013:

Fakultní nemocnice Brno

CAB Number 8213, Internal Hematology and Oncology Clinic, Center of Molecular Biology and Gene Therapy
Černopolní 212/9, 613 00 Brno

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.cmbgt.cz.

Examinatios:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
802 – Medical Microbiology					
1.	Detection of nucleic acids of infectious agents	RQ-PCR	Commercial procedure	Peripheral blood	A, B, C
813 - Allergology and Immunology Laboratory					
1.	Immunophenotyping of cell population	Flow cytometry	Commercial procedure	Peripheral blood	A, B, C
816 – Medical Genetics Laboratory					
1.	Examination of tumour karyotype	Conventional cytogenetic analysis	In-house method	Bone marrow, solid tumor tissue, peripheral blood, node	A, B
2.	Examination of constitutional karyotype	Conventional cytogenetic analysis	In-house method	Peripheral blood, umbilical cord blood, amniotic fluid, chorionic villi, fetal tissue	A, B
3.	Examination of acquired chromosomal aberrations	Microscopy	In-house method	Peripheral blood	A, B
4.	Examination of constitutional chromosomal aberrations	FISH	In-house method	Peripheral blood, umbilical cord blood, amniotic fluid, chorionic villi, fetal tissue, buccal smear, bone marrow, solid tumor tissue, node	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
5.	Examination of germline genome variants	aCGH	In-house method	Peripheral blood, umbilical cord blood, amniotic fluid, chorionic villi, fetal tissue, buccal smear, bone marrow, solid tumor tissue, node	A, B
6.	Examination of germline genome variants	PCR with electrophoretic product detection	Commercial procedure; In-house method	Biological material containing genomic DNA	A, B, C
7.	Examination of germline genome variants	Sanger sequencing	In-house method	Biological material containing genomic DNA	A, B, C
8.	Examination of germline genome variants	NGS	In-house method	Biological material containing genomic DNA	A, B, C
9.	Examination of somatic genome variants	NGS	Commercial procedure; In-house method	Peripheral blood, bone marrow	A, B, C
10.	Examination of germline genome variants	Real-time PCR	Commercial procedure; In-house method	Biological material containing genomic DNA	A, B, C
11.	*BCR::ABL1* fusion gene	Real-time PCR	Commercial procedure; In-house method	Peripheral blood, bone marrow	A, B, C
12.	Examination of germline genome variants	MLPA	Commercial procedure; In-house method	Biological material containing genomic DNA	A, B, C
13.	Examination of chromosomal aberrations	MLPA	Commercial procedure; In-house method	Biological material containing genomic DNA	A, B, C
14.	Examination of germline genome variants	Fragmentation analysis	Commercial procedure; In-house method	Biological material containing genomic DNA	A, B, C

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom[1]
15.	Examination of chromosome aneuploidies	Fragmentation analysis	Commercial procedure; In-house method	Peripheral blood, amniotic fluid, chorionic villi	A, B, C
16.	Examination of germline genome variants	Reverse hybridization	Commercial procedure; In-house method	Biological material containing genomic DNA	A, B, C
17.	Investigation of cellular microchimerism after allogeneic HSCT	RQ-PCR	Commercial procedure; In-house method	Biological material containing genomic DNA	A, B, C
18.	Examination of gene fusions	Multiplex PCR	Commercial procedure; In-house method	Peripheral blood, bone marrow	A, B, C
19.	Newborn screening for SCID and SMA	Real-time PCR	Commercial procedure	Dry blood spot	A, B

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.

PCR	Polymerase Chain Reaction
aCGH	array Comparative Genome Hybridization
ARMS	Amplification-Refractory Mutation System
FISH	Fluorescence *In-Situ* Hybridization
HLA	Human Leucocyte Antigen
HSCT	Hematopoietic Stem Cell Transplantation
MLPA	Multiplex ligation-dependent probe amplification
NGS	Next Generation Sequencing – Massively Parallel Sequencing
RQ-PCR	Quantitative Real-Time PCR
SCID	Severe Combined Immunodeficiency
SMA	Spinal muscular atrophy