The Appendix is an integral part of
Certificate of Accreditation No: 297/2024 of 24/06/2024

Accredited entity according to ČSN EN ISO/IEC 17025:2018:

Ústav hematologie a krevní transfuze
CAB number 1345, National Reference Laboratory for DNA Diagnostics
U Nemocnice 2094/1, 128 00 Praha 2

Testing laboratory locations:

1. **Department of Molecular Genetics** U Nemocnice 2094/1, 128 00 Praha
2. **Department of HLA** Kateřinská 521/19, 120 00 Praha 2
3. **Department of Cell Chimerism** Kateřinská 521/19, 120 00 Praha 2

The laboratory applies a flexible approach to the scope of accreditation.
The current list of activities carried out within the flexible scope is available on the laboratory's website https://www.uhkt.cz/laboratore/narodni-referencni-laboratore-nrl/nrl-pro-dna-diagnostiku in the form of the „List of activities within the flexible scope of accreditation".
The laboratory provides opinions and interprets test results.
Detailed information on activities within the scope of accreditation (determined analytes) is given in the section „Specification of the scope of accreditation".

1. Department of Molecular Genetics

Tests:

Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
1	Determination of BCR::ABL1 fusion gene rearrangements using multiplex RT PCR	NRL_03_SOP_14_02	Biological material containing human RNA	A, B, D
2	Determination of BCR::ABL1 transcript level using Real-time RT PCR	NRL_04_SOP_14_02 procedure A	Biological material containing human RNA	A, B, D
3	Determination of BCR::ABL1 kinase domain mutation using direct sequencing by Sanger method	NRL_04_SOP_14_02 procedure B	Biological material containing human RNA	A, B, D
4	Determination of the conversion factor for expressing the results of BCR::ABL1 transcript level on international scale	NRL_04_SOP_14_02 procedure C	Biological material containing human RNA	A, B, D

[1] asterisk at the ordinal number identifies the tests, which the laboratory is qualified to carry out outside the permanent laboratory premises

[2] if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest valid edition of the specified procedure is used (including any changes)

[3] degrees of freedom: A – Flexibility concerning materials/products (subject of the test), B – Flexibility concerning components/parameters/characteristics, C – Flexibility concerning the performance of the method, D – Flexibility concerning the method

The laboratory can modify the test procedures with the specified degree(s) of freedom in the scope of accreditation while maintaining the principle of measurement. If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for the test.

The Appendix is an integral part of
Certificate of Accreditation No: 297/2024 of 24/06/2024

Accredited entity according to ČSN EN ISO/IEC 17025:2018:

Ústav hematologie a krevní transfuze
CAB number 1345, National Reference Laboratory for DNA Diagnostics
U Nemocnice 2094/1, 128 00 Praha 2

Specification of the scope of accreditation:

Ordinal test number	Detailed information on activities within the scope of accreditation (determined analytes)
1	detected rearrangements: b2a2 (e13a2), b3a2 (e14a2), e1a2, e19a2 + rare rearrangements
2	detected rearrangements: b2a2 (e13a2) a b3a2 (e14a2), e1a2; control genes: GUSB and ABL1

2. **Department of HLA**

Tests:

Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
1	Determination of gene sequence variants related to haematological and immunological diseases and hematopoietic stem cell transplant program by PCR and gel electrophoresis	NRL_05_SOP_14_02 procedure A	Biological material containing human DNA of the cell nuclei	A, B, D
2	Determination of gene sequence variants related to haematological and immunological diseases and hematopoietic stem cell transplant program by Real-time PCR method	NRL_05_SOP_14_02 procedure C	Biological material containing human DNA of the cell nuclei	A, B, D
3	Determination of gene sequence variants related to haematological and immunological diseases and hematopoietic stem cell transplant program by NGS-MPS	NRL_05_SOP_14_02 procedure D	Biological material containing human DNA of the cell nuclei	A, B, D

[1] asterisk at the ordinal number identifies the tests, which the laboratory is qualified to carry out outside the permanent laboratory premises

[2] if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest valid edition of the specified procedure is used (including any changes)

[3] degrees of freedom: A – Flexibility concerning materials/products (subject of the test), B – Flexibility concerning components/parameters/characteristics, C – Flexibility concerning the performance of the method, D – Flexibility concerning the method

The laboratory can modify the test procedures with the specified degree(s) of freedom in the scope of accreditation while maintaining the principle of measurement. If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for the test.

Accredited entity according to ČSN EN ISO/IEC 17025:2018:

Ústav hematologie a krevní transfuze
CAB number 1345, National Reference Laboratory for DNA Diagnostics
U Nemocnice 2094/1, 128 00 Praha 2

Specification of the scope of accreditation:

Ordinal test number	Detailed information on activities within the scope of accreditation (determined analytes)
1	tested alleles: HLA I. class: loci A, B, C, HLA II. class: loci DRB1, DQA1, DQB1, DPB1, presence of DRB3-5 KIR genes: presence of 2DL1, 2DL2, 2DL3, 2DL4, 2DL5, 2DS1, 2DS2, 2DS3, 2DS4, 2DS5, 3DL1, 3DL2, 3DL3, 3DS1, 2DP1, 3DP1
2	tested alleles: HLA I. class: loci A, B, C on low resolution level HLA II. class: loci DRB1, DRB3-5, DQA1, DQB1 on low resolution level, DPB1
3	tested alleles: HLA I.class: loci A, B, C HLA II.class: loci DRB1, DQA1, DQB1, DPB1

3. **Department of Cell Chimerism**

Tests:

Ordinal number[1]	Test procedure / method name	Test procedure / method identification[2]	Tested subject	Degrees of freedom[3]
1	Genotype assessment of sequence polymorphisms by PCR and gel electrophoresis method	NRL_01_SOP_14_02 procedure A	Biological material containing human DNA of the cell nuclei	A, B, D
2	Assessment of quantitative representation of genotypes in a sample by analysis of sequence polymorphisms by PCR and gel electrophoresis method	NRL_01_SOP_14_02 procedure B	Biological material containing human DNA of the cell nuclei	A, B, D
3	Genotype assessment of sequence polymorphisms by Real-time PCR method	NRL_07_SOP_14_02 procedure A	Biological material containing human DNA of the cell nuclei	A, B, D
4	Assessment of quantitative representation of genotypes in a sample by analysis of sequence polymorphisms by Real-time PCR method	NRL_07_SOP_14_02 procedure B	Biological material containing human DNA of the cell nuclei	A, B, D

[1] asterisk at the ordinal number identifies the tests, which the laboratory is qualified to carry out outside the permanent laboratory premises

[2] if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest valid edition of the specified procedure is used (including any changes)

[3] degrees of freedom: A – Flexibility concerning materials/products (subject of the test), B – Flexibility concerning components/parameters/characteristics, C – Flexibility concerning the performance of the method, D – Flexibility concerning the method

The Appendix is an integral part of
Certificate of Accreditation No: 297/2024 of 24/06/2024

Accredited entity according to ČSN EN ISO/IEC 17025:2018:

Ústav hematologie a krevní transfuze
CAB number 1345, National Reference Laboratory for DNA Diagnostics
U Nemocnice 2094/1, 128 00 Praha 2

The laboratory can modify the test procedures with the specified degree(s) of freedom in the scope of accreditation while maintaining the principle of measurement. If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for the test.

Specification of the scope of accreditation:

Ordinal test number	Detailed information on activities within the scope of accreditation (determined analytes)
1, 2	Tested polymorphisms: STR: AMG, LPL, FESFPS, F13B, F13A01, D16S539, D7S820, D13S317, D5S818, D3S1358, D21S11, D18S51, Penta E, D8S1179, FGA, Penta D, Penta C, CSF1PO, TPOX, THO1, vWA, D22S1045, D2S1338, D19S433, D2S441, D10S1248, D1S1656, D12S391 and SE33. DIP: AM X, AM Y, HLD106, HLD70, HLD84, HLD103, HLD104, HLD116, HLD112, HLD307, HLD310, HLD110, HLD133, HLD79, HLD105, HLD140, HLD163, HLD91, HLD23, HLD88, HLD101, HLD67, HLD301, HLD53, HLD97, HLD152, HLD128, HLD134, HLD305, HLD48, HLD114, HLD304, HLD131, HLD38, HLD82.
3, 4	Tested specific sequence polymorphisms: S01 (ITGA2B), S04 (DBH), S07 (UXT/ZNF81), S08 (PAPPA2/ASTN1), S10 (LTBP1), S11 (DLG2) – each system has a variant A and B, S05B (EIF2S2), GAPDH, SMCY (AF273841), β-Globin, DIP see NRL_01_SOP_14_02 – variants of deletion and insertion, KMR501-A, KMR502-A, KMR504-A, KMR505-A, KMR506-A, KMR511-C, KMR512-C, KMR520-DPB1, KMR521-DPB1, KMR522-DPB1, REF 901.

Abbreviations used:

PCR	polymerase chain reaction
RT PCR	reverse transcription polymerase chain reaction
BCR::ABL1	fusion gene: breakpoint cluster region – abelson
HLA	human leukocyte antigens
STR	short tandem repeats
Real-time PCR	real-time polymerase chain reaction
NGS-MPS	next-generation sequencing - massive parallel sequencing
DNA	deoxyribonucleic acid
RNA	ribonucleic acid

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself. "