



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
(Czech Accreditation Institute)
Hájkova 2747/22, Žižkov, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products and on changes and amendments to some Acts, as amended

CERTIFICATE OF ACCREDITATION

No. 684/2025

Fakultní nemocnice Hradec Králové
with registered office Sokolská 581, 500 05 Hradec Králové - Nový Hradec Králové
Company Registration No. 00179906

for the Medical Laboratory No. **8267**
Transfusion Department, HLA System and PCR Diagnostics Laboratory

Scope of accreditation:

Laboratory examination methods in the field of immunohaematology and transfusion service to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO 15189 ed. 3:2023

In its activities performed within the scope and for the period of validity of this Certificate, the abovementioned Accredited Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited conformity assessment body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 680/2024 of 16/12/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **19/12/2030**

Prague: 19/12/2025



Signed in the Czech original:
Milena Lochmanová on 19/12/2025

Milena Lochmanová
Director of the Department
of Medical Laboratories
Czech Accreditation Institute

This translation of the Czech original has been issued by: Jana Chvalovská

**The Appendix is an integral part of
Certificate of Accreditation No. 684/2025 of 19/12/2025**

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

Fakultní nemocnice Hradec Králové
CAB Number 8267, Transfusion Department, HLA System and PCR Diagnostics Laboratory
Sokolská 581, 500 05 Hradec Králové - Nový Hradec Králové

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
222 - Transfusion Medicine					
1.	Typing of RHD variants and weak D-types	Real-Time PCR	TO_SOPV_LAB_609, v01; TO_SOPT_LAB_606, v01; TO_SOPT_LAB_602, v02; Cycler CFX Opus 96 Dx; Thermal Cycler C1000 Touch; Thermal Cycler T100	Blood	-
813 - Allergology and Immunology Laboratory					
1.	HLA system examination	PCR SSP	TO_SOPV_LAB_606, v03; TO_SOPT_LAB_602, v02; Thermal Cycler C1000 Touch; Thermal Cycler T100	Blood	-
2.	HLA system examination	Real-Time PCR	TO_SOPV_LAB_608, v01; TO_SOPT_LAB_606, v01; Cycler CFX Opus 96 Dx	Blood	-

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
222/1	Partial D-type, Weak D-type
813/1	genes (loci) HLA-A, -B, -C, -DRB1, -DQB1, low resolution
813/2	genes (loci) HLA-A, -B, -C, -DRB1, -DRB3, -DRB4, -DRB5, -DQA1, -DQB1, -DPA1, -DPB1, low resolution

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Fakultní nemocnice Hradec Králové

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Explanatory notes:

¹ The laboratory does not apply a flexible approach to the scope of accreditation

HLA	Major histocompatibility complex of humans (Human leukocyte antigens)
PCR SSP	Polymerase Chain Reaction with Sequence Specific Primers
RHD	RhD system antigens
Real-Time PCR	Polymerase Chain Reaction in real time