

List of activities within the flexible scope of accreditation

Accredited Body: HELLO LAB s.r.o.
CAB Name: HELLO LAB
CAB Number: 8326
Certificate of Accreditation No.: 362/2025
Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023
Updated: 29. 9. 2025

1. **Laboratory of Clinical Biochemistry and Haematology** Bozděchova 344/2, 150 16 Praha 5

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
222 - Transfusion Medicine					
1.	Screening of anti-erythrocyte antibodies	Gel column agglutination	SOP_HEM_823 version 05; Erytra Eflexis	Serum, plasma	A, B
2.	Screening of anti-erythrocyte antibodies	Gel column agglutination (manual)	SOP_HEM_824 version 05	Serum, plasma	A, B
3.	Blood type	Gel column agglutination	SOP_HEM_750 version 01; Erytra Eflexis	Blood	A, B
4.	Blood type	Gel column agglutination (manual)	SOP_HEM_755 version 01	Blood	A, B
801 – Clinical Biochemistry					
1.	Urea	Absorption spectrophotometry	SOP_BIO_001 version 04; Alinity ci	Serum	A, B
2.	Minerals	Potentiometry	SOP_BIO_004 version 04; SOP_BIO_005 version 05; SOP_BIO_006 version 04; Alinity ci	Serum	A, B, C
3.	Enzymes	Absorption spectrophotometry	SOP_BIO_015 version 02; SOP_BIO_016 version 05; SOP_BIO_017 version 04; Alinity ci	Serum	A, B, C

List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
4.	Total protein	Absorption spectrophotometry	SOP_BIO_025 version 05; Alinity ci	Serum, plasma	A, B
5.	Lipids	Absorption spectrophotometry	SOP_BIO_038 version 04; SOP_BIO_041 version 04; Alinity ci	Serum	A, B, C
6.	Glucose	Absorption spectrophotometry	SOP_BIO_049 version 05; Alinity ci	Serum, plasma	A, B
802 – Medical Microbiology					
1.	Antigens of infectious agents	Immunoassay with luminometric detection	SOP_SER_801 version 04; Alinity s	Serum, plasma	A, B, C
2.	Antibodies to infectious agents	Immunoassay with luminometric detection	SOP_SER_805 version 04; Alinity s	Serum, plasma	A, B, C
3.	HIV markers	Immunoassay with luminometric detection	SOP_SER_809 version 04; Alinity s	Serum, plasma	A, B
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunoturbidimetry	SOP_BIO_029 version 05; Alinity ci	Serum, plasma	A, B, C
2.	C-reactive protein (CRP)	Immunoturbidimetry	SOP_BIO_033 version 05; Alinity ci	Serum	A, B
815 - Nuclear Medicine Laboratory					
1.	Hormones	Immunoassay with luminometric detection	SOP_BIO_301 version 05; Alinity ci	Serum	A, B, C
818 - Haematology Laboratory					
1.	Blood count with a five-part differential leukocyte count	Flow cytometry Photometry; Impedance; Calculations	SOP_HEM_601 version 03; Sysmex XN-1000	Blood	A, B
2.	Prothrombin test	Coagulation method with optical detection of coagulum; Calculations	SOP_HEM_701 version 04; Sysmex CS-2500	Plasma	A, B

List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
3.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	SOP_HEM_703 version 04; Sysmex CS-2500	Plasma	A, B

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
222/1	NAT, Enzyme
222/2	NAT, Enzyme
222/3	AB0, RhD
222/4	AB0, RhD
801/2	Na ⁺ , K ⁺ , Cl ⁻
801/3	ALT, AST, GGT
801/5	Cholesterol, Triacylglycerols
802/1	HBV surface antigen (HBsAg)
802/2	HCV antibodies (anti-HCV)
802/3	Ag p24 HIV-1, anti-HIV-1, anti-HIV-2
813/1	IgG
815/1	Thyroid-stimulating hormone (TSH)
818/1	Leukocytes, Erythrocytes, Haemoglobin, Haematocrit, MCV, MCH, MCHC, RWD, Thrombocytes, PDW, MPV, PCT, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils
818/2	PT-time, PT-INR, PT-ratio
818/3	APPT-time, APPT-ratio

List of activities within the flexible scope of accreditation

2. Sample collection site Bozděchova Bozděchova 344/2, 150 16 Praha 5

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venepuncture	SOP_OM_001 version 03	Venous blood	A, B
2.	Capillary puncture	SOP_OM_002 version 03	Capillary blood	A, B

3. Sample collection site Doksy Tovární vrch 78, 472 01 Doksy

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venepuncture	SOP_OM_001 version 03	Venous blood	A, B
2.	Capillary puncture	SOP_OM_002 version 03	Capillary blood	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

E – Flexibility concerning the POCT delivery points

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.