The Appendix is an integral part of Certificate of Accreditation No. 139/2024 of 26/03/2024

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

Topelex s.r.o.

CAB Number 8078, Laboratory for CSF, Neuroimmunology, Pathology and Special Diagnostics Sokolovská 810/304, Vysočany, 190 00 Praha 9

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 <u>https://www.likvor.cz/?page_id=72</u>

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹				
801 – Clinical Biochemistry									
1.	Total protein	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D				
2.	Glucose	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D				
3.	Lactate	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D				
4.	Albumin	Absorption spectrophotometry	Commercial procedure	Body fluids	A, B, D				
5.	Quantitative cytological examination of cerebrospinal fluid	Microscopy	Published procedure	Cerebrospinal fluid	А, В				
6.	Qualitative cytological examination of cerebrospinal fluid	Microscopy	Published procedure	Cerebrospinal fluid	A, B				
7.	Albumin	Nephelometry	Commercial procedure	Body fluids	A, B, D				
802 – Medical Microbiology									
1.	Antibodies to infectious agents	Immunoassay with photometric detection	Commercial procedure	Body fluids	A, B, C, D				
2.	Antibodies to infectious agents	Immunoblotting	Commercial procedure	Body fluids	A, B, C, D				
3.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D				

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹				
813 - Allergology and Immunology Laboratory									
1.	Detection of oligoclonal immunoglobulins	Isoelectric focusing	Commercial procedure; In-house procedure	Cerebrospinal fluid, serum	A, B, C				
2.	Immunoglobulins	Nephelometry	Commercial procedure	Body fluids	A, B, C, D				
3.	Specific proteins	Nephelometry	Commercial procedure	Serum, plasma	A, B, C				
4.	Cytokines	Immunoassay with photometric detection	Commercial procedure	Body fluids	A, B, C, D				
	823 - Pathology Laboratory								
1.	Cytological examination and diagnostics	Microscopy	Published procedure	Cells from tissue puncture, body fluids and pathological cavities content	Α, Β				
2.	Histological examination and diagnostics	Microscopy	Published procedure	Tissues	А, В				
3.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Published procedure; Commercial procedure	Tissues, cells	A, B, C				

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.