



#### 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. 592/2025

Krajská nemocnice T. Bati, a.s. with registered office Havlíčkovo nábřeží 600, 762 75 Zlín Company Registration No. 27661989

for the Medical Laboratory No. **8339**Department of Clinical Biochemistry and Pharmacology

Scope of accreditation:

Laboratory examinations in the field of clinical biochemistry including shared examinations 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.

The Certificate of Accreditation is valid until: 13/11/2028

Prague: 13/11/2025





Signed in the Czech original: Milena Lochmanová on 13/11/2025

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. 592/2025 of 13/11/2025

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

**Krajská nemocnice T. Bati, a.s.**CAB Number 8339, Department of Clinical Biochemistry and Pharmacology Havlíčkovo nábřeží 600, 762 75 Zlín

### **Examination:**

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>			
801 – Clinical Biochemistry								
1.	Proteins	Absorption spectrophotometry	SOPV 114, version 07; Architect ci16200	Serum, plasma	-			
2.	Non-protein nitrogenous compounds	Absorption spectrophotometry	SOPV 031, version 07; SOPV 032, version 06; SOPV 395, version 01; SOPV 033, version 07; Architect ci16200	Serum, plasma, urine	-			
3.	Lipids	Absorption spectrophotometry	SOPV 075, version 07; SOPV 076, version 09; Architect ci16200	Serum, plasma	-			
4.	Enzymes	Absorption spectrophotometry	SOPV 039, version 05; SOPV 040, version 05; SOPV 041, version 06; Architect ci16200	Serum, plasma	-			
5.	Minerals	Absorption spectrophotometry	SOPV 016, version 05; Architect ci16200	Serum, plasma	-			
6.	Human chorionic gonadotropin (HCG)	Immunoassay with luminometric detection	SOPV 274, version 04; Cobas e411	Serum, plasma	-			
	812 – Laboratory for Pharmacology and Toxicology of Pharmaceuticals							
1.	Digoxin	Immunoassay with luminometric detection	SOPV 171, version 07; Architect c4000	Serum, plasma	-			
	813 - Allergology and Immunology Laboratory							
1.	Specific proteins	Immunoturbidimetry	SOPV 100, version 06; Architect ci16200	Serum, plasma	-			

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

### Krajská nemocnice T. Bati, a.s.

CAB Number 8339, Department of Clinical Biochemistry and Pharmacology Havlíčkovo nábřeží 600, 762 75 Zlín

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>			
	815 - Nuclear Medicine Laboratory							
1.	Hormones	Immunoassay with luminometric detection	SOPV 214, version 04; Architect ci16200	Serum, plasma	-			

### **Specification of the scope of accreditation:**

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation	
801/1	Albumin	
801/2	Urea, Creatinine, Uric acid	
801/3	Total cholesterol, Triacylglycerols (TAG),	
801/4	Alanine transaminase (ALT), Aspartate transaminase (AST), Gamma-glutamyltransferase (GGT)	
801/5	Total calcium	
813/1	C-reactive protein (CRP)	
815/1	Thyrotropin (TSH)	

### **Explanatory notes:**

<sup>&</sup>lt;sup>1</sup> The laboratory does not apply a flexible approach to the scope of accreditation

<sup>&</sup>quot;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."