

## List of activities within the flexible scope of accreditation

**Accredited Body:** Krajská zdravotní, a.s. - Masarykova nemocnice v Ústí nad Labem, o.z.

**CAB Name:** Clinical Biochemistry Department

**CAB Number:** 8290

**Certificate of Accreditation No.:** 364/2024

**Field of Accreditation:** Medical Laboratory - ČSN EN ISO 15189 ed. 2:2013

**Updated:** 24. 7. 2024

### Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identifik Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>801 – Clinical Biochemistry</b>					
1.	Non-protein nitrogenous compounds	Absorption spectrophotometry	KZ03_ST1241 UL OKB SOP version nr . 6; KZ03_ST1244 UL OKB SOP version nr . 6; KZ03_ST1255 UL OKB SOP version nr . 6; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B
2.	Minerals	Potentiometry	KZ03_ST1619 UL OKB SOP version nr . 5; KZ03_ST1620 UL OKB SOP version nr . 5; KZ03_ST1621 UL OKB SOP version nr . 5; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B, C
3.	Saccharides	Absorption spectrometry	KZ03_ST1235 UL OKB SOP version nr . 6; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B

## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identifik Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
4.	Minerals	Absorption spectrophotometry	KZ03_ST1257 UL OKB SOP version nr . 6; KZ03_ST1232 UL OKB SOP version nr . 6; KZ03_ST1237 UL OKB SOP version nr . 4; KZ03_ST1258 UL OKB SOP version nr . 4; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B
5.	Enzymes	Absorption spectrophotometry	KZ03_ST1273 UL OKB SOP version nr . 6; KZ03_ST1224 UL OKB SOP version nr . 6; KZ03_ST1219 UL OKB SOP version nr . 6; KZ03_ST1233 UL OKB SOP version nr . 6; KZ03_ST1221 UL OKB SOP version nr . 6; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B, C, D
6.	Pigments	Absorption spectrophotometry	KZ03_ST1225 UL OKB SOP version nr . 7; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B, C, D
7.	Proteins	Absorption spectrophotometry	KZ03_ST1228 UL OKB SOP version nr . 6; KZ03_ST1218 UL OKB SOP version nr . 7; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B, C, D

## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identifik Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
8.	Lipids	Absorption spectrophotometry	KZ03_ST1238 UL OKB SOP version nr . 6; KZ03_ST1254 UL OKB SOP version nr . 6; KZ03_ST1236 UL OKB SOP version nr . 4; KZ03_ST1247 UL OKB SOP version nr . 5; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B, C, D
9.	Glycated haemoglobin	Capillary electrophoresis	KZ03_ST2641 UL OKB SOP version nr . 3; KZ03_ST2640 UL OKB SOP Capillarys 3 Octa version nr . 3; Capillarys 3 Octa	Blood	A, B
10.	Cardiac markers	Immunoassay with luminometric detection	KZ03_ST2004 UL OKB SOP version nr . 5; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B
11.	Tumor markers	Immunoassay with luminometric detection	KZ03_ST2173 UL OKB SOP version nr . 5; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum	A, B, C, D
<b>813 - Allergology and Immunology Laboratory</b>					
1.	Specific proteins	Immunoturbidimetry	KZ03_ST1229 UL OKB SOP version nr . 7; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum, plasma	A, B, C

## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identifik Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>815 - Nuclear Medicine Laboratory</b>					
1.	Hormones	Immunoassay with luminometric detection	KZ03_ST1622 UL OKB SOP version nr . 7; KZ03_ST1624 UL OKB SOP version nr . 7; KZ03_ST1623 UL OKB SOP version nr . 6; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum	A, B, C, D
2.	Tumor markers	Immunoassay with luminometric detection	KZ03_ST2172 UL OKB SOP version nr . 5; KZ03_ST2174 UL OKB SOP version nr . 4; KZ03_ST2175 UL OKB SOP version nr . 4; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum	A, B, C, D
3.	Proteins	Immunoassay with luminometric detection	KZ03_ST2171 UL OKB SOP version nr . 3; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum	A, B, C, D
4.	Vitamins	Immunoassay with luminometric detection	KZ03_ST2270 UL OKB SOP version nr . 4; KZ03_ST1267 UL OKB SOP Cobas PRO version nr . 4; Cobas PRO	Serum	A, B, C, D

## List of activities within the flexible scope of accreditation

### Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
801/1	Urea, Creatinine, Uric acid
801/2	Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup>
801/3	Glucose
801/4	Total calcium, Inorganic phosphorus, Iron, Magnesium
801/5	Alanine transaminase (ALT), Aspartate transaminase (AST), Alkaline phosphatase (ALP), Gamma-glutamyltransferase (GGT), Alpha-amylase (AMS)
801/6	Total bilirubin
801/7	Total protein, Albumin
801/8	Total cholesterol, Triacylglycerols (TAG), HDL cholesterol, LDL cholesterol
801/10	Troponin T
801/11	Prostate-specific antigen - free (fPSA)
813/1	C-reactive protein (CRP)
815/1	Thyrotropin (TSH), Free Thyroxine (fT4), Free Triiodothyronine (fT3)
815/2	Prostate-specific antigen - total (PSA total), Carbohydrate tumor antigen 19-9 (CA19-9), Carcinoembryonic antigen (CEA)
815/3	Ferritin
815/4	Cobalamin (B12)

### Explanatory notes:

<sup>1</sup> 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.