

Accreditation scope

Name of the accredited subject: **«CDL OLYMP», Limited Liability Partnership**
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 Republic of Kazakhstan
**The Clinical Diagnostic Laboratory of the branch of «CDL OLYMP»,
 LLP in Almaty**
 Shevchenko Str, 89 “B“, Almaty, 050000, Republic of Kazakhstan

Laboratory with fixed scope

Item	Object of examination		Established method		Other specifications (range, uncertainty, purpose, equipment, etc.)
	System / Biological material	Indicator/ Analyte/ Parameter	Principle/ Kind / Type	Identification of method	
1	Serum / Plasma	Alanine aminotransferase	Photometry	Cobas ALTL enclosed leaflet (SOP 403-12)	Cobas 8000 (c502, c702), Cobas c311
2		Aspartate aminotransferase		Cobas ASTL enclosed leaflet (SOP 403-12)	
3		Alkaline phosphatase		Cobas ALP2 enclosed leaflet (SOP 403-12)	
4		Gamma glutamyl- transferase		Cobas GGT-2 enclosed leaflet (SOP 403-12)	
5		Lactate dehydrogenase		Cobas LDHI2 enclosed leaflet (SOP 403-12)	
6		Amylase		Cobas AMYL2 enclosed leaflet (SOP 403-12)	
7	Serum / Plasma	Pancreatic amylase	Photometry	Cobas AMY-P enclosed leaflet (SOP 403-12)	Cobas 8000 (c502, c702), Cobas c311
8		Lipase		Cobas LIPC enclosed leaflet (SOP 403-12)	
9		Creatine kinase		Cobas CKL enclosed leaflet (SOP 403-12)	
10		Total protein		Cobas TP2 enclosed leaflet (SOP 403-12)	
11		Albumin		Cobas ALB2 enclosed leaflet (SOP 403-12)	
12		Total bilirubin		Cobas BILT3 enclosed leaflet (SOP 403-12)	
13		Direct bilirubin		Cobas BILD2 enclosed leaflet (SOP 403-12)	
14		Uric acid		Cobas UA2 enclosed leaflet (SOP 403-12)	
15		Urea		Cobas UREAL enclosed leaflet (SOP 403-12)	
16		Creatinine		Cobas CREJ2 enclosed leaflet (SOP 403-12)	
17		Glucose		Cobas GLUC3 enclosed leaflet (SOP 403-12)	
18		Triglycerides		Cobas TRIGL enclosed leaflet (SOP 403-12)	
19		Cholesterol total		Cobas CHOL2 enclosed leaflet (SOP 403-12)	
20		HDL –cholesterol		Cobas HDLC3 enclosed leaflet (SOP 403-12)	

Annex to the Decision No. 574/10030/2022/1 and to the Certificate of Accreditation No. M-060 dated 10.05.2022.

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	System / Biological material	Indicator/ Analyte/ Parameter	Principle/ Kind / Type	Identification of method	
21	Serum / Plasma	LDL –cholesterol	Photometry	Cobas LDLC3 enclosed leaflet (SOP 403-12)	Cobas 8000 (c502, c702), Cobas c311
22		Calcium		Cobas CA2 enclosed leaflet (SOP 403-12)	
23		Magnesium		Cobas MG2 enclosed leaflet (SOP 403-12)	
24		Phosphate (Inorganic)		Cobas PHOS2 enclosed leaflet (SOP 403-12)	
25		Iron		Cobas IRON2 enclosed leaflet (SOP 403-12)	
26		Unsaturated Iron- Binding Capacity		Cobas UIBC enclosed leaflet (SOP 403-12)	
27	Serum / Plasma	Transferrin	Immuno- turbidimetry	Cobas TRSF2 enclosed leaflet (SOP 403-12)	
28	Serum / Plasma	Ferritin		Cobas FERR4 enclosed leaflet (SOP 403-12)	
29		Antistreptolysin O		Cobas ASLOT enclosed leaflet (SOP 403-12)	
30		C-reactive protein		Cobas CRPLX enclosed leaflet (SOP 403-12)	
31		Rheumatoid Factors		Cobas RF-II enclosed leaflet (SOP 403-12)	
32	Serum / Plasma	Ionized calcium Ca ²	Ion-selective	AVL 9180 Electrolyte Analyzer Operator's Manual (SOP 403-20)	AVL 9180
33		Sodium Na ⁺			
34		Potassium K ⁺			
35	Serum / Plasma	Immunoglobulin E	Electrogenerated chemi- luminescence	Cobas IGE II enclosed leaflet (SOP 403-13)	Cobas 8000 (e602), Cobas e411
36		Vitamin B12		Cobas Vitamin B12 II enclosed leaflet (SOP 403-13)	
37		Folate		Cobas Folate III enclosed leaflet (SOP 403-13)	
38		Antibody to cyclic citrullinated peptide (Anti- CCP)		Cobas Anti-CCP enclosed leaflet (SOP 403-13)	
39		Thyrotropin, thyroidstimulating -hormone (TSH)		Cobas TSH enclosed leaflet (SOP 403-13)	
40		Total triiodothyronine (T3)		Cobas T3 enclosed leaflet (SOP 403-13)	
41		Total thyroxin (T4)		Cobas T4 enclosed leaflet (SOP 403-13)	
42		Free triiodothyronine (FT3)		Cobas FT3 III enclosed leaflet (SOP 403-13)	
43		Free thyroxin (FT4)		Cobas FT4 II enclosed leaflet (SOP 403-13)	
44		Thyroglobulin (Tg)		Cobas Tg II enclosed leaflet (SOP 403-13)	
45		Antibody to thyroglobulin (anti-Tg)		Cobas Anti-Tg enclosed leaflet (SOP 403-13)	
46	Antibodies to TSH receptor (anti-TSHR)	Cobas Anti-TSHR enclosed leaflet (SOP 403-13)			

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47	Serum / Plasma	Antibodies to thyroid peroxidase (anti- TPO)	Electrogenerated chemi- luminescence	Cobas Anti-TPO enclosed leaflet (SOP 403-13)	Cobas 8000 (e602), Cobas e411
48		Parathyroid hormone (PTH)		Cobas PTH STAT enclosed leaflet (SOP 403-13)	
49		Follicle- stimulating hormone (FSH)		Cobas FSH enclosed leaflet (SOP 403-13)	
50		Luteinizing hormone (LH)		Cobas LH enclosed leaflet (SOP 403-13)	
51		Intact human chorionic gonadotropin + the β -subunit		Cobas HCG+ β enclosed leaflet (SOP 403-13)	
52		Prolactin		Cobas Prolactin II enclosed leaflet (SOP 403-13)	
53		Estradiol		Cobas Estradiol III enclosed leaflet (SOP 403-13)	
54		Progesterone		Cobas Progesterone II, III enclosed leaflet (SOP 403-13)	
55		Testosterone		Cobas Testosterone II enclosed leaflet (SOP 403-13)	
56		Human sex hormone-binding globulin		Cobas SHBG enclosed leaflet (SOP 403-13)	
57		Dehydroepiandro- sterone sulfate		Cobas DHEA-S enclosed leaflet (SOP 403-13)	
58		Cortisol		Cobas Cortisol II enclosed leaflet (SOP 403-13)	
59		Insulin		Cobas Insulin enclosed leaflet (SOP 403-13)	
60		C-Peptide		Cobas C-Peptide enclosed leaflet (SOP 403-13)	
61		Human growth hormone		Cobas hGH enclosed leaflet (SOP 403-13)	
62		α 1 - fetoprotein (AFP)		Cobas AFP enclosed leaflet (SOP 403-13)	
63		Carcinoembryoni- c antigen (CEA)		Cobas CEA enclosed leaflet (SOP 403-13)	
64		Carbohydrate Antigen 19-9		Cobas CA 19-9 enclosed leaflet (SOP 403-13)	
65		Cancer Antigen 125		Cobas CA 125 II enclosed leaflet (SOP 403-13)	
66	Total PSA (prostate specific antigen)	Cobas total PSA enclosed leaflet (SOP 403-13)			
67	Free PSA (prostate specific antigen)	Cobas free PSA enclosed leaflet (SOP 403-13)			
68	Cancer Antigen 72-4	Cobas CA 72-4 enclosed leaflet (SOP 403-13)			
69	CYFRA 21-1	Cobas CYFRA 21-1 enclosed leaflet (SOP 403-13)			

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	System / Biological material	Indicator/ Analyte/ Parameter	Principle/ Kind / Type	Identification of method	
70	Serum / Plasma	Neuron-specific enolase	Electrogenerated chemi-luminescence	Cobas NSE enclosed leaflet (SOP 403-13)	Cobas 8000 (e602), Cobas e411
71		S100		Cobas S100 enclosed leaflet (SOP 403-13)	
72		Cancer Antigen 15-3		Cobas CA 15-3 II enclosed leaflet (SOP 403-13)	
73		Tacrolimus		Cobas TCL enclosed leaflet (SOP 403-13)	
74		Osteocalcin		Cobas Osteocalcin enclosed leaflet (SOP 403-13)	
75		Procalcitonin		Cobas Elecsys BRAHMS PCT enclosed leaflet (SOP 403-13)	
76		IgM antibodies to the hepatitis A virus		Cobas Anti-HAV IgM enclosed leaflet (SOP 403-13)	
77		HBsAg hepatitis B surface antigen		Cobas HbsAG II enclosed leaflet (SOP 403-13)	
78		Antibody to hepatitis C virus (anti-HCV)		Cobas Anti-HCV II enclosed leaflet (SOP 403-13)	
79		IgG antibodies to Rubella virus		Cobas Rubella IgG enclosed leaflet (SOP 403-13)	
80		IgM antibodies to Rubella virus		Cobas Rubella IgM enclosed leaflet (SOP 403-13)	
81		IgM antibodies to Toxoplasma gondii		Cobas Toxo IgM enclosed leaflet (SOP 403-13)	
82		IgG antibodies to Toxoplasma gondii		Cobas Toxo IgG enclosed leaflet (SOP 403-13)	
83		IgG antibodies to Cytomegalovirus		Cobas CMV IgG enclosed leaflet (SOP 403-13)	
84		IgM antibodies to Cytomegalovirus		Cobas CMV IgM enclosed leaflet (SOP 403-13)	
85	Blood	White blood cell (WBC)	Electrical impedance	UniCel DxH 800 Coulter User's Manual Chapter 2 «Working Principles» (SOP 403-44)	Beckman Coulter DxH800
86		Basophilic cell (Bas)	Optical cytometry		
87		Neutrophilic (Neu)			
88		Eosinophilic cell (Eos)			
89		Lymphocyte (Lym)			
90		Monocyte (Mon)	Electrical impedance		
91		Red blood cells (RBC)			
92		Platelet (PLT)	Photometry		
93		Hemoglobin (HGB)			
94		Hematocrit (HCT)			
95	Mean cell haemoglobin (MCH)	Calculation			

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96	Blood	Mean corpuscular hemoglobin concentration (MCHC)	Calculation	UniCel DxH 800 Coulter User's Manual Chapter 2 «Working Principles» (SOP 403-44)	Beckman Coulter DxH800
97		Red cell distribution width (RDW)			
98		Mean platelet volume (MPV)			
99	Plasma	Activated partial thromboplastin time	Clotting methods	IL HemosIL SynthASil Reagent enclosed leaflet (SOP 403-57)	ACL TOP 550, ACL TOP 700
100		Lupus anticoagulant on screening		IL dRVVT Screen / dRVVT Confirm Reagent enclosed leaflet (SOP 403-57)	
101		Lupus anticoagulant on confirmation	Clotting methods	IL dRVVT Screen / dRVVT Confirm Reagent enclosed leaflet (SOP 403-57)	
102		International normalized ratio (INR)	Calculation	IL RecombiPlasTin 2G Reagent enclosed leaflet SOP 403-57)	
103		Prothrombin time	Clotting methods	IL Thrombin Time Reagent enclosed leaflet (SOP 403-57)	
104	Thrombin time				
105	Plasma	Fibrinogen	Clotting methods	IL HemosIL 2G Q.F.A. Reagent enclosed leaflet (SOP 403-57)	ACL TOP 550, ACL TOP 700
106		D-dimer HS	Immunoturbidimetry	IL D-dimer HS Reagent enclosed leaflet (SOP 403-57)	
107		Adrenocorticotropic hormone	Electrogenated chemiluminescence	Cobas ACTH enclosed leaflet (SOP 403-13)	Cobas 8000 (e602), Cobas e411
108	Blood	Erythrocyte Sedimentation Rate (ESR)	Capillary photometry	Alifax TEST1 THL User's Manual (SOP 403-09)	ALIFAX TEST1
109		Glycosylated hemoglobin	Immunoturbidimetry	Cobas A1C-3 enclosed leaflet (SOP 403-12)	Cobas 8000 (c502, c702), Cobas c311

Specification of sampling activities

Item	Object			Method		Other specifications
	Biological material / System	Indicator/ Analyte	Place of sampling	Kind/Principle	Identification	
1	Serum / Plasma	1-84	procedure room	Blood sampling from a vein, injection	WI 401-03-15	
2	Blood	85-98, 108, 109	procedure room	Blood sampling from a vein, injection	WI 401-03-15	
3	Plasma	99-107	procedure room	Blood sampling from a vein, injection	WI 401-03-15	
