

Scope of Accreditation

Accredited body: Medirex, a.s.
Holubyho 35, 902 01 Pezinok

Organizational unit and workplace performing the activity of the Accredited Body:

Western Slovakia, Central Laboratory Bratislava, Galvaniho 17/C, 821 04 Bratislava

Western Slovakia, Central Laboratory Nitra, Novozámocká 67, 949 05 Nitra

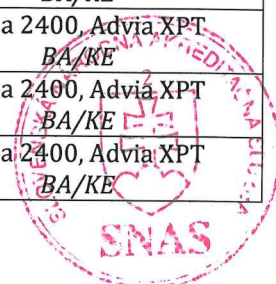
Eastern Slovakia, Central Laboratory Košice, Magnezitárska 2/C, 040 13 Košice

Identification number of the accredited body: 407/M-032

Laboratory with fixed scope

Item	Object of examination		Established method		Other specifications (equipment, workplace etc.)
	Biological material/ matrix	Analyte / Parameter	Principle	Identification of method	
1.1	serum	Alanine Aminotransferase (ALT)	photometry	ALT, Lachema (SOP-M 1.1)	Advia 2400, Advia XPT BA/KE
1.2		Albumin (ALB)		Albumin, Siemens (SOP-M 1.2)	Advia 2400, Advia XPT BA/KE
1.3		Alkaline Phosphatase (ALP)		ALP, Lachema (SOP-M 1.3)	Advia 2400, Advia XPT BA/KE
1.4		α -Amylase (AMS)		AMS, Lachema (SOP-M 1.4)	Advia 2400, Advia XPT BA/KE
1.5		Aspartate Aminotransferase (AST)		AST, Lachema (SOP-M 1.5)	Advia 2400, Advia XPT BA/KE
1.6		Bilirubin Total (BILT)		BILT, Lachema (SOP-M 1.6)	Advia 2400, Advia XPT BA/KE
1.7		Total Protein (TP)		TP, Siemens (SOP-M 1.7)	Advia 2400, Advia XPT BA/KE
1.8		γ -Glutamyl- transferase (GGT)		GMT, Lachema (SOP-M 1.8)	Advia 2400, Advia XPT BA/KE
1.9		Cholesterol Total (CHOL)		CHOL, Lachema (SOP-M 1.9)	Advia 2400, Advia XPT BA/KE
1.10		Creatine Kinase (CK)		CK, Lachema (SOP-M 1.10)	Advia 2400, Advia XPT BA/KE
1.11		Lactate Dehydrogenase (LDH)		LDH, Lachema (SOP-M 1.11)	Advia 2400, Advia XPT BA/KE
1.12		Triacylglycerols (TAG)		TG, Lachema (SOP-M 1.12)	Advia 2400, Advia XPT BA/KE
1.13		Iron (Fe)		IRON_2, Siemens (SOP-M 1.13)	Advia 2400, Advia XPT BA/KE
1.14	serum, urine	Phosphorus (P)		IP, Siemens (SOP-M 1.14)	Advia 2400, Advia XPT BA/KE
1.15		Glucose (GLU)		GLU, Lachema (SOP-M 1.15)	Advia 2400, Advia XPT BA/KE
1.16		Magnesium (Mg)		MG, Siemens (SOP-M 1.16)	Advia 2400, Advia XPT BA/KE
1.17		Creatinine (CREA)		Creatinine, Dialab (SOP-M 1.17)	Advia 2400, Advia XPT BA/KE
1.18		Uric Acid (UA)		UA, Lachema (SOP-M 1.18)	Advia 2400, Advia XPT BA/KE
1.19		Urea (UREA)		UREA, Lachema (SOP-M 1.19)	Advia 2400, Advia XPT BA/KE
1.20		Calcium (Ca)		CA, Siemens (SOP-M 1.20)	Advia 2400, Advia XPT BA/KE

Číslo reg. záznamu: 12010/353414



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1.21	serum, urine	Chloride (Cl)	potentiometry	Chloride, Siemens (SOP-M 1.21)	Advia 2400, Advia XPT BA/KE
1.22		Potassium (K)		Potassium, Siemens (SOP-M 1.22)	Advia 2400, Advia XPT BA/KE
1.23		Sodium (Na)		Sodium, Siemens (SOP-M 1.23)	Advia 2400, Advia XPT BA/KE
1.24		C-Reactive Protein (CRP)	immunoturbidimetry	CRP, DiaSys (SOP-M 1.24)	Advia 2400, Advia XPT BA/KE
1.25		Immunoglobulin A (IgA)		IgA, DiaSys (SOP-M 1.25)	Advia 2400, Advia XPT BA/KE
1.26		Immunoglobulin G (IgG)		IgG, DiaSys (SOP-M 1.26)	Advia 2400, Advia XPT BA/KE
1.27		Immunoglobulin M (IgM)		IgM, DiaSys (SOP-M 1.27)	Advia 2400, Advia XPT BA/KE
1.28		Transferrin (Trf)		TRF, Siemens (SOP-M 1.28)	Advia 2400, Advia XPT BA/KE
2.1		α -Fetoprotein (AFP)		AFP cobas, Roche (SOP-M 2.1)	cobas 8000 BA/KE
2.2	serum	Procollagen-type 1 N-terminal propeptide (P1NP)	electrochemi- luminescence immunoassay	total P1NP cobas, Roche (SOP-M 2.2)	cobas 8000 BA/KE
2.3		β - Isomerized C - terminal telopeptides of type I collagen (CTX)		β - CrossLaps/ serum cobas, Roche (SOP-M 2.3)	cobas 8000 BA/KE
2.4		Cancer antigen 125 (CA-125)		CA 125 II cobas, Roche (SOP-M 2.4)	cobas 8000 BA/KE
2.5		17 β -Estradiol (E2)		Estradiol III cobas, Roche (SOP-M 2.5)	cobas 8000 BA/KE
2.6		Follicle stimulating hormone (FSH)		FSH cobas, Roche (SOP-M 2.6)	cobas 8000 BA/KE
2.7		Choriogonadotropin (hCG)		HCG+ β cobas, Roche (SOP-M 2.7)	cobas 8000 / BA/KE cobas e411 / KE
2.8		Immunoglobulin E (IgE)	chemiluminiscence immunoassay	IgE Advia Centaur, Siemens (SOP-M 2.8)	Advia Centaur XPT / BA/KE Advia Centaur XP / KE
2.9		Carcinoembryo- nic antigen (CEA)		CEA Advia Centaur, Siemens (SOP-M 2.9)	Advia Centaur XPT / BA/KE Advia Centaur XP / KE
2.10		Luteinizing hormone (LH)	electrochemi- luminescence immunoassay	LH cobas, Roche (SOP-M 2.10)	cobas 8000 BA/KE
2.11		N-terminal pro-B- type natriuretic peptide (NT-proBNP)		proBNP II cobas, Roche (SOP-M 2.11)	cobas 8000 / BA/KE cobas e411 / KE
2.12		Pregnancy associated plasma protein A (PAPP-A)		PAPP-A cobas, Roche (SOP-M 2.12)	cobas 8000 / BA/KE cobas e411 / KE



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2.13	serum	Parathyroid hormone intact (PTH)	electrochemi – luminescence immunoassay	PTH cobas, Roche (SOP-M 2.13)	cobas 8000 BA/KE
2.14		Progesterone (PROG)		Progesterone III cobas, Roche (SOP-M 2.14)	cobas 8000 BA/KE
2.15		Testosterone (TST)		Testosterone II cobas, Roche (SOP-M 2.15)	cobas 8000 BA/KE
2.16		Troponin T cardiac – high sensitive (hs cTnT)		Troponin T hs, STAT cobas, Roche (SOP-M 2.16)	cobas 8000 / BA/KE cobas e411 / KE
2.17		Ferritin (FER)	chemiluminescence immunoassay	FER Advia Centaur, Siemens (SOP-M 2.17)	Advia Centaur XPT / BA/KE Advia Centaur XP / KE
2.18		Prostate-specific antigen (tPSA)		PSA Advia Centaur, Siemens (SOP-M 2.18)	Advia Centaur XPT / BA/KE Advia Centaur XP / KE
2.19		Prostate-specific antigen free (fPSA)		fPSA Advia Centaur, Siemens (SOP-M 2.19)	Advia Centaur XPT BA/KE
2.20		Thyrotropin (TSH)	electrochemi – luminescence immunoassay	TSH cobas, Roche (SOP-M 2.20)	cobas 8000 BA/KE
2.21		Triiodothyronine free (fT3)		FT3 III cobas, Roche (SOP-M 2.21)	cobas 8000 BA/KE
2.22		Thyroxine free (fT4)		FT4 IV cobas, Roche (SOP-M 2.22)	cobas 8000 BA/KE
3.1			Protein electrophoresis (ELFO)	agarose gel electrophoresis	Hydragel 54 β1-β2, Sebia (SOP-M 3.1)
3.2	serum, urine	Monoclonal proteins (IF)	agarose gel electrophoresis and immuno-fixation	Hydragel 4 IF, Hydragel 4 Urine Profil, Sebia (SOP-M 3.2)	Hydrasys qualitative method BA/KE
3.3	peripheral blood	Glycated haemoglobin A1c (HbA1c)	HPLC	D-100, BioRad (SOP-M 3.3)	BioRad D-100 ionex HPLC method BA/KE/NR
4.1	peripheral blood	Blood cell count with differential:		BC-6800, BC-6200, BC-6000 Auto Hematology Analyzer, Mindray (SOP-M 4.1)	Mindray BC-6800 / BA Mindray BC-6200 / KE/NR Mindray BC-6000 / BA/KE/NR
		Hemoglobin (HGB)	photometry		
		Erythrocytes (RBC)	electrical impedance		
		Platelets (PLT)			
		Leukocytes (WBC)	flow cytometry		
		Neutrophils granulocytes (NEU)			
		Lymphocytes (LYM)			
		Monocytes (MONO)			
		Eosinophils granulocytes (EOS)			
		Basophils granulocytes (BASO)			



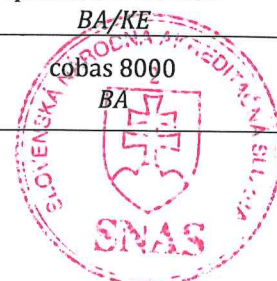
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4.2	plasma	Prothrombin time (PT)	coagulation assay	Thromborel S, Siemens (SOP-M 4.2)	Sysmex CS-5100 / BA/KE Sysmex CS-2500 / KE/NR
4.3		Thrombin time (TT)		Thromboclotin, Siemens (SOP-M 4.3)	Sysmex CS-5100 / BA/KE Sysmex CS-2500 / KE/NR
4.4		Fibrinogen (FBG)		Dade Thrombin Reagent, Siemens (SOP-M 4.4)	Sysmex CS-5100 / BA/KE Sysmex CS-2500 / KE/NR
4.5		Antithrombin III (AT III)	chromogenic assay	Berichrom Antithrombin III, Siemens (SOP-M 4.5)	Sysmex CS-5100 / BA/KE Sysmex CS-2500 / KE
4.6		D-dimer	immuno- turbidimetric assay	INNOVANCE D-Dimer, Siemens (SOP-M 4.6)	Sysmex CS-5100 / BA/KE Sysmex CS-2500 / KE/NR
5.1	peripheral blood	CD3+	flow cytometry	Navios Flow Cytometer, Monoclonal Antibodies, Beckman Coulter (SOP-M 5.1)	Navios, Navios EX / BA/KE Navios EX / NR
		CD3+CD4+			
		CD3+CD8+			
		NK cells			
		B lymphocytes			
5.2	serum	Specific IgE	fluorescence immunoassay	ImmunoCAP 250, ImmunoCAP 1000, Phadia, Specific IgE (SOP-M 5.2)	ImmunoCAP 1000 / BA ImmunoCAP 250 / KE investigated allergens according to the manufacturer's offer of the mentioned measuring systems
6.1	peripheral blood, bone marrow	Fusion genes (BCR- ABL)	Real Time PCR	Reference 6.1 (SOP-M 6.1)	BA/KE
6.2	peripheral blood, bone marrow	V617F mutation of JAK2 gene	Real Time PCR	Reference 6.2 (SOP-M 6.2)	qualitative method BA/KE
6.3	peripheral blood, bone marrow, amniotic fluid	Molecular - cytogenetic analysis	FISH fluorescent in situ hybridization	Reference 6.3 (SOP-M 6.3)	qualitative method BA
6.4	peripheral blood	Karyotyping of chromosomes	Cytogenetic analysis of chromosomes after 72 hours peripheral blood cultivation	Reference 6.4 (SOP-M 6.4)	qualitative method BA
6.5	amniotic fluid	Chromosome aneuploidy 13,18,21,X and Y	PCR/fluorescent PCR	Reference 6.5 (SOP-M 6.5)	qualitative method BA
7.1	serum, plasma	Hepatitis B virus surface antigen (HBsAg)	electrochemi – luminescence immunoassay	HBsAg II cobas, Roche (SOP-M 7.1)	cobas 8000 qualitative method BA/KE
7.2		Hepatitis B virus surface antibodies (anti-HBs)		Anti-HBs II cobas, Roche (SOP-M 7.2)	cobas 8000 BA



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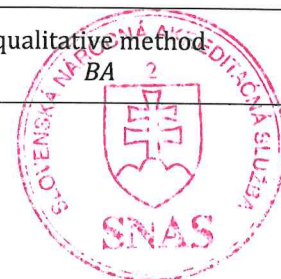
Item	Object of examination		Established method		Other specifications (equipment, workplace etc.)
	Biological material/ matrix	Analyte / Parameter	Principle	Identification of method	
7.3	serum, plasma	Hepatitis B virus core IgM antibodies (anti-HBc IgM)	electrochemi – luminescence immunoassay	Anti-HBc IgM cobas, Roche (SOP-M 7.3)	cobas 8000 qualitative method BA
7.4		Hepatitis B virus core antibodies (anti-HBc total)		Anti-HBc total cobas, Roche (SOP-M 7.4)	cobas 8000 qualitative method BA
7.5		Hepatitis B virus e antigen (HBeAg)		HBeAg cobas, Roche (SOP-M 7.5)	cobas 8000 qualitative method BA
7.6		Hepatitis B virus e antibodies (anti-HBe)		Anti-HBe cobas, Roche (SOP-M 7.6)	cobas 8000 qualitative method BA
7.7		Hepatitis C virus antibodies (anti-HCV)		Anti-HCV II cobas, Roche (SOP-M 7.7)	cobas 8000 qualitative method BA/KE
7.8		Human immunodeficiency virus antigen and antibodies (HIV Ag/Ab)		HIV Combi PT, HIV duo cobas, Roche (SOP-M 7.8)	cobas 8000 qualitative method BA/KE
7.9		Hepatitis B virus DNA (HBV DNA)	Real Time PCR	HBV cobas, Roche (SOP-M 7.9)	cobas 6800 BA
7.10		Hepatitis C virus RNA (HCV RNA)		HCV cobas, Roche (SOP-M 7.10)	cobas 6800 BA
7.11	swabs, urine	DNA <i>Chlamydia trachomatis</i>		CT/NG cobas, Roche (SOP-M 7.11)	cobas 6800 qualitative method BA
7.12		DNA <i>Neisseria gonorrhoeae</i>		CT/NG cobas, Roche (SOP-M 7.12)	cobas 6800 qualitative method BA
8.1	blood culture	The presence of diagnostically significant microorganisms	cultivation	Reference 8.1 (SOP-M 8.1)	qualitative method BA/KE/NR
8.2	body fluid cultures (excluding blood, cerebrospinal fluid and urine)	The presence of diagnostically significant microorganisms		Reference 8.2 (SOP-M 8.2)	qualitative method BA/KE/NR
8.3	catheter tip cultures	The presence of diagnostically significant microorganisms		Reference 8.3 (SOP-M 8.3)	qualitative method BA/KE
8.4	cerebrospinal fluid	The presence of diagnostically significant microorganisms		Reference 8.4 (SOP-M 8.4)	qualitative method BA/KE



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8.5	fecal and other gastrointestinal specimens	The presence of diagnostically significant microorganisms	cultivation	Reference 8.5 (SOP-M 8.5)	qualitative method BA/KE/NR
8.6	specimens from genital tract	The presence of diagnostically significant microorganisms		Reference 8.6 (SOP-M 8.6)	qualitative method BA/KE/NR
8.7	human biological material (wound, ocular and otitis cultures)	The presence of diagnostically significant microorganisms		Reference 8.7 (SOP-M 8.7)	qualitative method BA/KE/NR
8.8	specimens from respiratory tract	The presence of diagnostically significant microorganisms		Reference 8.8 (SOP-M 8.8)	qualitative method BA/KE/NR
8.9	urine	The presence of diagnostically significant microorganisms		Reference 8.9 (SOP-M 8.9)	semiquantitative method BA/KE/NR
8.10	culture of microorganisms	Identification of microorganisms	mass spectrometry	Reference 8.10 (SOP-M 8.10)	Maldi Biotyper qualitative method BA/KE
8.11	human biological material and culture of microorganisms	The presence of microorganisms, cellular elements and identification of microorganisms	microscopic examination/staining procedures	Reference 8.11 (SOP-M 8.11)	qualitative method BA/KE/NR
8.12	culture of microorganisms	Identification of aerobic, fakultative anaerobic, microaerophilic and anaerobic bacteria	conventional biochemical tests, growth properties and antigen characteristic	Reference 8.12 (SOP-M 8.12)	qualitative method BA/KE/NR
8.13	culture of microorganisms	Growth and/or inhibition growth in the presence of antimicrobial agents	antimicrobial susceptibility testing (disc diffusion and microdilution method, MIC)	Reference 8.13 (SOP-M 8.13)	qualitative method BA/KE/NR
9.1	human biological material	The presence of microscopic fungi	cultivation	Reference 9.1 (SOP-M 9.1)	qualitative method BA
9.2	biological material	The presence of microscopic fungi and cell elements	microscopic examination	Reference 9.2 (SOP-M 9.2)	qualitative method BA
9.3	cultures of microscopic fungi	Micromorphological features of microscopic fungi		Reference 9.3 (SOP-M 9.3)	qualitative method BA



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9.4	cultures of microscopic fungi	Growth of microscopic fungi in presence specific substance and temperature	analysis of metabolic and growth features	Reference 9.4 (SOP-M 9.4)	qualitative method BA
9.5	cultures of microscopic fungi	Identification of microscopic fungi	mass spectrometry	Reference 9.5 (SOP-M č. 9.5)	Maldi Biotyper qualitative method BA
10.1	serum, plasma	IgM antibodies against <i>Toxoplasma gondii</i>	electrochemi – luminiscence immunoassay	Elecsys Toxo IgM cobas, Roche (SOP-M 10.1)	cobas 8000 qualitative method BA
10.2		IgG antibodies against <i>Toxoplasma gondii</i>		Elecsys Toxo IgG cobas, Roche (SOP-M 10.2)	cobas 8000 BA
10.3		Avidity of IgG antibodies against <i>Toxoplasma gondii</i>		Elecsys Toxo IgG Avidity cobas, Roche (SOP-M 10.3)	cobas 8000 qualitative method BA
10.4	stool	The presence of helminth eggs and protozoan cysts	microscopy	Reference 10.4 (SOP-M 10.4)	qualitative method BA
10.5	perianal tape test	The presence of <i>Enterobius vermicularis</i>		Reference 10.5 (SOP-M 10.5)	qualitative method BA

REMARKS:

SOP-M - Standard Operating Procedure for Method

BA - examination is done in Medirex, a.s. Western Slovakia, Central Laboratory Bratislava

KE - examination is done in Medirex, a.s. Eastern Slovakia, Central Laboratory Košice

NR - examination is done in Medirex, a.s. Western Slovakia, Central Laboratory Nitra

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Slovenská národná akreditačná služba, Karloveská 63, P.O.BOX 74, 840 00 Bratislava



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