



REPUBLIC OF BULGARIA
Executive agency
Bulgarian accreditation service



Signatory to the EA Multilateral Agreement in this field

ORDER

№ A 475

Sofia, 17.12.2024

Pursuant to Art. 10, para. 1, item 2a of the Law on National Accreditation of Conformity Assessment Bodies and item 5.3.1 in connection with amendment of an element of the certificate content, according to item 4.3.8. of the BAS QR 2 Accreditation Procedure, assessment report reg. № 521/6 МЛ/8/В/09.09.2024, annex reg. № 521/6 МЛ/12/В/08.10.2024 and EA BAS order reg. № A 474/ 17.12.2024, I hereby

AMEND

EA BAS order reg. № 495/01.12.2023

INDEPENDENT MEDICAL DIAGNOSTIC LABORATORY KANDILAROV LTD
KANDILAROV MEDICAL DIAGNOSTIC LABORATORY

Management address: 1463, Sofia, Triaditsa District, 64 Buzludzha Str, Ground Floor
Laboratory address: 1700, Sofia, Mladost 2, Building 261 D, Ground Floor

To perform testing of:

Type of the scope: <i>Fixed</i>			
№	Tested products	Type of test / characteristic	Testing methods (standard / validated method)
1	2	3	4
Area(s) of activity of the medical laboratory: Hematology, Biochemistry, Immunology			
Hematology			
1.	Blood count	1.1 Complete Blood Count (CBC) / Differential Blood Count (DBC) - Hematocrit - Hemoglobin - Platelets - Erythrocytes - Leukocytes - Lymphocytes - Neutrophils - Monocytes - Basophils - Eosinophils - MCH - MCV - MCHC - Neutrophils %	SOP-X-036/2023 Sysmex XN1000 Analyzer

52 A "Dr. G. M. Dimitrov" Blvd. 1797 Sofia Bulgaria
 phone: +359 2 9766 401; fax: +359 2 873 53 02
 e-mail: office@nab-bas.bg; web: www.nab-bas.bg

Type of the scope: Fixed			
№	Tested products	Type of test / characteristic	Testing methods (standard / validated method)
1	2	3	4
		- Lymphocytes % - Monocytes % - Basophils % - Eosinophils %	
Biochemistry			
2.	Serum	2.1 Total protein	SOP-BH-001/2023 Cobas 6000 Analyzer
		2.2 Albumin	SOP-BH-002/2023 Cobas 6000 Analyzer
		2.3 Glucose	SOP-BH-003/2023 Cobas 6000 Analyzer
		2.4 Creatinine	SOP-BH-004/2023 Cobas 6000 Analyzer
		2.5 Urea	SOP-BH-005/2023 Cobas 6000 Analyzer
		2.6 Uric acid	SOP-BH-006/2023 Cobas 6000 Analyzer
		2.7 Total bilirubin	SOP-BH-007/2023 Cobas 6000 Analyzer
		2.8 Direct bilirubin	SOP-BH-008/2023 Cobas 6000 Analyzer
		2.9 Cholesterol	SOP-BH-009/2023 Cobas 6000 Analyzer
		2.10 Triglycerides	SOP-BH-012/2023 Cobas 6000 Analyzer
		2.11 Lactate dehydrogenase LDH	SOP-BH-017/2023 Cobas 6000 Analyzer
		2.12 ASAT	SOP-BH-013/2023 Cobas 6000 Analyzer
		2.13 ALAT	SOP-BH-014/2023 Cobas 6000 Analyzer
		2.14 Alkaline phosphatase	SOP-BH-016/2023 Cobas 6000 Analyzer
		2.15 Amylase	SOP-BH-018/2023 Cobas 6000 Analyzer
		2.16 Amylase - pancreas	SOP-BH-019/2023 Cobas 6000 Analyzer
		2.17 Lipase	SOP-BH-020/2023 Cobas 6000 Analyzer
		2.18 Creatine kinase CK	SOP-BH-021/2023 Cobas 6000 Analyzer
		2.19 Calcium	SOP-BH-023/2023 Cobas 6000 Analyzer
		2.20 Phosphorus	SOP-BH-024/2023 Cobas 6000 Analyzer
		2.21 Potassium	SOP-BH-025/2023 Cobas 6000 Analyzer
		2.22 Sodium	SOP-BH-025/2023 Cobas 6000 Analyzer

Type of the scope: Fixed			
Nº	Tested products	Type of test / characteristic	Testing methods (standard / validated method)
1	2	3	4
		2.23 Chlorides	SOP-BH-025/2023 Cobas 6000 Analyzer
		2.24 Iron	SOP-BH-026/2023 Cobas 6000 Analyzer
		2.25 Iron-binding capacity	SOP-BH-027/2023 Cobas 6000 Analyzer
		2.26 Magnesium	SOP-BH-029/2023 Cobas 6000 Analyzer
Immunology			
2.	Serum	2.27 Immunoglobulin A (IgA)	SOP-I-076/2023 Cobas 6000 Analyzer
		2.28 Immunoglobulin G (IgG)	SOP-I-077/2023 Cobas 6000 Analyzer
		2.29 Immunoglobulin M (IgM)	SOP-I-075/2023 Cobas 6000 Analyzer

To perform sampling of:

Type of the scope: Fixed		
Nº	Product	Sampling methods (standard/validated method)
1	2	3
1.	Venous blood	SOP-PP-01/2023
2.	Capillary blood	SOP-PP-02/2023

References:

Code/Validation Date	Procedure Name	Procedure Type
Biochemistry - Analytical procedures		
<i>Quantitative determination of total protein in human serum and plasma</i>	<i>SOP-BH-001/ 10.01.2023</i>	<i>Operational internal documented procedures developed in accordance with manufacturer's instructions and kit packaging inserts.</i>
<i>Quantitative determination of albumin in human serum and plasma</i>	<i>SOP-BH-002/ 10.01.2023</i>	
<i>Quantitative determination of glucose in human serum and plasma</i>	<i>SOP-BH-003/ 10.01.2023</i>	
<i>Quantitative determination of creatinine in human serum and plasma</i>	<i>SOP-BH-004/ 10.01.2023</i>	
<i>Quantitative determination of urea in human serum and plasma</i>	<i>SOP-BH-005/ 10.01.2023</i>	
<i>Quantitative determination of urinary acid in human serum and plasma</i>	<i>SOP-BH-006/ 10.01.2023</i>	
<i>Quantitative determination of total bilirubin in human serum and plasma</i>	<i>SOP-BH-007/ 10.01.2023</i>	
<i>Quantitative determination of direct bilirubin in human serum and plasma</i>	<i>SOP-BH-008/ 10.01.2023</i>	
<i>Quantitative determination of cholesterol in human serum and plasma</i>	<i>SOP-BH-009/ 10.01.2023</i>	
<i>Quantitative determination of triglycerides in human serum and plasma</i>	<i>SOP-BH-012/ 10.01.2023</i>	
<i>Quantitative determination of aspartate aminotransferase in human serum and plasma</i>	<i>SOP-BH-013/ 12.01.2023</i>	

Code/Validation Date	Procedure Name	Procedure Type
Quantitative determination of alanine aminotransferase in human serum and plasma	SOP-BH-014/ (ALAT)12.01.2023	
Quantitative determination of alkaline phosphatase in human serum and plasma	SOP-BH-016/ 12.01.2023	
Quantitative determination of lactate dehydrogenase in human serum and plasma	SOP-BH-017/ 12.01.2023	
Quantitative determination of alpha-amylase in human serum and plasma	SOP-BH-018/ 12.01.2023	
Quantitative determination of pancreatic alpha amylase in human serum and plasma	SOP-BH-019/ 12.01.2023	
Quantitative determination of lipase in human serum and plasma	SOP-BH-020/ 12.01.2023	
Quantitative determination of creatine kinase in human serum and plasma	SOP-BH-021/ 12.01.2023	
Quantitative determination of calcium in human serum and plasma	SOP-BH-023/ 11.01.2023	
Quantitative determination of phosphorus in human serum and plasma	SOP-BH-024/ 11.01.2023	
Quantitative determination of sodium, potassium and chlorine in serum and plasma	SOP-BH-025/ 11.01.2023	
Quantitative determination of iron in human serum and plasma	SOP-BH-026/ 11.01.2023	
Quantitative determination of unsaturated iron-binding capacity in human serum and plasma	SOP-BH-027/ 11.01.2023	
Quantitative determination of magnesium in human serum and plasma	SOP-BH-029/ 11.01.2023	
Hematology - Analytical procedures		
Complete Blood Count (CBC)/ Differential Blood Count (DBC) in whole blood	SOP-X-036/ 19.01.2023	Operational internal documented procedure developed in accordance with manufacturer's instructions and kit packaging inserts.
Immunology - Analytical procedures		
Quantitative determination of IgM in human serum and plasma	SOP-I-075/ 06.02.2023	Operational internal documented procedures developed in accordance with manufacturer's instructions and kit packaging inserts.
Quantitative determination of IgA in human serum and plasma	SOP-I-076/ 06.02.2023	
Quantitative determination of IgG in human serum and plasma	SOP-I-077/ 06.02.2023	
Sampling - Pre-analytical procedures		
For venous blood sampling	SOP-PP-01/ 21.07.2023	Operational internal documented procedures developed in accordance with manufacturer's instructions and kit packaging inserts.
For capillary blood sampling	SOP-PP-02/ 21.07.2023	

I ORDER

To issue the certificate of accreditation reg. № 6 МЛ/17.12.2024, valid until 01.12.2027, and this order as an integral part of it.

The certificate of accreditation with the enclosure to be received by the manager/ representative of Independent medical diagnostic laboratory KANDILAROV Ltd, the head of KANDILAROV Medical diagnostic laboratory, at Independent medical diagnostic laboratory KANDILAROV Ltd, or other authorized person in the office of EA BAS.

Upon receipt of the certificate and the enclosure issued, the accredited person is obliged to return to EA BAS the originals of accreditation certificate № 6 МЛ/01.12.2023, valid until 01.12.2027 and an enclosure, EA BAS order reg. № A 495/01.12.2023 as an integral part of it.

This order shall be notified to Independent medical diagnostic laboratory KANDILAROV Ltd, within 3 (three) days from its issuance.

Eng. Irena Borissova

Executive Director of EA BAS

