



ORDER

№ A 12

Sofia, 10.01.2023

Pursuant to Art. 10, para. 1, item 2a, of the Law on National Accreditation of Conformity Assessment Bodies, item 5.1.3 in connection with amendment of an element of the certificate content according to the item 4.3.8 f) of the BAS QR 2 Accreditation Procedure, assessment report reg. № 439/3 МЛ/13/В/01.07.2021, annex reg. № 439/3 МЛ/15/В/14.11.2022, report BAS QF 2.9.5.5 reg. № 439/3 МЛ/18/В/19.12.2022 and EA BAS order reg. № A 11/10.01.2023, I hereby

AMEND

EA BAS order reg. № A 687/30.11.2020,
of

**Independent Medical Diagnostics Laboratory
Synevo Bulgaria EOOD**

Clinical Laboratory

Management address:

1000 Sofia, Sredets District, 34 Angel Kanchev Str, floor 1

Laboratory address:

1404 Sofia, 49 A Bulgaria Blvd.

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
Field(s) of activity of the medical laboratory: Hematology			
1	blood	Erythrocytes	SOP-5.5.3-02/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
2	blood	Haematocrit	SOP-5.5.3-03/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
3	blood	Haemoglobin	SOP-5.5.3-04/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
4	blood	Leukocytes	SOP-5.5.3-05/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure

Type of the scope: *fixed*

№	Tested products	Type of test / characteristic	Testing methods (standard / validated method)
1	2	3	4
5	blood	Platelets	SOP-5.5.3-06/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
6	blood	Basophilic granular leucocytes	SOP-5.5.3-07/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
7	blood	Eosinophilic granular leukocytes	SOP-5.5.3-08/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
8	blood	Neutrophil granular leukocytes	SOP-5.5.3-09/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
9	blood	Monocytes	SOP-5.5.3-10/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
10	blood	Lymphocytes	SOP-5.5.3-11/21.12.2015 - Automated Hematology Analyzer, Closed System: - Sysmex XN 1000 Pure
Field(s) of activity of the medical laboratory: Biochemistry			
11	serum	Alanine aminotransferase	SOP-5.5.3-12/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
12	serum	Albumin	SOP-5.5.3-13/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
13	serum	Alkaline phosphatase	SOP-5.5.3-14/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
14	serum	Aspartate aminotransferase	SOP-5.5.3-15/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
15	serum	Bilirubin total	SOP-5.5.3-16/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
16	serum	Bilirubin direct	SOP-5.5.3-17/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
17	serum	Calcium	SOP-5.5.3-18/21.12.2015 - Automated Hematology Analyzer, Closed System:

Type of the scope: fixed			
No	Tested products	Type of test / characteristic	Testing methods (standard / validated method)
1	2	3	4
			- Cobas Pro (module c503)
18	serum	Chlorides	SOP-5.5.3-19/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
19	serum	Total cholesterol	SOP-5.5.3-20/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
20	serum	Creatine kinase	SOP-5.5.3-21/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
21	serum	Creatinine	SOP-5.5.3-22/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
22	serum	Gamma Glutamyltranspeptidase	SOP-5.5.3-23/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
23	serum	Glucose	SOP-5.5.3-24/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
24	serum	Lactate dehydrogenase	SOP-5.5.3-25/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
25	serum	Potassium	SOP-5.5.3-26/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
26	plasma	Prothrombin time	SOP-5.5.3-27/21.12.2015 - Automated coagulometer-analyzer, Closed system: - Sysmex CA-600
27	serum	Sodium	SOP-5.5.3-28/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
28	serum	Triglycerides	SOP-5.5.3-29/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
29	serum	Uric acid	SOP-5.5.3-30/21.12.2015 - Automated Hematology Analyzer, Closed System: - Cobas Pro (module c503)
30	serum	Urea BUN	SOP-5.5.3-31/21.12.2015 - Automated Hematology Analyzer, Closed System:

Type of the scope: <i>fixed</i>			
No	Tested products	Type of test / characteristic	Testing methods (standard / validated method)
1	2	3	4
			- Cobas Pro (module c503)

References:

Code/Validation date	Name of procedure	Type of procedure
SOP-5.5.3-02/21.12.2015	Procedure for analysis of B - Erythrocytes RBC (Erythrocytes)	Operational Internal Documented Procedure, developed in accordance with instructions of manufacturer and inserts to packaging of the kit
SOP-5.5.3-03/21.12.2015	Procedure for analysis of B - Hematocrit HCT (Hematocrit)	
SOP-5.5.3-04/21.12.2015	Procedure for analysis of B - Haemoglobin HG B (Hemoglobin))	
SOP-5.5.3-05/21.12.2015	Procedure for analysis of B Leukocytes WBC (Leucocytes)	
SOP-5.5.3-06/21.12.2015	Procedure for analysis of B - Platelets PLT (Platelets)	
SOP-5.5.3-07/21.12.2015	Procedure for analysis of B - Basophils BASO (Basophilic granular leukocytes)	
SOP-5.5.3-08/21.12.2015	Procedure for analysis of B - Eosinophils EO (Eosinophilic granular leukocytes)	
SOP-5.5.3-09/21.12.2015	Procedure for analysis of B - Neutrophils NEUT (Neutrophilic granular leukocytes)	
SOP-5.5.3-10/21.12.2015	Procedure for analysis of B - Monocytes MONO (Monocytes)	
SOP-5.5.3-11/21.12.2015	Procedure for analysis of B - Lymphocytes LYMPH (Lymphocytes)	
SOP-5.5.3-12/21.12.2015	Procedure for analysis of S - Alanine Aminotransferase (ALT) Alanine aminotransferase	
SOP-5.5.3-13/21.12.2015	Procedure for analysis of S - Albumin (Albumin)	
SOP-5.5.3-14/21.12.2015	Procedure for analysis of S - Alkaline Phosphatase (ALP) Alkaline Phosphatase	
SOP-5.5.3-15/21.12.2015	Procedure for analysis of S - Aspartate Aminotransferase (AST) Aspartate Aminotransferase	
SOP-5.5.3-16/21.12.2015	Procedure for analysis of S - Bilirubin, total (Bilirubin, total)	
SOP-5.5.3-17/21.12.2015	Procedure for analysis of S - Bilirubin, direct (Bilirubin, direct)	
SOP-5.5.3-18/21.12.2015	Procedure for analysis of S - Calcium, total (Calcium)	
SOP-5.5.3-19/21.12.2015	Procedure for analysis of S - Chloride (Chlorides)	
SOP-5.5.3-20/21.12.2015	Procedure for analysis of S - Cholesterol, total (Cholesterol, total)	
SOP-5.5.3-21/21.12.2015	Procedure for analysis of S - Creatine Kinase; CK (Creatine Kinase)	
SOP-5.5.3-22/21.12.2015	Procedure for analysis of S - Creatinine (Creatinine)	
SOP-5.5.3-23/21.12.2015	Procedure for analysis of S - Gamma-glutamyltranspeptidase γ GT (GGTP (Gamma-glutamyltranspeptidase	
SOP-5.5.3-24/21.12.2015	Procedure for analysis of S - Glucose	

Code/Validation date	Name of procedure	Type of procedure
	<i>(Glucose)</i>	
SOP-5.5.3-25/21.12.2015	<i>Procedure for analysis of S - Lactate Dehydrogenase LDH (Lactate Dehydrogenase)</i>	
SOP-5.5.3-26/21.12.2015	<i>Procedure for analysis of S - Potassium (Potassium)</i>	
SOP-5.5.3-27/21.12.2015	<i>Procedure for analysis of P - Prothrombin Time PT (Prothrombin Time)</i>	
SOP-5.5.3-28/21.12.2015	<i>Procedure for analysis of S - Sodium (Sodium)</i>	
SOP-5.5.3-29/21.12.2015	<i>Procedure for analysis of S - Triglycerides (Triglycerides)</i>	
SOP-5.5.3-30/21.12.2015	<i>Procedure for analysis of S - Uric Acid (Uric Acid)</i>	
SOP-5.5.3-31/21.12.2015	<i>Procedure for analysis of S - Urea/BUN (Urea/BUN)</i>	

I ORDER

To issue the Certificate of accreditation reg. № 3 ЛИ/10.01.2023, valid until 30.11.2024 of and this order as an integral part of it.

The Certificate of accreditation with the enclosure to be received by the Manager/ representative of the Independent Medical Diagnostics Laboratory Synevo Bulgaria EOOD, the head of Clinical Laboratory, at Independent Medical Diagnostics Laboratory Synevo Bulgaria EOOD, 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 № 3 МЛ/30.11.2020, and its enclosure - EA BAS order reg. № А 687 /30.11.2020.

This order shall be notified to the Independent Medical Diagnostics Laboratory Synevo Bulgaria EOOD, within 3 (three) days from its issuance.

Eng. Irena Borislavova

Executive Director of EA BAS

