



Signatory to the EA Multilateral Agreement in this field

### ORDER

#### Nº A 12

## Sofia, 20.01.2025

Pursuant to Art. 10, para. 1, item 2a of the Law on National Accreditation of Conformity Assessment Bodies and item 5.3.1 of the BAS QR 2 Accreditation Procedure, assessment report 2.9.5.5, reg. № 496/5 МЛ/В/10.01.2025 and EA BAS order reg. № A 11/ 20.01.2025, I hereby

#### AMEND

EA BAS order reg. № 491/20.12.2024

# OF INDEPENDENT MEDICAL DIAGNOSTIC LABORATORY RAMUS OOD MEDICAL LABORATORY

Management address: 1527, Sofia, 2-4 Angista Str. Laboratory address: 1592, Sofia, Iskar District, 26 Kapitan Dimitar Spisarevski Str.

To perform testing of:

Type of the scope: Fixed				
Tested products	Type of test / characteristic	Testing methods (standard / validated method)		
1	2	3		
Area(s) of activity of the medical laboratory: Virology				
Blood	Quantification of hepatitis B (determination of HBV DNA viral load).	OI-02-SOP-019-ML Alinity m HBV AMP Kit Alinity m, cep. № M00973, Abbott Molecular		
Blood	Quantification of hepatitis C (HCV RNA viral load determination).	OI-03-SOP-019-ML Alinity m HCV AMP Kit Alinity m, cep. № M00973, Abbott Molecular		
Blood	Determination of hepatitis C (HCV) genotype and/or subtype	OI-04-SOP-019-ML, HCV Genotyping Kit, Montania 4896 Real- Time PCR Instruments & Automatic Extractor UNIO B24 Extraction System		

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

#### References:

Code/Validation Date	Procedure Name	Procedure Type
OI-02-SOP-019-ML / 20.06.2022	Quantification of HBV DNA in clinical materials	Operating internal documented procedure developed in accordance with manufacturer's instruction and inserts to kit packaging
OI-03-SOP-019-ML / 28.09.2022	Quantification of HCV RNA in clinical materials	
OI-04-SOP-019-ML / 03.11.2023	Determination of HCV genotype and/or subtype	

#### I ORDER

To issue the certificate of accreditation reg. Nº 5 M $\Pi$ /20.01.2025, valid until 17.01.2026, 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 Ramus OOD, the head of the CAB, 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  $N^{\circ}$  5 MJ/20.12.2024, valid until 17.01.2026 and an enclosure, EA BAS order reg.  $N^{\circ}$  A 491/20.12.2024 as an integral part of it.

This order shall be notified to the legal entity, within 3 (three) days from its issuance.

Eng. Irena Borislavova

Executive Director of Executive Agency Bulgarian Accreditation Service