



REPUBLIC OF BULGARIA  
Executive agency  
Bulgarian accreditation service



*Signatory to the EA Multilateral Agreement in this field*

**ORDER**

**№ 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:**

<b>Type of the scope: Fixed</b>		
<b>Tested products</b>	<b>Type of test / characteristic</b>	<b>Testing methods (standard / validated method)</b>
1	2	3
<b>Area(s) of activity of the medical laboratory: Virology</b>		
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 (HBV 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

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**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. № 5 МЛ/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 № 5 МЛ/20.12.2024, valid until 17.01.2026 and an enclosure, EA BAS order reg. № 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

