



ORDER

№ A 340

Sofia, 10.09.2024

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. e) of the BAS QR 2 Accreditation Procedure, assessment reports reg. № 347/1 МЛ/6/В/18.06.2024, reg. № 347/1 МЛ/11/В/04.09.2024 annex reg. № 347/1 МЛ/9/В/26.07.2024 and EA BAS order reg. № A 339/10.09.2024, I hereby

AMEND

EA BAS order reg. № 342/01.06.2022

**UMBAL SVETI IVAN RILSKI EAD
/UNIVERSITY GENERAL HOSPITAL FOR ACTIVE TREATMENT/
LABORATORY ON PORPHYRIA AND
MOLECULAR DIAGNOSIS OF LIVER DISEASES
AT CLINICAL LABORATORY**

Management address: 1431 Sofia, Triaditsa District, 15 Acad. Ivan Gesshov Blvd.
Laboratory address: 1431 Sofia, Triaditsa District, 15 Acad. Ivan Gesshov Blvd.

To perform testing of:

Type of the scope: *Fixed*

№	Tested products	Type of test / characteristic	Testing methods (standard / validated method)
1	2	3	4
Field of activity of the medical laboratory: Virology			
1.	Blood serum/ plasma	Quantification of HBV DNA	Real Time PCR ПК-5.5.3-04/2023 - PRM: 3th WHO IS for HBV NAT, NIBSC code 10/264, - PEI Reference Preparation, HBV DNA - LightCycler 1.5 – PCR Real-Time, Roche Diagnostic.
2.		Quantification of HCV RNA	Real Time PCR ПК-5.5.3-03/2023 - PRM: 5th WHO IS for HCV NAT, NIBSC code 14/150, PEI Reference Preparation, HCV RNA - LightCycler 1.5 – PCR Real-Time, Roche Diagnostic.
3.		Determination of HCV genotype	Real Time PCR ПК-5.5.3-03/2023 - PRM: 5th WHO IS for HCV NAT, NIBSC code 14/150, PEI Reference Preparation, HCV RNA - LightCycler 1.5 – PCR Real-Time, Roche Diagnostic.

References:

Code/Validation Date	Procedure Name	Procedure Type
ПК-5.5.3-04/2023	Quantification of HBV DNA	Operating internal documented procedure developed in accordance with manufacturer's instruction and inserts to kit packaging
ПК-5.5.3-03/2023	Quantification of HCV RNA	
ПК-5.5.3-03/2023	Determination of HCV genotype	

I ORDER

To issue the certificate of accreditation reg. № 1 МЛ/10.09.2024, valid until 01.06.2026, and this order as an integral part of it.

The certificate of accreditation with the enclosure to be received by the director/ representative of UMBAL Sveti Ivan Rilski EAD, the head of Laboratory on Porphyria and Molecular Diagnosis of Liver Diseases, at the Clinical Laboratory of UMBAL Sveti Ivan Rilski EAD, 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 № 1 МЛ/01.06.2022, valid until 01.06.2026 and its enclosure, EA BAS order reg. № A 342/01.06.2022.

This order shall be notified to UMBAL Sveti Ivan Rilski EAD, within 3 (three) days from its issuance.

Eng. Irena Borislavova

*Executive Director
of Executive Agency Bulgarian Accreditation Service*

