



Signatory to the EA Multilateral Agreement in this field

ORDER

№ A 26

Sofia, 29.01.2025

Pursuant to Art. 10, para. 1, item 4, Art. 28, para. 1 of the Law on National Accreditation of Conformity Assessment Bodies and item 6 of the BAS QR 2 Accreditation Procedure, in connection with an open procedure reg. № 485/4 МЛ/ПА/20.06.2024, assessment report, reg. № 485/4 МЛ/7/В/04.12.2024 and statement of the Accreditation Commission reg. № 485/4 МЛ/ПА/В/10.01.2025, I hereby

RE-ACCREDIT

**MEDICAL CENTER TRANSHelix EOOD
CLINICAL & MOLECULAR PATHOLOGY LABORATORY**

Management and laboratory address:

1700 Sofia, Studentski Grad, 2D Prof. Petar Dzhidrov Str.

To perform testing of:

Type of the scope: <i>flexible*</i>			
№	Tested products	Type of test/ characteristic	Testing methods (standard / validated method)
1	2	3	4
1.	Tissue	Histology	ПК 7.3-2 Light microscope
		Immunohistochemistry	ПК 7.3-3 Immunostainer and light microscope
		Fluorescence in situ hybridization (FISH).	ПК 7.3-4 Fluorescence microscope
		Multigenic expression analysis	ПК 7.3-5 PCR Real-time
2.	Tissue/blood serum (plasma)	Molecular genetic analysis of prognostic and predictive markers	ПК 7.3-6 PCR Real-time
		Multigenic molecular genetic analysis of prognostic and predictive markers	ПК 7.3-7 PCR Sequencer

***Flexible scope:** In the framework of its competence, the Laboratory is authorized to determine all characteristics (Column 3) according to the stated methods (Column 4) relevant to the product group (Column 2) upon completion of verification/validation, provision of Certified Reference Materials (CRMs) / Reference Materials (RMs) and calibrated technical equipment.

An updated list of products and characteristics, relevant to the products and characteristics as stated within the scope of accreditation is provided by the laboratory.

References:

ПК 7.3-2/01.02.2024 Histology
ПК 7.3-3/01.02.2024 Immunohistochemistry
ПК 7.3-4/01.02.2024 Fluorescence in situ hybridization (FISH)
ПК 7.3-5/01.02.2024 Multigenic expression analysis
ПК 7.3-6/01.02.2024 Molecular genetic analysis of prognostic and predictive markers
ПК 7.3-7/01.02.2024 Multigenic molecular genetic analysis of prognostic and predictive markers

I ORDER

To issue the certificate of accreditation reg. № 4 МЛ/29.01.2025, valid until 29.01.2029 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 Medical Center Transhelix EOOD, the head of Clinical & Molecular Pathology Laboratory, at Medical Center Transhelix 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 № 4 МЛ/14.11.2024, valid until 29.01.2025 and its enclosure - EA BAS order № A 428/14.11.2024.

This order shall be notified to Medical Center Transhelix EOOD, within 3 (three) days from its issuance.

Eng. Irena Borislavova

*Executive Director
of Executive Agency Bulgarian Accreditation Service*

