



ORDER

№ A 286

Sofia, 18.07.2023

Pursuant to Art. 10, para. 1, item 2a, of the Law on National Accreditation of Conformity Assessment Bodies, assessment report reg. № 485/4 МЛ/5/В/07.04.2023 and EA BAS order reg. № A 285/18.07.2023, I hereby

AMEND

Certificate reg. № 4 МЛ/14.07.2022, valid until 29.01.2025 and its enclosure - EA BAS order № A 447 /14.07.2022, as follows:

Medical Center TRANSHELIX EOOD

Clinical & Molecular Pathology Laboratory

Management and Laboratory address:

1784 Sofia, Mladost 1, 22 Andrey Saharov Blvd.

To perform testing of:

Type of the scope: flexible*

№ 1	Tested products 2	Type of test / characteristic 3	Testing methods (standard / validated method) 4
1.	Tissue	Histology	PK 5.5-2 Light microscope
		Immunohistochemistry	PK 5.5-3 Immunostainer and light microscope
		Fluorescence in situ hybridization (FISH).	PK 5.5-4 Fluorescence microscope
		Multigenic expression analysis	PK 5.5-5 PCR Real-time
2.	Tissue/blood serum (plasma)	Molecular genetic analysis of prognostic and predictive markers	PK 5.5-6 PCR Real-time
		Multigenic molecular genetic analysis of prognostic and predictive markers	PK 5.5-7 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.

The Laboratory keeps a detailed, dated list of products and characteristics relevant to the products and characteristics as stated within the scope of accreditation.

References:

ПК 5.5-2/10.12.2019 Histology

ПК 5.5-3/10.12.2019 Immunohistochemistry

ПК 5.5-4/10.12.2019 Fluorescence in situ hybridization (FISH)

ПК 5.5-5/10.12.2019 Multigenic expression analysis

ПК 5.5-6/10.12.2019 Molecular genetic analysis of prognostic and predictive markers

ПК 5.5-7/10.12.2019 Multigenic molecular genetic analysis of prognostic and predictive markers

I ORDER

To issue the certificate of accreditation reg. № 4 ЛИ/18.07.2023, valid until 29.01.2025 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 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/14.07.2022, valid until 29.01.2025 and its enclosure - EA BAS order № A 447 /14.07.2022.

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

Eng. Irena Borislavova

Executive Director of EA BAS

