**SCOPE 4 МЛ**

**Sofia, 29.01.2025**

**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:** *flexible\** | | | |
| **№** | **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