**SCOPE 5 МЛ**

**Sofia, 20.01.2025**

**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**:

| **Type of the scope:** *Fixed* | | | |
| --- | --- | --- | --- |
| **Tested products** | | **Type of test / characteristic** | **Testing methods**  **(standard / validated method)** |
|  | 1 | 2 | 3 |
| **Area(s) of activity of the medical laboratory:** Virology | | | |
| Blood | | Quantification of hepatitis B (determination of HBV DNA viral load). | OI-02-SOP-019-ML  Alinity m HBV AMP Kit  Alinity m, сер. № M00973,  Abbott Molecular |
| Blood | | Quantification of hepatitis C (HCV RNA viral load determination). | OI-03-SOP-019-ML  Alinity m HCV AMP Kit  Alinity m, сер. № 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 |

**References:**

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| --- | --- | --- |
| **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 |