**SCOPE 6 МЛ**

**INDEPENDENT MEDICAL DIAGNOSTIC LABORATORY KANDILAROV LTD**

**KANDILAROV MEDICAL DIAGNOSTIC LABORATORY**

**Management address:** 1463, Sofia, Triaditsa District, 64 Buzludzha Str, Ground Floor

**Laboratory address:** 1700, Sofia, Mladost 2, Building 261 D, Ground Floor

**To perform testing of**:

| **Type of the scope:** *Fixed* |
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| **№** | **Tested products** | **Type of test / characteristic** | **Testing methods****(standard / validated method)** |
| 1 | 2 | 3 | 4 |
| **Area(s) of activity of the medical laboratory:**Hematology, Biochemistry. Immunology |
| **Hematology** |
| 1. | Blood count | 1.1 Complete Blood Count (CBC) / Differential Blood Count (DBC)* Hematocrit
* Hemoglobin
* Platelets
* Erythrocytes
* Leukocytes
* Lymphocytes
* Neutrophils
* Monocytes
* Basophils
* Eosinophils

- MCH- MCV- MCHC- Neutrophils %* Lymphocytes %
* Monocytes %
* Basophils %

- Eosinophils % | SOP-X-036/2023Sysmex XN1000 Analyzer |
| **Biochemistry** |
| 2. | Serum  | 2.1 Total protein | SOP-BH-001/2023Cobas 6000 Analyzer |
| 2.2 Albumin | SOP-BH-002/2023Cobas 6000 Analyzer |
| 2.3 Glucose | SOP-BH-003/2023Cobas 6000 Analyzer |
| 2.4 Creatinine | SOP-BH-004/2023Cobas 6000 Analyzer |
| 2.5 Urea | SOP-BH-005/2023Cobas 6000 Analyzer |
| 2.6 Uric acid | SOP-BH-006/2023Cobas 6000 Analyzer |
| 2.7 Total bilirubin | SOP-BH-007/2023Cobas 6000 Analyzer |
| 2.8 Direct bilirubin  | SOP-BH-008/2023Cobas 6000 Analyzer |
| 2.9 Cholesterol | SOP-BH-009/2023Cobas 6000 Analyzer |
| 2.10 Triglycerides | SOP-BH-012/2023Cobas 6000 Analyzer |
| 2.11 Lactate dehydrogenase LDH | SOP-BH-017/2023Cobas 6000 Analyzer |
| 2.12 ASAT | SOP-BH-013/2023Cobas 6000 Analyzer |
| 2.13 ALAT | SOP-BH-014/2023Cobas 6000 Analyzer |
| 2.14 Alkaline phosphatase | SOP-BH-016/2023Cobas 6000 Analyzer |
| 2.15 Amylase | SOP-BH-018/2023Cobas 6000 Analyzer |
| 2.16 Amylase - pancreas | SOP-BH-019/2023Cobas 6000 Analyzer |
| 2.17 Lipase | SOP-BH-020/2023Cobas 6000 Analyzer |
| 2.18 Creatine kinase CK | SOP-BH-021/2023Cobas 6000 Analyzer |
| 2.19 Calcium | SOP-BH-023/2023Cobas 6000 Analyzer |
| 2.20 Phosphorus | SOP-BH-024/2023Cobas 6000 Analyzer |
| 2.21 Potassium | SOP-BH-025/2023Cobas 6000 Analyzer |
| 2.22 Sodium | SOP-BH-025/2023Cobas 6000 Analyzer |
| 2.23 Chlorides | SOP-BH-025/2023Cobas 6000 Analyzer |
| 2.24 Iron | SOP-BH-026/2023Cobas 6000 Analyzer |
| 2.25 Iron-binding capacity | SOP-BH-027/2023Cobas 6000 Analyzer |
| 2.26 Magnesium | SOP-BH-029/2023Cobas 6000 Analyzer |
| **Immunology** |
| 2. | Serum  | 2.27 Immunoglobulin A (IgA) | SOP-I-076/2023Cobas 6000 Analyzer |
| 2.28 Immunoglobulin G (IgG) | SOP-I-077/2023Cobas 6000 Analyzer |
| 2.29 Immunoglobulin M (IgM) | SOP-I-075/2023Cobas 6000 Analyzer |

**To perform sampling of:**

| **Type of the scope:** *Fixed* |
| --- |
| **№** | **Product** | **Sampling methods****(standard/validated method)** |
| 1 | 2 | 3 |
| 1. | Venous blood | SOP-PP-01/2023 |
| 2. | Capillary blood | SOP-PP-02/2023 |

**References:**

| ***Code/Validation Date*** | ***Procedure Name*** | ***Procedure Type*** |
| --- | --- | --- |
| ***Biochemistry - Analytical procedures*** |
| *Quantitative determination of total protein in human serum and plasma* | *SOP-BH-001/ 10.01.2023* | *Operational internal documented procedures developed in accordance with manufacturer's instructions and kit packaging inserts.* |
| *Quantitative determination of albumin in human serum and plasma* | *SOP-BH-002/ 10.01.2023* |
| *Quantitative determination of glucose in human serum and plasma* | *SOP-BH-003/ 10.01.2023* |
| *Quantitative determination of creatinine in human serum and plasma* | *SOP-BH-004/ 10.01.2023* |
| *Quantitative determination of urea in human serum and plasma* | *SOP-BH-005/ 10.01.2023* |
| *Quantitative determination of urinary acid in human serum and plasma*  | *SOP-BH-006/ 10.01.2023* |
| *Quantitative determination of total bilirubin in human serum and plasma*  | *SOP-BH-007/ 10.01.2023* |
| *Quantitative determination of direct bilirubin in human serum and plasma*  | *SOP-BH-008/ 10.01.2023* |
| *Quantitative determination of cholesterol in human serum and plasma* | *SOP-BH-009/ 10.01.2023* |
| *Quantitative determination of triglycerides in human serum and plasma* | *SOP-BH-012/ 10.01.2023* |
| *Quantitative determination of aspartate aminotransferase in human serum and plasma* | *SOP-BH-013/ 12.01.2023* |
| *Quantitative determination of alanine aminotransferase in human serum and plasma* | *SOP-BH-014/* *(ALAT)12.01.2023* |
| *Quantitative determination of alkaline phosphatase in human serum and plasma*  | *SOP-BH-016/ 12.01.2023* |
| *Quantitative determination of lactate dehydrogenase in human serum and plasma*  | *SOP-BH-017/ 12.01.2023* |
| *Quantitative determination of alpha-amylase in human serum and plasma* | *SOP-BH-018/ 12.01.2023* |
| *Quantitative determination of pancreatic alpha amylase in human serum and plasma*  | *SOP-BH-019/ 12.01.2023* |
| *Quantitative determination of lipase in human serum and plasma* | *SOP-BH-020/ 12.01.2023* |
| *Quantitative determination of creatine kinase in human serum and plasma* | *SOP-BH-021/ 12.01.2023* |
| *Quantitative determination of calcium in human serum and plasma* | *SOP-BH-023/ 11.01.2023* |
| *Quantitative determination of phosphorus in human serum and plasma* | *SOP-BH-024/ 11.01.2023* |
| *Quantitative determination of sodium, potassium and chlorine in serum and plasma*  | *SOP-BH-025/ 11.01.2023* |
| *Quantitative determination of iron in human serum and plasma* | *SOP-BH-026/ 11.01.2023* |
| *Quantitative determination of unsaturated iron-binding capacity in human serum and plasma*  | *SOP-BH-027/ 11.01.2023* |
| *Quantitative determination of magnesium in human serum and plasma* | *SOP-BH-029/ 11.01.2023* |
| ***Hematology - Analytical procedures*** |
| *Complete Blood Count (CBC)/ Differential Blood Count (DBC) in whole blood* | *SOP-X-036/ 19.01.2023* | *Operational internal documented procedure developed in accordance with manufacturer's instructions and kit packaging inserts.* |
| ***Immunology - Analytical procedures*** |
| *Quantitative determination of IgM in human serum and plasma* | *SOP-I-075/ 06.02.2023* | *Operational internal documented procedures developed in accordance with manufacturer's instructions and kit packaging inserts.* |
| *Quantitative determination of IgA in human serum and plasma* | *SOP-I-076/ 06.02.2023* |
| *Quantitative determination of IgG in human serum and plasma* | *SOP-I-077/ 06.02.2023* |
| ***Sampling - Pre-analytical procedures*** |
| *For venous blood sampling* | *SOP-PP-01/ 21.07.2023* | *Operational internal documented procedures developed in accordance with manufacturer's instructions and kit packaging inserts.* |
| *For capillary blood sampling* | *SOP-PP-02/ 21.07.2023* |