

## Area of analysis: Evaluation of medical devices

### Mode of analysis: hemocompatibility tests

| Analyte (measured variable)                                                                                                                                                                                      | Sample material (Matrix)                                                    | Method                                             | SOP/Standard                             | Equipment                        | Accredited |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------|------------------------------------------|----------------------------------|------------|
| Evaluation of hemocompatibility of dialyzers, oxygenators, plasma filters and other medical devices according to DIN EN ISO 10993-4:2017 (sC5b-9, C3a, C5a, TAT, Cell count, Heparin, Hemolysis, NIH and others) | Medical devices, biomaterials                                               | Ex vivo recirculation with heparinized human blood | AA-001, 17/02.2025                       | Ismatec MCP, Ismatec MCP-Process | +          |
| Evaluation of hemocompatibility of flat sheet membranes and medical devices according to DIN EN ISO 10993-4:2017 in petri-dish-model                                                                             | Medical devices, Flat sheets, Flat sheet membranes, Particles, biomaterials | Ex vivo incubation with heparinized human blood    | AA-010, 10/02.2025                       | Certomat U                       | +          |
| MAT - Monocyte activation test according to Ph. Eur. 2.6.30, Quantitative detection of pyrogens in human whole blood model by IL-1 $\beta$                                                                       | Medical devices, biomaterials                                               | Incubation with heparinized human blood            | AA-012, 20/02.2025<br>AA-096, 02/02.2025 | Certomat U                       | +          |
| Pyrogenretention (ex vivo)                                                                                                                                                                                       | Hemodialyzers, medical devices with hollow fiber membranes                  | Ex vivo Hemodialysis, Cytokine induction           | AA-011, 05/05.2011                       | Ismatec MCP, Ismatec MCP-Process | -          |

Released:

Date:

## Area of analysis: Microbiological-hygienic testing of medical devices

Mode of analysis: Quantitive determination of pyrogenic contaminants

| Analyte (measured variable)                                                   | Sample material (Matrix)        | Method       | SOP/Standard       | Equipment     | Accredited |
|-------------------------------------------------------------------------------|---------------------------------|--------------|--------------------|---------------|------------|
| Determination of endotoxins/pyrogens by LAL-Assay accoring to Ph. Eur. 2.6.14 | Medical products, raw materials | Turbidimetry | AA-013, 05/02.2025 | BioTek ELx808 | +          |

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## Area of analysis: Evaluation of medical devices

### Mode of analysis: Quality testing

| Analyte (measured variable)                                                                                         | Sample material (Matrix)                                    | Method                                                                                                     | SOP/Standard       | Equipment                                 | Accredited |
|---------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------------|-------------------------------------------|------------|
| Evaluation of redness                                                                                               | Hemodialyzer, medical devices with hollow fiber membranes   | 1) Recirculation model with heparinized human blood; Image analysis<br>2) Clinical testing; Image analysis | AA-067, 03/12.2017 | Minolta Chroma-Meter CR-310               | -          |
| Particle count                                                                                                      | Hemodialyzer, medical devices, tubing sets                  | Particel count in rinsing solution                                                                         | AA-079, 03/03.2017 | Ismatec MCP                               | -          |
| Gravity driven plasmaseparation                                                                                     | Loop module                                                 | Plasmaseparation                                                                                           | AA-087, 03/06.2016 | Test Rig, Plasmafilter                    | -          |
| Structural integrity according to DIN EN ISO 8637-1:2020                                                            | Hemodialyzers, hemodiafilter, hemofilter, hemoconcentrators | Pressure hold test                                                                                         | AA-094, 03/06.2025 | Pressure hold equipment, vacuum pump      | +          |
| Integrity test of the blood compartment according to DIN EN ISO 8637-1:2020                                         | Hemodialyzers, hemodiafilter, hemofilter, hemoconcentrators | Pressure hold test of the blood compartment                                                                | AA-104, 01/07.2023 | Pressure hold equipment, dialysis monitor | +          |
| Structural integrity test/Leak test and integrity of the blood compartment of plasmafilters according to ISO 8637-3 | Plasmafilters                                               | Pressure hold test                                                                                         | AA-091, 05/06.2025 | Pressure hold equipment, vacuum pump      | -          |

## Area of analysis: Evaluation of medical devices

### Mode of analysis: Determination of performance parameters

| Analyte (measured variable)                                                                                                                                                               | Sample material (Matrix)                                    | Method                                                         | SOP/Standard                             | Equipment        | Accredited |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------|------------------------------------------|------------------|------------|
| Low molecular weight solute clearance according to DIN EN ISO 8637-1:2020 (ex vivo)                                                                                                       | Hemodialyzers, hemodiafilter, hemofilter, hemoconcentrators | Ex vivo Hemodialysis                                           | AA-039, 19/04.2024                       | Dialysis monitor | +          |
| Blood clearance of middle molecules with albumin loss according to DIN EN ISO 8637-1:2020                                                                                                 | Hemodialyzers, hemodiafilter, hemofilter, hemoconcentrators | Ex vivo Hemodialysis                                           | AA-039, 19/04.2024                       | Dialysis monitor | +          |
| Clearance according to japanese standard: Manual for Functional Classification of Dialyzers; Methods for performance evaluation of blood purifiers                                        | Hemodialyzers, hemodiafilter, hemofilter, hemoconcentrators | Ex vivo Hemodialysis                                           | AA-100, 01/05.2020                       | Dialysis monitor | +          |
| Determination of sieving coefficients according to DIN EN ISO 8637-1:2020 (ex vivo)                                                                                                       | Hemodialyzers, hemodiafilter, hemofilter, hemoconcentrators | Ex vivo Hemodialysis                                           | AA-040, 11/04.2024                       | Dialysis monitor | +          |
| Determination of pressure drop, Volume of blood compartment, transmembrane pressure TMP, ultrafiltration rate UFR and ultrafiltration coefficient KUF according to DIN EN ISO 8637-1:2020 | Hemodialyzers, hemodiafilter, hemofilter, hemoconcentrators | Hemodialysis; Recirculation model with heparinized human blood | AA-065, 10/04.2024<br>AA-042, 03/05.2013 | Dialysis monitor | +          |
| Determination of performance parameters of plasmafilters (Sieving coefficients, filtration rate, hemolysis, TMP) according to ISO 8637-3                                                  | Plasmafilter                                                | ex vivo Recirculation model with heparinized human blood       | AA-091, 06/06.2025                       | Dialysis monitor | -          |

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| Analyte (measured variable)                                                                                                   | Sample material (Matrix)                | Method                                                                             | SOP/Standard       | Equipment                                  | Accredited |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------------------------------------------------|--------------------|--------------------------------------------|------------|
| Isolation of proteins from hemofiltrate of patients with Kidney Failure (ex vivo)                                             | Hemofiltrate                            | Ultrafiltration, Chromatography                                                    | AA-037, 07/08.2022 | Ismatec MCP, Ismatec MCP-Process           | -          |
| Determination of performance parameters of plasmafractionation devices (Sieving Coefficients, ex vivo)                        | Plasmafractionation devices             | ex vivo Plasmafractionation                                                        | AA-077, 05/03.2016 | Plasmafractionation monitor Infomed CF-100 | -          |
| Determination of O <sub>2</sub> and CO <sub>2</sub> transfer rates of oxygenators according to DIN EN ISO 7199:2020           | Oxygenators                             | ex vivo Recirculation model with heparinized human blood                           | AA-102, 01/02.2022 | Customer specified blood pump              | +          |
| Retention and damage of blood cells/plasma components by transfusion sets according to DIN EN ISO 1135-4:2016 and 1135-5:2016 | Transfusion sets, pumps for transfusion | Filtration of different media (blood/plasma products) through the transfusion sets | AA-105, 01/01.2024 | Transfusion sets, pumps for transfusion    | +          |
| Blood Cell Damage (BCD) according to DIN EN ISO 7199                                                                          | Oxygenators                             | ex vivo Recirculation model with heparinized human blood                           | AA-106, 01/06.2025 | Customer specified blood pump              | -          |

## Area of analysis: Biochemistry/Clinical chemistry

### Mode of analysis: Spectrometry (UV-/ VIS-Photometry/ Nephelometry)

| Analyte (measured variable)    | Sample material (Matrix)                                      | Method                  | SOP/Standard       | Equipment          | Accredited |
|--------------------------------|---------------------------------------------------------------|-------------------------|--------------------|--------------------|------------|
| $\alpha$ -Amylase              | Heparinized and EDTA plasma, Serum                            | Photometry              | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| $\alpha$ 1-Antitrypsin         | Heparinized and EDTA plasma, Serum                            | Nephelometry            | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| $\alpha$ 1-acidic Glycoprotein | Heparinized plasma, Serum, Aqueous Solutions*                 | Nephelometry            | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| $\alpha$ 1-Microglobulin       | Heparinized plasma, Serum, Urine, Aqueous Solutions*          | Nephelometry            | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| $\alpha$ 2-Macroglobulin       | Heparinized plasma, Serum, Urine, Aqueous Solutions*          | Nephelometry            | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| ADNase B                       | Serum                                                         | Nephelometry            | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Alanine aminotransferase       | Heparinized and EDTA plasma, Serum                            | Photometry              | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Albumin                        | Heparinized and EDTA plasma, Serum                            | Photometry              | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Albumin                        | Citrated plasma, Serum, Aqueous Solutions*                    | Photometry (BCG method) | AA-103, 01/10.2022 | BioTek ELx808      | +          |
| Albumin                        | Heparinized and EDTA plasma, Serum, Urine, Aqueous Solutions* | Nephelometry            | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |

\* aqueous solution: in house validated; out of scope of D-PL-19275-01-00, within the scope of D-PL-19275-02-00

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| Analyte (measured variable) | Sample material (Matrix)                                         | Method       | SOP/Standard       | Equipment          | Accredited |
|-----------------------------|------------------------------------------------------------------|--------------|--------------------|--------------------|------------|
| Alkaline phosphatase        | Heparinized plasma, Serum                                        | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Ammonia                     | EDTA plasma                                                      | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Antistreptolysin (ASL)      | Heparinized and EDTA plasma, Serum                               | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Antithrombin III            | EDTA and citrated plasma                                         | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Apolipoprotein A-I          | Heparinized plasma, Serum                                        | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Apolipoprotein A-II         | Serum                                                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Apolipoprotein B            | Heparinized plasma, Serum                                        | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Apolipoprotein E            | Serum                                                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Aspartate aminotransferase  | Heparinized and EDTA plasma                                      | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| β2-Microglobulin            | Heparinized plasma, Serum, Urine, Aqueous Solutions*             | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| BCA, Protein determination  | Heparinized, citrated and EDTA plasma, Serum, Aqueous Solutions* | Photometry   | AA-074, 06/02.2025 | BioTek ELx808      | +          |
| Bicarbonate                 | Heparinized plasma                                               | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Bilirubin Direct            | Heparinized and EDTA plasma, Serum                               | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |

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| Analyte (measured variable)             | Sample material (Matrix)                                      | Method       | SOP/Standard       | Equipment          | Accredited |
|-----------------------------------------|---------------------------------------------------------------|--------------|--------------------|--------------------|------------|
| Bilirubin Total                         | Heparinized and EDTA plasma, Serum                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| C1-Inhibitor                            | EDTA and citrated plasma, Serum                               | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Calcium                                 | Heparinized and EDTA plasma, Serum                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Carbohydrate-Deficient Transferrin      | Heparinized and EDTA plasma, Serum                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Cholesterol                             | Heparinized and EDTA plasma, Serum, Aqueous solutions*        | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Coeruloplasmin                          | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| C-reactive Protein (CRP)                | Heparinized and EDTA plasma, Serum                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| C-reactive Protein (CRP)                | Heparinized and EDTA plasma, Serum                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| C-reactive Protein (CRP) High Sensitive | Heparinized and EDTA plasma, Serum                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Creatinine                              | Heparinized and EDTA plasma, Serum, Urine, Aqueous solutions* | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Creatinine (Jaffé)                      | Heparinized and EDTA plasma, Serum                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Creatine kinase                         | Heparinized plasma, Serum                                     | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Cystatin C                              | Heparinized and EDTA plasma, Serum, Aqueous solutions*        | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |

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| Analyte (measured variable)           | Sample material (Matrix)                               | Method       | SOP/Standard       | Equipment          | Accredited |
|---------------------------------------|--------------------------------------------------------|--------------|--------------------|--------------------|------------|
| DEHP equivalents                      | Aqueous solutions                                      | Photometry   | AA-099, 01/07.2019 | Shimadzu UV-1650PC | -          |
| D-Dimer                               | Heparinized, EDTA and Citrated plasma                  | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Ferrum                                | Heparinized plasma, Serum                              | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Factor VIII Coatest                   | Citrated plasma                                        | Photometrie  | AA-093, 02/07.2019 | BioTek ELx808      | +          |
| Ferritin                              | Heparinized plasma, Serum                              | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Fibrinogen                            | EDTA and citrated plasma, Aqueous solutions*           | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| Fibronectin                           | EDTA and citrated plasma                               | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| free Hemoglobin in plasma (hemolysis) | Heparinized plasma, Serum                              | Photometry   | AA-056, 13/02.2025 | Shimadzu UV-1650PC | +          |
| Glucose                               | Heparinized and EDTA plasma, Serum                     | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Hemopexin                             | Heparinized plasma, Serum                              | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Haptoglobin                           | Heparinized and EDTA plasma, Serum                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| HbA1c                                 | Heparinized and EDTA plasma                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| HDL Cholesterol                       | Heparinized and EDTA plasma, Serum, Aqueous solutions* | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |

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| Analyte (measured variable)                   | Sample material (Matrix)                                      | Method       | SOP/Standard       | Equipment          | Accredited |
|-----------------------------------------------|---------------------------------------------------------------|--------------|--------------------|--------------------|------------|
| Heparin                                       | Citrated plasma                                               | Photometry   | AA-002, 16/06.2025 | BioTek ELx808      | +          |
| Homocysteine                                  | Heparinized and EDTA plasma, Serum                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Free Immunoglobulin Light chains, Type kappa  | Heparinized and EDTA plasma, Serum, Urine, Aqueous solutions* | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| Free Immunoglobulin Light chains, Type lambda | Heparinized and EDTA plasma, Serum, Urine, Aqueous solutions* | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| Immunoglobulin A (IgA)                        | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Immunoglobulin E (IgE)                        | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Immunoglobulin G (IgG)                        | Heparinized plasma, Serum, Urine, Aqueous solutions*          | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| Immunoglobulin G (IgG) Subclass 1             | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Immunoglobulin G (IgG) subclass 2             | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Immunoglobulin G (IgG) subclass 3             | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Immunoglobulin G (IgG) subclass 4             | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Immunoglobulin M (IgM)                        | Heparinized plasma, Serum, Aqueous solutions*                 | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| Inulin                                        | CPD, Citrated and Heparinized plasma, Aqueous solutions*      | Photometry   | AA-048, 10/04.2023 | Shimadzu UV-1650PC | +          |

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| Analyte (measured variable)  | Sample material (Matrix)                                      | Method       | SOP/Standard       | Equipment          | Accredited |
|------------------------------|---------------------------------------------------------------|--------------|--------------------|--------------------|------------|
| Iron                         | Heparinized plasma, Serum                                     | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Complement factor C3c        | Heparinized and EDTA plasma, Serum                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Complement factor C4         | Heparinized and EDTA plasma, Serum                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Lactate                      | Heparinized plasma                                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| LDH                          | Heparinized plasma, Serum                                     | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| LDL-Cholesterol              | Heparinized plasma, Serum, Aqueous solutions*                 | Photometrie  | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Lipase                       | Heparinized plasma, Serum                                     | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Lipoprotein (a)              | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Magnesium                    | Heparinized plasma, Serum                                     | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Myoglobin                    | Heparinized and EDTA plasma, Serum, Aqueous solutions*        | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| Pancreatic $\alpha$ -Amylase | Heparinized plasma, Serum                                     | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Peroxide (PerOX)             | EDTA plasma, Serum                                            | Photometry   | AA-019, 13/02.2025 | BioTek ELx808      | +          |
| Phosphate                    | Heparinized and EDTA plasma, Serum, Urine, Aqueous solutions* | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Plasminogen                  | EDTA and citrated plasma                                      | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |

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| Analyte (measured variable)   | Sample material (Matrix)                                      | Method       | SOP/Standard       | Equipment          | Accredited |
|-------------------------------|---------------------------------------------------------------|--------------|--------------------|--------------------|------------|
| Pre albumin                   | Heparinized and EDTA plasma, Serum                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Retinol binding Protein (RBP) | Heparinized plasma, Serum, Aqueous solutions*                 | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | +          |
| Rheumatoid factor (RF)        | Heparinized and EDTA plasma, Serum                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Serum Amyloid A Protein (SAA) | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Soluble Transferrin Receptor  | Heparinized plasma, Serum                                     | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Total protein                 | Heparinized and EDTA plasma, Serum, Urine, Aqueous solutions* | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Transferrin                   | Heparinized and EDTA plasma, Serum                            | Nephelometry | AA-014, 12/07.2019 | Siemens BN ProSpec | -          |
| Triglyceride                  | Heparinized and EDTA plasma, Serum                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Urea                          | Heparinized and EDTA plasma, Serum, Urine, Aqueous solutions* | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | +          |
| Uric Acid                     | Heparinized and EDTA plasma, Serum                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |
| Vitamin B12                   | Heparinized and EDTA plasma, Serum, Aqueous solutions*        | Photometry   | AA-047, 14/06.2025 | Shimadzu UV-1650PC | +          |
| γ-Glutamyltransferase         | Heparinized and EDTA plasma, Serum                            | Photometry   | AA-057, 10/07.2019 | Roche cobas c111   | -          |

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## Area of analysis: Biochemistry/Clinical chemistry

### Mode of analysis: Flow cytometry

| Analyte (measured variable)                                                   | Sample material (Matrix)                            | Method           | SOP/Standard       | Equipment        | Accredited |
|-------------------------------------------------------------------------------|-----------------------------------------------------|------------------|--------------------|------------------|------------|
| Apoptose / Annexin V                                                          | Heparinized blood                                   | Flow cytometry   | AA-020, 05/07.2019 | BD FACSVerse     | +          |
| Characterisation MSC                                                          | Cell culture                                        | Flow cytometry   | AA-095, 01/02.2016 | BD FACSVerse     | -          |
| Oxidative Burst                                                               | Heparinized blood                                   | Flow cytometry   | AA-021, 14/02.2025 | BD FACSVerse     | +          |
| Granulocyte Activation                                                        | EDTA blood                                          | Flow cytometry   | AA-075, 04/02.2025 | BD FACSVerse     | +          |
| Monocyte Subpopulations                                                       | EDTA blood                                          | Flow cytometry   | AA-080, 07/03.2017 | BD FACSVerse     | +          |
| BD Leucocount                                                                 | Heparinized plasma                                  | Flow cytometry   | AA-083, 02/06.2015 | BD FACSVerse     | +          |
| TBNK-Lymphocyte Subpopulations                                                | EDTA blood                                          | Flow cytometry   | AA-084, 02/07.2014 | BD FACSVerse     | +          |
| BD Plasma Count                                                               | Heparinized, Citrated and EDTA plasma               | Flow cytometry   | AA-085, 07/10.2017 | BD FACSVerse     | +          |
| Dentritic cells                                                               | EDTA blood                                          | Flow cytometry   | AA-086, 03/06.2015 | BD FACSVerse     | +          |
| Platelet activation PAC-1/CD62P                                               | Citrated blood                                      | Flow cytometry   | AA-098, 08/02.2025 | BD FACSVerse     | +          |
| Blood cells: Platelets, Erythrocytes, Leucocytes, Hematocrit, Hemoglobin etc. | Heparinized, Citrated and EDTA blood                | Impedance method | AA-005, 13/02.2025 | ABX Pentra 60 C+ | +          |
| Cell Viability                                                                | Heparinized, Citrated and EDTA plasma, Cell culture | Flow cytometry   | AA-092, 03/03.2017 | BD FACSVerse     | -          |

## Area of analysis: Biochemistry/Clinical chemistry

### Mode of analysis: Ligand assays (ELISA)

| Analyte (measured variable)             | Sample material (Matrix)                     | Method | SOP/Standard                   | Equipment     | Accredited |
|-----------------------------------------|----------------------------------------------|--------|--------------------------------|---------------|------------|
| HMW-Adiponectin                         | Heparinized and Citrated plasma, Serum       | ELISA  | Instructions from the supplier | BioTek ELx808 | -          |
| Total-Adiponectin                       | Heparinized and Citrated plasma, Serum       | ELISA  | Instructions from the supplier | BioTek ELx808 | -          |
| Apolipoprotein C3                       | Heparinized and EDTA plasma, Serum           | ELISA  | Instructions from the supplier | BioTek ELx808 | -          |
| Bisphenol A (BPA)                       | Heparinized and Citrated plasma, Serum       | ELISA  | AA-030, 05/06.2015             | BioTek ELx808 | +          |
| BNP                                     | Plasma, Serum                                | ELISA  | Instructions from the supplier | BioTek ELx808 | -          |
| Bradykinin                              | EDTA plasma                                  | ELISA  | AA-017, 07/05.2020             | BioTek ELx808 | +          |
| Fetuin A                                | Serum                                        | ELISA  | Instructions from the supplier | BioTek ELx808 | -          |
| FGF23                                   | EDTA plasma, cell culture medium             | ELISA  | Instructions from the supplier | BioTek ELx808 | -          |
| Interleukin 1-β                         | Heparinized, Citrated and EDTA plasma, Serum | ELISA  | AA-012, 20/02.2025             | BioTek ELx808 | +          |
| Interleukin 6                           | Heparinized, Citrated and EDTA plasma, Serum | ELISA  | AA-038, 09/02.2021             | BioTek ELx808 | +          |
| Complement activation: C3a, C5a, sC5b-9 | Citrated and EDTA plasma                     | ELISA  | AA-004, 13/02.2025             | BioTek ELx808 | +          |

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| Analyte (measured variable)             | Sample material (Matrix)                     | Method | SOP/Standard       | Equipment     | Accredited |
|-----------------------------------------|----------------------------------------------|--------|--------------------|---------------|------------|
| Leptin                                  | Heparinized, Citrated and EDTA plasma, Serum | ELISA  | AA-101, 01/05.2020 | BioTek ELx808 | -          |
| Myeloperoxidase (MPO)                   | EDTA plasma                                  | ELISA  | AA-024, 10/02.2025 | BioTek ELx808 | +          |
| ox LDL                                  | Heparinized and EDTA plasma, Serum           | ELISA  | AA-036, 09/02.2025 | BioTek ELx808 | +          |
| Platelet factor 4 (PF4)                 | CTAD plasma                                  | ELISA  | AA-015, 16/02.2025 | BioTek ELx808 | +          |
| PMN Elastase                            | Citrated and EDTA plasma                     | ELISA  | AA-022, 08/02.2025 | BioTek ELx808 | +          |
| Thrombin-Antithrombin III-Complex (TAT) | Citrated plasma                              | ELISA  | AA-003, 13/02.2025 | BioTek ELx808 | +          |
| TNF- $\alpha$                           | Heparinized, Citrated and EDTA plasma, Serum | ELISA  | AA-029, 05/04.2023 | BioTek ELx808 | +          |
| Factor V                                | Citrated and EDTA plasma                     | ELISA  | AA-069, 06/07.2019 | BioTek ELx808 | +          |
| Factor X                                | Citrated and EDTA plasma                     | ELISA  | AA-070, 04/07.2019 | BioTek ELx808 | +          |
| Protein C                               | Citrated plasma                              | ELISA  | AA-071, 04/06.2015 | BioTek ELx808 | -          |

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## Area of analysis: Biochemistry/Clinical chemistry

### Mode of analysis: Chromatography

#### *High Performance Liquid Chromatography (HPLC)*

| Analyte (measured variable) | Sample material (Matrix)                     | Method | SOP/Standard       | Equipment            | Accredited |
|-----------------------------|----------------------------------------------|--------|--------------------|----------------------|------------|
| Indoxyl sulfate             | Heparinized, Citrated and EDTA plasma, Serum | HPLC   | AA-060, 09/02.2025 | Dionex Ultimate 3000 | +          |
| p-Cresyl sulfate            | Heparinized, Citrated and EDTA plasma, Serum | HPLC   | AA-060, 09/02.2025 | Dionex Ultimate 3000 | +          |

## Area of analysis: Biochemistry/Clinical chemistry

### Mode of analysis: Elektrophoresis

#### *Elektrophoresis (SDS-Gelelektrophoresis)*

| Analyte (measured variable)           | Sample material (Matrix)                     | Method                               | SOP/Standard       | Equipment                         | Accredited |
|---------------------------------------|----------------------------------------------|--------------------------------------|--------------------|-----------------------------------|------------|
| Relative molecular weight of proteins | Heparinized, Citrated and EDTA plasma, Serum | SDS-Gel electrophoresis              | AA-051, 04/02.2025 | Electrophoresis equipment EPS 301 | +          |
| Proteins                              | Heparinized, Citrated and EDTA plasma, Serum | Gel electrophoresis (IEF / 2-D PAGE) | AA-073, 01/12.2013 | Electrophoresis equipment EPS 301 | +          |



## Area of analysis: Biochemistry/Clinical chemistry

**Mode of analysis: Electrochemical measurements**

### *Potentiometry*

| Analyte (measured variable) | Sample material (Matrix) | Method        | SOP/Standard                             | Equipment                  | Accredited |
|-----------------------------|--------------------------|---------------|------------------------------------------|----------------------------|------------|
| Na <sup>+</sup>             | Heparinized blood        | Potentiometry | BA-014, 02/01.2024<br>BA-022, 01/06.2015 | Cobas b 123<br>OPTI CCA-TS | +          |
| K <sup>+</sup>              | Heparinized blood        | Potentiometry | BA-014, 02/01.2024<br>BA-022, 01/06.2015 | Cobas b 123<br>OPTI CCA-TS | +          |
| Cl <sup>-</sup>             | Heparinized blood        | Potentiometry | BA-014, 02/01.2024<br>BA-022, 01/06.2015 | Cobas b 123<br>OPTI CCA-TS | +          |
| Ca <sup>2+</sup>            | Heparinized blood        | Potentiometry | BA-014, 02/01.2024<br>BA-022, 01/06.2015 | Cobas b 123<br>OPTI CCA-TS | +          |
| pH                          | Heparinized blood        | Potentiometry | BA-014, 02/01.2024<br>BA-022, 01/06.2015 | Cobas b 123<br>OPTI CCA-TS | +          |
| PO <sub>2</sub>             | Heparinized blood        | Amperometry   | BA-014, 02/01.2024<br>BA-022, 01/06.2015 | Cobas b 123<br>OPTI CCA-TS | +          |
| PCO <sub>2</sub>            | Heparinized blood        | Potentiometry | BA-014, 02/01.2024<br>BA-022, 01/06.2015 | Cobas b 123<br>OPTI CCA-TS | +          |
| Glucose                     | Heparinized blood        | Amperometry   | BA-014, 02/01.2024                       | Cobas b 123                | +          |

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## Area of analysis: Biochemistry/Clinical chemistry

### Mode of analysis: Fluorescence spektrometry

| Analyte (measured variable)                          | Sample material (Matrix)    | Method      | SOP/Standard                                                     | Equipment     | Accredited |
|------------------------------------------------------|-----------------------------|-------------|------------------------------------------------------------------|---------------|------------|
| Cytotoxicity ex vivo according to DIN EN ISO 10993-5 | Aqueous solutions, Extracts | Fluorimetry | AA-035, 07/07.2019<br>DIN EN ISO 10993-5,<br>DIN EN ISO 10993-12 | BioTek ELx808 | -          |

## Area of analysis: Biochemistry/Clinical chemistry

### Mode of analysis: Light microscopy

| Analyte (measured variable)                                        | Sample material (Matrix) | Method     | SOP/Standard       | Equipment                                     | Accredited |
|--------------------------------------------------------------------|--------------------------|------------|--------------------|-----------------------------------------------|------------|
| Blood slides, Microscopic evaluation of blood slides, Erythrocytes | Blood slide              | Microscopy | AA-097, 01/06.2016 | RAL Stainbox, HemaPrep,<br>Leitz, Laborlux 12 | -          |

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## Area of analysis: Biochemistry/Clinical chemistry

### Mode of analysis: Coagulometry

| Analyte (measured variable)                 | Sample material (Matrix) | Method       | SOP/Standard       | Equipment         | Accredited |
|---------------------------------------------|--------------------------|--------------|--------------------|-------------------|------------|
| Determination of ACT with GEM Hemochron 100 | Heparinized blood        | Coagulometry | AA-108, 01/06.2025 | GEM Hemochron 100 | -          |