


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

| | | |
|---|--|--|
|  <p>UKAS MEDICAL</p> <p>8169</p> <p>Accredited to ISO 15189:2022</p> | <p>HSL (Analytics) LLP</p> <p>Issue No: 033 Issue date: 13 May 2026</p> | |
| | <p>Department of Blood Sciences The Halo Building 1 Mabledon Place London WC1H 9AJ</p> | <p>Contact: Jacqueline Sutherland Tel: +44 (0)20 307 7342 E-Mail: jacqueline.sutherland@hslpathology.com Website: www.hslpathology.com</p> |
| <p>Testing performed at the above address only</p> | | |

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---------------------------------|---|--|
| HUMAN BODY FLUIDS | General Biochemistry | |
| | <u>Biochemical examination activities for the purposes of clinical diagnosis.</u> | |
| Serum (unless otherwise stated) | Quantification of: | In house documented procedures based on equipment manuals and standard methods as specified: |
| Urine also | Sodium | Ion Sensitive Electrode method using Roche Cobas 702 |
| Urine also | Potassium | SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37 |
| | Chloride | |
| | Quantification of: | Photometry method using Roche Cobas 702 |
| Urine also | Alanine Aminotransaminase | SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37 |
| | Albumin | |
| | Alkaline Phosphatase | |
| | Alpha-1 Antitrypsin | |
| | Amikacin | |
| Urine also | Amylase | |
| | Angiotensin Converting Enzyme | |
| | Aspartate Aminotransferase | |
| | Bicarbonate | |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless otherwise stated) (cont'd)</p> <p>Urine also</p> <p>Urine also</p> <p>Urine and Serum</p> <p>Urine also</p> | <p>General Biochemistry (cont'd)</p> <p><u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Quantification of: (cont'd)</p> <p>B2 Microglobulin</p> <p>Bile Acids</p> <p>Bilirubin (total and conjugated)</p> <p>Complement C3</p> <p>Complement C4</p> <p>Calcium</p> <p>Carbamazepine</p> <p>Caeruloplasmin</p> <p>Cholesterol</p> <p>Cholinesterase</p> <p>Creatine Kinase</p> <p>Creatinine (Jaffe)</p> <p>Creatinine (enzymatic)</p> <p>C-Reactive Protein (CRP)</p> <p>CRP (High Sensitivity)</p> <p>Ethanol</p> <p>Fructosamine</p> <p>Gentamicin</p> <p>Gamma Glutamyl Transferase</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless otherwise stated) (cont'd)</p> <p>CSF & urine also</p> <p>CSF & plasma only</p> <p>Urine also</p> <p>Urine also</p> <p>Urine and CSF also</p> | <p>General Biochemistry (cont'd)</p> <p><u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Quantification of: (cont'd)</p> <p>Glutamate dehydrogenase</p> <p>Glucose</p> <p>Haptoglobin</p> <p>HDL Cholesterol</p> <p>IgG</p> <p>IgA</p> <p>IgM</p> <p>Iron</p> <p>Lactate</p> <p>Lactate Dehydrogenase</p> <p>Lipase</p> <p>Lipoprotein (a)</p> <p>Lithium</p> <p>Magnesium</p> <p>Phenytoin</p> <p>Phosphate</p> <p>Rheumatoid Factor</p> <p>Theophylline</p> <p>Total Protein</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless otherwise stated) (cont'd)</p> <p>Urine also</p> <p>Urine also</p> <p>Urine</p> | <p>General Biochemistry (cont'd)</p> <p><u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Quantification of: (cont'd)</p> <p>Transferrin</p> <p>Triglyceride</p> <p>Teicoplanin</p> <p>Urate</p> <p>Urea</p> <p>Unsaturated Iron Binding Capacity</p> <p>Valproate</p> <p>Vancomycin</p> <p>Examination activities for the purposes of clinical diagnosis.</p> <p>Quantification of:</p> <p>Amphetamine</p> <p>Barbiturates</p> <p>Benzodiazepine</p> <p>Cannabinoids</p> <p>Cocaine</p> <p>Cotinine</p> <p>Methadone</p> <p>Opiates</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37</p> <p>Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless otherwise stated) (cont'd)</p> <p>Plasma only</p> | <p>General Biochemistry (cont'd)</p> <p><u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Quantification of: (cont'd)</p> <p>Adrenocorticotrophic Hormone</p> <p>Alpha-Fetoprotein</p> <p>Anti-Mullerian Hormone</p> <p>Anti-Thyroglobulin antibodies</p> <p>Beta-Human Chorionic Gonadotrophin</p> <p>CA125</p> <p>CA153</p> <p>CA199</p> <p>Calcitonin</p> <p>Carcinoembryonic Antigen</p> <p>Creatine Kinase MB</p> <p>Cortisol</p> <p>Dehydroepiandrosterone Sulphate</p> <p>Digoxin</p> <p>Oestradiol</p> <p>Ferritin</p> <p>Folate</p> <p>Follicle Stimulating Hormone</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Immunoassay methods using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless otherwise stated) (cont'd)</p> | <p>General Biochemistry (cont'd)</p> <p><u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Quantification of: (cont'd)</p> <p>Human Chorionic Gonadotrophin (free)</p> <p>Prostate Specific Antigen (free & total)</p> <p>FT3</p> <p>FT4</p> <p>Growth Hormone</p> <p>IgE</p> <p>Insulin</p> <p>Luteinising Hormone</p> <p>Macroprolactin (PEG Precipitation)</p> <p>Myoglobin</p> <p>NT-Pro B-Type Natriuretic Peptide</p> <p>Pregnancy Associated Plasma Protein (PAPP-A)</p> <p>Progesterone</p> <p>Prolactin</p> <p>Parathyroid Hormone</p> <p>Procalcitonin</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Immunoassay methods using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37</p> <p>SOP BIO-MP1-45</p> |



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| HUMAN BODY FLUIDS (cont'd) | General Biochemistry (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum (unless otherwise stated) (cont'd) | <u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd) | |
| | Quantification of: (cont'd) | Immunoassay methods using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37 |
| | Sex Hormone-Binding Globulin | |
| | T3 (total) | |
| | T4 (total) | |
| | Testosterone | |
| | Thyroglobulin | |
| | Thyroid Stimulating Hormone | |
| | Troponin T (High Sensitivity) | |
| | Vitamin B12 | |
| | 25-hydroxy Vitamin D | |
| | Thyroid Peroxidase Antibody | |
| | Quantification of: | |
| | CA125 | |
| | HE4 | |
| Serum/EDTA | Homocysteine | |
| | ROMA | |
| Whole Blood EDTA | Red Cell Folate | |
| | Troponin I (High Sensitivity) | |
| | Vitamin B12 (Active) | |



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| | General Biochemistry (cont'd) | |
| HUMAN BODY FLUIDS (cont'd) | <u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum (unless otherwise stated) | Biochemistry Calculated Parameters: | By calculation using Cobas c702 SOP-MP1-16-Q-1 |
| Urine | <u>Albumin:Creatinine ratio</u> | |
| | Anion Gap | |
| | Corrected Calcium | |
| Urine also | Creatinine Clearance | |
| | LDL Cholesterol | |
| | eGFR | |
| Urine | Protein : Creatinine Ratio | |
| Urine also | Renal Tubular reabsorption of Phosphate | |
| | Total Iron Binding Capacity | |
| | Transferrin Saturation | |
| Urine and Serum | Creatinine Clearance | By calculation in Middleware LIMS |
| Calculation | eGFR | By calculation in Middleware LIMS |
| Serum | Amyloid A | Immunoassay using Siemens BNII SOP MCH-MP2-2 |
| | Apolipoproteins A1 & B | SOP MCH-MP2-4 |
| EDTA Whole Blood | Glycated Haemoglobin HbA1c | Ion-exchange HPLC using TOSOH G11 SOP HAE-60RR-4 |



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| HUMAN BODY FLUIDS (cont'd) | General Biochemistry (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum | <u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd) Alpha-1 Antitrypsin Phenotyping | SOP MCH-MP2-42 (focussing method) |
| Faeces | Alkaline Phosphatase Isoenzymes Calprotectin | SOP MCH-MP2-10 Latex agglutination turbidimetric assay using OC-Sensor Pledia SOP BIO-MP1-48 |
| Plasma | Chromogranin A | ELISA using Dynex DS2 and Euro Diagnostica kit SOP MCH-MP2-46 |
| EDTA Whole Blood | Ciclosporin A Tacrolimus Sirolimus | LCMSMS using Shimadzu 8050 SOP MCH-MP2-13 |
| Serum/urine | <u>Trace Metals</u> Copper Zinc Selenium | NexION 1000 ICP-MS SOP MCH-MP2-68 |
| Whole Blood Whole Blood | Chromium Cobalt | NexION 1000 ICP-MS SOP MCH-MP2-69 |
| Urine | Metanephrines / Metadrenalines: Metanephrine Normetanephrine 3-Methoxytyramine 5-Hydroxyindoleacetic acid (5HIAA) | HPLC using Shimadzu Prominence SOP MCH-MP2-6 SOP MCH-MP2-7 |



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| HUMAN BODY FLUIDS (cont'd) | General Biochemistry (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum | <u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd) | |
| Serum | IgG Subclasses (IgG 1-4) | Immunoassay using Binding Site Optilite SOP MCH-MP2-55 & MCH-MP2-31 |
| Serum | Enhanced Liver Fibrosis: Procollagen 3 Amino terminal peptide (P3NP) Hyaluronic acid (HA) Tissue inhibitor of metalloproteinase (TIMP-1) | Siemens Atellica IM analyser using chemiluminescent technology SOP BIO-MP1-51 |
| Serum | Erythropoietin | Siemens Atellica IM analyser using chemiluminescent technology SOP BIO-MP1-51 |
| Serum/ Plasma / Whole Blood | Active B12 | Immunoassay on Abbott Alinity I using CMIA SOP BIO-MP1-55 |
| | CA 125 | |
| | HE4 | |
| | Homocysteine | |
| | High sensitivity Troponin I | |
| | Red Cell Folate | |
| | ROMA Score (calculated using HE4 and CA 125) | |
| Serum & urine | Osmolality | Freezing point depression using Advanced Instruments OsmoPRO MAX SOP BIO-60RR-2 |



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| <p>HUMAN BODY FLUIDS</p> <p>Serum / Plasma</p> <p>Serum / Plasma</p> <p>Venous samples in serum tube</p> <p>Serum / Plasma</p> | <p>Virology</p> <p><u>Examination activities for the purposes of clinical diagnosis.</u></p> <p>Qualitative of:</p> <p>Hepatitis A Total & IgM</p> <p>Hepatitis B Core Total Antibody</p> <p>Hepatitis B Envelope Antigen</p> <p>Hepatitis B Envelope Antibody</p> <p>Hepatitis B Surface Antigen</p> <p>Hepatitis C antibody</p> <p>HIV 1 & 2 Antibody and p24 Antigen</p> <p>Syphilis Total Antibody</p> <p><u>Quantitative detection of:</u></p> <p>Hepatitis B Surface Antibody</p> <p>SARS-CoV-2 (COVID-19) spike total antibody (quantitative)</p> <p>HIV 1 & 2 Antibody and p24 Antigen</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Documented in-housed methods to meet the requirements of the of Infectious Diseases in Pregnancy Screening programme as defined in the 'Infectious Diseases in Pregnancy Screening Programme: laboratory QA evidence requirements'</p> <p>Immunoassay using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7, BIO-MP1-37</p> <p>Immunoassay using Roche Cobas e801 SOPs BIO-MP1-8, BIO-MP1-7, BIO-MP1-37</p> <p>Elecsys SARS-CoV-2 S kit using Roche Cobas e801 SOP BIO-MP1-8</p> <p>Multiplex Flow Immunoassay using Bio-Rad Bioplex SOP IMM-MP1-17</p> |



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| HUMAN BODY FLUIDS (cont'd) | Virology (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum / plasma | <u>Examination activities for the purposes of clinical diagnosis.</u> (cont'd) | Immunoassay using Abbott Alinity I SOPs BIO-MP1-55 |
| Serum & plasma | Detection of: Cytomegalovirus (CMV) IgM & IgG | |
| Serum & plasma | Hepatitis B Core IgM | |
| Serum & plasma | Hepatitis B Surface Antigen (quantitation) | |
| Serum & plasma | Hepatitis C antigen | |
| Serum & plasma | Human T-Cell Lymphotropic Virus (HTLV) I / II Antibody | |
| Serum & plasma | Rubella IgM & IgG | |
| Serum & plasma | Toxoplasma IgM & IgG | |
| Serum & plasma | HIV-1 p24 Antigen and HIV-1 / HIV-2 Antibodies | Abbott Alinity HIV Ag/Ab Combo |
| Serum & plasma | TPHA | New Bio Manual Agglutination SOP IMM-MP2-46 |
| Serum & plasma | TPHA | Fortress Diagnostics Manual Agglutination SOP IMM-MP2-46 |
| Plasma | TB Interferon Gamma | TB Quantiferon assay using commercial kits and DiaSorin Liasion analyser SOP IMM-MP1-8, IMM-MP1-18 |



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| HUMAN BODY FLUIDS (cont'd) | Virology (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum / Plasma (unless otherwise stated) (cont'd) | <u>Examination activities for the purposes of clinical diagnosis.</u> (cont'd) | |
| | Borrelia IgM & IgG | Chemiluminescence using Diasorin Liaison XL |
| | Epstein Barr Virus VCA IgM | SOP IMM-MP1-8, |
| | EBNA IgG | SOP IMM-MP1-23 |
| | EBV VCA-IgG | SOP IMM-MP1-24 |
| | Hepatitis B Core Antibody | SOP IMM-MP1-35 |
| | Hepatitis B Surface Antigen | SOP IMM-MP1-25 |
| | Hepatitis Delta Total Antibodies | SOP IMM-MP1-22 |
| | Herpes Simplex Virus (HSV) 1 & 2 IgG (combined) | SOP IMM-MP1-27 |
| | Herpes Simplex Virus (HSV) 1 & 2 IgM (combined) | SOP IMM-MP1-27 |
| | Herpes Simplex Virus (HSV) 1 IgG | SOP IMM-MP1-28 |
| | Herpes Simplex Virus (HSV) 2 IgG | SOP IMM-MP1-28 |
| Faeces | Helicobacter Pylori Antigen | SOP BIO-MP1-50 |
| Plasma / Serum | Rapid Plasma Reagin (RPR) | Manual RPR flocculation test using New Bio commercial kit SOP IMM-MP2-46 |



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| HUMAN BODY FLUIDS (cont'd) | Virology (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum / Plasma (unless otherwise stated) (cont'd) | <u>Examination activities for the purposes of clinical diagnosis.</u> (cont'd) | |
| | Detection of: | Chemiluminescence using Diasorin Liaison XL SOP IMM-MP1-8 |
| | Insulin-Like Growth Factor 1 | SOP IMM-MP1-8 |
| | Measles IgM & IgG | SOP IMM-MP1-30 |
| | Mumps IgM & IgG | SOP IMM-MP1-31 |
| | Mycoplasma IgM & IgG | SOP IMM-MP1-32 |
| | Parvovirus IgM & IgG | SOP IMM-MP1-33 |
| | Varicella Zoster Virus IgM & IgG | SOP IMM-MP1-34 |
| | CMV IgG Avidity | SOP IMM-MP1-37 |
| | Hepatitis C Antibody | SOP IMM-MP1-26 |
| Serum only | CMV Avidity | Immunoassay using Biomerieux Vidas 3 SOP IMM-MP2-25, IMM-MP2-69 |
| Serum only | Borrelia IgM & IgG | SOP IMM-MP2-61 |
| Serum only | Syphilis | RPR using AIX-1000 SOP IMM-MP2-4, IMM-MP2-46 |



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| <p>HUMAN BODY FLUIDS</p> <p>Serum / plasma (unless otherwise stated)</p> <p>Serum / plasma (unless otherwise stated)</p> | <p>Immunology</p> <p><u>Examination activities for the purposes of clinical diagnosis.</u></p> <p>Quantification of:</p> <p>Mast Cell Tryptase</p> <p>Specific IgE</p> <p>Quantification of:</p> <p>Allergen Specific IgE</p> <p>Deamidated Gliadin IgG</p> <p>Tissue Transglutamase IgA</p> <p>Extractable Nuclear Antigen IgG</p> <p>Sm IgG</p> <p>Jo-1 IgG</p> <p>Ro (SSA) IgG</p> <p>La (SSB) IgG</p> <p>CENP-B IgG</p> <p>U1-RNP-IgG</p> <p>Scl-70 IgG</p> <p>Cyclic Citrullinated Protein IgG</p> <p>Myeloperoxidase IgG</p> <p>Proteinase 3 IgG</p> <p>dsDNA IgG</p> <p>Beta-2 Glycoprotein IgM & IgG</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Immunoassay using Thermo Phadia 250 Immunocap SOP IMM-MP1-11</p> <p>SOP IMM-MP1-10</p> <p>SOP IMM-MP1-11</p> <p>Immunoassay using Thermo Phadia 2500 Immunocap SOP IMM-MP1-14</p> <p>SOP IMM-MP1-16</p> <p>SOP IMM-MP1-1</p> <p>SOP IMM-MP1-6</p> <p>SOP IMM-MP1-6</p> <p>SOP IMM-MP1-6</p> <p>SOP IMM-MP1-6</p> <p>SOP IMM-MP1-6</p> <p>SOP IMM-MP1-6</p> <p>SOP IMM-MP1-6</p> <p>SOP IMM-MP1-6</p> <p>SOP IMM-MP1-12</p> <p>SOP IMM-MP1-3</p> <p>SOP IMM-MP1-3</p> <p>SOP IMM-MP1-2</p> <p>SOP IMM-MP1-7</p> |



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| HUMAN BODY FLUIDS (cont'd) | Immunology (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum / plasma (unless otherwise stated) (cont'd) | <u>Examination activities for the purposes of clinical diagnosis.</u> (cont'd) | |
| | Quantification of: (cont'd) | Immunoassay using Thermo Phadia 2500 Immunocap SOP IMM-MP1-14 SOP IMM-MP1-13 |
| | Glomerular Basement Membrane IgG | |
| | Mitochondrial M2 IgG | IMM-MP1-14, IMM-MP1-19 |
| | Fibrillarin (U3RNP) IgG | IMM-MP1-14, IMM-MP1-20 |
| Serum (unless stated) | Quantification of: | Immunofluorescence using Grifols / Aesku Helios SOP IMM-MP2-1 with use of the following kits and SOPs: |
| | Antinuclear Antibodies - IgG | AESKU (Grifols) – SOP IMM-MP2-2 |
| | Anti-Neutrophil Cytoplasmic Antibodies - IgG | AESKU (Grifols) – SOP IMM-MP2-53 |
| | Endomysial IgA | AESKU (Grifols) – SOP IMM-MP2-20 |
| | ds DNA IgG (Crithidia) | AESKU (Grifols) – SOP IMM-MP2-3 |
| | Gastric Parietal Cell IgG | AESKU (Grifols) – SOP IMM-MP2-3 |
| | Liver Kidney Microsomal IgG | AESKU (Grifols) – SOP IMM-MP2-3 |
| | Mitochondrial IgG | AESKU (Grifols) – SOP IMM-MP2-3 |
| | Skin IgG (Pemphigus & Pemphigoid) | AESKU (Grifols) – SOP IMM-MP2-3 |
| | Smooth muscle IgG | Biodiagnostics – SOP IMM-MP2-3 |
| | Adrenal Gland IgG | Biodiagnostics - SOP IMM-MP2-3 |
| | Chlamydia IgM & IgG | SeroFIA Savyon (Launch) – SOP IMM-MP2-24 |
| | Islet Cell IgG | Biodiagnostics - SOP IMM-MP2-3 |
| | Legionella IgG | Vircell (Quest Biomedical) – SOP IMM-MP2-23 |
| | Ovarian IgG | Biodiagnostics - SOP IMM-MP2-3 |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless stated)</p> <p>Serum</p> <p>Serum</p> | <p>Immunology (cont'd)</p> <p><u>Examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Quantification of:</p> <p>Striated Muscle IgG</p> <p><u>Scleroderma Immunoblot:</u></p> <p>Antibodies against:</p> <p>Scl-70 CENP A CENP B RP11 RP155 Fibrillarin NOR90 Th/To PM-Scl100 PM-Scl75 Ku PDGFR Ro-52</p> <p><u>Liver Immunoblot</u></p> <p>Antibodies against:</p> <p>AMA-M2 M2-3E (BPO) Sp100 PML gp120 LKM-1 LC-1 SLA/LP Ro-52</p> | <p>Immunofluorescence using Grifols / Aesku Helios SOP IMM-MP2-1 with use of the following kits and SOPs:</p> <p>AESKU (Grifols) – SOP IMM-MP2-3</p> <p>Immunoassay using EuroblotOne analyser with reference to the following SOPs:</p> <p>SOP IMM-MP2-73, IMM-MP2-21</p> <p>Immunoassay using EuroblotOne analyser with reference to the following SOPs:</p> <p>SOP IMM-MP2-54, IMM-MP2-73</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum</p> <p>Serum</p> | <p>Immunology (cont'd)</p> <p><u>Examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p><u>Myositis Immunoblot</u></p> <p>Antibodies against:</p> <p>Mi-2 alpha Mi-2 beta TIF1-gamma MDA5 NXP2 SAE1 Ku PM-Scl100 PM-Scl75 Jo-1 SRP PL-7 PL-12 EJ OJ Ro-52</p> <p>Quantification of:</p> <p>Hepatitis E IgM and IgG</p> <p>Helicobacter pylori IgG</p> <p>Intrinsic Factor IgG</p> <p>TB Interferon Gamma</p> <p>Haemophilus influenzae type b antibody</p> <p>Pneumococcal C.P. Antibodies</p> | <p>Immunoassay using EuroblotOne analyser with reference to the following SOPs:</p> <p>SOP IMM-MP2-58, IMM-MP2-73</p> <p>ELISA (automated) using commercial kits and Dynex Agility analyser SOP IMM-MP2-62</p> <p>Fortress Diagnostics – SOP IMM-MP2-56</p> <p>Premier – SOP IMM-MP2-26</p> <p>Orgentec – SOP IMM-MP2-8</p> <p>TB Quantiferon assay - SOP IMM-MP2-27</p> <p>Binding site VaccZyme - SOP IMM-MP2-14</p> <p>Binding site VaccZyme - SOP IMM-MP2-18</p> |



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| HUMAN BODY FLUIDS (cont'd) | Immunology (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: |
| Serum (cont'd) | <u>Examination activities for the purposes of clinical diagnosis</u> (cont'd) | |
| | Quantification of: (cont'd) | ELISA (automated) using commercial kits and Dynex Agility analyser SOP IMM-MP2-62 |
| | Tetanus Toxoid Antibodies | Binding Site VaccZyme – SOP IMM-MP2-19 |
| | RNA Polymerase Antibodies | QUANTA Lite III – SOP IMM-MP2-15 |
| | TSH receptor antibodies | ELISA SOP IMM-MP2-22 |
| Serum / plasma (unless stated) | Quantification of: C1 Esterase Inhibitor | Immunonephelometry on Siemens BNIIMCH-MP2-70 |
| Serum | ALEX Allergen Specific IgE | Multi Array Xplorer (MAX) 45K analyser IMM-MP2-68 |
| Serum | Anti-Cardiolipin IgM & IgG | BioFlash chemiluminescent immunoassay IMM-MP2-75 IMM-MP2-74 |
| Serum (unless otherwise stated) | Rheumatoid Factor | Latex agglutination using Rheumajet SOP IMM-MP2-28 |
| | Anti-Streptolysin O | Latex agglutination using Rheumajet SOP IMM-MP2-29 |
| | Herpes (HSV) 1& 2 Type specific IgG | Immunoblot using Focus Diagnostics Herpeselect 1&2 immunoblot IgG kit SOP IMM-MP2-10 |



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| <p>HUMAN BODY FLUIDS</p> <p>Peripheral Blood</p> <p>Bone Marrow, Peripheral Blood, CSF, Pleural Fluid, Ascitic Fluid</p> | <p>Haematology / Flow Cytometry</p> <p>Haematology / Immunology examination activities for the purposes of clinical diagnosis.</p> <p>Lymphocyte subsets CD19 Natural Killer cells</p> <p>Acute Leukaemia Screen: Detection of: <u>Acute Primary</u></p> <p>CD3 CD7 CD34 CD33 CD10 CD117 CD20 CD19 HLADR CD45</p> <p><u>Acute Intracellular</u></p> <p>TPT MPO CD34 CD79a CD3 CD45</p> <p><u>Acute Myeloid</u></p> <p>CD11b CD18 CD34 CD13 CD33 CD117 CD56 CD2 CD15 CD45</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Flow cytometry using Beckman Coulter Aquios SOP FFC-MP2-3</p> <p>Flow cytometry using DuraClone kit with Beckman Coulter T-Q Prep, DX-Flex & microscopy SOP FFC-MP2-24, FFC-MP2-8, FFC-MP2-6, FFC-MP2-4</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Bone Marrow, Peripheral Blood, CFS, Pleural Fluid, Ascitic Fluid (cont'd)</p> | <p>Haematology / Flow Cytometry (cont'd)</p> <p>Haematology / Immunology examination activities for the purposes of clinical diagnosis. (cont'd)</p> <p>Acute Leukaemia Screen: (cont'd)</p> <p>Detection of: (cont'd)</p> <p><u>Acute B-Lymphoid</u></p> <p>Kappa Lambda CD34 CD13 CD10 CD79b CD38 CD19 CD22</p> <p><u>Chronic B-Lymphoid</u></p> <p>Kappa Lambda CD10 CD25 (stacked tube) CD103 CD5 CD19 FMC7 CD45 CD22 CD79b</p> <p><u>Chronic T-Lymphoid</u></p> <p>CD4 CD8 CD3 CD56 CD7 CD16 CD2 CD57 CD45</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Flow cytometry using DuraClone kit with Beckman Coulter T-Q Prep, DX-Flex & microscopy SOP FFC-MP2-24 FFC-MP2-8, FFC-MP2-6, FFC-MP2-4</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Bone Marrow, Peripheral Blood, CFS, Pleural Fluid, Ascitic Fluid (cont'd)</p> | <p>Haematology / Flow Cytometry (cont'd)</p> <p><u>Haematology / Immunology examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Acute Leukaemia Screen: (cont'd)</p> <p>Detection of: (cont'd)</p> <p><u>Chronic Screen</u></p> <p>CD8/Kappa CD4/Lambda CD5 CD14 CD33 CD23 CD20 CD56 CD34 CD19 CD10 CD3 CD45</p> <p><u>Acute T lymphoid</u></p> <p>CD1a CD7 CD34 CD13 CD16 CD4 CD5 CD2 CD8 CD45</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Flow cytometry using DuraClone kit with Beckman Coulter T-Q Prep, DX-Flex & microscopy SOP FFC-MP2-24, FFC-MP2-8, FFC-MP2-6, FFC-MP2-4</p> |



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| HUMAN BODY FLUIDS (cont'd) | Haematology | In house documented procedures based on equipment manuals and standard methods as specified: |
| EDTA Blood | Haematological examination activities for the purposes of clinical diagnosis. | |
| | Full Blood Count: | Sysmex XN10 & XN20 with reference to the following methods: SOP HAE-MP1-2, HAE-MP1-14, |
| | White blood cells, neutrophils, lymphocytes, eosinophils, monocytes, basophils, nucleated red blood cells | by fluorescence flow cytometry |
| | Red blood cells, platelets | by impedance |
| | Haemoglobin | by SLS photometry |
| | Mean cell volume, mean cell haemoglobin, mean cell haemoglobin concentration, red cell distribution width, | by calculation |
| EDTA Whole Blood | Reticulocytes | Flow cytometry using Sysmex XN10 SOP HAE-MP1-14 |
| EDTA Blood | Blood film morphology (including malaria) | Sysmex SP50 Automated Blood Film Maker and Stainer using May Grunwald Giemsa stain SOP HAE-60RR-50, HAE-MP1-7, HAE-MP1-8, HAE-MP1-1 |
| EDTA Blood | Erythrocyte sedimentation rate | Starrsed Interrliner (automated) SOP HAE-MP1-9 |
| EDTA Blood | Erythrocyte sedimentation rate | Manual method using Dispettes SOP HAE-60RR-16 |
| EDTA Blood | Glycated Haemoglobin (Boronate Affinity A1c) | Boronate Affinity using Menarini Hb9210 Premier SOP SHAE-MP2-6 |



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| HUMAN BODY FLUIDS (cont'd) | Haematology (cont'd) Haematological examination activities for the purposes of clinical diagnosis. (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified: Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia screening programme, as defined in the as defined in the Sickle cell and Thalassaemia screening programme: laboratory QA evidence requirements |
| Serum / Plasma | Detection of Infectious Mononucleosis Heterophile Antibody | Agglutination using BioKit Monolatex Rapid test SOP HAE-60RR-14 |
| Plasma | Coagulation: Prothrombin Time International Normalised ratio Activated Partial Thromboplastin Time (APTT) APTT ratio Fibrinogen Thrombin D-Dimer | By light absorption using Sysmex CS5100 SOPs COAG-RF-1-113, HAE-MP1-3 |
| Bone Marrow & Urine | Haemosiderin | Sigma Iron Stain kit followed by microscopy SOP FFC-MP2-7 |
| Bone marrow aspirate | Film assessment & cell differential | MGG Staining kit with Sysmex RAL Stainer followed by microscopy SOP FFC-MP2-6 |
| EDTA Blood | Detection of Sickle Cell Abnormal haemoglobin | Manual method using which Helena HBS Solubility kit SOP HAE-60RR-13 |
| EDTA / Lithium Heparin | Identification and quantitation of Haemoglobin variants | Capillary electrophoresis using Sebia Capillarys 2 SOP SHAE-MP2-2 |



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| HUMAN BODY FLUIDS (cont'd) | Haematology (cont'd) <u>Haematological examination activities for the purposes of clinical diagnosis. (cont'd)</u> | In house documented procedures based on equipment manuals and standard methods as specified: |
| EDTA Blood | Eosin 5-maleimide (Hereditary Spherocytosis Detection) | Flow Cytometry using Beckman Coulter DX-Flex SOP SHAE-MP2-5 |
| EDTA / Lithium Heparin | G6PD Quantitation | Spectrophotometry using Pointe Scientific kit and Shimadzu UV-1800 Spectrophotometer SOP SHAE-MP2-7 |
| EDTA / Lithium Heparin | Pyruvate Kinase | Spectrophotometry using Shimadzu UV-1800 Spectrophotometer SOP SHAE-MP2-8 |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Urine</p> | <p>Manual Biochemistry</p> <p><u>Biochemical examination activities for the purposes of clinical diagnosis.</u></p> <p>Quantification of:</p> <p>Steroid profile:</p> <p>Androsterone (5a) Aetiocholanolone (5b) Dehydroepiandrosterone 11-hydroxyandrosterone 11-hydroxyaetiocholanolone 16-hydroxy-DHA (Pk 1) 16-hydroxy-DHA (Pk 2) Pregnanediol (Progesterone) Pregnanetriol (17-OH-Prog) Androstetriol Tetrahydro-11-deoxycortisol Tetrahydrocortisone Allo-Tetrahydrocorticosterone Tetrahydrocortisol Allo-THF Alpha-Cortolone Beta Cortolone + Beta cortol Alpha Cortol 17-hydroxypregnanolone Pk1 17-hydroxypregnanolone Pk2 11-oxo-pregnanetriol Tetrahydro-11-Deoxycortisol Hexahydro-11-deoxycortisol Pk1 Hexahydro-11-deoxycortisol Pk2 Androstenediol Pregnenediol Pregnenetriol 16β-hydroxy-DHA (16-oxo-androstenediol) and 15,16-dihydroxy-DHA 16,18 dihydroxy-DHA (Pk 1) 16,18 dihydroxy-DHA (Pk 2) 16-hydroxypregnenolone 6-hydroxy- THE 20beta-cortolone</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>Gas chromatography mass spectrometry using Shimadzu TQ 8040 with reference to:</p> <p>SOP MCH-MP2-41</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Urine (cont'd)</p> <p>Plasma / Serum</p> <p>Plasma</p> <p>Serum</p> | <p>Manual Biochemistry (cont'd)</p> <p><u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Quantification of: (cont'd)</p> <p>Steroid profile: (cont'd)</p> <p>6-hydroxy-20alphacortolone 6-hydroxy-20beta-cortolone 1-hydroxy-20beta-cortolone 15,17-dihydroxypregnanolone Oestriol 3,16, 17-trihydroxy-5-pregnane-7,20-dione 6-hydroxy-tetrahydro-11-deoxycortisol</p> <p>17-Hydroxyprogesterone</p> <p>Metanephrines / Metadrenalines: Normetanephrine Metanephrine 3-Methoxytyramine</p> <p>Androstenedione</p> | <p>In house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>Gas chromatography mass spectrometry using Shimadzu TQ 8040 with reference to:</p> <p>SOP MCH-MP2-41</p> <p>Liquid chromatography mass spectrometry using Shimadzu 8060:</p> <p>SOP MCH-MP2-54</p> <p>SOP MCH-MP2-26</p> <p>SOP MCH-MP2-54</p> |



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| HUMAN BODY FLUIDS (cont'd) | Manual Biochemistry (cont'd) <u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified below: |
| Urine | Oxalate & Citrate | Spectrophotometry using Randox RX Daytona SOPs MCH-MP2-61, MCH-MP2-64 & MCH-MP2-65 |
| Urine | Oxalate & Citrate | Spectrophotometry using IL Aries SOPs MCH-MP2-19, MCH-MP2-20 & MCH-MP2-22 |
| Plasma | Oxalate | Spectrophotometry using Randox RX Daytona SOP MCH-MP2-61, MCH-MP2-63, |
| Plasma | Oxalate | Spectrophotometry using IL Aries SOPs MCH-MP2-19, MCH-MP2-21 |



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| HUMAN BODY FLUIDS (cont'd) | Manual Biochemistry (cont'd) | In house documented procedures based on equipment manuals and standard methods as specified below: |
| Urine | <u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd) Primary hyperoxaluria metabolites: Glycolate Glycolate: creatinine ratio Glycerate Glycerate: creatinine ratio Dihydroxyglutarate (DHG) DHG: creatinine ratio | SOP MCH-MP2-25 by liquid chromatography – mass spectrometry using Shimadzu 8060 |
| Renal calculi | Qualitative and semi-quantitative detection of organic and inorganic compounds | Fourier Transform Infrared Spectroscopy using Thermo Nicolet iS10 SOP MCH-MP2-24 |
| Serum | Detection of normal and abnormal protein fractions and electrophoretic patterns | Capillary zone electrophoresis using Sebia Capillarys 3 SOP BIO-MP1-13 |
| Serum | Quantitation of Paraproteins | SOP BIO-MP1-13 Agarose gel electrophoresis and immunofixation using Sebia Hydrasys 2 SOP MCH-MP2-9 with reference to: |
| Serum / Urine | Detection of paraproteins and bence jones proteins (immunofixation) | SOP MCH-MP2-32 |
| Urine | Quantitation of Bence Jones protein (electrophoresis) | SOP MCH-MP2-12 |
| Serum & plasma | Lipoprotein electrophoresis (floating beta) | Lipid gel electrophoresis using Sebia Hydrasys 2 and floating beta-lipoprotein assay SOP MCH-MP2-56 |



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| HUMAN BODY FLUIDS (as stated) | Other Protein Biochemistry Biochemical examination activities for the purposes of clinical diagnosis. Quantification of: | In house documented procedures based on equipment manuals and standard methods as specified below: |
| Serum | Detection / quantification of cryoglobulins | SOP MCH-MP2-40 |
| Serum | Creatine kinase isoenzymes | SOP MCH-MP2-11 |
| Serum | Free light chains | Immunoturbidimetry using Optilite SOP MCH-MP2-31 and MCH-MP2-33 |
| Serum | Prealbumin (transthyretin) | Turbidimetry using Optilite MCH-MP2-66 |
| Urine | Total porphyrins / porphobilinogen | Spectrophotometry using Shimadzu UV-1800 SOP MCH-MP2-37, MCH-MP2-38 |
| CSF | Haem pigments (xanthochromia) | Spectrophotometry using Shimadzu UV-1800 Spectrophotometer SOP MCH-MP2-34 |
| Urine | Reducing substances | by colourimetry using Benedicts solution SOP MCH-MP2-39 |
| Urine | Cystine and homocystine | using manual colourimetric method SOP MCH-MP2-14 |
| Faeces | Faecal haemoglobin | Latex-enhanced turbidimetry using OC-Sensor Pledia SOP BIO-MP1-48 |
| END | | |