


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: 032 Issue date: 27 April 2026</p>	
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<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	
Serum (unless otherwise stated)	<u>Biochemical examination activities for the purposes of clinical diagnosis.</u>	In house documented procedures based on equipment manuals and standard methods as specified:
Urine also	Quantification of:	Ion Sensitive Electrode method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37
Urine also	Sodium	
Urine also	Potassium	
Urine also	Chloride	
Urine also	Quantification of:	Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37
Urine also	Alanine Aminotransaminase	
Urine also	Albumin	
Urine also	Alkaline Phosphatase	
Urine also	Alpha-1 Antitrypsin	
Urine also	Amikacin	
Urine also	Amylase	
Urine also	Angiotensin Converting Enzyme	
Urine also	Aspartate Aminotransferase	
Urine also	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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HUMAN BODY FLUIDS (cont'd)	General Biochemistry (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified: Photometry method using Roche Cobas 702 SOPs BIO-MP1-8, BIO-MP1-7 & BIO-MP1-37
Serum (unless otherwise stated) (cont'd)	<u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd)	
CSF & urine also	Quantification of: (cont'd) Glutamate dehydrogenase	
	Glucose	
	Haptoglobin	
	HDL Cholesterol	
	IgG	
	IgA	
	IgM	
	Iron	
CSF & plasma only	Lactate Lactate Dehydrogenase	
	Lipase	
	Lipoprotein (a)	
Urine also	Lithium Magnesium	
	Phenytoin	
Urine also	Phosphate Rheumatoid Factor	
	Theophylline	
Urine and CSF also	Total Protein	



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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



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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 CA 125 HE4 Homocysteine High sensitivity Troponin I Red Cell Folate ROMA Score (calculated using HE4 and CA 125)	Immunoassay on Abbott Alinity I using CMIA SOP BIO-MP1-55
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 (unless otherwise stated)</p> <p>Venous samples in serum tube</p> <p>Serum / Plasma (unless otherwise stated)</p>	<p>Virology</p> <p><u>Examination activities for the purposes of clinical diagnosis.</u></p> <p>Quantification 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 B Surface Antibody</p> <p>Hepatitis C antibody</p> <p>HIV 1 & 2 Antibody and p24 Antigen</p> <p>Syphilis Total 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>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) <u>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 / plasma (unless otherwise stated)	Detection of: Cytomegalovirus (CMV) IgM & IgG Hepatitis B Core IgM Hepatitis B Surface Antigen (quantitation)	Immunoassay using Abbott Alinity I SOPs BIO-MP1-55
Serum & plasma	Hepatitis C antigen Human T-Cell Lymphotropic Virus (HTLV) I / II Antibody Rubella IgM & IgG 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 & plasm	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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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum / Plasma (unless otherwise stated) (cont'd)</p> <p>Faeces</p> <p>Plasma / Serum</p>	<p>Virology (cont'd)</p> <p><u>Examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Borrelia IgM & IgG</p> <p>Epstein Barr Virus VCA IgM</p> <p>EBNA IgG</p> <p>EBV VCA-IgG</p> <p>Hepatitis B Core Antibody</p> <p>Hepatitis B Surface Antigen</p> <p>Hepatitis Delta Total Antibodies</p> <p>Herpes Simplex Virus (HSV) 1 & 2 IgG (combined)</p> <p>Herpes Simplex Virus (HSV) 1 & 2 IgM (combined)</p> <p>Herpes Simplex Virus (HSV) 1 IgG</p> <p>Herpes Simplex Virus (HSV) 2 IgG</p> <p>Helicobacter Pylori Antigen</p> <p>Rapid Plasma Reagin (RPR)</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Chemiluminescence using Diasorin Liaison XL</p> <p>SOP IMM-MP1-8,</p> <p>SOP IMM-MP1-23</p> <p>SOP IMM-MP1-24</p> <p>SOP IMM-MP1-35</p> <p>SOP IMM-MP1-25</p> <p>SOP IMM-MP1-22</p> <p>SOP IMM-MP1-27</p> <p>SOP IMM-MP1-27</p> <p>SOP IMM-MP1-28</p> <p>SOP IMM-MP1-28</p> <p>SOP BIO-MP1-50</p> <p>Manual RPR flocculation test using New Bio commercial kit</p> <p>SOP IMM-MP2-46</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum / Plasma (unless otherwise stated) (cont'd)</p> <p>Serum only</p> <p>Serum only</p> <p>Serum only</p>	<p>Virology (cont'd)</p> <p><u>Examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Detection of:</p> <p>Insulin-Like Growth Factor 1</p> <p>Measles IgM & IgG</p> <p>Mumps IgM & IgG</p> <p>Mycoplasma IgM & IgG</p> <p>Parvovirus IgM & IgG</p> <p>Varicella Zoster Virus IgM & IgG</p> <p>CMV IgG Avidity</p> <p>Hepatitis C Antibody</p> <p>CMV Avidity</p> <p>Borrelia IgM & IgG</p> <p>HIV 1 & 2 Antibody and p24 Antigen</p> <p>Syphilis</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Chemiluminescence using Diasorin Liaison XL SOP IMM-MP1-8</p> <p>SOP IMM-MP1-8</p> <p>SOP IMM-MP1-30</p> <p>SOP IMM-MP1-31</p> <p>SOP IMM-MP1-32</p> <p>SOP IMM-MP1-33</p> <p>SOP IMM-MP1-34</p> <p>SOP IMM-MP1-37</p> <p>SOP IMM-MP1-26</p> <p>Immunoassay using Biomerieux Vidas 3 SOP IMM-MP2-25, IMM-MP2-69</p> <p>SOP IMM-MP2-61</p> <p>HIV 6 Duo Quick assay SOP IMM-MP2-43</p> <p>RPR using AIX-1000 SOP IMM-MP2-4, IMM-MP2-46</p>



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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>Specific IgG4 (Peanut)</p> <p>Mast Cell Tryptase</p> <p>Specific IgE</p> <p>Quantification of:</p> <p>Allergen Specific IgE</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 SOP IMM-MP1-15</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-MP1-1</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-MP1-6</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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HUMAN BODY FLUIDS (cont'd)	Immunology (cont'd)	Immunoassay using EuroblotOne analyser with reference to the following SOPs:
Serum	<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>	SOP IMM-MP2-58, IMM-MP2-73
Serum	<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>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, Navios & 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, Navios & 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, Navios & 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-60RR-3,
	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-60RR-3
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 HbA1c	Ion-exchange HPLC using TOSOH G11 SOP HAE-60RR-4
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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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>EDTA Blood</p> <p>EDTA / Lithium Heparin</p> <p>EDTA / Lithium Heparin</p>	<p>Haematology (cont'd)</p> <p><u>Haematological examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Eosin 5-maleimide (Hereditary Spherocytosis Detection)</p> <p>G6PD Quantitation</p> <p>Pyruvate Kinase</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Flow Cytometry using Beckman Coulter Navios SOP SHAE-MP2-5</p> <p>Spectrophotometry using Pointe Scientific kit and Shimadzu UV-1800 Spectrophotometer SOP SHAE-MP2-7</p> <p>Spectrophotometry using Shimadzu UV-1800 Spectrophotometer SOP SHAE-MP2-8</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<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) Androstenetriol 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 1 Hexahydro-11-deoxycortisol 2 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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd) Urine Urine Plasma Plasma	<p>Manual Biochemistry (cont'd)</p> <p><u>Biochemical examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Oxalate & Citrate</p> <p>Oxalate & Citrate</p> <p>Oxalate</p> <p>Oxalate</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified below:</p> <p>Spectrophotometry using Randox RX Daytona SOPs MCH-MP2-61, MCH-MP2-64 & MCH-MP2-65</p> <p>Spectrophotometry using IL Aries SOPs MCH-MP2-19, MCH-MP2-20 & MCH-MP2-22</p> <p>Spectrophotometry using Randox RX Daytona SOP MCH-MP2-61, MCH-MP2-63,</p> <p>Spectrophotometry using IL Aries SOPs MCH-MP2-19, MCH-MP2-21</p>



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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.	In house documented procedures based on equipment manuals and standard methods as specified below:
Serum	Quantification of: 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