


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8699</p> <p>Accredited to ISO 15189:2012</p>	<h3>NHS Lothian</h3> <p><b>Issue No: 008    Issue date: 01 March 2021</b></p>	
	<p><b>Blood Sciences</b> Lothian Headquarters Waverley Gate 2-4 Waterloo Place Edinburgh EH1 3EG</p>	<p><b>Contact: Nadine Wilkinson</b> Tel: +44 (0) 131 242 6809 E-Mail: <a href="mailto:nadine.wilkinson@nhslothian.scot.nhs.uk">nadine.wilkinson@nhslothian.scot.nhs.uk</a> Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>
<p><b>Testing performed by the Organisation at the locations specified below</b></p>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<p><b>Address</b> St John's Hospital Howden Road West Livingston Scotland EH54 6PP</p> <p><b>Local contact</b> Contact: Wendy Callan Tel: +44 (0) 1506 523078 E-Mail: <a href="mailto:Wendy.callan@nhslothian.scot.nhs.uk">Wendy.callan@nhslothian.scot.nhs.uk</a> Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>	<p>Haematology and Blood Transfusion Clinical Biochemistry</p>	A
<p><b>Address</b> NHS Lothian Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4SA</p> <p><b>Local contact</b> Una Jarrold Tel 0131 242 6830 <a href="mailto:una.jarrold@nhslothian.scot.nhs.uk">una.jarrold@nhslothian.scot.nhs.uk</a> Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>	<p>Haematology Coagulation Specialist Haematology Haemostasis General Chemistry Endocrine/Tumour marker/Haematinics/Cardiac markers Toxicology Therapeutic Drug Monitoring (TDM) Microbiology Serology</p>	C
<p><b>Address</b> Blood Sciences Department Western General Hospital Crewe Road Edinburgh EH4 2XU</p> <p><b>Local contact</b> Louise McVicar Tel: 0131 537 1896 <a href="mailto:Louise.McVicar@nhslothian.scot.nhs.uk">Louise.McVicar@nhslothian.scot.nhs.uk</a> Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>	<p>Clinical Chemistry Antenatal Screening Inherited Metabolic Haematology Blood Transfusion</p>	E



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**Site activities performed away from the locations listed above:**

Location details	Activity	Location code
<p><b>Address</b> Diabetic Outpatients Department St John's Hospital Howden Road West Livingston Scotland EH54 6PP</p>	<p><b>Local Contact:</b> Wendy Callan Tel: +44 (0) 1506 523078 E-Mail: wendy.callan@nhslothian.scot.nhs.uk Website: www.edinburghlabmed.co.uk</p>	<p>Clinical Biochemistry B</p>
<p>Theatre Western General Hospital Crewe Road Edinburgh EH4 2XU</p>	<p><b>Local Contact:</b> Louise McVicar Tel: 0131 537 1896 Louise.McVicar@nhslothian.scot.nhs.uk Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>	<p>Blood Storage only F</p>
<p>Ward 1 Western General Hospital Crewe Road Edinburgh EH4 2XU</p>	<p><b>Local Contact:</b> Louise McVicar Tel: 0131 537 1896 Louise.McVicar@nhslothian.scot.nhs.uk Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>	<p>Blood Storage only G</p>
<p>Clinical Immunology Laboratory NHS Lothian Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4SA</p>	<p><b>Local Contact:</b> Gemma Ruck Tel 0131 242 6830 gemma.ruck@nhslothian.scot.nhs.uk Website: <a href="http://www.edinburghlabmed.co.uk">www.edinburghlabmed.co.uk</a></p>	<p>Clinical Immunology H</p>



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES  Venous Blood	<u>Blood Transfusion Testing for the purpose of clinical diagnosis</u>	Documented In-house methods using:	
	Automated Blood Grouping <ul style="list-style-type: none"> <li>• A B O</li> <li>• Rhesus: C, c, D, E, e,</li> <li>• K</li> </ul>	Diamed GelStation and BioRad IH1000 analysers and associated testing protocols – fully automated Diamed cassette technology using SOP: BBANK-71, BBANK-75BBANK-102 and BBANK 107	A and E
	Manual Blood Grouping <ul style="list-style-type: none"> <li>• A B O</li> <li>• Rhesus: Cw,C, c, D, E, e,</li> <li>• K</li> <li>• Fya, Fyb</li> <li>• Jka, Jkb</li> <li>• Kpa</li> <li>• Lea, Leb</li> <li>• Lua</li> <li>• M, N, S, s</li> </ul>	Manual procedures by Diamed cassette technology/tube technology using SOP: BBANK-34	A, E
	Automated Antibody Detection and identification <ul style="list-style-type: none"> <li>• Cw, C, c, D, E, e</li> <li>• K, Kpa</li> <li>• Fya, Fyb</li> <li>• Jka, Jkb</li> <li>• Lea, Leb</li> <li>• P1</li> <li>• M, N, S, s</li> <li>• Lua</li> </ul>	Diamed GelStation/ BioRad IH1000 analyser using 3 cell panels, 11 cell panels using SOP: BBANK-30 BBANK-71 BBANK-75 and BBANK 107	A and E



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Venous Blood</p>	<p><u>Blood Transfusion Testing for the purpose of clinical diagnosis (cont'd)</u></p> <p>Manual Antibody Detection and identification</p> <ul style="list-style-type: none"> <li>• Cw, C, c, D, E, e</li> <li>• K, Kpa</li> <li>• Fya, Fyb</li> <li>• Jka, Jkb</li> <li>• Lea, Leb</li> <li>• P1</li> <li>• M, N, S, s</li> <li>• Lua</li> </ul>	<p>Documented In-house methods using:</p> <p>Manual procedures by tube and Diamed cassette technology-red cell agglutination, macroscopic visual detection and Antibody screen-3 cell panel and 11 cell panel using SOP: BBANK-34</p>	A, E
	<p>Automated compatibility testing of patients plasma with donor cells</p>	<p>Fully automated Diamed cassette technology using SOP: BBANK-72</p> <p>Crossmatch on the ID-Gelstation and IH-1000 analyser SOP: BBANK-72</p>	A and E
	<p>Manual compatibility testing of patients plasma with donor cells</p>	<p>Manual procedures by Diamed cassette technology and manual procedures by tube technology-red cell agglutination including macroscopic visual detection using SOP: BBANK-34</p>	A, E
	<p>Direct Anti-Human Globulin</p>	<p>Manual procedures by immediate spin tube technology-red cell agglutination, macroscopic visual detection SOP: BBANK-100</p>	E
		<p>Diamed GelStation/ BioRad IH1000 analysers and associated testing protocols – fully automated Diamed cassette technology using SOP: BBANK-121</p>	A and E



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HUMAN BODY FLUIDS AND TISSUES	<u>Blood Transfusion Testing for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Venous Blood	Direct Anti-Human Globulin	Manual procedures by Diamed cassette technology. Key SOP: BBANK-34	A, E
	Kleihauer- quantitation of foetal bleed in maternal circulation.	Acid Elution using SOP : BBANK-98	A
	<u>Blood Coagulation Testing for the purpose of clinical diagnosis</u>		
Venous Blood	<ul style="list-style-type: none"> <li>• Prothrombin time (PT)               <ul style="list-style-type: none"> <li>○ INR</li> </ul> </li> <li>• Activated Partial Thromboplastin Time (APTT)</li> <li>• Activated Partial Thromboplastin Time Mix (APTT Mix)</li> <li>• Fibrinogen estimation by Clauss</li> <li>• D-Dimers</li> </ul>	Automated ACL TOP 500 clot detection and latex Immuno analyser using manufacturers instructions and SOP: HAEM-S-52, HAEM-S-53, and Automated ACL TOP 750 clot detection and latex Immuno analyser using manufacturers instructions and SOP: HAEM-R-1, HAEM-R-5 and HAEM-R-32	A,
		And Automated ACL TOP 550 clot detection and latex Immuno analyser using manufacturers instructions and SOP: Haem-W-24	C
			E



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HUMAN BODY FLUIDS AND TISSUES	<u>Haematology Testing for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Venous Blood	Erythrocyte Sedimentation Rate (ESR)	Visual detection of sedimentation interface by automated photometric detection on the Sarstedt SediPlus 2000 using SOP: HAEM-S-1, HAEM-W-63 Visual detection of sedimentation interface by manual inspection by Westergren Method using SOP HAEM-S-1.	A, E
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Semi-automatic using SOP: HAEM-R-71	C
Venous whole blood	Full blood count (FBC)	Sysmex XE2100 series Haematology Analysers using SOP: HAEM-S-21, HAEM-S-44	A
		Sysmex XE Series: XE5000 using manufacturers instructions and SOP: HAEM-R-66, 219, HAEM-W-82.	C, E
	White blood count (WBC)	Laser light scatter flow	
	Red blood cell count (RBC)	Laser light scatter flow	
	Haemoglobin estimation	Colourmetric	
	Haematocrit (HCT)	Height pulse flow	
	Mean Cell Volume (MCV)	Calculated parameters	
	Mean Cell Haemoglobin (MCH)	Calculated parameters	
	Mean Cell Haemoglobin concentration (MCHC)	Calculated parameters	
	Platelet count (PLT)	Laser light scatter and absorbance	
	Neutrophils	Laser light scatter and absorbance	
	Lymphocytes	Laser light scatter and absorbance	
	Monocytes	Laser light scatter and absorbance	



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HUMAN BODY FLUIDS AND TISSUES	<u>Haematology Testing for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Venous whole blood	Full blood count (FBC) cont'd	<p>Sysmex XE2100 series Haematology Analysers using SOP: HAEM-S-21, HAEM-S-44</p> <p>Sysmex XE Series: XE5000 using manufacturers instructions and SOP: HAEM-R-66, 219, HAEM-W-82.</p>	A  C, E
	Eosinophils	Laser light scatter and absorbance	
	Basophils	Laser light scatter and absorbance	
	Reticulocyte count	Laser light scatter and absorbance	
Venous whole blood	Film reporting – assessment for cell typing and morphology manual White Blood Cell Differential for enumeration of cell types.	<p>Blood film preparation using SOP: HAEM-S-21 and Automated Sysmex SP1000i – May Grunwald Giemsa stain – examined by microscopy using SOP: HAEM-S-43, HAEM-R-89/90, HAEM-W-54</p> <p>Manual staining - Modified Wright's stain – examined by microscopy using SOP: HAEM-S-51</p> <p>Semi-automated Hematek Staining machine and microscopy SOP: HAEM-R-72</p>	A, C, E  C only
Venous whole blood	<p>Malaria Parasite detection</p> <ul style="list-style-type: none"> <li>• P.Falciparum</li> <li>• P.Vivax</li> <li>• P.Ovale</li> <li>• P.Malariae</li> </ul>	Antigen testing with CARESTART Rapydtest kit using SOP: HAEM991	A, C, E
	<p>Malaria Parasite detection</p> <ul style="list-style-type: none"> <li>• P.Falciparum</li> <li>• P.Vivax</li> <li>• P.Ovale</li> <li>• P.Malariae</li> </ul> <p>P Knowlesi (A, C only)</p>	Thick film – Clintech Field Stain and Thin Film – Giemsa pH7.2 stain examined by microscopy using SOP: HAEM991	A,C,E



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HUMAN BODY FLUIDS AND TISSUES cont	<u>Haematology Testing for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Venous whole blood	Malaria Parasite detection of Plasmodium Falciparum Parasitaemia	Thin Film – Giemsa pH7.2 stain, enumeration by microscopy using SOP: HAEM991	A, C, E
Bone Marrow	Bone Marrow Reporting- assessment for cell typing and morphology	SP1000i – May Grunwald Giemsa stain – examined by microscopy using SOP: HAEM-S-43, HAEM-S-7, HAEM-R-89/90, HAEM:W-57	A, C, E
Urine, Bone marrow and blood	Haemosiderin	Perl's Prussian Blue staining examined by microscopy using SOP: HAEM990	A, C, E
Venous whole blood: EDTA	Haemoglobin S	Perl's Prussian Blue staining examined by microscopy using SOP: HAEM-W-57 (iron Stain), HAEM-W-31 (urinary haemosiderin)	, E
Venous Whole Blood, Plasma or Serum	Infectious Mononucleosis antibody detection.	Detection of decreased solubility of haemoglobin S with Clin-Tek: Hb S Test Kit using manufacturers instructions using SOP: HAEM-R-117	C
Plasma, Serum	Haematinics: <ul style="list-style-type: none"> <li>• Vitamin B12</li> <li>• Folate</li> <li>• Ferritin</li> </ul>	Clearview IM II Card agglutination interpreted by visual inspection. SOP HAEM 995	A, C, E
		Abbot Architect i2000 detected by Chemiluminescent microparticle Immunoassay using SOP: BIO-S-186, BIO-S-187, BIO-S-185, BIO-R-276, BIO-W-228.	A, C, E





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HUMAN BODY FLUIDS AND TISSUES	<u>Haematology Testing for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
	<u>Specialist Haematology</u>		
Whole Blood: EDTA	Glucose-6-Phosphate Dehydrogenase (G6PD)	Trinty Biotech G6PD Assay kit, using manufacturers instructions and SOP: HAEM-R-110	C
	Haemoglobinopathy Screening Quantification Haemoglobin A2 (HbA2) Haemoglobin F (HbF) Haemoglobin S (HbS)	Capillary Electrophoresis (CE) on Sebia Capillarys 2 SOP HAEM R 365	C
	Determination of variants Hb A2 Hb F Hb S Hb E Hb AC Hb D Hb H disease Hb Lepore Hb O <sup>Arab</sup>		
Whole Blood: EDTA	Variant Hb confirmation	PerkinElmer Isoelectric focusing Kit using manufacturers instructions and SOP: HAEM-R-323	C



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HUMAN BODY FLUIDS	<u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Plasma / Venous blood-citrated plasma	Anti Xa Assay (unfractionated heparin)	Chromogenic Xa assays on ACL TOP 750 analyser using manufacturers instructions and SOP: HAEM-R-21,26,33,198 and 300 covering Therapeutics-Danaparoid,LMWH, Rivaroxaban, Apixaban,Fondaparinix	C
	Dabigatran DTI assay	Using SOP: HAEM-R-20	
	Anticardiolipin IgG	Chemiluminescent Werfen Acustar using manufacturers instructions and SOP: HAEM-R-287,291,293	C
	Anticardiolipin IgM		
	Beta 2 Glycoprotein IgG		
	Beta 2 Glycoprotein IgM		
	vWF:RiCof	SOP: HAEM-R-287,291 and 292	
	vWF antigen		
	vWF:Collagen binding		
	Heparin Induced Thrombocytopenia ( HIT)	SOP HAEM-R-293, 290 and 291	
Venous blood-citrated plasma	LUPUS Sensitive APTT / Mix	Assays by ACL TOP 750 Clot detection using Manufacturers instructions and SOP: HAEM-R-42	C
	DRVV Screen		
	DRVV Confirm		



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Venous blood-citrated plasma</p>	<p><u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Factor II:c</u></p> <p>Factor V:c</p> <p>Factor VII:c</p> <p>Factor VIII:c</p> <p>Factor IX:c</p> <p>Factor X:c</p> <p>Factor XI:c</p> <p>Factor XII:c</p> <p>Factor VIII Inhibitor</p> <p>Factor IX Inh (human)</p> <p>Factor XIII Assay</p> <p>Chromogenic Factor VIII</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Assays by ACL TOP 750 Clot detection using Manufacturers instructions and SOP: HAEM-R-25</p> <p>Assays by ACL TOP 750 Clot detection using Manufacturers instructions and SOP: HAEM-R-24</p> <p>Photochromic assay using manufacturers instructions and SOP: HAEM-R-48</p> <p>Assays by ACL TOP 750 Chromogenic detection using Manufacturers instructions and SOP: HAEM-R-22</p>	<p>C</p> <p>C</p> <p>C</p>



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Plasma</p>	<p><u>Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Plasminogen</p> <p>Anti-thrombin Activity</p> <p>Anti-thrombin immune</p> <p>Free Protein S Immune</p> <p>Alpha-2 Antiplasmin</p> <p>Protein C</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Thrombophilia and Fibrinolytic tests using ACL TOP 750 Clot detection, chromogenic and latex immuno analyser using manufacturers instructions and SOP: HAEM-R-16,17,18,27,29 &amp; 30 HAEM-R-32</p>	<p>C</p>



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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis</u>	Documented In-house methods using: Automated Abbott Architect c16000 by Photometry using: (site C: Bio-R-2)	A, C, E
Serum, Plasma	Albumin	SOP: BIO-S-17, BIO-W-144 & BIO-W-263	
	Alcohol/ Ethanol	SOP: BIO-W-129, BIO-S-62	E
	Alkaline Phosphatase (ALP)	SOP: BIO-S-18, BIO-W-264	A, C, E
	Alanine aminotransferase (ALT)	SOP: BIO-S-19, BIO-W-117	
	Ammonia	SOP: BIO-R-434, BIO-W-443	C, E
	Amylase	SOP: BIO-S-22, BIO-W-265	A, C, E
	Angiotensin Converting Enzyme	SOP: BIO-W-116	E
	Aspartate aminotransferase (AST)	SOP: BIO-S-42, BIO-W-119	A C E
	Bile acid	SOP: BIO-R-1	C
	Total Bilirubin	SOP: BIO-S-118, BIO-W-147	A, C, E
	Caeruloplasmin	SOP: BIO-R-2	C
	Calcium	SOP: BIO-S-45, BIO-W-121	A, C, E
	Carbamazepine	SOP: BIO-W-380, BIO -R-12	C,E
	Cholesterol	SOP: BIO-S-52, BIO-W-123	A, C, E
	Creatine kinase (CK)	SOP: BIO-S-53, BIO-W-126	A,C,E
	C-Reactive Protein	SOP: BIO-S-57, BIO-W-381	A,C,E
	Creatinine	SOP: BIO-S-56, BIO-W-158 & BIO-W-418	A,C,E
	D-3 hydroxybutyrate	SOP BIO-E-20 BIO-R-578	A, C, E
	Direct Bilirubin	SOP: BIO-S-48 BIO-R-2	A,C
	Enzymatic Creatinine	SOP: BIO-S-229, SOP: BIO-R-482 BIO-W-417	A,C
	Free Fatty Acids	SOP: BIO-E-17, BIO-R-577	C,E



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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Serum, Plasma		Automated Abbott Architect c16000 by Photometry using: (site C: Bio-R-2)	
	γ-glutamyl transferase (GGT)	SOP: BIO-S-71, BIO-W-131	A, C, E
	Glucose	SOP: BIO-S-72, BIO-W-133	
	HDL Cholesterol	SOP: BIO-S-76, BIO-W-266	A, C, E
	Iron	SOP: BIO-S-64, BIO-W-139	
	Lactate	SOP: BIO-S-81, BIO-W-140 BIO-R-8	
	Lithium	SOP: BIO-S-85, BIO-R-9, BIO-W-142	
	Lactate Dehydrogenase (LDH)	SOP: BIO-S-82, BIO-W-141	
	Magnesium	SOP: BIO-S-87, BIO-W-257	
	Phenytoin	SOP: BIO-W-380	
	Phosphate	SOP: BIO-S-96, BIO-W-143	A, C, E
	Theophylline	SOP: BIO-W-380 BIO-R-12	C,E
	Total CO2 ( Bicarbonate)	SOP: BIO-S-54 BIO-W-125	A, C, E
	Total Protein	SOP: BIO-S-121, BIO-W-152	A, C, E
	Transferrin	SOP: BIO-S-122, BIO-W-382	
	Triglyceride	SOP: BIO-S-123, BIO-W-153	
	Urate	SOP: BIO-S-129	A, C



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**NHS Lothian**

**Issue No: 008 Issue date: 01 March 2021**

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Serum, Plasma	Urea	Automated Abbott Architect c16000 by Photometry using: SOP: BIO-S-128 , BIO-W-154	A, C, E
	Urate/Uric Acid	SOP: BIO-S-129,BIO-W-155	A,C,E
CSF	Total Protein	SOP: BIO-S-130, BIO-W-62	A, C, E
	Glucose	SOP: BIO-S-72, BIO-R-2 and BIO-R-15, BIO-W-133	
Serum, Plasma	Lactate	SOP: BIO-R-2 BIO-R-15	C
	Amylase	SOP: BIO-S-22, BIO-W-265	A, C,E
	Caeruloplasmin	SOP: BIO-R-2	C
	Calcium	SOP: BIO-S-45, BIO-W-121	A, C, E
Urine	Creatinine	SOP: BIO-S-56, BIO-W-158 & BIO-W-418	A, C, E
	Magnesium	SOP: BIO-S-87, BIO-R-2, BIO-W-257	A, C, E
	Microalbumin	SOP: BIO-S-89, BIO-R-2 and BIO-W-144	A, C, E
	Phosphate	SOP: BIO-S-96, BIO-R-2, BIO-W-143	A, C, E
	Total Protein	SOP: BIO-S-130, BIO-W-156	
	Urate	SOP: BIO-S-129, BIO-W-155	A, C, E
	Urea	SOP: BIO-S-128 , BIO-W-154	A, C, E
	Urine Oxalate	SOP: BIO-W-145	E



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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Serum, Plasma, Urine	Chloride	Automated Abbott Architect c16000 by Potentiometry using:  SOP: BIO-S-78, BIO-R-2, BIO-W-136	A, C, E
	Potassium		
	Sodium		
	<u>Therapeutic drug monitoring</u>		
Serum, Plasma	Digoxin	Abbott Architect c16000 by Particle enhanced turbidimetric inhibition immunoassay using:  SOP: BIO-S-59, SOP: BIO-R-7 and BIO-W-127	A, C, E
	Gentamicin	SOP: BIO-S-70, BIO-R-416 and BIO-W-132	
	Vancomycin	SOP: BIO-S-184, BIO-R-416, BIO-W-157	
	Valproate	SOP: BIO-S-131, BIO-R-493, BIO-W-160	
	Carbamazepine	SOP: BIO-R-12 and BIO-W-380	C, E
	Phenobarbitone	SOP: BIO-R-493	E
	Alpha-1-antitrypsin	SOP: BIO-W-114	E
	Amikacin	SOP: BIO-W-297	
	Haptoglobin	SOP: BIO-W-134	C
	Immunoglobulins – IgA, IgG, IgM	SOP: BIO-W-137, BIO-W-163, BIO-W-138	E
	Tobramycin	SOP: BIO-W-146	E





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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Serum, Plasma	Methotrexate	Abbott Architect c16000 by Homogenous enzyme immunoassay using  SOP : BIO-W-379	E
	Phenytoin	SOP :BIO-S-95, BIO-R-12, BIO-W-380	
	Theophylline	SOP :BIO-S-119, BIO-R-12, BIO-W-380	
Serum, Plasma	<u>Endocrine/Tumour Markers/ Haematinics/Cardiac Markers</u>	Abbott Architect i2000 – Chemiluminescent Microparticle Immunoassay using:	
	Alphafetoprotein (AFP)	SOP: BIO-R-276, BIO-W-384	C, E
	CA125	SOP: BIO-S-46, BIO-R-276, BIO-W-230	A, C, E
	Carcinoembryonic antigen (CEA)	SOP: BIO-S-49 , BIO-R-276, BIO-W-231	
	Cortisol	SOP: BIO-S-55, BIO-R-276, BIO-W-229	
	C-peptide	SOP: BIO-W-232	E
	Free T3	SOP: BIO-R-276, BIO-W-225	
	Free T4	SOP: BIO-S-67, BIO-R-276, BIO-W-220	A, C, E



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HUMAN BODY FLUIDS AND TISSUES  Serum, Plasma	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
	<u>Endocrine/Tumour Markers/ Haematinics/Cardiac Markers (cont'd)</u>	Abbott Architect i2000 – Chemiluminescent Microparticle Immunoassay using:	
	Follicle stimulating hormone (FSH)	SOP: BIO-S-66, BIO-R-276, BIO-W-334	A, C, E
	Human Chorionic Gonadotrophin (HCG)	SOP: BIO-S-75, BIO-R-276, BIO-W-383	
	Insulin	SOP: BIO-W-234	E
	Luteinising Hormone (LH)	SOP: BIO-S-83, BIO-R-276, BIO-W-335	A, C, E
	Oestradiol	SOP: BIO-S-90, BIO-R-276, BIO-W-291	
	25-OH Vitamin D	SOP: BIO-S-241, BIO-R-276, BIO-W-479	A, C, E
	Pro-BNP	SOP: BIO R 276	C
	Progesterone	SOP: BIO-S-100, BIO-R-276, BIO-W-290	
	Prolactin (Macroprolactin)	SOP: BIO-S-101, BIO-R-372BIO-W-294 & BIO-W-344	A,C,E
	Prostate specific antigen (PSA)	SOP: BIO-S-102 , BIO-R-276, BIO-W-235	
	High Sensitivity Troponin I	SOP: BIO-S-188, BIO-R-276, BIO-W-411	
	Total T3	SOP: BIO-S-126, BIO-R-276	
Thyroid stimulating hormone (TSH)	SOP: BIO-S-125, BIO-R-276, BIO-W-222		
Sex hormone binding globulin (SHBG)	SOP: BIO-R-276, BIO-W-413	C, E	



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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
	<u>Endocrine/Tumour Markers/ Cardiac Markers</u>	Abbott Architect i2000 – Chemiluminescent Microparticle Immunoassay using:	
Serum, Plasma	Dehydroepiandrosterone sulphate (DHEAS)	SOP: BIO-R-276	C
	Testosterone	SOP: BIO-R-276, BIO-W-418	C, E
Urine	Urinary Free Cortisol	SOP: BIO-W-226	E
Urine	Urinalysis - glucose, bilirubin, ketones, Specific gravity, pH, proteins, urobilinogen, nitrates and leukocytes.	Manual Clinistix Tests using SOP: BIO-W-124	E
EDTA Plasma	Adrenocorticotrophic hormone (ACTH)	Roche Elecsys E411 Immunoassay system Chemiluminescence. Microparticle Immunoassay ( competitive and Sandwich) SOP: BIO-R-379, BIO-R-492	C, E
Serum, Plasma	Anti Mullerian Hormone (AMH)	SOP: BIO-R-539, BIO-R-379	
	Growth Hormone	SOP: BIO-R-491, BIO-R-379	
EDTA Plasma	Parathyroid hormone (PTH)	SOP: BIO-R-457, BIO-R-379	
Serum	Thyroid stimulating hormone receptor antibodies (TRAB)		C
Whole blood	Glycated Haemaglobin HbA1c	Menarini HA8180 HPLC by Reversed phase partition and cation exchange chromatography using SOP-BIO-S-191, BIO-R-397, BIO-W-288	A, B, C, E
	Haemoglobin F (HbF)	SOP: BIO-R-397	



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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Serum/Plasma/Urine	Osmolality	Vitech 2020 Osmometer by freezing point depression using SOP: BIO-W-217	E
Blood/Urine	Osmolality	Advanced Instruments Micro-Osmometer 3320 – Freezing point depression using SOP: BIO-R-63	A, C
Whole Blood		Radiometer Abflex90 by Potentiometry, Amperometry, Optical, Spectrophotometry using: SOP: POCT-SOP:3 Measured values	A, C, E
	pH		
	Lactate		
	Glucose		
	Sodium		
	Potassium		
	Chloride		
	pCO <sub>2</sub>		
	PO <sub>2</sub>		
	Fluid pH		
	Total haemoglobin (tHb)		
	Carboxyhaemoglobin (CoHb)		
	Oxyhaemoglobin (O <sub>2</sub> Hb)		
	Oxygen Saturation ( SO <sub>2</sub> )		
	Met-Haemoglobin (MetHb)		
	Deoxyhaemoglobin (HHb)		
	Hydrogen Ion	Calculated Values	



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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
	Bicarbonate <ul style="list-style-type: none"> <li>• Standard Bicarbonate</li> <li>• Base Excess</li> </ul>	Radiometer Abflex90 by Potentiometry, Amperometry, Optical, Spectrophotometry using: SOP: POCT-SOP:3 Calculated Values	A,C,E
Whole Blood	Ionised Calcium		A, C, E
CSF	Xanthochromia ( Hb Pigments)	Uvikon XS Spectrophotometer by Spectrophotometry using SOP: BIO-W-99	E
	Xanthochromia	Uvikon XL Spectrophotometer by Spectrophotometry (Labpower J software and BIO-C interpretation software) using SOP: BIO-R-112	C
	<u>Calculated tests</u>	Automated using Apex VALR 1012 v 1.1	
Serum, Plasma	Total cholesterol:HDL cholesterol ratio		A, C
	Free Androgen Index		C
	Calculated free testosterone		
	Free testosterone albumin		
	Estimated glomerular filtration rate (eGFR)		A, C, E
	LDL Cholesterol		A, C, E
	Transferrin saturation		
	Calculated nitrogen loss		
	BCCA Adjusted calcium		
	Acute Kidney Injury (AKI)		
	Adjusted Phenytoin		
	AST:ALT ratio		



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Serum, Plasma, Urine</p> <p>Urine</p>	<p><u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Calculated tests (cont'd)</u></p> <p>Creatinine clearance</p> <p>Renal phosphate reabsorption</p> <p>Albumin:Creat ratio</p> <p>Albumin Excretion Rate</p> <p>Protein:creatinine ration</p> <p>Oxylate:creatinine ratio</p> <p>Total Porhyrin: Creatinin ratio</p> <p>PBG:creatinine ratio</p> <p>Amylase output</p> <p>Calcium output</p> <p>Chloride output</p> <p>Creatinine output</p> <p>Potassium output</p> <p>Magnesium output</p> <p>Sodium output</p> <p>Protein output</p> <p>Urate output</p> <p>Phosphate output</p> <p>Urea output</p> <p>Cortisol output</p> <p>Oxylate output</p> <p>Metadrenaline output</p> <p>Normetadrenaline output</p>	<p>Documented In-house methods using:</p> <p>Automated using Apex using SOP: VALR-1012 v 1.1</p>	<p>A, C, E</p> <p>C, E</p> <p>A,C,E</p> <p>E</p> <p>E</p> <p>E</p> <p>A,C,E</p> <p>A,C,E</p> <p>E</p> <p>A,C,E</p> <p>E</p>



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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u> <u>Calculated tests (cont'd)</u>	Documented In-house methods using:	A, C, E	
	5HIAA output	Automated using Apex using SOP: VALR-1012 v 1.1		
	<u>Toxicology</u>	Abbott Architect c16000 – Photometry SOP: BIO-R-10		
	Serum / Plasma	Paracetamol		SOP: BIO-S-94 and BIO-W-442.
		Salicylate		SOP: BIO-R-11, BIO-S-113
		Ethanol		SOP: BIO-W-62 BIO-R-2 and BIO-S-62
		Testosterone		WatersXevoLC Tandem Mass Spectrometer – Triple quadrupole spectrometry using SOP: BIO-R-386, 387 and 514
	Whole Blood	Ciclosporin		
		Sirolimus		
		Tacrolimus		
Urine	Tetrahydrocannabinol (THC)	Abbott Architect c16000 Enzyme immunoassay using SOP: BIO-R-2 Urine THC screen on Abbott c16000 using SOP: BIO-R179	C	
	Morphine	Waters AcquityLC Tandem Mass Spectrometer– Triple quadrupole spectrometry Semi-quantitation of Drugs of abuse in urine by LC-MS using SOP: BIO-R-418	C	
	Codeine			
	6-mono-acetyl morphine			
	Dihydrocodeine			
	Amphetamine			



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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u> <u>Toxicology (cont'd)</u>	Documented In-house methods using:	C
Urine	EDDP (Methadone metabolite) Methadone Benzoylcegonine Diazepam	Waters Acquity LC Tandem Mass Spectrometer– Triple quadrupole spectrometry Semi-quantitation of Drugs of abuse in urine by LC-MS using SOP: BIO-R-418	C
Oral Fluid	Oxazepam Nitrazepam Temazepam Nordiazepam 7-Aminoclonazepam Gabapentin Tramadol Norbuprenorphine Pregabalin Oxycodone 3,4-Methylenedioxymethamphetamine (MDMA) Methamphetamin Morphine Codeine 6-Monoacetyl morphine	Using SOP: BIO-R-501	





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HUMAN BODY FLUIDS AND TISSUES	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u> <u>Toxicology (cont'd)</u>	Documented In-house methods using:	
Oral Fluid	Dihydrocodeine  Amphetamine  3,4-Methylenedioxymethamphetamine (MDMA)  Cocaine  Methadone  Diazepam  Nordiazepam  Metamphetamine  Nitrazepam  Tramadol  Gabapentin  Buprenorphine  Oxycodone  Pregabalin	Waters Xevo LC Tandem Mass Spectrometer– Triple quadrupole spectrometry using SOP: BIO-R-501	C
Urine and Oral fluid	Drugs of Abuse	Flexible Scope on the Waters LC Tandem Mass Spectrometer– Triple quadrupole spectrometry using Xevo- SOP: BIO-R-501 for Oral fluid and Acquity -BIO-R-418 for Urine and BIO-R-568 for Flexible Scope. Listed in spreadsheet on User info on website. BIO-R-567	C



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HUMAN BODY FLUIDS AND TISSUE	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	In house methods using manufacturer's instructions	
Urine	5HIAA	Detected by Chromsystems HPLC system using SOP: BIO-W-518, BIO-W-487	E
	Metadrenaline		
	Total Normetadrenaline		
	<u>Protein Electrophoresis</u>		
Serum	Paraprotein bands	Sebia capillarys by Detection of paraprotein bands using SOP BIO-W-30	E
		Sebia Hydrasys by electrophoretic separation and isoelectrofocusing techniques using SOP:	E
Serum	Alpha-1 Antitrypsin Phenotyping	SOP: BIO-W-95	
Serum/CSF	Alkaline Phosphatase iso-enzymes	SOP: BIO-W-95	
Serum / CSF / Fluid (nasal)	Oligoclonal bands	SOP: BIO-W-35	
CSF	CSF Beta-2 Transferrin	SOP: BIO-W-98	
Serum/Urine	Urine Bence Jones Protein	SOP: BIO-W-96	
	Serum and Urine	SOP: BIO-W-32	
	Immunofixation	SOP: BIO-W-31 & BIO-W-33	



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HUMAN BODY FLUIDS AND TISSUE	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u>	In house methods using manufacturer's instructions	E
	<u>Special Chemistry</u>		
Serum	Antenatal screening assays <ul style="list-style-type: none"> <li>• FFree Beta HCG</li> <li>• PPAPP-A</li> <li>• AAFP</li> <li>• TTotal HCG</li> </ul>	ecys Perkin Elmer AutoDelfia by dissociation enhanced lanthanide fluoroimmunoassay using SOP: BIO-W-312, BIO-W-311, BIO-W-71, BIO-W-79	
Serum	Antenatal screening assays <ul style="list-style-type: none"> <li>• Inhibin A</li> <li>• UE3</li> <li>•</li> </ul>	Beckmann Access by chemiluminescent detection using SOP: BIO-W-315, BIO-W-313, BIO-W-341	
Faeces	Coeliac Screening: Tissue Transglutamase IgG <ul style="list-style-type: none"> <li>• Calprotectin</li> <li>• Elastase</li> </ul>	Dynex DS2 (ELISA) using SOP: BIO-W-1, BIO-W-287, BIO-W-84, BIO-W-88	
Serum/Plasma	<ul style="list-style-type: none"> <li>• Aldosterone</li> <li>• Renin</li> </ul>	Diasorin Liaison- Specialist Immunoassays (competitive chemiluminescent assays) using SOP: BIO-W-38, BIO-W-271	
Urine	<ul style="list-style-type: none"> <li>• Porphobilinogen</li> </ul>	BIO-RAD commercial kit- anion exchange & absorbance spectroscopy BIO-W-26	
	<ul style="list-style-type: none"> <li>• Total Porphyrins</li> </ul>	Direct Spectrophotometry using SOP: BIO-W-281	
Serum/Plasma	Serum Cryoglobulin	Manual- visual inspection- protein aggregation using SOP: BIO-W-100	



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HUMAN BODY FLUIDS AND TISSUE cont	<u>Clinical Biochemistry for the purpose of clinical diagnosis (cont'd)</u> Inherited Metabolic	In house methods using manufacturer's instructions	E
Plasma/Urine/	Amino Acid profile	Biochrome 30+ Ion exchange HPLC Amino Acid Analyser	
Plasma, Urine	Alanine	SOPs: BIO-E-100 Amino acids	
Plasma, Urine	Arginine	SOP: BIO-E-100	
	Aspartate	SOP: BIO-E-100	
	Citrulline	SOP: BIO-E-100	
	Cystine	SOP: BIO-E-100	
	Glutamate	SOP: BIO-E-100	
Plasma, Urine, CSF	Glutamine	SOP: BIO-E-100	
	Glycine	SOP: BIO-E-100	
Plasma, Urine	Histidine	SOP: BIO-E-100	
	Isoleucine	SOP: BIO-E-100	
	Leucine	SOP: BIO-E-100	
	Lysine	SOP: BIO-E-100	
Plasma, Urine	Methionine	SOP: BIO-E-100	
	Proline	SOP: BIO-E-100	
	Phenylalanine	SOP: BIO-E-100	
Plasma	Phenylalanine	Short method SOP: BIO-E-43	
Plasma, Urine, CSF	Serine	SOP: BIO-E-100	
Plasma, Urine	Taurine	SOP: BIO-E-100	
Plasma, Urine	Threonine	SOP: BIO-E-100	
	Tyrosine	SOP: BIO-E-100	
	Valine	SOP: BIO-E-100	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Clinical Biochemistry testing for the purpose of clinical diagnosis</u> (cont'd) Inherited Metabolic cont	Documented In-house methods using:	E
Plasma	Tyrosine, Phenylalanine, Homocysteine	Agilent HPLC using isocratic HPLC with fluorescence detection using SOP: BIO-E-99  SOP: BIO-E-99  SOP: BIO-E-62	
Urine	Organic Acid Profile Orotic Acid Methylmalonic acid	Agilent GCMS using Gas chromatography with mass spectra. SOPs: BIO-E-71; SOP: BIO-E-73 SOP: BIO-E-68	
Plasma	Biotinidase	Perkin Elmer Spectrophotometer detected by Photometry  SOP : BIO-E-53	
Leukocytes	Protein	Lowry method, photometry using SOP: BIO-E-65	
Leukocytes, Fibroblasts	Arylsulphatase A	SOP: BIO-E-157, BIO-E-66	
Urine	Mucopolysaccharide quantitative	SOP: BIO-E-70	
Urine	Mucopolysaccharide electrophoresis	Electrophoresis: one dimensional electrophoresis - manual method using SOP: BIO-E-69	
Biopsy (Duodenal,Jejunal)	<u>Disaccharidase Enzyme analysis</u>	Perkin Elmer Fluorimeter LS45 detected by Fluorimetry SOP: BIO-E-54	
Sweat	Lactase Maltase Sucrase Sweat Chloride  Sweat conductivity	SOP: BIO-E-54  SOP: BIO-E-54  Perkin Elmer Spectrophotometer, detected by Photometry using SOP: BIO-E-35  Wescor WE-3120 Sweat conductivity meter detected by Conductivity using SOP: BIO-E-1	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Clinical Biochemistry testing for the purpose of clinical diagnosis</u> (cont'd) Inherited Metabolic cont	Documented In-house methods using:  Perkin Elmer Fluorimeter LS45 detected by Fluorimetry using	
Leukocytes, Fibroblast	Leucocyte screen Lysosomal enzyme screen (panel of enzymes)	SOP: BIO-E-157, BIO-E-66	
Leukocytes/Fibroblasts	Acid esterase  B-galactosidase a-mannosidase  a-fucosidase B-mannosidase  hexosaminidase total	SOP: BIO-E-157, BIO-E-66      SOP: BIO-E-157, BIO-E-66, BIO-E-67	
Leukocytes, Fibroblasts, Plasma	hexosaminidase A  B-glucosidase  Sphingomyelinase  Galactocerebrosidase  <u>Individual lysosomal enzymes</u>	SOP: BIO-E-157, BIO-E-66  SOP: BIO-E-157, BIO-E-66	
Leukocytes	a-galactosidase	SOP: BIO-E-44	
Leukocytes, Fibroblasts	a-Glucosidase  a-iduronidase	SOP: BIO-E-46  SOP: BIO-E-47	
Plasma	B-glucuronidase	SOP: BIO-E-51, BIO-E-67	
Whole Blood	Galactose-1-Phosphate uridylyltransferase - quantitative  Galactose-1- Phosphate uridylyltransferase - qualitative	SOP: BIO-E-60  Manual method using Water bath, UV lamp, and detected using UV light fluorescence using SOP: BIO-E-61	



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<p>HUMAN BODY FLUIDS AND TISSUE</p> <p>Serum, Plasma</p>	<p><u>Microbiology Serology for the purpose of clinical diagnosis</u></p> <p>Hepatitis B Surface Antigen (HBsAg)</p> <p>Cytomegalovirus IgG assay (CMV IgG)</p> <p>Hepatitis A antibodies IgG (HAVAb-IgG)</p> <p>Hepatitis B Core antibodies II (Anti-HBc)</p> <p>Human T-lymphotropic virus I/II (HTLV-I/II)</p> <p>Human Immunodeficiency virus (HIV Ag/Ab)</p> <p>Hepatitis B Core IgM antibodies (Anti-HBc IgM)</p> <p>Hepatitis B e antibodies (Anti-HBe)</p> <p>Hepatitis B e antigen (HBeAg)</p> <p>Hepatitis B surface antibody (Anti-HBs)</p> <p>Hepatitis B surface antigen confirmatory (HBsAg)</p> <p>Hepatitis A IgM antibody (HAVAb-IgM)</p> <p>Hepatitis C antibodies (Anti-HCV)</p> <p>Hepatitis C antigen (HCV Ag)</p> <p>Rubella IgG</p> <p>Treponema pallidum (Syphilis)</p> <p>Toxoplasma IgG</p>	<p>In house methods using manufacturer's instructions</p> <p>Abbott Architect i2000 – Chemiluminescent Microparticle Immunoassay using SOP: VIRS-114</p> <p>Antigen/Antibody Combination assay</p> <p>Antigen/Antibody Combination assay</p>	<p>C</p>



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HUMAN BODY FLUIDS AND TISSUE	<u>Microbiology Serology for the purpose of clinical diagnosis</u>	In house methods using manufacturer's instructions Abbott Architect i2000 – cont using SOP: VIRS-114	C
Serum, Plasma	Ebstein-Barr virus viral capsid antigen IgG (EBV VCA IgG)		
Dried blood spots	Human Immunodeficiency virus (HIV Ag/Ab)	Antigen/Antibody Combination assay	
	Hepatitis B Surface Antigen (HBsAg)		
Serum, Plasma	SARS-CoV-2 (COVID-19) IgG	Abbott SARS-CoV-2 IgG antibody kit using Abbott Architect.i2000SR SOP: VIRS-284 V1.0	
Dried blood spots	Hepatitis B Core antibodies II (Anti-HBc)		
	Hepatitis C antibodies (Anti-HCV)		
Serum, Plasma	Epstein-Barr virus capsid antigens IgM (EBV VCA IgM)	Diasorin Liaison XL by Qualitative, Quantitative determination of Ag/Ab status by Indirect chemiluminescence immunoassay (CLIA) using SOP: VIRS-157	C
	Epstein-Barr virus capsid antigens IgG (EBV VCA IgG)		
	Epstein-Barr virus Nuclear Antigen IgG (EBV EBNA)		
	Parvovirus B19 IgG		
	Parvovirus B19 IgM		
	Hepatitis B surface antigen (HBsAg)		
	Varicella Zoster virus IgG (VZG IgG)		
	Measles IgG		
	Cytomegalovirus IgM (CMV IgM)		





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	Total antibodies to Herpes Simplex virus I/II (HSV Ag/Ab)  CMV IgG avidity		
HUMAN BODY FLUIDS	<u>Microbiology Serology for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	C
Whole blood (Test specific tubes)	Interferon gamma	Chemiluminescence Immunoassays DiaSorin Liasion XL using SOP: BLSC-21 and QuantiFERON –TB GOLD (QFT) measuring responses to TB peptide antigens using SOP: VIRS-172	
Serum/Plasma	Hepatitis delta antibody (HDV)	HDV total antibody in serum by competitive manual ELISA using DiaSorin commercial kit using SOP: BBV26	
Serum, Plasma	Hepatitis B core IgG/IgM (HBc IgG/IgM)	Biomerieux Mini VIDAS by Qualitative, Quantitative determination of Ag/Ab status by immunoassay sandwich method with a final fluorescent detection, Enzyme Linked Fluorescent Assay (ELFA) using SOP: VIRS-121	
Serum, Plasma	Human Immunodeficiency virus I/II (HIV I/II Ag/Ab) Hepatitis B surface antigen (HBs Ag)		
Serum	Hepatitis C antibody (Anti-HCV) Cytomegalovirus IgM (CMV IgM)		
Serum/Plasma	Mumps IgG Varicella Zoster IgG (VZV IgG) Rubella IgM HAV IgM HEV IgG HEV IgM		



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HUMAN BODY FLUIDS	<u>Microbiology Serology for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	C
Serum, Plasma (Citrate, EDTA, Heparin)	Human immunodeficiency virus I or II (HIV I or II)	Bio-Rad Geenius HIV Confirmatory Assay by immunochromatographic test for the confirmation and differentiation of antibodies to HIV-1 and HIV-2 using SOP: VIRS-181	
Serum, Plasma (EDTA, Heparin)	Human immunodeficiency virus I/II (HIV I/II Ab)	Innogenetics INNOLIA HIV I/II Score assay by western blot using SOP: VIRS-130	
Clotted Blood/CSF/EDTA	Treponema pallidum (Syphilis) IgM	Detection of IgM specific antibodies to Treponema Pallidum by ELISA. SOP: VIRS-126, SOP: VIRS-138	
	Treponema pallidum (Syphilis) Rapid plasma reagin (RPR)	Slide Agglutination Assay using SOP: VIRS-128, SOP VIRS-138	
	Treponema Pallidum Particle Agglutination Assay (TPPA)	Agglutination Assay using SOP: VIRS-125, SOP VIRS-138	
Clotted blood	Anti-Streptolysin O (ASO)	Rapid Slide Agglutination Assay using SOP: VIRS-137	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS cont  Serum/Plasma	<u>Immunology examination activities for the purpose of clinical diagnosis</u>  Immunofluorescence – antibodies to: Anti nuclear antibody (ANA)- Gastric parietal cell antibody (GPC) Anti mitochondrial antibody (AMA) Smooth muscle antibody (SMA) Liver Kidney Microsomal antibody (LKM) Anti Neutrophil cytoplasmic antibody (ANCA)	Documented In-house methods using  <u>Autoimmune Immunofluorescence</u>  Quantalyser 2 slide processor using indirect immunofluorescence BS-IMM-S29 Operation and maintenance of the Quanta-lyser 2 Slide Processor  BS-IMM-S26 Measurement of anti-nuclear antibody using NOVA Lite Hep2 DAPI ANA kit and the Quantlyser 2  BS-IMM-S27 Measurement of gastric parietal cell, anti-mitochondrial and smooth muscle antibody and liver kidney microsomal using NOVA Lite rat liver, kidney, stomach kit and the Quantalyser 2  BS-IMM-S28 Measurement of anti-neutrophil cytoplasmic antibody using the NOVA Lite DAPI ANCA Kit and the Quantalyser 2  BS-IMM-S39 Operation and maintenance of the NOVAvue automated slide reader  BS-IMM-S10 Operation of Olympus CX41 Microscope	H



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<p>HUMAN BODY FLUIDS cont</p> <p>Serum/Plasma</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Autoantibodies to cont</p> <p>Thyroid peroxidase antibody (TPO)          Glutamic acid decarboxylase (GAD)          Islet Antigen 2 (IA2)          Zinc transporter (ZnT8)          Intrinsic factor (IFA)          Rheumatoid factor(RF)          M2 (MIT3) antigen</p>	<p>Documented In-house methods using:</p> <p><u>Autoimmune ELISA Autoantibodies</u></p> <p>DS2 ELISA processor using enzyme immunoassay          BS-IMM-S11 Operation and Maintenance of the DS2 ELISA Processor          BS-IMM-S17 Measurement of TPO antibodies using the DS2 ELISA Processor          BS-IMM-S12 Measurement of GAD, IA2 and ZnT8 using the DS2 ELISA processor          BS-IMM-S14 Measurement of IF antibodies using the DS2 ELISA processor          BS-IMM-S16 Measurement of RF antibodies using the DS2 ELISA Processor          BS-IMM-15 Measurement of M2 antibodies using the DS2 ELISA Processor</p>	<p>H</p>
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<p>HUMAN BODY FLUIDS cont</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Autoimmune FEA</u></p> <p>Autoantibodies to (cont'd):</p> <p>Cyclic citrullinated peptide (CCP)</p> <p>Glomerular basement membrane (GMB)</p> <p>dsDNA antibody</p> <p>Extractable nuclear antigen(ENA) profile (consisting of Ro (SS-A), La (SS-B), SmDP, U1RNP, Scl-70S, Jo-1)</p> <p>Myeloperoxidase (MPO) Proteinase 3 (PR3)</p> <p><u>Allergy</u></p> <p>Total IgE</p> <p>Tryptase</p>	<p>Documented In-house methods using</p> <p>ImmunoCAP 250 using fluorescence enzyme immunoassay (FEIA)</p> <p>BS-IMM-S24 Operation and Maintenance of the Immunocap 250 BS-IMM-S34 Measurement of anti-CCP by FEIA using the Immunocap 250</p> <p>BS-IMM-S13 Measurement of anti-GBM antibodies by FEIA using Immunocap 250</p> <p>BS-IMM-S37 Measurement of dsDNA by FEIA using the ImmunoCAP 250</p> <p>BS-IMM-S18 Measurement of ENA screen and Ro, La, SmDP, U1RNP, Scl-70S &amp; Jo-1 by FEIA using Immunocap 250</p> <p>BS-IMM-S36 Measurement of MPO &amp; PR3 antibodies by FEIA using Immunocap 250</p> <p>ImmunoCAP 250 using sandwich immunoassay BS-IMM-S24 Operation and maintenance of the ImmunoCAP 250</p> <p>BS-IMM-S22 Measurement of Total IgE using the ImmunoCAP 250</p> <p>BS-IMM-S23 Measurement of Tryptase using the ImmunoCAP 250</p>	<p align="center">H</p>
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<p>HUMAN BODY FLUIDS Cont</p> <p>Serum/Plasma</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Allergy cont</p> <p><u>Food Allergens</u> Egg white f1 Milk f2 Cod f3 Wheat f4 Sesame f10 Peanut f13 Soya f14 Hazelnut f17 Brazil nut f18 Almond f20 Crab f23 Shrimp f24 Pork f26 Coconut f36 Blue mussel f37 Tuna f40 Salmon f41 Gluten f79 Kiwi f84 Melon f87 Banana f92 Pecan nut f201 Cashew nut f202 Pistachio f203 Pine nut f253 Walnut f256 Omega-5 gliadin f416</p> <p><u>Food mixes</u> Mixed nuts fx1 Mixed fish fx2 Mixed nuts (2) fx22</p> <p><u>Animal/ birds</u> Cat dander e1 Horse dander e3 Dog dander e5 Mouse epithelium e71 Mouse urine e72 Rat epithelium e73 Rat urine e74</p>	<p>Documented In-house methods using:</p> <p>ImmunoCAP 250 using sandwich immunoassay</p> <p>BS-IMM-S24 Operation and maintenance of the Immunocap 250 BS-IMM-S35 Measurement of Specific IgE using Immunocap 250</p>	<p>H</p>
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<p>HUMAN BODY FLUIDS cont</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p>	<p>Documented In-house methods using:</p>	
<p>Serum/Plasma</p>	<p><u>Allergy cont</u></p>	<p>ImmunoCAP 250 using sandwich immunoassay BS-IMM-S24 Operation and maintenance of the Immunocap 250 BS-IMM-S35 Measurement of Specific IgE using Immunocap 250</p>	<p>H</p>
	<p><u>Animal/ bird mixes</u> Mixed animal ex1 Mixed rodent ex70 Mixed feathers ex71 Mixed cagebird ex72</p>		
	<p><u>Drugs</u> Pennicilloyl G c1 Pennicilloyl V c2 Ampicilloyl c5 Amoxicilloyl c6 Suxamethonium c202</p>		
	<p><u>Venoms</u> Honey bee venom i1 Wasp venom i3</p>		
	<p><u>Pollen/ mould mixes</u> Mixed grass gx3 Mixed tree tx1 Mixed moulds mx1</p>		
	<p><u>Miscellaneous</u> Latex k82 House dust mite d1</p>		
	<p><u>Pollens/ Moulds</u> Aspergillus m3 Rape pollen w203</p>		
	<p><u>Avian and Aspergillus precipitins</u>  Aspergillus precipitins Gm3</p>	<p>BS-IMM-S25 Measurement of Avian and Fungal related antibodies using Immunocap 250</p>	
<p>Serum</p>	<p>Budgie antigen Ge90 Pigeon antigen Ge91 Parrot antigen Ge92</p>		



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HUMAN BODY FLUIDS cont  Serum/Plasma	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>  Immunochemistry  C1 esterase inhibitor Complement 3 Complement 4 Total IgG IgG subclasses ( IgG1, IgG2, IgG3, IgG4)	Documented In-house methods using:  SPA Plus turbimetric analyser  BS-IMM-S20 Operation and maintenance of the SPA Plus turbidimetric analyser BS-IMM-S19 Measurement of Human Complement (C1 inactivator, C3 & C4) using the BS-IMM-S21 Measurement of Human IgG and IgG subclasses	H
END			