


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>Accredited to ISO 15189:2012</b>	<b>University Hospitals Plymouth NHS Trust</b>	
	<b>Issue No: 007 Issue date: 19 January 2021</b>	
	<b>Derriford Combined Laboratory University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Plymouth Devon PL6 8DH</b>	<b>Contact: Carole Stoddard Tel: +44 (0) 1752 430097 E-Mail: <a href="mailto:carole.stoddard@nhs.net">carole.stoddard@nhs.net</a> Website: <a href="http://www.plymouthhospitals.nhs.uk">www.plymouthhospitals.nhs.uk</a></b>
<b>Testing performed at the above address only</b>		

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

Location details	Activity
Derriford Combined Laboratory (Blood Bank) University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Plymouth Devon PL6 8DH	Storage & issue of blood & blood products only
Cardiac Theatre University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Plymouth Devon PL6 8DH	Storage & issue of blood & blood products only
Cardiac Intensive Care University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Plymouth Devon PL6 8DH	Storage & issue of blood & blood products only



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

<b>Location details</b>	<b>Activity</b>
Maternity Delivery and Theatre University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Plymouth Devon PL6 8DH	Storage & issue of blood & blood products only
Theatre Suite (Level 2) University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Plymouth Devon PL6 8DH	Storage & issue of blood & blood products only
Theatre Suite (Level 4) University Hospitals Plymouth NHS Trust Derriford Hospital Derriford Plymouth Devon PL6 8DH	Storage & issue of blood & blood products only
Peninsula NHS Orthopaedic Treatment Centre Brest Road Plymouth PL6 5XP	Storage & issue of blood & blood products only
St. Luke's Hospice Stamford Close Plymouth PL9 9XA	Storage & issue of blood & blood products only
Main Ward Plymouth Hospitals NHS Trust Tavistock Hospital Spring Hill Tavistock PL19 8LD	Storage & issue of blood & blood products only



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

<b>Location details</b>	<b>Activity</b>
Renal Unit Plymouth Hospitals NHS Trust Renal Unit Plymbridge Road Estover Plymouth PL6 7FL	Storage & issue of blood & blood products only
NHS South Devon and Torbay CCG Main Ward South Hams Hospital Plymouth Road Kingsbridge Devon TQ7 1AT	Storage & issue of blood & blood products only



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUID	<u>Coagulation examinations for the purpose of clinical diagnosis and management</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below
Citrated Plasma	Clotting Tests	Stago STA-R Max: Viscosity clot detection method
	Prothrombin Time - PT Activated Partial Thromboplastin Time	SOP: DC0041, DC37
	Clauss Fibrinogen	SOP: DC0099
	INR Internal Normalised Ratio (INR)	Calculated using the patient's PT and reagent ISI Technoclone Ak-calibrant SOP: DC0041
	Lupus Anticoagulant	Viscosity clot detection method SOP DC0012
	Thrombophiliascreening:	Chromogenic detection method
	Free Protein S Activity	SOP:DC0032
	Protein C Activity	SOP:DC0028
	Anti Thrombin III	SOP: DC0002
	Clotting factors: Factor II Factor V Factor VII Factor VIII Factor IX Factor X Factor XI Factor XII Factor XIII	Viscosity clot detection SOP DC0029 and DC0036
	Von Willebrand Factor Antigen	Immunoturbimetric method SOP: DC0027
	D-dimer (FDP)	SOP: DC0001
	Von Willebrand Factor Activity	SOP:DC0151



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HUMAN BODY FLUIDS (cont'd)	<p><u>Coagulation examinations for the purpose of clinical diagnosis and management</u></p> <p>Anti-Xa Assay for Anticoagulant Control</p> <ul style="list-style-type: none"> <li>- LMW Heparin</li> <li>- Fondaparinux</li> <li>- Rivaroxban</li> <li>- Apixaban</li> </ul> <p>Thrombin Time</p> <p>Reptilase Time</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below</p> <p>Chromogenic detection method SOP: DC0098</p> <p>Viscosity clot detection method SOP: DC0034</p> <p>Viscosity clot detection method SOP: DC0097</p>
Citrated plasma	<p>Platelet Function Studies</p> <ul style="list-style-type: none"> <li>- PFA-100</li> <li>- Platelet Aggregation</li> </ul>	<p>PFA-100 analyser SOP: DC0048 PAP-8E aggregometer SOP: DC0045</p>
Serum (unless otherwise specified)	<p><u>Immunology examinations for the purpose of clinical diagnosis</u></p> <p>Investigation of auto immunity</p> <p>IgG Anti-Cardiolipin antibodies IgM Anti-Cardiolipin antibodies</p> <p>Anti Double stranded DNA Antibodies</p> <p>Anti Tissue Transglutaminase antibodies</p> <p>Anti Glomerular Basement Membrane (GMB) antibodies</p> <p>Anti Mitochondrial 2 (M2) Antibodies</p> <p>Anti TSH Receptor Autoantibodies</p> <p>Extractable Nuclear Antigen (ENA) Screen</p>	<p>Phadia UniCap 250 SOP UNI250/007</p> <p>DS2 analyser ELISA SOP: ELI/027 and ELI/013</p> <p>SOP:ELI/004</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Immunology examinations for the purpose of clinical diagnosis</u></p> <p>Extractable Nuclear Antigens;</p> <p>Anti - nRNP/Sm Anti - Sm Anti - SSA/Ro Anti - Ro- 52 Anti - SS- B/La Anti - SCL70 Anti - PM-Sci Anti - Jo1 Anti - CENBPB Anti - PCNA Anti - Nucleosomes Anti - Hhistone Anti - Ribosomal P</p> <p>Anti Myeloperoxidase (MPO) antibodies</p> <p>Anti Proteinase 3 (PR3) antibodies</p> <p>Investigation of Auto Immune Disease:</p> <p>Anti-Nuclear Antibodies</p> <p>Anti-Neutrophil Cytoplasmic Antibodies Cytoplasmic ANCA Perinuclear ANCA</p> <p>Liver Auto Antibody screen</p> <p>Anti Mitochondrial Antibodies Antinuclear Antibodies Anti Smooth Muscle Antibodies</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below</p> <p>EuroImm Profile 3. Euroline method Immunoblot Immunofluorescence microscopy SOP AUT/004</p> <p>Werfen BioFlash analyser Chemiluminescence SOP: AUT/029</p> <p>Manual indirect immunofluorescence using Rat Liver Kidney Stomach Tissue slides. Fluorescence microscopy SOP AUT/002</p> <p>Indirect Immunofluorescence Microscopy ANCA (ethanol FNH) kit fluorescence microscopy SOP AUT/008 and AUT/028</p> <p>Manual indirect immunofluorescence assay using innova tissue slides and fluorescence microscopy</p> <p>SOPs AUT/002, SOP AUT/003 and AUT/028</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Immunology examinations for the purpose of clinical diagnosis</u></p> <p><u>Anti Endomysial Autoantibodies:</u> IgA IgG</p> <p><u>Skin Antibodies:</u> Skin Intracellular cement (Desmosome) Skin Basement membrane</p> <p>Haemophilus influenza type B antibodies</p> <p>Tetanus toxoid antibodies Total Pneumococcal antibodies</p> <p><u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u></p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below</p> <p>Manual indirect immunofluorescence assay using innova tissue slides and fluorescence microscopy</p> <p>SOP:AUT/028 SOP:AUT/006</p> <p>SOP: AUT/021 SOP: AUT/028</p> <p>DS2 Analyser ELISA: Binding Site IgG anti HIB method SOP: ELI/027 and SOP: ELI/009</p> <p>Binding site Tetanus Toxoid IgG SOP: ELI/027 and SOP: ELI/028</p>
Peripheral Blood (EDTA) Bone marrow Aspirate CSF Fine needle Aspirate Pleural Fluid	<p>Haematological malignancy investigations using abnormal intracellular and extracellular marker expression for:</p> <p>Acute Leukaemia Panel: CD2, CD34, CD7, CD34, HLA-DR, CD33, CD13, CD20, CD117, CD19, CD10, CD14</p> <p>Chronic Leukaemia / Lymphoma panel: CD5, CD19, CD22, CD23, CD3, FMC7, Kappa, Lambda, CD25, CD4, CD10, CD103, CD38, CD20</p>	<p>Becton Dickinson FACSLyric flow cytometer fluorescent labelled monoclonal antibody panels, acquired via laser using hydrodynamic focussing</p> <p>SOP: IMMHI/013, IMMHI/043, IMMHI/002B, IMMHI/003B</p> <p>SOP: IMMHI/040, IMMHI/046, IMMHI/050, IMMHI/030, IMMHI/001</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below
Peripheral Blood (EDTA) Bone marrow Aspirate CSF Fine needle Aspirate Pleural Fluid (cont'd)	Haematological malignancy investigations using abnormal intracellular and extracellular marker expression for: (cont'd)	Becton Dickinson FACSLyric flow cytometer fluorescent labelled Monoclonal antibody panels, acquired via laser using hydrodynamic focussing
	Lymphocyte Subset Analysis: TSET, CD19, CD56, CD3, CD4, CD8, CD4/CD8 Ratio	SOP: IMMHI/001 IMMHI/30
	T Cell profile: CD4%, CD3, CD4, CD8, CD4/CD8 Ratio	SOP IMMHI/001 IMMHI/030
	PID: Primary Immunodeficiency B Cell Phenotyping (BSET) CD38, CD19, CD21, CD27, IgM, IgG	SOP; IMMHI/047 IMMHI/013
Peripheral Blood EDTA	PNH (Paroxysmal Nocturnal Haematuria) Screening CD59, CD15, CD33	Alexa 488 SOP: IMMHI/041
Bone Marrow	Myeloma Immunophenotyping: CD38, CD138, CD19+, CD56+	Becton Dickinson Fascanto II flow Cytometer: MA Hydro dynamic focusing SOP IMMHI/044 IMMHI/013
Peripheral Blood EDTA	Hereditary Spherocytosis screening	Flow fluorescent expression EMA binding to RBC membrane. SOP: IMMHI/024
Peripheral Blood (Lithium Heparin)	Neutrophil Function	Oxidative burst measured by Flow Cytometry. SOP: IMMHI/015
Serum	Protein electrophoresis Alpha-1 globulins Alpha-2 globulins Beta globulins Gamma globulins	Helena V8 capillary zone electrophoretic separation SOP: PROT/027, PROT/025





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HUMAN BODY FLUIDS (cont'd)	<u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below
Serum	Paraprotein Identification	Immunofixation by gel electrophoresis SOP: PROT/022
Urine	Bence Jones Protein  Urine immunofixation of GAM Kappa / Lambda	Gel based Electrophoresis protein separation SAS-3 and SAS-4 systems and Immuno fixation SOP: PROT/023, SOP: PROT/024
Serum	Serum Free Light Chains: Kappa / Lambda ratio Serum free Kappa Serum free Lambda  IgG Sub- classes: IgG1 subclass IgG2 subclass IgG4 subclass	SPA+ Binding Site Turbimeter Turbidity SOP: PROT/017 PROT/018
Paired Serum and CSF	IgG Oligoclonal Bands	Electrophoretic separation of protein by isoelectric point. Agarose gel pH gradient using Helena Isoelectric system SOP: PROT/026
Whole Blood	Cryoglobulins	Gel based Electrophoresis protein separation SAS-3 and SAS-4 systems Immunofixation SOP: PROT/ 016  Thermofisher Phadia UniCap 250 Sandwich Immunoassay measuring high total binding capacity:
Serum	Total IgE  Specific IgE antibodies: c1 Penicillin G c3 Penicillin V c6 Amoxycilloxyl d1 D.pteronyssinus e1 Cat dander	UNICAP/003  UNICAP/004



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below
Serum	Specific IgE antibodies (cont'd): e3 Horse dander e5 Dog dander e6 Guinea pig epithelium e73 Rat epithelium e78 Budgerigar feathers e82 Rabbit epithelium ex71 Mixed feathers (goose, chicken, duck, turkey). ex72 Mixed caged bird feathers (budgerigar, canary, parakeet, parrot, finch) f1 Egg White f2 Cow's milk f3 Cod fish f4 Wheat f6 Barley f7 Oat f8 Maize f10 Sesame Seed f13 Peanut f14 Soybean f15 White bean f17 Hazel nut f18 Brazil nut f20 Almond f23 Crab f24 Shrimp f25 Tomato f26 Pork 27 Beef f33 Orange f35 Potato f36 Coconut f37 Blue Mussel f40 Tuna f41 Salmon f44 Strawberry	Thermofisher Phadia UniCap 250 Sandwich Immunoassay measuring high total binding capacity:  UNICAP/004



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below
Serum	Specific IgE antibodies (cont'd): f45 Yeast f48 Onion f49 Apple f75 Egg Yolk f79 Gluten f80 Lobster f81 Cheese (Cheddar) f83 Chicken f84 Kiwi f87 Melon f89 Mustard f92 Banana f93 Cacao f94 Pear f95 Peach f201 Pecan f202 Cashews f203 Pistachio f208 Lemon f212 Potato f218 Paprika f235 Lentil f242 Cherry f247 Honey f253 Pine nut f256 Walnut f259 Grape f279 Chilli Pepper f287 Red kidney beans f299 Sweet chestnut f309 Chick pea f319 Beetroot f416 Wheat Omega 5 Gliadin gx1 Grass mix - Cocksfoot grass, Fescue grass, Rye grass, Timothy Grass, Meadow grass. i1 Honey Bee venom i3 Common Wasp (yellow jacket) k82 Latex	Thermofisher Phadia UniCap 250 Sandwich Immunoassay measuring high total binding capacity:  UNICAP/004



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below
Serum	Specific IgE antibodies (cont'd): k84 Sunflower seed m3 Aspergillus fumigatus mx1 Mould mix (m1, m2, m3, m6) m1 – Penicillium chrysogenum m2 – Cladosporium herbarum m3 – Aspergillus fumigatus m6 – Alternaria alternata rx1 Regional mix (g6, w6, w9, w21, t3 w9, w21, t3) g6 – Timothy grass w6 - Mugwort w21 Pellitory t3 – Silver Birch rx7 Regional mix (d1,e1,e3,e5,e82) d1 – (House dust mite) e1 – (Cat dander) e3 – (Horse dander) e5 – (Dog dander) e82 – (Rabbit epithelium) t3 – Silver birch tx1 Tree mix (t1, t3, t7, t8, t10) t1 – Box elder - Maple t3 – Silver Birch t7 – White Oak t8 – American Elm t10 - California Black Walnut w6 Mugwort (Artemisia) w9 Plantain w21 Wall Pellitory	Thermofisher Phadia UniCap 250 Sandwich Immunoassay measuring high total binding capacity:  UNICAP/004
Serum	Mast Cell Tryptase	UNICAP250/008



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below:
Peripheral Blood EDTA Spleen or lymph nodes for cadaveric donors	HLA Typing of Donors, renal patients and disease association studies: HLA-A, -B, -C, DRB1, DRB3/4/5 -DQA1, DQB1, DPB1	VH Bio. Luminex PCR-SSO (Bead array technology) SOP: HANDICALL001 SOP: HANDICALL005 SOP: HANDICALL006 SOP: HANDILUM002 SOP: HANDILUM004 SOP: HANDILUM026
Peripheral blood EDTA	HLA typing of cadaveric donors (second method) HLA -A, -B, -C, DRB1, DRB3/4/5, -DQB1	PCR-SSP run on generic thermal cyclers with gel electrophoresis (commercial kits) And PCR-SSO as above (dual Method) SOP: HANDIMOL037 SOP: HANDIMOL003 SOP: HANDIMOL005 SOP: HANDIMOL012 SOP: HANDIMOL026 SOP: HANDIMOL032
Peripheral blood EDTA	HLA B27 typing for disease Associations	PCR-SSP run on generic thermal cyclers with electrophoresis (in-house primers) SOP: HANDIMOL032 SOP: HANDIMOL018
Peripheral blood EDTA	HLA typing for other disease associations: Coeliac (DQB1) Birdshot chorioretinopathy (HLA A) Behcet's (HLA B)	PCR-SSO (Bead array technology), VH Bio. Luminex SOP: HANDILUM 002 SOP: HANDILUM 026 SOP: HANDILUM 032
Peripheral blood EDTA	HLA B*57:01 typing for Abacavir reactivity	PCR-SSP run on generic thermal cyclers with gel electrophoresis (in-house primers) SOP: HANDIMOL019 SOP: HANDIMOL026 SOP: HANDIMOL032



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below:
Peripheral blood EDTA	Virtual cross matching for deceased donor kidneys and living donor kidneys	PCR-SSP run on generic thermal cyclers with gel electrophoresis (in-house primers) SOP: HANDICALL015 SOP: HANDICALL016 SOP: HANDIFLOW014 SOP: HANDIMOL024 WAF0331
Serum	HLA antibody screening to all common and well defined (CWD) HLA class I and II antigens (pos/neg)	Bead array technology; VHBio, Luminex SOP: HANDILUM005 SOP: HANDILUM011 SOP: HANDIFLOW007 SOP: HANDIFLOW018 SOP: HANDIFLOW037
Serum	HLA antibody identification to all common and well defined (CWD) HLA class I and II antigens	Bead array technology; VHBio, Luminex SOP: HANDILUM008 SOP: HANDIFLOW018 SOP: HANDIFLOW037 SOP: HANDIMOL024
Serum sample(s) from Recipient. EDTA (living) or spleen cadaveric) samples	Flow cytometric crossmatching for transplant  Identifies HLA specific IgG antibodies on T and B cells which are an increased risk to transplant	3 colour flow cytometry using BD Flow Cytometer (in-house method)  SOP: HANDICALL006 SOP: HANDIFLOW006 SOP: HANDIFLOW007 SOP: HANDIMOL024 SOP: TT/CALL/008



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:
Whole blood EDTA	Blood group determination By detection and Identification of red cell Antigens: A Rh D Positive AB Rh D Positive B Rh Positive O Rh Positive A Rh Negative AB Rh Negative B Rh Negative O Rh Negative	BIO RAD Monoclonal antibody column agglutination technology, automated using the Immucor NEO blood grouping analyser SOP: BB111 and:
Whole Blood EDTA/ Red cells	Red cell atypical antibody Screening for the detection of: Rhesus system antibodies: Anti Cw, anti C, anti c, Anti D anti E, anti e. Kell system antibodies: anti K, anti k, anti Kpa, anti Kpb. Kidd system antibodies: anti Jka, anti Jkb. Duffy system antibodies: anti Fya, anti Fyb. Lutheran system antibodies: Lua, Lub. MNS system antibodies: anti M, anti N, anti s. Lewis system antibodies: anti Lea, anti Leb. P system: anti P	Using phenotyped red cell screening cells on automated Immunocor NEO blood group Analyser SOP: BB111
Whole Blood EDTA	Direct Antiglobulin Test (DAT)	BIO RAD column agglutination technology, using automated using the Immucor NEO blood grouping analyser SOP: BB016
Whole blood EDTA	Manual ABO and Rh Blood Grouping and Atypical Antibody screening:	Manual techniques using BIO RAD Column agglutination technology and tube methods, using monoclonal antibodies and phenotyped red cells SOP: BB102



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:
Plasma EDTA	Automated or Manual Atypical Investigation and identification by Indirect Antiglobulin Test (IAT)	Automated Capture R technology using the Immucor NEO blood grouping analysers. Manual using IAT BIO-RAD Column agglutination technology. SOP: BB062
Plasma EDTA	Antibody titration	Automated techniques using the Immunocor NEO blood grouping analysers SOP: BB090
Red Cells	Antibody Elution	Manual techniques using BIO RAD Column agglutination technology and tube methods SOP: BB103
Red Cells	Red Cell Phenotyping	Manual techniques using BIO RAD Column technology using monoclonal antibodies. SOP: BB23
Red Cells	Feto Maternal Haemorrhage screening	Manual Kleihauer method SOP: BB027
Red Cells	Feto Maternal Haemorrhage Quantitative method	Red Cell Automated Flow Cytometry SOP: BB058
Red Cell Unit Issue	Electronic issue of red cell units for transfusion	Automated techniques using Immunocor NEO blood grouping Analysers and IT methodology SOP: BB055
Plasma	Manual Crossmatch of Red Cell units for transfusion	Manual techniques using tube and BIO RAD column technology. SOP: BB010





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Serum Plasma (unless otherwise stated)	<u>Biochemical examinations for the purpose of clinical diagnosis</u>	Abbott Architect c16000 analyser SOP: ARC 001 SOPs: ARC 010 to ARC 019 inclusive and method sheets
	Acetaminophen	Enzymatic/Colorimetric
	Alkaline Phosphatase	Para-Nitrophenyl Phosphate
	Albumin	Dye binding Bromocresol green
	ALT	NADH (without P-5'-P)
Including urine	Amylase	CNPG3 Substrate
EDTA Plasma	Ammonia	Glutamate Dehydrogenase
Urine	Amphetamine	Enzyme Immunoassay (EMIT)
	Alpha 1 Antitrypsin	Immunoturbidimetric
	AST	NADH (without P-5'-P)
	Bilirubin (total)	Diazonium Salt
Urine	Benzodiazepine	Enzyme Immunoassay (EMIT)
	Bicarbonate (CO2)	PEP carboxylase
Including Urine Fluid	Calcium	Arsenazo III Dye
	Calcium (Adjusted)	Calculated: Calcium+(0.017 x (43- albumin))
Including Drain Fluids	Cholesterol	Enzymatic
Serum Plasma	Cholesterol HDL ratio (CHDLR)	Calculated = Cholesterol / HDL
Including Plasma Urine	Chloride	Indirect Ion Selective electrode
Urine	Cocaine	Enzyme Immunoassay (EMIT)
	Carbamazepine	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)
	C3	Immunoturbidimetric
	C4	Immunoturbidimetric



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

**University Hospitals Plymouth NHS Trust**  
**Issue No: 007 Issue date: 19 January 2021**

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Serum Plasma (unless otherwise stated)	<u>Biochemical examinations for the purpose of clinical diagnosis</u>	Abbott Architect c16000 analyser SOP: ARC 001 SOPs: ARC 010 to ARC 019 inclusive and method sheets
Including Urine Fluids	Creatinine	Kinetic Alkaline Picrate (jaffe reaction)
	Creatine Kinase (CK)	NAC (N-acetyl-L-cysteine)
	C Reactive Protein (CRP)	Immunoturbidimetric
	eGFR	Calculated: EGFR EPI Calculation applied
	Enzymatic creatinine	Enzymatic
Including Urine	Ethanol	Alcohol dehydrogenase
	Free Androgen Index (FAI)	Calculated: = (Testosterone/SHBG) x 100
	Gentamicin	Particle enhanced turbidimetric inhibition immunoassay (PETINIA)
	Globulin	Calculated = Total Protein - Albumin
Including CSF Fluids	Glucose	Hexokinase/G-6-PHD
	GGT	L-Gamma-glutamyl-3-carboxy-4-nitroanilide substrate
Including Fluids	HDL Cholesterol	Homogenous accelerator selective detergent
	Haptoglobin	Immunoturbidimetric
	IgA	Immunoturbidimetric
	IgG	Immunoturbidimetric
	IgM	Immunoturbidimetric
	Iron	Ferene
Plasma	Lactate	Oxidation of lactate to pyruvate



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	LDH Lactate Dehydrogenase	IFCC lactase to pyruvate (NADH)
	LDL	Calculated: Cholesterol -(Trig / 2.21) + HDL
	Lipase	Quinone Dye
	Lithium	Colorimetric
Including Urine	Magnesium	Arsenazo
Urine	Methadone	Enzyme Immunoassay (EMIT)
Urine	Micro Albumin	Immunoturbidimetric
Urine	Micro Albumin Creatinine ratio (MCR)	Calculated: = microalbumin / creatinine
Urine	Opiate	Enzyme Immunoassay (EMIT)
	Non-HDL Cholesterol (NHDL)	Calculated: = Cholesterol - HDL
	Phenobarbitone	Particle- enhanced turbidimetric inhibition Immunoassay (PETINIA)
	Phenytoin	Enzyme Immunoassay
Including Urine	Phosphate	Phosphomolybdate
Including Urine	Potassium	Indirect Ion Selective electrode
Urine	Protein Creatinine ratio (PCR)	Calculated = (Urine protein / Urine creatinine) x 100
	Rheumatoid Factor	Immunoturbidimetric
	Salicylate	Enzymatic/colorimetric
Including Urine	Sodium	Indirect Ion Selective electrode
	Theophylline	Enzyme Immunoassay
Urine	TH5Q2 (Cannabis)	Enzyme Immunoassay (EMIT)



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	Tobramycin	Particle-enhanced Turbidimetric Immunoassay (PETINIA)
	Total Protein (Biuret)	Biuret/Immunoturbidimetric
	Transferrin	Immunoturbidimetric
	Transferrin saturation % TRF	Calculated = Iron x 3.98 / Transferrin
	Triglyceride	Glycerol Phosphate Oxidase
	Unconjugated Bilirubin (UCBIL)	Calculated: = T.Bilirubin – Conj. Bilirubin
Including Urine	Urate	Uricase
Including Urine	Urea	Urease
Urine	Urine Calcium Creatinine ratio (UCCR)	Calculated = urine calcium / urine creatinine
Urine and CSF	Total Protein	Benezethonium chloride
Urine	Urine 24 hour (Calcium, creatinine, urate, protein, microalbumin, magnesium, sodium, potassium, chloride, phosphate, urea).	Calculated = Analyte x (urine volume /1000)
	Valporate	Homogeneous microparticle – enhanced turbidimetric immunoassay
	Vancomycin	Particle-enhanced Turbidimetric Immunoassay (PETINIA)
	Wako Direct Bilirubin L Type	Vanadate oxidation



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Serum Plasma (unless otherwise stated)	<u>Biochemical examinations for the purpose of clinical diagnosis</u>  Anti - Thyroid Peroxidase AFP (Alpha Fetoprotein) bHCG BNP - (Brain Natriuretic Peptide) B12 (Vitamin) CA-125 CA –19-9 CEA Cortisol Digoxin Oestradiol Ferritin FSH (Follicle Stimulating Hormone) Folate Free T3 Free T4 LH (Luteinising Hormone) Methotrexate Prolactin (Macroprolactin) Progesterone PTH (Parathyroid Hormone) PSA (Total Prostate Specific Antigen)	Architect i2000: Abbott Chemiluminescent Microparticle Immuno Assay (CMIA) SOP: ARC 003 + Insert on board



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Serum Plasma (unless otherwise stated)	<u>Biochemical examinations for the purpose of clinical diagnosis</u>  SHBG (Sex Hormone Binding Globulin)  Testosterone  hsTroponin I  TSH (Thyroid Stimulating Hormone)  Total Vitamin D	Architect i2000: Abbott Chemiluminescent Microparticle Immuno Assay (CMIA) SOP: ARC 003 + Insert on board
Serum Plasma, Urine	Osmolality	Vitach 3320 Osmolality Depression of Freezing Point. ARC 020
Whole blood EDTA	HbA1c	TOSOH G8 HPLC Method ACTOSOP 01
Whole blood	Therapeutic Drug monitoring  Ciclopprin Tacrolimus Sirolimus	LCMS WatersAcquity TDD method for measurement of immunosuppressant drugs SOP: CSI 107
Serum	Trace Metals - Zinc	AAS – Trace Metal Analysis Atomic absorbance spectroscopy. SOP: CSI 112
Serum, Urine	Trace Metals - Copper	Agilent tech 1260: HPLC with UV Detection
Serum	Vitamin A, Vitamin E	SOP: CSI 111
Urine	Metanephrines: Metadrenaline Normetadrenaline 3-Methoxytyramine	SOP: CSI 114
Urine	5HIAA (5 hydroxyindole acetic acid)	SOP: CSI 133



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemical examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:
Serum	AMH (Anti Mullerin Hormone) Growth Hormone Thyroglobulin Anti Thyroglobulin	Access2. Beckman Chemiluminescent Microparticle Immunoassay SOP: CSI137
Urine	Drugs of Abuse: Opiate Identification including Buprenorphine Tramadol	LC-MS, Isotope dilution LC tandem mass spectrometry SOP: CSI 109
Faeces	Calprotectin	Phadia 250 assay SOP: CSI 095 Fluorezyme immunoassay (EiLA)
Sweat	Chloride	Sherwood Mk II 926S Chloride Analyser SOP: CSI 097
Urine Fluid	pH measurement	Jenway 3510 pH meter Potentiometry SOP: CSI 135
CSF	Bilirubin	Northstar Scientific Uvikon Spectrophotometry SOP: CSI 094
CSF	Oxyhaemoglobin	



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Pre-examination sample preparation and Nucleic Acid Extraction</p>	<p><u>Molecular examinations for the purpose of clinical diagnosis</u></p>	<p>Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:</p> <p>Separation of mononuclear cells from Peripheral Blood and Bone Marrow – manual methodology using Lymphoprep (DMB013)</p> <p>Manual extraction of DNA from paraffin embedded and fresh frozen tissue using the NucleoSpin tissue kit (DMB017)</p> <p>Manual extraction of RNA and DNA from separated mononuclear cells and tissue using TRI Reagent (DMB018)</p> <p>Manual extraction of RNA and DNA from a limited peripheral blood, bone marrow or paraffin embedded (FFPE) sample using TRIZOL-LS reagent (DMB019)</p> <p>Manual extraction and purification of DNA from liquid samples using ReliaPrep gDNA miniprep spin column system (DMB067)</p> <p>Automated DNA extraction from whole peripheral blood/bone marrow and buffy coat cells of peripheral blood/bone marrow using Maxwell16 (DMB053)</p>
<p>DNA from FFPE tumour samples</p>	<p>Detection of SNVs, indels and CNVs - Oncomine Focus Targeted Oncology Panel</p>	<p>Preparation using Hi-Q view chemistry, Ion One Touch 2 system, Ion One Touch ES and sequencing using Ion Torrent PGM. Data analysis using 3rd party commercial bioinformatics pipeline managed through Ion Reporter. SOP DMB075</p>





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HUMAN BODY FLUIDS (cont'd)	Molecular examinations for the purpose of clinical diagnosis	Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below: PCR-RFLP with acrylamide electrophoresis SOP: DMB028 Use of conventional thermal cycler
DNA from whole blood	Inherited thrombophilia - Factor V Leiden & Prothrombin	PCR-RFLP with agarose electrophoresis SOP: DMB029
DNA from whole blood	Inherited HFE genotyping- H63D and C282Y	Microsatellite marker PCR with acrylamide electrophoresis SOP: DMB045 Use of conventional thermal cycler
DNA from whole blood and Formalin Fixed Paraffin Embedded tissue (FFPE) or frozen tissue	Neuropathology loss of heterozygosity at Chromosome loci 1p & 19q	Bisulfite conversion with methylation specific PCR and acrylamide electrophoresis SOP: DMB044 Use of conventional thermal cycler
DNA from FFPE or frozen tissue with Bisulfite modification	Neuropathology – MGMT methylation in glioma and sarcoma	PCR and RT-PCR with agarose electrophoresis. Use of conventional thermal cycler SOPs: DMB025, DMB031, DMB040, DMB041, DMB042, DMB043, DMB064
DNA and RNA from blood, bone marrow, FFPE or frozen tissue	Haemato-oncology for AML: FLT3-ITD - DNA NPM1 - DNA t(8;21) - RNA t(15;17) - RNA inv(16) - RNA	t (9;22) using RT-PCR. Use of conventional thermal cycler (qualitative) and QuantStudio 6 Flex based real time PCR (RQ PCR) (quantitative) (major breakpoint regions only) SOP: DMB031 and DMB032
DNA and RNA from blood, bone marrow, FFPE or frozen tissue	Haemato-oncology for CML, ALL and AML; t (9;22) qualitative & quantitative	PCR with High Resolution Melt analysis using ABI QuantStudio 6 Flex SOPs: DMB069 and DMB070
DNA from peripheral blood, buffy coat and bone marrow	Detection of CALR exon 9 and MPL exon 10 mutations	Multiplex PCR and RT-PCR with acrylamide electrophoresis including single stranded conformation polymorphism (SSCP) and use of conventional thermal cycler SOP's: DMB034, DMB035
DNA and RNA from blood, bone marrow, FFPE or frozen tissue	Lymphoma: T cell clonality by TCRB and TCRG gene rearrangement analysis	



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:
DNA and RNA from blood, bone marrow, FFPE or frozen tissue	Mantle Cell Lymphoma: Cyclin D1 (CCND1) over expression (RNA) and t (11;14) (DNA)	Nested PCR (t11;14)/and RT-PCR (CCND1) with agarose electrophoresis using conventional thermal cycler SOP's: DMB036, DMB037
DNA and RNA from blood, bone marrow, FFPE or frozen tissue	Follicular Lymphoma: t (14;18) (DNA)	Nested PCR with agarose electrophoresis using conventional thermal cycler SOP's: DMB038.
DNA from whole blood, buffy coat or bone marrow	Myeloproliferative neoplasms JAK2 p.Val617Phe	ASO-PCR with agarose electrophoresis. use of conventional thermal cycler SOP: DMB030
	<u>Haematology examinations for the purpose of clinical diagnosis</u>	
Whole blood EDTA (unless otherwise specified)	Peripheral blood film preparation and stain	Manual film preparation Abbott Alinity HS Slide maker and stainer (SMS) (May Grunwald Giemsa stain) SOP DH00141
	Reviewing blood films - morphology examination and differential	Nikon Eclipse. Light Microscopy SOP DH0137 Manual examination by Microscopy SOP DH0011
Plasma EDTA	Glandular Fever screen (Infectious Mononucleosis screen)	Manual Monogen method Agglutination: SOP DH0018
	G6PD deficiency screening	Trinity BioTech G6PD Deficiency kit fluorescence under UV SOP DH0012
	Sickle cell screening	Manual method – MicroGen S Kit Deoxygenation observed turbidity SOP DH0036



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Whole blood ETDA	Haemoglobinopathy screening for Thalassaemia and Haemoglobin variants quantitation of HbA2, HbF and HbS	TOSOH G8 Cation exchange HPLC SOP ACTOS001
	Haemoglobin Electrophoresis using acid and alkaline gels	Gel based electrophoresis protein separation SAS-3 and SAS-4 SOP: DH0016
	Detection of HRP2 and pLDH antigens for the identification of Malaria parasites	Carestart. Malaria HRP2 pLDH Combo test DH0021 and DH0112
	Detection and Identification of Malaria parasite species by Microscopy of stained preparations <i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> <i>Plasmodium ovale</i> <i>Plasmodium vivax</i> <i>Plasmodium knowlesi</i>	Preparation and staining of Thick and Thin Films, Giemsa stain SOP:DH0021
CSF Fluid	Fluid Cytospin cell morphology	Aerospray Haematology Pro Light Microscopy SOP DH0101, DH0110 and DH0011
	Plasma Viscosity	Benson Viscometer Viscosity SOP DH0014
Urine	Hemosiderin	Manual slide preparation, stain and examination by light microscopy SOP DH00118
END		