


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	Barts Health NHS Trust	
	Issue No: 003 Issue date: 24 December 2019	
	Pathology Barts Health NHS Trust Pathology and Pharmacy Building Royal London Hospital 80 Newark Street London E1 1ES	Contact: Nicole Gresham Tel: +44 (0)203 246 0257 E-Mail: ngresham@nhs.net Website: http://www/bartshealth.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Department of Pathology The Royal London Hospital Pathology and Pharmacy Building 80, Newark Street London E1 1ES	Local Contact As specified below	RLH
Haematology & Blood Transfusion	Reza Mirza 020 3246 0374 Anand Pancholi 020 3246 0408 Julia Lancut 020 32460 1117 Minal Dave 020 3246 1106	RLH
Clinical Biochemistry	Reza Mirza 020 3246 0374 Greg Dearman 020 3246 0409 Andrew Staunton 020 3246 0382	RLH
	Routine Haematology Special Haematology Routine Coagulation Special Coagulation Blood Transfusion	
	Automated biochemistry Proteins Immunoassay LCMS HPLC	



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Location details	Activity	Location code
Microbiology Melvyn Eydmann 020 3246 0309 David Ball 020 3246 0307 Maryia Long 020 3246 1084 Heather Dolphin 020 3246 0308 Nathan North 020 3246 0306	Bacteriology Parasitology Mycology Molecular microbiology	RLH
Virology Melvyn Eydman 0203 246 0309 Xose Couto Parada 020 3246 0471 Emily Kilpin 0203 246 0300 Spiro Pereira 0203 246 0328	Virology Infectious diseases serology Molecular virology	RLH
Histopathology Matt Miller 020 3246 0185 Dean Mcdonald 020 3246 0218 Graham McPhail 020 3246 0218 Suzanne Jordan 020 3246 0184 Keziban Rehman 020 3246 0170 Lynne Pulham 020 3246 0190	Histology Non-gynae cytology Frozen Sections Electron Microscopy preparation of sample and electron micrograph qualitative analysis Body Storage and Release	RLH



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Location details	Activity	Location code
Immunology Chris Scott 020 3246 0287	Immunology Allergy Autoimmune serology Immunodeficiency Flow Cytometry	RLH
Clinical Transplantation Delordson Kallon 020 3246 0233	Clinical Transplantation	RLH
Cytogenetics & Molecular Haematology Marianne Grantham 0203 2460118	Cytogenetics Molecular genetics	RLH
Immunophenotyping Timothy Farren 020 3246 0228	Immunophenotyping	RLH
Retinoblastoma Zerrin Onadim 020 3246 0265	Retinoblastoma	RLH
Address St Bartholomew's Hospital Pathology Laboratory 2 nd Floor Museum block North Wing West Smithfield London EC1A 7BE	Local Contact As specified below	SBH
Haematology & Blood Transfusion	Pamela McColgan 020 3465 5362 Anand Pancholi 020 3246 0408 Julia Lancut 020 32460 1117 Minal Dave 020 3246 1106	Haematology Coagulation Blood Transfusion SBH
Clinical Biochemistry	Pamela McColgan 020 3465 5362 Greg Dearman 020 3246 0409	Clinical Biochemistry SBH



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Location details	Activity	Location code
<p>Histopathology</p> <p align="center">Matt Miller 020 3246 0185</p> <p align="center">Dean McDonald 020 3246 0218</p>	Frozen Sections	SBH
<p>Address Whipps Cross University Hospital Pathology Whipps Cross Road Leytonstone London E11 1NR</p>	<p>Local Contact As specified below</p>	Specimen Reception
<p>Haematology & Blood Transfusion</p>	<p>Pamela McColgan 0208 535 6982</p> <p>Gareth Heywood-Beldon 020 3416 5000 Ext 5734</p>	<p>Haematology Coagulation Blood Transfusion</p>
<p>Haematology & Blood Transfusion</p>	<p>Pamela McColgan 0208 535 6982</p> <p>Gareth Heywood-Beldon 020 3416 5000 Ext 5734</p>	<p>Haematology Coagulation Blood Transfusion</p>
<p>Haematology & Blood Transfusion</p>	<p>Pamela McColgan 0208 535 6982</p> <p>Gareth Heywood-Beldon 020 3416 5000 Ext 5734</p>	<p>Haematology Coagulation Blood Transfusion</p>
<p>Clinical Biochemistry</p>	<p>Pamela McColgan 0208 535 6982 Lindiwe Mangena 020 8539 5522 x5887</p>	Clinical Biochemistry



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Location details	Activity	Location code
<p>Address Newham University Hospital Pathology Glen Road Plaistow London E13 8SL</p>	<p>Local Contact As specified below</p>	<p>Specimen Reception</p> <p>NUH</p>
<p>Haematology Blood Transfusion</p>	<p>Pamela McColgan 020 7363 8068</p> <p>Gareth Heywood-Beldon 020 7363 8123</p>	<p>Haematology Coagulation Blood Transfusion</p> <p>NUH</p>
<p>Clinical Biochemistry</p>	<p>Pamela McColgan 020 7363 8068</p> <p>Lindiwe Mangena 020 7363 8002</p>	<p>Clinical Biochemistry</p> <p>NUH</p>

Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Address Electron Microscopy Laboratory Nanovision Centre Bancroft Building Queen Mary University of London Mile End Road London E1 4NS</p>	<p>Local Contact Matt Miller 020 3246 0185</p> <p>Graham McPhail 020 3246 0218</p>	<p>Production of electron micrograph</p> <p>QMUL</p>
<p>Address Theatre Fridge Level 1, zone 10 Newham University Hospital Glen Road Plaistow London E13 8SL</p>	<p>Local Contact Gareth Heywood-Beldon</p>	<p>Blood Collection Fridge No testing occurs, blood storage only</p> <p>NUH-BF-1</p>



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Location details		Activity	Location code
<p>Address Gateway Surgical Centre 3rd Floor Newham University Hospital Glen Road Plaistow London E13 8SL</p>	<p>Local Contact Gareth Heywood- Beldon</p>	<p>Blood Collection Fridge No testing occurs, blood storage only</p>	<p>NUH-BF- 2</p>
<p>Address A&E Resus Room Level 0 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB</p>	<p>Local Contact Julia Lancut</p>	<p>HemoNine Remote Issue Fridge No testing occurs, blood storage only</p>	<p>RLH-BF- 1</p>
<p>Address Adult Theatres Level 4 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB</p>	<p>Local Contact Julia Lancut</p>	<p>HemoSafe Remote Issue Fridge No testing occurs, blood storage only</p>	<p>RLH-BF- 2</p>
<p>Address CCU Level 4 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB</p>	<p>Local Contact Julia Lancut</p>	<p>HemoSafe Remote Issue Fridge No testing occurs, blood storage only</p>	<p>RLH-BF- 3</p>
<p>Address HDU Level 12 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB</p>	<p>Local Contact Julia Lancut</p>	<p>HemoNine Remote Issue Fridge No testing occurs, blood storage only</p>	<p>RLH-BF- 4</p>



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Location details		Activity	Location code
Address Interventional Radiology Level 1 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	HemoNine Remote Issue Fridge No testing occurs, blood storage only	RLH-BF-5
Address Royal London Hospital Paediatric Theatres Level 6	Local Contact Julia Lancut	HemoSafe Remote Issue Fridge No testing occurs, blood storage only	RLH-BF-6
Address ACAD Theatres Level 3 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	HemoSafe Remote Issue Fridge No testing occurs, blood storage only	RLH-BF-7
Address Renal Department Level 9 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	HemoSafe Remote Issue Fridge No testing occurs, blood storage only	RLH-BF-8
Address KGV Building Level 1E St Bartholomew's Hospital West Smithfield London EC1A 7BE	Local Contact Julia Lancut	HemoSafe Remote Issue Fridge No testing occurs, blood storage only	SBH-BF-01



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Location details		Activity	Location code
Address KGV Building Level 1 Theatres St Bartholomew's Hospital West Smithfield London EC1A 7BE	Local Contact Julia Lancut	HemoNine Remote Issue Fridge No testing occurs, blood storage only	SBH-BF-02
Address KGV Building Level 7A St Bartholomew's Hospital West Smithfield London EC1A 7BE	Local Contact Julia Lancut	HemoSafe Remote Issue Fridge No testing occurs, blood storage only	SBH-BF-03
Address KGV Building Level 5 6A St Bartholomew's Hospital West Smithfield London EC1A 7BE	Local Contact Julia Lancut	HemoNine Remote Issue Fridge No testing occurs, blood storage only	SBH-BF-04
Address A&E Resus Junction 5/6 Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood-Beldon	Blood Collection Fridge No testing occurs, blood storage only	WCUH-BF-1
Address Woodlands Day Unit Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood-Beldon	Blood Collection Fridge No testing occurs, blood storage only	WCUH-BF-2



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Location details		Activity	Location code
Address Maternity Operating Theatres Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood- Beldon	Blood Collection Fridge No testing occurs, blood storage only	WCUH- BF-3
Address Theatres Fridge Junction 7/8 Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood- Beldon	Blood Collection Fridge No testing occurs, blood storage only	WCUH- BF-4



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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	<u>Haematology examination activities for the purposes of clinical diagnosis:</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Venous whole blood: EDTA	<u>Routine Haematology</u> Full Blood Count Haemoglobin Red Cell Count White Cell Count Platelet Count Haematocrit Total White Cell Count Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Mean Cell Haemoglobin (MCH) Mean Cell Volume (MCV) Mean Cell Haemoglobin Concentration (MCHC)	Sysmex XE-2100, multiple cell counting techniques Haem-Haem-Sysmex-002	RLH
Venous whole blood: EDTA	Full Blood Count Haemoglobin Red Cell Count White Cell Count Platelet Count Haematocrit Total White Cell Count Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Mean Cell Haemoglobin (MCH) Mean Cell Volume (MCV) Mean Cell Haemoglobin Concentration (MCHC)	Sysmex XN-2000, multiple cell counting techniques Haem-Haem-Sysmex-026	SBH



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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'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Routine Haematology (cont'd)</u>		
Venous whole blood: EDTA	Erythrocyte Sedimentation Rate	Beckman Coulter Alifax, Aggregation capacity mm/hr Haem_028	NUH
Venous whole blood: EDTA	Erythrocyte Sedimentation Rate	Sysmex Autocompact (stand-alone) Aggregation capacity mm/hr Haem-Haem-ESR-007 Haem-Haem-ESR-008 Haem-Haem-ESR-009	WCUH
Venous whole blood: EDTA	Erythrocyte Sedimentation Rate	StaRRsed InteRRliner Aggregation capacity mm/hr Haem-Haem-Sysmex-002	RLH
Venous whole blood: EDTA	Erythrocyte Sedimentation Rate	Manual method Haem-Haem-Gen-002	RLH WCUH NUH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Venous whole blood: EDTA	<u>Routine Haematology (cont'd)</u> <u>Blood Film</u>	<u>Automated Staining</u> SP1000 fully automated stainer and slide maker. May Grunwald Giemsa stain HAEM-HAEM-SYSMEX-002	RLH
		<u>Automated Staining</u> Wescor Aerospray staining machine Thaizine stain Eosin stain Azure B HAEM_020 HAEM_002	NUH WCUH
		Quick Diff -Manual staining HAEM-HAEM-MORPH-008 HAEM-HAEM-MORPH-025	RLH WCUH NUH
	Examination of Peripheral blood film, detection of normal and abnormal morphologies, white blood cell differential	Blood film examination by light microscopy HAEM-HAEM-MORPH-005 HAEM-HAEM-MORPH-004	RLH WCUH NUH
Venous whole blood: EDTA	Detection and Identification of Malaria Parasites	Manual staining Thin Film Stain:- Giemsa Thick Film Stain:- Field's Stain A, Field's Stain B Thick and thin film microscopy Haem-Haem-Morph-015 Haem-Haem-Morph-028	RLH WCUH NUH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Venous whole blood: EDTA	<u>Routine Haematology (cont'd)</u> Detection and Identification of Malaria Parasites	Binax Now ICT Rapid Diagnostic – immunochromatogenic membrane assay – manual kit Haem-Haem-Morph-015 Haem-Haem-Morph-028	RLH WCUH NUH
Bone Marrow (Aspirate and Trepine)	<u>Special Haematology</u> Bone Marrow examination	Bone marrow film preparation and staining using SP1000 Fully Automated Stainer with May-Grunwald Giemsa stain and examination by light microscopy Haem-Haem-Morph-002 Haem-Haem-Morph-026	RLH
Bone Marrow (Aspirate and Trepine)	Bone Marrow examination Hemosiderin	Manual method Perl's iron stain Haem-Haem-Morph-017	RLH
Urine	Hemosiderin	Manual method Perl's iron stain Haem-Haem-Morph-017	RLH
Venous whole blood: EDTA	Infectious mononucleosis screening for Heterophile Antibodies	Qualitative immunochromatogenic membrane assay Monogen Kit HAEM-HAEM-GEN-003 HAEM-HAEM-EXT-72	RLH WCUH NUH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Venous Plasma: Citrate	<u>Routine Coagulation</u> Routine clotting screen <ul style="list-style-type: none"> • Prothrombin Time [PT] with International Normalised Ratio [INR] • PT 50/50 mix • Activated Partial Thromboplastin Time [APTT] with APTT ratio • APTT 50/50 mix • Clauss Fibrinogen Thrombin Time [TT] with TT ratio 	Sysmex CS2100 Photometric end-point clot detection Haem-Coag-Rout-001 Haem-Coag-Rout-018 Haem-Coag-Rout-024	RLH SBH WCUH
Venous Plasma: Citrate	Routine clotting screen <ul style="list-style-type: none"> • Prothrombin Time [PT] with International Normalised Ratio [INR] • PT 50/50 mix • Activated Partial Thromboplastin Time [APTT] with APTT ratio • APTT 50/50 mix • Clauss Fibrinogen Thrombin Time [TT] with TT ratio 	Sysmex CA1500 Photometric end-point clot detection HAEM-COAG-ROUT-002	NUH
Venous Plasma: Citrate	Routine clotting screen <ul style="list-style-type: none"> • Prothrombin Time with International Normalised Ratio (INR) • Activated Partial Thromboplastin Time [APTT] with APTT ratio 	Amelung KC4 End-point clot detection Haem-Coag-manual-001	RLH SBH



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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'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Routine Coagulation (cont'd)</u>		
Venous Plasma: Citrate	D-dimer	Sysmex CS2100 Latex immunoassay Haem-Coag-Rout-001 Haem-Coag-Rout-018 Haem-Coag-Rout-024	RLH WCUH
Venous Plasma: Citrate	D-dimer	Sysmex CA1500 Latex immunoassay HAEM-COAG-ROUT-002	NUH
	<u>Special Coagulation</u>		
Venous Plasma: Citrate	Factors VIII, IX, XI, XII, II, V, VII and X	Sysmex CS2100 One stage assay using multi dilution analysis Haem-Coag-Haem-001	RLH
Venous Plasma: Citrate	Factor VIII and factor XIII,	Sysmex CS2100 Chromogenic assays Haem-Coag-Haem-001	RLH
Venous Plasma: Citrate	α 2-antiplasmin	Sysmex CS2100 Chromogenic assay Haem-Coag-Haem-001	RLH
Venous Plasma: Citrate		Sysmex CS2100 Haem-Coag-Haem-001 Haem-Coag-Haem-020	RLH
	Von Willebrand factor antigen (vW:Ag)	Latex assay	
	von Willebrand factor activity (vW:RCo)	Platelet agglutination assay	
	von Willebrand factor activity (vW:GplbM)	Latex assay	



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Venous Plasma: Citrate	<u>Special Coagulation (cont'd)</u> Anti-Xa Activity (Heparin) and direct Xa inhibitors Assay <ul style="list-style-type: none"> • Anti-Xa activity assay for apixaban • Anti-Xa activity assay for fondaparinux • Anti-Xa activity assay for low molecular weight heparin • Anti-Xa activity assay for orgaran • Anti-Xa activity assay for rivaroxaban • Anti-Xa activity assay for unfractionated heparin 	Sysmex CS2100 Chromogenic kinetic assay Haem-Coag-Haem-003	RLH
Venous Plasma: Citrate	Prekallikrein assay, high molecular weight Kininogen (HMWK)	Sysmex CS2100 One stage end-point assay Haem-Coag-Haem-001 Haem-coag-ext-116 Haem-coag-ext-115	RLH
Venous Plasma: Citrate	Inhibitor screen and assay <ul style="list-style-type: none"> • For factor VIII inhibitors • For factor IX inhibitors • For factor XI inhibitors • For factor II inhibitors • For factor V inhibitors • For factor VII inhibitors • For factor X inhibitors • For factor XIII inhibitors • For vWF inhibitors 	Sysmex CS2100 End-point clot detection Bethesda assay (Nijmegen modification) Bethesda assay Bethesda-style assay Haem-Coag-Haem-004	RLH
Venous Plasma: Citrate	Inhibitor screen for non-specific inhibitors	Sysmex CS2100 APTT-based screen Haem-Coag-Haem-004	RLH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Special Coagulation (cont'd)</u>		
Venous Plasma: Citrate	Lupus Anticoagulant screen <ul style="list-style-type: none"> Lupus Anticoagulant screen by DRVVT Lupus Anticoagulant screen by dilute APTT 	Sysmex CS2100 dAPTT end point clot detection DRVVT Haem-Coag-Lupus-001	RLH
Venous Plasma: Citrate	Thrombophilia Assays <ul style="list-style-type: none"> Antithrombin activity assay Free Protein S antigen assay Protein C activity assay Plasminogen activity assay 	Sysmex CS2100 Turbidimetric immunoassay End point clot detection Chromogenic assay Latex immunoassay Haem-Coag-Throm-001	RLH
Venous Platelet Rich plasma: citrate	Platelet Function Ristocetin Induced Platelet Aggregation	Helena AggRam Light Absorption Borne aggregometry Haem-Coag-PLTF-001	RLH
Venous Plasma: Citrate	Heparin Induced Thrombocytopenia Screen (IgG/IgM)	Manual method Diamed Particle Gel Immunoassay Haem-Coag-Manual-018	RLH
Venous Plasma: Citrate	Heparin Induced Thrombocytopenia Screen (IgG)	Manual method Lifecodes IgG anti-PF4 ELISA Haem-Coag-Manual-018	RLH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Venous whole blood: EDTA	<u>Red Cell</u> Haemoglobinopathy screen for the detection of: <ul style="list-style-type: none"> • HbF • HbA2 • HbA1c • Hb J • Hb Ao • Hb D-Eran • Hb Lepore • Hb E • Hb G • Hb D • Hb stanelyville II • Hb S • Hb O-arab • Hb C 	Sebia Hydrasys HPLC, capillary electrophoresis BioRad Variant II Beta Thal Dual kit. Haem-Red-HBO-Auto-04 Haem-Red-HBO-Auto-05 Haem-Red-HBO-Auto-06 Haem-Red-HBO-Auto-08	RLH
Venous whole blood: EDTA	Sickle Cell screening	Manual method Relative insolubility Microgen S-Test kit. Haem-Red-HBO-Man-02	RLH SBH WCUH NUH
Venous whole blood: EDTA	Red Cell Folate	Access2 Beckman Coulter Competitive binding paramagnetic particle immunoassay Haem-Red-B12F-003	RLH
Venous Serum: SST	Erythropoietin	Access2 Beckman Coulter Two-site immuno-enzymatic assay with chemiluminescent substrate Haem-Red-B12F-004	RLH
Venous whole blood: EDTA	G6PD Spot test	Manual method Detection of Fluorescence Trinity Biotech G6PD screening kit. Haem-Red-Haemolysis-14	RLH



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Venous whole blood: EDTA</p>	<p><u>Blood Transfusion examination activities for the purposes of clinical diagnosis:</u></p> <p><u>Blood Transfusion</u></p> <p>Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens</p> <p>Antibody screening and identification: Rh blood group antibodies: Anti-Cw, C, c, E, e and D. Kell blood group antibodies: Anti-Kell, k, Kpa and Kpb. Kidd blood group antibodies: Anti-Jka and Jkb. Duffy blood group antibodies: Anti-Fya, and Fyb. Lutheran blood group antibodies: Anti-Lua and Lub. MNS blood group antibodies: Anti-M, N, S and s. Lewis blood group antibodies: Anti-Lea and Leb P blood group antibodies: Anti-P1</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p><u>Manual</u> Bio-Rad Micro column agglutination immunoassay HAEM-BT-Group-014 HAEM-BT-INVGN-002</p>	<p>RLH SBH WCUH</p>



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

Barts Health NHS Trust

Issue No: 003 Issue date: 24 December 2019

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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 (cont'd)</p> <p>Venous whole blood: EDTA</p>	<p><u>Blood Transfusion examination activities for the purposes of clinical diagnosis: (cont'd)</u></p> <p><u>Blood Transfusion (cont'd)</u></p> <p>Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens</p> <p>Antibody screening and identification: Rh blood group antibodies: Anti-Cw, C, c, E, e and D. Kell blood group antibodies: Anti-Kell, k, Kpa and Kpb. Kidd blood group antibodies: Anti-Jka and Jkb. Duffy blood group antibodies: Anti-Fya, and Fyb. Lutheran blood group antibodies: Anti-Lua and Lub. MNS blood group antibodies: Anti-M, N, S and s. Lewis blood group antibodies: Anti-Lea and Leb P blood group antibodies: Anti-P1</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p><u>Automated</u> Immucor NEO Solid phase red cell adherence Haem-BT-Group-022 Haem-BT-Group-023 Haem-BT-Group-021 HAEM-BT-INVGN-002 Haem-BT-Group-013</p>	<p>RLH SBH</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Blood Transfusion (cont'd)</u>		
Venous whole blood: EDTA	Direct Antiglobulin Test	Bio-Rad Micro column agglutination immunoassay Haem-BT-INVGN-003	RLH SBH WCUH
Venous whole blood: EDTA	Elutions	Acid elution followed by Micro column agglutination immunoassay Haem-BT-INVGN-004	RLH
Venous whole blood: EDTA	Red Cell phenotyping for antigens of the following blood group systems: Rh: C, D, E, c, e, and Cw Kell: K, k and Kpa Duffy: Fya and Fyb Kidd: Jka and Jkb MNS: M, N, S and s Lewis: Lea and Leb	Direct agglutination in tube Bio-Rad Micro column agglutination immunoassay Haem-BT-INVGN-014	RLH WCUH SBH
Venous whole blood: EDTA Cord Blood: EDTA	Kleihauer test	Source Biosciences foetal red cell detection kit Acid elution resistance identified by light microscopy Haem-BT-INVGN-016	RLH
Venous whole blood: EDTA	Crossmatch by IAT	Bio-Rad Micro column agglutination immunoassay Haem-BT-XM-001	RLH SBH
Venous whole blood: EDTA	Crossmatch by IAT	Bio-Rad Micro column agglutination immunoassay Haem-BT-XM-030	WCUH



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Venous whole blood: EDTA	<u>Blood Transfusion (cont'd)</u> Crossmatch by IAT	OCD Bio-Vue Micro column agglutination immunoassay Immediate Spin BT_005	NUH
Venous whole blood: EDTA	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens Antibody screening and identification: Rh blood group antibodies: Anti-Cw, C, c, E, e and D. Kell blood group antibodies: Anti-Kell, k, Kpa and Kpb. Kidd blood group antibodies: Anti-Jka and Jkb. Duffy blood group antibodies: Anti-Fya, and Fyb. Lutheran blood group antibodies: Anti-Lua and Lub. MNS blood group antibodies: Anti-M, N, S and s. Lewis blood group antibodies: Anti-Lea and Leb P blood group antibodies: Anti-P1	<u>Automated</u> Immucor Galileo Immucor Echo Solid phase red cell adherence Haem-BT-Group-025 Haem-BT-Group-027 Haem-BT-Group-030 Haem-BT-Group-028 Haem-BT-Group-029	WCUH



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HUMAN BODY FLUIDS (cont'd)	<u>Blood transfusion examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Venous whole blood: EDTA Cord Blood: EDTA	<u>Blood Transfusion (cont'd)</u> Kleihauer test	Guest Medical foetal red cell detection kit Acid elution resistance identified by light microscopy BT007	NUH
Venous whole blood: EDTA	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens Antibody screening and identification: Rh blood group antibodies: Anti-Cw, C, c, E, e and D. Kell blood group antibodies: Anti-Kell, k, Kpa and Kpb. Kidd blood group antibodies: Anti-Jka and Jkb. Duffy blood group antibodies: Anti-Fya, and Fyb. Lutheran blood group antibodies: Anti-Lua and Lub. MNS blood group antibodies: Anti-M, N, S and s. Lewis blood group antibodies: Anti-Lea and Leb P blood group antibodies: Anti-P1	<u>Automated</u> Ortho Clinical Diagnostics Innova Micro column agglutination immunoassay BT_101	NUH



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HUMAN BODY FLUIDS (cont'd)	<u>Blood transfusion examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Venous whole blood: EDTA	<u>Blood Transfusion (cont'd)</u> Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens Antibody screening and identification: Rh blood group antibodies: Anti-Cw, C, c, E, e and D. Kell blood group antibodies: Anti-Kell, k, Kpa and Kpb. Kidd blood group antibodies: Anti-Jka and Jkb. Duffy blood group antibodies: Anti-Fya, and Fyb. Lutheran blood group antibodies: Anti-Lua and Lub. MNS blood group antibodies: Anti-M, N, S and s. Lewis blood group antibodies: Anti-Lea and Leb P blood group antibodies: Anti-P1	OCD Bio-Vue Micro column agglutination immunoassay BT_001	NUH
Venous whole blood: EDTA	Direct Antiglobulin Test	OCD Bio-Vue Micro column agglutination immunoassay BT_101	NUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Serum	<u>Clinical Biochemistry</u> Determination of:	Roche c8000 (c701/702) – Automated Roche photometric Chemistry methods.	
	Alanine Aminotransferase (ALT)	BCHEM-COBAS-702-METHOD-7 Enzymatic Method	RLH SBH
	Albumin	BCHEM-COBAS-702-METHOD-6 Colorimetric BCG	RLH SBH
	Alkaline Phosphatase (ALP)	BCHEM-COBAS-702-METHOD-49 Colorimetric	RLH SBH
	Alpha – 1 Antitrypsin	BCHEM-COBAS-702-METHOD-30 Immunoturbidimetric	RLH
	Amikacin	BCHEM-COBAS-702-METHOD-50 Roche KIMS	RLH
	Ammonia	BCHEM-COBAS-702-METHOD-35 Enzymatic	RLH
	Amylase	BCHEM-COBAS-702-METHOD-16 Enzymatic colorimetric	RLH
	Aspartate Aminotransferase (AST)	BCHEM-COBAS-702-METHOD-15 Enzymatic	RLH SBH
	Bicarbonate	BCHEM-COBAS-702-METHOD-18 Enzymatic	RLH
	C3	BCHEM-COBAS-702-METHOD-51 Immunoturbidimetric	RLH SBH
	C4	BCHEM-COBAS-702-METHOD-52 Immunoturbidimetric	RLH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (cont'd)	<u>Clinical Biochemistry</u> (cont'd)		
	Determination of: (cont'd)	Roche c8000 (c701/702) – Automated Roche photometric Chemistry methods.	
	Caeruloplasmin	BCHEM-COBAS-702-METHOD-32 Immunoturbidimetric	RLH SBH
	Calcium	BCHEM-COBAS-702-METHOD-24 Photometric	RLH
	Carbamazepine	BCHEM-COBAS-702-METHOD-40 Roche KIMS	RLH SBH
	Chloride	BCHEM-COBAS-702-METHOD-23 Indirect ISE	RLH
	Cholesterol	BCHEM-COBAS-702-METHOD-29 Enzymatic colorimetric	RLH
	C-Reactive Protein (CRP)	BCHEM-COBAS-702-METHOD-20 Immunoturbidimetric	RLH SBH
	Creatine Kinase (CK)	BCHEM-COBAS-702-METHOD-19 Enzymatic	RLH SBH
	Creatinine	BCHEM-COBAS-702-METHOD-25 Enzymatic	RLH
	Digoxin	BCHEM-COBAS-702-METHOD-8 Roche KIMS	RLH
	Ethanol	BCHEM-COBAS-702-METHOD-33 Enzymatic	RLH
	Fructosamine	BCHEM-COBAS-702-METHOD-56 Colorimetric	RLH SBH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (cont'd)	<u>Clinical Biochemistry</u> (cont'd)		
	Determination of: (cont'd)	Roche c8000 (c701/702) – Automated Roche photometric Chemistry methods.	
	Gamma-Glutamyltransferase	BCHEM-COBAS-702-METHOD-26 Enzymatic colorimetric	RLH SBH
	Glucose	BCHEM-COBAS-702-METHOD-9 Enzymatic	RLH
	HDL Cholesterol	BCHEM-COBAS-702-METHOD-28 Enzymatic colorimetric	RLH
	Immunoglobulin A	BCHEM-COBAS-702-METHOD-38 Immunoturbidimetric	RLH
	Immunoglobulin G	BCHEM-COBAS-702-METHOD-38 Immunoturbidimetric	RLH
	Immunoglobulin M	BCHEM-COBAS-702-METHOD-38 Immunoturbidimetric	RLH
	Iron	BCHEM-COBAS-702-METHOD-36 Colorimetric	RLH
	Lactate	BCHEM-COBAS-702-METHOD-34 Colorimetric	RLH
	Lactate Dehydrogenase (LDH)	BCHEM-COBAS-702-METHOD-27 Enzymatic	RLH SBH
	Lithium	BCHEM-COBAS-702-METHOD-14 Colorimetric	RLH SBH
	Magnesium	BCHEM-COBAS-702-METHOD-2 Colorimetric using xylidyl blue	RLH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (cont'd)	<u>Clinical Biochemistry</u> (cont'd)		
	Determination of: (cont'd)	Roche c8000 (c701/702) – Automated Roche photometric Chemistry methods.	
	Paracetamol	BCHEM-COBAS-702-METHOD-5 Colorimetric	RLH
	Phenobarbitone	BCHEM-COBAS-702-METHOD-41 Roche KIMS	RLH
	Phenytoin	BCHEM-COBAS-702-METHOD-42 Roche KIMS	RLH SBH
	Phosphate	BCHEM-COBAS-702-METHOD-10 Molybdate UV	RLH
	Potassium	BCHEM-COBAS-702-METHOD-23 Indirect ISE	RLH SBH
	Rheumatoid Factor	BCHEM-COBAS-702-METHOD-48 Immunoturbidimetric	RLH
	Salicylate	BCHEM-COBAS-702-METHOD-11 Enzymatic	RLH
	Sodium	BCHEM-COBAS-702-METHOD-23 Indirect ISE	RLH SBH
	Theophylline	BCHEM-COBAS-702-METHOD-43 Roche KIMS	RLH
	Tobramycin	BCHEM-COBAS-702-METHOD-45 Roche KIMS	RLH
	Total Bilirubin	BCHEM-COBAS-702-METHOD-22 Colorimetric Diazomethod	RLH SBH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (cont'd)	<u>Clinical Biochemistry</u> (cont'd) Determination of: (cont'd)	Roche c8000 (c701/702) – Automated Roche photometric Chemistry methods.	
	Total Protein	BCHEM-COBAS-702-METHOD-12 Colorimetric	RLH SBH
	Transferrin	BCHEM-COBAS-702-METHOD-37 Immunoturbidimetric	RLH
	Triglycerides	BCHEM-COBAS-702-METHOD-1 Enzymatic colorimetric Uricase	RLH
	Urate	BCHEM-COBAS-702-METHOD-13 Enzymatic colorimetric	RLH SBH
	Urea	BCHEM-COBAS-702-METHOD-3 Enzymatic Urase	RLH SBH
	Vancomycin	BCHEM-COBAS-702-METHOD-46 Roche KIMS	RLH
	Valprorate	BCHEM-COBAS-702-METHOD-44 Roche KIMS	RLH
CSF	Determination of:	Roche c8000 (c701/702) – Automated Roche photometric Chemistry methods.	
	Lactate	BCHEM-COBAS-702-METHOD-34 Colorimetric	RLH
	Total protein	BCHEM-COBAS-702-METHOD-61 Turbidimetric method	RLH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Urine	<u>Clinical Biochemistry (cont'd)</u> Determination of:	Roche c8000 (c701/702) – Standard Automated Roche photometry methods	RLH
	Albumin	BCHEM-COBAS-702-METHOD-83 Turbidimetric method	
	Calcium	BCHEM-COBAS-702-METHOD-40 Photometric	
	Creatinine	BCHEM-COBAS-702-METHOD-59 Colorimetric assay Jaffé method	
	Magnesium	BCHEM-COBAS-702-METHOD-2 Colorimetric using xylidyl blue	
	Phosphate	BCHEM-COBAS-702-METHOD-10 Molybdate UV	
	Potassium	BCHEM-COBAS-702-METHOD-23 Indirect ISE	
	Protein	BCHEM-COBAS-702-METHOD-61 Turbidimetric method	
	Sodium	BCHEM-COBAS-702-METHOD-23 Indirect ISE	
Serum	Angiotensin Converting Enzyme (ACE)	Roche c8000 (c701/702) – Using Trinity Biotech-Kinetic rate method BCHEM-COBAS-702-METHOD-60	RLH
Serum	Total Bile Acids	Roche c8000 (c701/702) –using Dialab enzymatic rate method BCHEM-COBAS-702-METHOD-47	RLH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Data	<u>Clinical Biochemistry (cont'd)</u>		
	Calculation of:	<u>Calculated Tests</u>	
	Corrected Calcium	Adj calcium = Total Ca + 0.02(40-Alb)	
	TIBC	BCHEM-COBAS-702-METHOD-40 Transferrin x 0.0251	
	Corrected Phenytoin	Measured phenytoin/ 1-α(P1/P)+ α BCHEM-COBAS-702-Method-42	
	Macro Prolactin	%Recovery = ((Monomeric prolactin)/Total PRL) X100 BCHEM-E-UNIT-METHOD-SOP25	
Serum Urine	Osmolality	Advanced Micro-Osmometer Freezing point depression BCHEM-P-METHOD-SOP62	RLH NUH WCUH SBH
Serum	Measurement of:	Roche c602/E170- Standard Automated Roche ECL Immunoassay methods	RLH
	Adrenocorticotrophic Hormone (ACTH)	BCHEM-E-UNIT-METHOD-SOP30 Sandwich Assay	
	Alpha Feto Protein (AFP)	BCHEM-E-UNIT-METHOD-SOP3 Sandwich Assay	
	BNP (NT-Pro)	BCHEM-E-UNIT-METHOD-SOP33 Sandwich Assay	
	CA125	BCHEM-E-UNIT-MET HOD-SOP4 Sandwich Assay	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (cont'd)	<u>Clinical Biochemistry</u> (cont'd) Measurement of: (cont'd)	Roche c602/E170- Standard Automated Roche ECL Immunoassay methods	RLH
	CA15-3	BCHEM-E-UNIT-METHOD-SOP2 Sandwich Assay	
	CA19-9	BCHEM-E-UNIT-METHOD-SOP5 Sandwich Assay	
	Calcitonin	BCHEM-E-UNIT-METHOD-SOP37 Sandwich Assay	
	Carcinoembryonic Antigen (CEA)	BCHEM-E-UNIT-METHOD-SOP29 Sandwich Assay	
	Cortisol	BCHEM-E-UNIT-METHOD-SOP7 Competitive Assay	
	C-Peptide	BCHEM-E-UNIT-METHOD-SOP35 Sandwich Assay	
	Ferritin	BCHEM-E-UNIT-METHOD-SOP9 Sandwich Assay	
	Follicle Stimulating Hormone (FSH)	BCHEM-E-UNIT-METHOD-SOP10 Sandwich Assay	
	FT4	BCHEM-E-UNIT-METHOD-SOP11 Competitive Assay	
	Growth Hormone	BCHEM-E-UNIT-METHOD-SOP32 Sandwich Assay	
	Human Chorionic Gonadotrophin (HCG)	BCHEM-E-UNIT-METHOD-SOP12 Sandwich Assay	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (cont'd)	<u>Clinical Biochemistry</u> (cont'd)		RLH
	Measurement of: (cont'd)	Roche c602/E170- Standard Automated Roche ECL Immunoassay methods	
	Insulin	BCHEM-E-UNIT-METHOD-SOP34 Sandwich Assay	
	Lutenizing Hormone (LH)	BCHEM-E-UNIT-METHOD-SOP13 Sandwich Assay	
	Parathyroid Hormone (PTH)	BCHEM-E-UNIT-METHOD-SOP22 Sandwich Assay	
	Oestradiol	BCHEM-E-UNIT-METHOD-SOP8 Competitive Assay	
	Progesterone	BCHEM-E-UNIT-METHOD-SOP15 Competitive Assay	
	Prolactin	BCHEM-E-UNIT-METHOD-SOP14 Sandwich Assay	
	Prostate Specific Antigen (PSA)	BCHEM-E-UNIT-METHOD-SOP16 Sandwich Assay	
	Folate	BCHEM-E-UNIT-METHOD-SOP28 Competitive Assay	
	Sex Hormone Binding Globulin (SHBG)	BCHEM-E-UNIT-METHOD-SOP31 Sandwich Assay	
	Testosterone	BCHEM-E-UNIT-METHOD-SOP18 Competitive Assay	
	Thyroglobulin	BCHEM-E-UNIT-METHOD-SOP38 Sandwich Assay	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (cont'd)	<u>Clinical Biochemistry</u> (cont'd) Measurement of: (cont'd)	Roche c602/E170- Standard Automated Roche ECL Immunoassay methods	RLH
	Thyroid Stimulating Hormone (TSH)	BCHEM-E-UNIT-METHOD-SOP20 Sandwich Assay	
	Troponin T	BCHEM-COBAS-601-METHOD-19 Sandwich Assay	
	Free T3	BCHEM-E-UNIT-METHOD-SOP36 Competitive Assay	
	Vitamin B12	BCHEM-COBAS-601-METHOD-2 Competitive Assay	
	Vitamin D	BCHEM-COBAS-601-METHOD-1 Competitive Assay	
	<u>Proteins</u>		
Serum	Detection of: Beta 2 Microglobulin	Sebia Spa plus immunoturbimetry	RLH
CSF	IgG	BCHEM-PROT-METHOD-SOP32	
	Detection of:	BCHEM-PROT-METHOD-SOP29	
Serum	Paraprotein	Sebia Capillarys Electrophoretic system	RLH
	Paraprotein	Electrophoresis BCHEM-PROT-METHOD-SOP26	
	Paraprotein	Immunotyping BCHEM-PROT-METHOD-SOP27	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Proteins (cont'd)</u>		
Serum	Paraprotein	Immunofixation Sebia Hydrasys system BCHEM-PROT-METHOD-SOP10	RLH
Serum	Cystine/Homocystine Screen	In house qualitative method using Sodium nitroprusside (nitroferricyanide) solution BCHEM-PROT-METHOD-SOP33	RLH
Serum	Determination of: Aldosterone	Diasorin Liason competitive assay using sheep monoclonal antibody BCHEM-LIASON-METHOD-SOP3	RLH
	Insulin Growth Factor-1 (IGF-1)	BCHEM-LIASON-METHOD-SOP4	
Sweat	Chloride	M926S Digital Sweat Chloride meter- titrimetric method BCHEM-PROT-METHOD-SOP11	RLH
	<u>LCMS</u>		
Serum	Determination of:	Waters Acquity UPLC-Quattro Premier XE liquid chromatography-tandem mass spectrometry (LCMS/MS)	RLH
	Androstenedione (A4)	BCHEM-LCMS-METHOD-SOP8	
	Dihydroepiandrosterone Sulphate (DHEAS)	BCHEM-LCMS-METHOD-SOP8	
	Extracted Testosterone (LCMS)	BCHEM-LCMS-METHOD-SOP8	
	11-Deoxycortisol	BCHEM-LCMS-METHOD-SOP8	



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum (cont'd)	<u>LCMS (cont'd)</u> Determination of: (cont'd)	Waters Acquity UPLC-Quattro Premier XE liquid chromatography-tandem mass spectrometry (LCMS/MS)	RLH
	17-Hydroxyprogesterone	BCHEM-LCMS-METHOD-SOP8	
	Dihydrotestosterone (DHT)	BCHEM-LCMS-METHOD-SOP9	
	25OH-Vitamin D	BCHEM-LCMS-METHOD-SOP4	
Whole Blood	Determination of:	Waters Acquity UPLC-Quattro Premier XE liquid chromatography-tandem mass spectrometry (LCMS/MS)	RLH
	Cyclosporin A Tacrolimus Sirolimus	BCHEM-LCMS-METHOD-SOP2	
Urine	Drugs of Abuse	CEDIA Drugs of Abuse assay on the Thermo Scientific Indiko Plus Clinical Chemistry analyser BCHEM-INDIKO-5	RLH
	Amphetamine Barbiturate Benzodiazepines Buprenorphine Cocaine EDDP (Methadone metabolite) Opiates THC (Cannabinoids) 6MAM (heroin metabolite)		



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum	HPLC Measurement of: Copper Selenium Zinc	AAS on the •AAlyst 800 Atomic Absorption Spectrophotometer BCHEM-AAS-METHOD-SOP7 BCHEM-AAS-METHOD-SOP8 BCHEM-HPLC-METHOD-SOP6	RLH
Serum	Measurement of: Vitamin A Vitamin E	Dionex Ultimate 3000 HPLC-using Chromsystems Vitamins A & E kit. BCHEM-HPLC-METHOD-SOP9	RLH
Urine	Measurement of: 5HIAA Metanephrines Screen for: Metaadrenaline Normetadrenaline 3-methoxytyramine	Dionex Ultimate 3000 HPLC System Using 150 mm Allsphere ODS column BCHEM-HPLC-METHOD-SOP1 Using Chromsystems Urine Metadrenalines Kit BCHEM-HPLC-METHOD-SOP4	RLH



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HUMAN BODY FLUIDS AND TISSUES	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis	RLH
Urine Wound swabs Genital swabs Throat swabs Oral swabs Skin swabs Eye swabs Ear swabs Nose swabs	<u>Bacteriology</u> Isolation and characterisation of micro-organisms of clinical significance	Automated inoculation of plates using: Culture media BioMérieux Previ-Isola MICR.E.SOP022	RLH
Urine Wound swabs Genital swabs Throat swabs Oral swabs Skin swabs Eye swabs Ear swabs Nose swabs Tissue Dialysis fluid Ascitic Fluid Pleural fluid Other Body fluids CSF Tips Sputa Brochoalveolar lavage Faeces	Isolation and characterisation of micro-organisms of clinical significance	Manual inoculation of plates Culture media MICR.B.SOP014 MICR.B.SOP013 MICR.B.SOP007 MICR.B.SOP008 MICR.B.SOP015 MICR.B.SOP016 MICR.B.SOP001 MICR.B.SOP043 MICR.B.SOP017 MICR.B.SOP021 MICR.B.SOP003 MICR.B.SOP029	RLH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Rectal Swabs Wound swabs Throat swabs Skin swabs Nose swabs	<u>Bacteriology (cont'd)</u> Antibiotic resistance screening: CRE MRSA MSSA VRE Ciprofloxacin	Culture, identification and susceptibility testing as described above. Culture media. Oxoid PBP2a Bioconnections OXA-48 and KPC lateral flow device MICR.B.SOP009 MICR.B.SOP001	RLH
Inoculated plates for <i>Neisseria gonorrhoea</i>	Isolation of <i>Neisseria gonorrhoea</i>	MICR.B.SOP016	RLH
Blood	Isolation and characterisation of micro-organisms of clinical significance	Automated culture BioMérieux BacTAlert Media BioMérieux Blood cultures MICR.B.SOP012	RLH
Faeces Rectal swab	Culture and identification of: Salmonella Shigella Campylobacter E coli 0157 Vibrio Yersinia VRE	Manual culture using culture media and identification using manual biochemical tests MICR.B.SOP010	RLH
Bacterial and yeast isolates cultured in-house	Identification of microorganisms of clinical significance	Bruker Maldi-ToF BioMérieux Vitek Matrix Assisted Laser Desorption/Ionization MICR.E.SOP015 MICR.E.SOP023	RLH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Bacterial Isolates cultured in-house	<u>Bacteriology (cont'd)</u> Sensitivity testing	Automated: Siemens MicroScan WalkAway for Sensitivity testing (MIC) by broth dilution method MICR.E.SOP012 Manual: BSAC sensitivity testing using Oxoid and Mast antibiotic discs and Oxoid, BioMérieux and Liofilchem MIC strips MICR.B.SOP003	RLH RLH
Tissue Dialysis fluid Ascitic Fluid Pleural fluid Other Body fluids CSF	White and red cell count, white cell differentiation and microscopic detection of bacteria and fungi.	Gram stain and differential stain by Romanowsky method examined with bright field using Nikon microscope Cell count by phase contrast using LEICA microscope MICR.M.SOP006 MICR.B.SOP014	RLH
Urine	Detection, identification and quantification of red blood cells, white cells and epithelial cells of clinical significance in urine	Automated: Urine microscopy and particle recognition by BioMérieux UF1000i Flow cytometer. Manual: Phase contrast microscopy using Olympus microscope MICR.B.SOP004	RLH RLH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Urine	<u>Bacteriology (cont'd)</u> Pneumococcal Antigen	TRU Pneumococcal kit Rapid immuno-chromatographic assay MICR.B.SOP019	RLH
Urine	Legionella Antigen	TRU Legionella kit Rapid immuno-chromatographic assay MICR.B.SOP019	RLH
Sputa Brochoalveolar lavage Tissue Dialysis fluid Ascitic fluid Pleural fluid Other Body fluids CSF Cystic Fibrosis Sputa	Isolation and detection of Mycobacteria	<u>Automated culture</u> BioMérieux BactAlert machine and BioMérieux liquid culture bottles MICR.B.SOP006 <u>Manual culture</u> E&O solid media slopes MICR.B.SOP006	RLH
Sputa Brochoalveolar lavage Tissue Dialysis fluid Ascitic Fluid Pleural fluid Other Body fluids CSF Cystic Fibrosis Sputa	Detection of Mycobacteria	ZEISS UV microscope is used to examine Auramine slides LEICA bright field microscope is used to examine Ziel-Neelsen slides Slides are stained manually MICR.B.SOP006	RLH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
	<u>Parasitology</u>		
Faeces	Detection of cryptosporidium	LEICA light microscope is used to examine Cold Ziel Neelsen slides ZEISS UV microscope is used to examine Auramine slides that are stained manually MICR.M.SOP006 MICR.B.SOP011	RLH
Faeces	Detection of ova, cysts and parasites	Parasep and the LEICA light microscope is used for the concentration method MICR.M.SOP006 MICR.B.SOP011	RLH
	<u>Clostridium Toxin Testing</u>		
Faeces	Detection of <i>Clostridium difficile</i> toxin	Prolab GDH EIA test kit using Launch Best DS2 MICR.B.SOP038	RLH
Faeces	Detection of <i>Clostridium difficile</i> toxin and GDH	Quick ChekComplete lateral flow device MICR.B.SOP039	RLH
Faeces	Detection of <i>Clostridium difficile</i> toxin genes	LAMP by Meridian illuminopro-10 using the Meridian kit MICR.B.SOP042	RLH
	<u>Helicobacter Testing</u>		
Faeces	Helicobacter Antigen	Amplified IDEIA Hp StAR test kit using Launch Best DS2 MICR.B.SOP030	RLH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Skin Nail Hair Respiratory sample Bodily Fluids Tissue samples	<u>Mycology</u> Isolation and identification of fungal pathogens	Calcofluor White and ZEISS UV microscope Culture media Lactophenol blue for identification LEITZ microscope MICR.B.SOP020	RLH
Bacterial or yeast isolates Sterile fluids Sterile tissues Bacterial/fungal Isolates Paediatric plasma Blood culture	<u>Molecular Microbiology</u> Extraction of DNA for the molecular detection of bacteria or yeast	Automated extraction of DNA. QIASymphony extraction and the QiAgility VIRO.E.EOP0049 MICR.MOL.SOP017	RLH
DNA extracted in-house	Detection of 16S and 18S ribosomal DNA	PCR for product amplification Bio-rad thermocycler and Gel electrophoresis using the Bio-rad Gel tank MICR.EXT007 MICR.MOL.SOP018 Analysis of DNA sequence data generated externally	RLH
DNA sequence data			
DNA extracted in-house	Detection of femB and mecA DNA.	PCR for product amplification Bio-rad thermocycler and Gel electrophoresis using the Bio-rad Gel tank MICR.MOL.SOP017	RLH



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Blood. Serum (and EDTA)</p>	<p><u>Virology examination activities for the purposes of clinical diagnosis</u></p> <p><u>Virology</u></p> <p><u>Infectious Diseases</u></p> <p><u>Serology</u></p> <p>Detection of:</p> <p>Hepatitis A Virus IgG antibody Hepatitis A Virus IgM antibody Hepatitis B Virus surface antigen Hepatitis B Virus surface antigen quantitation Hepatitis B Virus surface antigen confirmation by neutralisation Hepatitis B Virus core total antibody Hepatitis B Virus surface antibody Hepatitis B Virus e antibody Hepatitis B Virus e antigen Hepatitis B Virus core IgM antibody Hepatitis C IgG antibody Human Immunodeficiency Virus 1/2 antibody/antigen Human T-Lymphotropic Virus 1/2 antibody Rubella Virus IgG antibody Rubella Virus IgM antibody Epstein Barr Virus EBNA IgG antibody Epstein Barr Virus VCA IgG antibody</p>	<p>Documented Procedures as indicated. (based on manufacturer instructions and/ or validated in-house developed assays)</p> <p>ARCHITECT i2000SR analyser Abbott Diagnostics Chemiluminiscent Microparticle Immunoassay Standard kits for this analyser VIRO.B.SER0141</p>	<p>RLH</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated. (based on manufacturer instructions and/ or validated in-house developed assays)	RLH
Blood. Serum (and EDTA)	<u>Infectious Diseases Serology (cont'd)</u> Detection of: Epstein Barr Virus VCA IgM antibody Cytomegalovirus IgM antibody Cytomegalovirus IgG antibody Avidity Treponema pallidum (Syphilis) total antibody Toxoplasma IgG antibody Toxoplasma IgM antibody	ARCHITECT i2000SR analyser Abbott Diagnostics Chemiluminiscent Microparticle Immunoassay Standard kits for this analyser VIRO.B.SER0141	RLH
Blood. Serum (and EDTA)	Detection of: Hepatitis B Virus core total antibody (confirmation of screening assay) Measles Virus IgG antibody Measles Virus IgM antibody Mumps Virus IgG antibody Mumps Virus IgG antibody Varicella Zoster IgG antibody Parvovirus B19 IgG antibody Parvovirus B19 IgM antibody	LIAISON® analyser – DiaSorin Immuno Chemiluminescence Immunoassay Standard kits for this analyser VIRO.B.SER0154	RLH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated. (based on manufacturer instructions and/ or validated in-house developed assays)	RLH
Blood. Serum (and EDTA)	<u>Infectious Diseases Serology (cont'd)</u> Detection of: Human Immunodeficiency Virus 1/2 antibody/antigen Human Immunodeficiency Virus p24 antigen	VIDAS analyser- Biomerieux Combination of a two-step enzyme immunoassay sandwich method with a final fluorescent detection. Standard kits for this analyser VIRO.B.SER0152	RLH
Blood. Serum (and EDTA)	Detection of: HDV antibodies	<u>Manual assays</u> ETI-AB-DELTAK-2 Anti-HDV EIA (from DiaSorin) VIRO.B.SER0145	RLH
Blood. Serum (and EDTA)	HEV IgM antibodies	HEV IgM ELISA (from Fortress Diagnostics) VIRO.B.SER0155	
Blood. Serum (and EDTA)	HSV1 and HSV2 antibodies by immunoblot	HerpeSelect® 1 and 2 Immunoblot IgG (from Focus Diagnostics /Sterilab) VIRO.B.SER0143	
Blood. Serum (and EDTA)	RPR test (non-treponemal test for the rapid detection of syphilis)	RPR REDITEST (from Biokit/ Werfen). VIRO.B.SER0130	
Blood. Serum (and EDTA)	Antibodies to Treponema Pallidum TPPA	SERODIA®-TP-PA (from Fujirebio) VIRO.B.SER0130	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated. (based on manufacturer instructions and/ or validated in-house developed assays)	RLH
Blood. EDTA (and Serum)	<u>Molecular</u> Quantification of Blood borne viruses: Hepatitis B Virus DNA Hepatitis C Virus RNA Human Immunodeficiency Virus Type 1 RNA	<u>Automated</u> COBAS® AmpliPrep/COBAS® TaqMan® - Roche Molecular Diagnostics. Quantitative PCR Standard kits for this analyser. VIRO.B.MOL0052	RLH
CSF	Human Immunodeficiency Virus Type 1 RNA	COBAS® AmpliPrep/COBAS® TaqMan® - Roche Molecular Diagnostics. Quantitative PCR Standard kits for this analyser. VIRO.B.MOL0052	RLH
Biopsy tissue (wet), blood (plasma, serum), human body fluids and cellular material (including those collected with a swab suitable for viral sampling)	<u>Molecular</u>	<u>In-House Based Assays</u> <u>Purification of nucleic acid material</u> QIASymphony SP/AS instruments - QIAGEN Ltd. QIASymphony Virus/Bacteria mini kit VIRO.B.MOL0069	RLH
CSF, Biopsy tissue (wet), blood (whole blood, plasma, serum), human body fluids and cellular material (including those collected with a swab suitable for viral sampling)		<u>Purification of nucleic acid material</u> Qiagen BioRobot™ EZ1 and EZ1 Advanced XL - QIAGEN Ltd. EZ1 virus mini kit, EZ1 DNA blood 350µl kit, EZ1 DNA tissue kit VIRO.B.MOL0065	RLH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated. (based on manufacturer instructions and/ or validated in-house developed assays)	RLH
	<u>Molecular (cont'd)</u>	<u>In-House Based Assays</u>	
	Detection and/or quantification of Virus:	Rotor gene- QIAGEN Ltd QIAgen Quantitect Multiplex PCR kit QIAgen Quantitect Multiplex RT-PCR kit	RLH
Biopsy tissue (wet), blood (plasma, serum), human body fluids and cellular material (including those collected with a swab suitable for viral sampling)	Quantitative detection of Human Cytomegalovirus DNA	VIRO.B.MOL0057	
Biopsy tissue (wet), blood (plasma, serum), human body fluids and cellular material (including those collected with a swab suitable for viral sampling)	Quantitative detection of Epstein Barr Virus DNA	VIRO.B.MOL0064	
EDTA plasma	Quantitative detection of Human Immunodeficiency Virus Type 2 RNA	VIRO.B.MOL0067	
Respiratory samples, blood and urine	Detection of Measles Virus RNA	VIRO.B.MOL0090	
EDTA plasma and urine	Quantification of BK virus DNA	VIRO.B.MOL0093	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated. (based on manufacturer instructions and/ or validated in-house developed assays)	RLH
Biopsy tissue (wet), blood (plasma, serum), human body fluids and cellular material (including those collected with a swab suitable for viral sampling)	<u>Molecular (cont'd)</u> Detection of Human Herpes Viruses: Herpes Simplex Virus Type 1 DNA Herpes Simplex Virus Type 2 DNA Varicella Zoster Virus DNA	<u>In-House Based Assays</u> Rotor gene- QIAGEN Ltd QIAgen Quantitect Multiplex PCR kit VIRO.B.MOL0051	RHL
Respiratory	Detection of respiratory viruses: Adenovirus DNA Enterovirus RNA Influenza A Virus RNA Influenza B Virus RNA Respiratory Syncytial Virus RNA Parainfluenza 1 Virus RNA Parainfluenza 2 Virus RNA Parainfluenza 3 Virus RNA Rhinovirus RNA Human Metapneumovirus RNA Molecular typing of Influenza A Virus Human Betacoronavirus 2c (MERS) RNA	Rotor gene- QIAGEN Ltd QIAgen Quantitect Multiplex PCR kit QIAgen Quantitect Multiplex RT-PCR kit VIRO.B.MOL0054 VIRO.B.MOL0089 VIRO.B.MOL0089	RHL



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated. (based on manufacturer instructions and/ or validated in-house developed assays)	RLH
Stool	<u>Molecular (cont'd)</u> Detection of gastrointestinal viruses: Adenovirus DNA Enterovirus RNA Sapovirus RNA Astrovirus RNA Norovirus GI RNA Norovirus GII RNA	<u>In-House Based Assays</u> Rotor gene- QIAGEN Ltd QIAgen Quantitect Multiplex PCR kit QIAgen Quantitect Multiplex RT-PCR kit VIRO.B.MOL0088	RLH
CSF	Detection of viral infection in cerebrospinal fluid: Enterovirus RNA Herpes Simplex Virus Type 1 DNA Herpes Simplex Virus Type 2 DNA Varicella Zoster Virus DNA Parechovirus RNA	Rotor gene- QIAGEN Ltd QIAgen Quantitect Multiplex PCR kit QIAgen Quantitect Multiplex RT-PCR kit VIRO.B.MOL0063	RHL



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Virology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated. (based on manufacturer instructions and/ or validated in-house developed assays)	RLH
Blood (serum/plasma)	<u>Molecular (cont'd)</u> Detection of Viruses Detection of Human Immunodeficiency Virus Type 1 proviral DNA	<u>In-House Based Assays</u> Veriti® Thermal Cycler - Applied Biosystems QIAgen Quantitect Multiplex PCR kit VIRO.B.MOL0078 HIV-1 Proviral DNA PCR	RLH
Blood (serum/plasma)	Viral sequencing Human Immunodeficiency Virus Type 1 genotypic resistance testing including: Protease-Rverse Transcriptase sequencing Integrase sequencing and Envelope V3 loop (receptor tropism) sequencing Hepatitis B Virus genotypic Hepatitis C Virus genotyping	3730xl DNA Analyzer- Applied Biosystems QIAgen Onestep RT-PCR kit ABI BigDye® Terminator v1.1 Cycle Sequencing kit VIRO.B.MOL0053 VIRO.B.MOL0079 VIRO.B.MOL0061	RLH



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Fixed and fresh excisional and incisional biopsies and surgical resection specimens	<u>Histopathology</u> Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	<u>Specimen dissection, tissue processing, embedding, sectioning and automated staining-cover slipping</u> Specimen Dissection CP-HIST-SR-CU11 CP-HIST-SR-CU9 CP-HIST-SR-DECAL1 Tissue processors Using Leica ASP300, and Sakura VIP6 tissue processors; Sakura Tissue Tek V embedding consoles, Paratrimmers, Leica Slide writer, Microtomy Leica microtomes, Leica ST4040 Linear staining machine, Leica CV5030 coverslipper, Sakura SCA coverslipper	RLH
Formalin fixed paraffin embedded (FFPE), fresh and frozen tissue			
Tissue: biopsy, excision, resection and post-mortem specimens Specialties include Ear, Nose and Throat Oral Pathology Skin Breast Gynaecological Renal Gastro-intestinal Endocrine Paediatric Lymphopoietic Urology		CP-HIST-TECH-AUTO1 CP-HIST-TECH-AUTO35 CP-HIST-TECH-AUTO3 CP-HIST-TECH-AUTO17 CP-HIST-TECH-AUTO15 CP-HIST-TECH-CUT1-16 CP-HIST-TECH-AUTO4 CP-HIST-TECH-AUTO5 CP-HIST-TECH-AUTO9 CP-HIST-TECH-AUTO8 CP-HIST-TECH-STAIN33	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Formalin fixed paraffin embedded (FFPE), fresh and frozen tissue	Routine morphological staining for the detection of basophilic and eosinophilic structures	H&E staining, automated methods using Leica ST4040 Linear staining machine Manual staining method Sakura SCA coverslipper CP-HIST-TECH-STAIN9 CP-HIST-TECH-FS3 CP-HIST-TECH-SORT7 CP-HIST-TECH-SORT4	
Frozen tissue	Intraoperative frozen sections	Brights Cryostat Thermoshandon Cryotome CP-HIST-TECH-FS1-9, 20-14	RLH SBH
FFPE slides	Special stains for the detection of: Hemosiderin Amyloid TB Acid Fast Bacteria Haematopoietic cells Connective tissues Fungi & Pneumocystis jiroveci (carinii) Reticulin fibres Glomerular Basement membrane Spirochetes	Automated Staining Staining of special stains on the Artisan Automated stainer CP-HIST-TECH-AUTO2 CP-HIST-TECH-AUTO29 Iron stain (AR158) Congo Red (AR161) Acid Fast Bacteria (AR161) Giemsa (AR164) Masson's Trichrome (AR173) Groccott (AR176) Reticulin (AR179) Jones Basement Membrane (AR180) Warthin Starry (AR181)	RLH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
FFPE slides	Special stains for the detection of:	Automated Staining Staining of special stains using the Leica XL Automated staining Machine CP-HIST-TECH-SORT5 CP-HIST-TECH-STAIN34 CP-HIST-TECH-STAIN31 Alcian Blue Alcian Blue Periodic Schiffs Periodic Acid Shiffs Cresyl Violet Acetate (CFV)	RLH
FFPE slides	Special stains for the detection of:	Hand Staining	RLH
	Acid mucins	Alcian Blue	
	Acid & Neutral mucins	(CP-HIST-TECH-STAIN2) Alcian Blue- PAS	
	Carbohydrates	(CP-HIST-TECH-STAIN3) Congo Red	
	Helicobacter pylori	(CP-HIST-TECH-STAIN4) Cresyl Violet Acetate (CFV)	
		(CP-HIST-TECH-STAIN5)	
	Elastic fibres & connective tissue	Miller's Elastic Van Geison (EVG)	
	Bile pigment	(CP-HIST-TECH-STAIN5) Fouchet	
		(CP-HIST-TECH-STAIN7)	
	Haematopoietic cells	Giemsa	
		(CP-HIST-TECH-STAIN8)	
	Gram positive and negative bacteria	Gram	
	Fungi & Pneumocystis jiroveci (carinii)	(CP-HIST-TECH-STAIN10) Grocott	
	Basement membranes	(CP-HIST-TECH-STAIN11) Hexamine silver	
	Melanin	(CP-HIST-TECH-STAIN12) HVG	
	Connective Tissue	(CP-HIST-TECH-STAIN13)	
	Melanin	Masson Fontana (CP-HIST-TECH-STAIN14)	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
FFPE slides	Special stains for the detection of: (cont'd) Connective tissue	Hand Staining (cont'd)	RLH
	Removal of melanin pigment	Masson Trichrome (CP-HIST-TECH-STAIN15)	
	Fibrin	Melanin Bleach (CP-HIST-TECH-STAIN16)	
	Hepatitis B surface antigen and copper associated protein	MSB (CP-HIST-TECH-STAIN17)	
	Lipids	Orcein (CP-HIST-TECH-STAIN18)	
Frozen tissue		Oil-Red-O (CP-HIST-TECH-STAIN19)	
FFPE slides	Polysaccharides including glycogen	PAS (CP-HIST-TECH-STAIN10)	
	Glycogen	DPAS (CP-HIST-TECH-STAIN21)	
	Hemosiderin	Perls (CP-HIST-TECH-STAIN22)	
	Fibrin connective tissue	Reticulin, Gordon and Sweets (CP-HIST-TECH-STAIN23)	
	Copper	Rhodanine (CP-HIST-TECH-STAIN24)	
	Calcium salts	von Kossa (CP-HIST-TECH-STAIN27)	
	Mycobacterium leprae	Wade Fite (CP-HIST-TECH-STAIN28)	
	Spirochetes	Warthin & Starry (CP-HIST-TECH-STAIN29)	
	<i>Mycobacterium spp including tuberculosis</i>	Ziehl Neelsen (CP-HIST-TECH-STAIN30)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
FFPE slides	<u>Immunohistochemistry</u> Detection of: Intestinal epithelial Gastrointestinal epithelia Glandular, transitional epithelial RS cells N killer (NK) cells, NK like T-cells, neural cell adhesion molecule Intermediate filament Adhesion molecule predominantly in epithelial tissue Melanosomes Proliferation marker Melanocytes	Automated Immuno-staining using the BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9 using antibodies: Cdx-2 (Epr2764y) Pab, Cell Marque Roche 5463491001 Confirm Cytokeratin 20 Rabbit Monoclonal Roche 5587760001 Confirm Cytokeratin 7 Rabbit Monoclonal Roche 5986818001 Anti-Cd30 (Ber-H2) Roche 7007841001 Confirm Anti-Cd56 (123c3) Mab Roche 86017496 Intermediate filament Confirm Anti-Desmin (De-R-11) Pab Roche 5267005001 Ventana Anti-E Cadherin (36) Roche 5905290001 Confirm Anti-Melanosome (Hmb45) Mouse Monoclonal Roche 5479282001 Confirm Anti-Ki-67 (30-9) Rabbit Monoclonal Roche 5278384001 Confirm Mart-1/Melan A (A103) Primary Antibody Roche 5278350001	RLH



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
FFPE slides (cont'd)	<u>Immunohistochemistry (cont'd)</u> Detection of: (cont'd) Mismatch repair (MMR) protein MSH6 Germinal centre cells Mismatch repair protein Cervical Ca Tumour suppressor gene Programmed death-1 molecule Progesterone receptor Protein involved in the mismatch repair pathway) Intronless gene which encodes a member of the SOX family of transcription factors Melanoma, neuroendocrine Simian virus 40	Automated Immuno-staining using the BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9 using antibodies: Confirm Anti-Msh6 (44) Mouse Mono Roche 5929911001 Mlh-1 (M1) Pab Roche 6472966001 Cell Marque, Msh-2 Roche 5269270001 Cintec P16 Histology (250) Ce Roche 86017496 Confirm Anti-P53 (Do-7) Primary Antibody Roche 5278775001 Pd-1 (Nat105) Pab, Cell Marque Roche 7099029001 Pr Confirm Anti-Or (1e2) Roche 5277990001 Pms2 (Epr3947) Roche 6419216001 Sox 11 Nexes Reagent, Cell Marque, Sox 11 Roche 7047738001 S100 Confirm Anti-S100 (4c4.9) Primary Antibody Roche 5278104001 Sv-40 (Mrq-4) Pab, Cell Marque Roche 5973775001	RLH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
FFPE slides (cont'd)	<u>Immunohistochemistry (cont'd)</u> Detection of: (cont'd) Thyroid transcription factor-1 Wilms tumour gene product	Automated Immuno-staining using the BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9 using antibodies: Ttf-1 (Sp141) Pab Roche 6640613001 Wt1 96f-H2) Pab, Cell Marque Roche 5435706001	RLH
Formalin fixed tissue	Over expression of the Her2 protein (NEU) in breast cancer specimens. <u>HER2-DDISH</u>	PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONO (CN:86017496) 5278368001antibody CP-HIST-IMMUNO-BREAST 3(2) CP-HIST-IMMUNO-BREAST 4(3)	RLH
Formalin fixed tissue (cont)	Assessment of Chr17/Her2 ratio in Her2 borderline cases (2+) by DDISH to determine patients to receive the drug Herceptin.	BenchMark ULTRA Automated IHC/ISH slide staining system INFORM HER2 DUAL ISH DNA PROBE CKTL 5899826001 CP-HIST-IMMUNO-AUTO9 CP-HIST-IMMUNO-BREAST11(1) CP-HIST-IMMUNO-BREAST -10(2) CP-HIST-IMMUNO-BREAST 4(3) CP-HIST-IMMUNO-BREAST -12(4)	RLH
Fresh muscle tissue	<u>Muscle</u> Examination of muscle tissue in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Cryotomy using Bright cryostat OFT-5000 CP-HIST-TECH-FS1 CP-HIST-NEURO-MUSCLE-SOP3	RLH



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Fresh muscle tissue	<p><u>Muscle (cont'd)</u></p> <p>Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers:</p> <p>Dystrophin 1 Dystrophin 2 Dystrophin 3 Spectrin Merosin Alpha Sarcoglycan Beta Sarcoglycan Delta Sarcoglycan Gamma Sarcoglycan Beta Dystroglycan Utrophin Dysferlin 1 (Hamlet 1) Fast Myosin Slow Myosin Neonatal Myosin HLA ABC CD68 CD3</p>	<p>Hand- Immuno-staining</p> <p>In house documented procedures: CP-HIST-NEURO-MUSCLE-SOP1(1) CP-HIST-NEURO-MUSCLE-SOP2(1) CP-HIST-NEURO-MUSCLE-SOP3(1) CP-HIST-NEURO-MUSCLE-SOP4(3) CP-HIST-NEURO-MUSCLE-IMMUNO 1(4) CP-HIST-NEURO-MUSCLE-IMMUNO(2) CP-HIST-NEURO-MUSCLE-IMMUNO3(1) CP-HIST-IMMUNO-GEN-SOP2(1) using antibodies: Leica NCL-DYS1 Leica NCL-DYS2 Leica NCL-DYS3 Leica NCL-SPEC1 Leica NCL-MEROSIN Leica NCL-a-SARC Leica NCL-b-SARC Leica NCL-d-SARC Leica NCL-g-SARC Leica NCL-b-DG Leica NCL-DRP2 Leica NCL-Hamlet Leica NCL-MHCf Leica NCL-MHCs Leica NCL-MHCn Dako M0736 Dako M0814 Leica NCL-L-CD3-565</p>	RLH



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Fresh muscle tissue	<u>Muscle (cont'd)</u> Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers: CD4 CD8 CD20 Vimentin Myotilin MAC C5 b9 P62	Hand- Immuno-staining In house documented procedures: CP-HIST-NEURO-MUSCLE-SOP1(1) CP-HIST-NEURO-MUSCLE-SOP2(1) CP-HIST-NEURO-MUSCLE-SOP3(1) CP-HIST-NEURO-MUSCLE-SOP4(3) CP-HIST-NEURO-MUSCLE-IMMUNO 1(4) CP-HIST-NEURO-MUSCLE-IMMUNO(2) CP-HIST-NEURO-MUSCLE-IMMUNO3(1) CP-HIST-IMMUNO-GEN-SOP2(1) using antibodies: Leica NCL-L-CD4-368 Dako M7103 Dako M756 Dako M0725 Leica NCL-Myotilin Dako M0777 BD Transduction Laboratory 610833	RLH
Fresh muscle tissue	Routine stains used for For the demonstration of morphology of muscle fibres H&E stain	Hand Staining Hand Staining techniques using documented in-house methods H&E Stain Muscle H&E CP-HISTO-NEURO-MUSCLE-STAIN(3)	RLH



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	RLH
Fresh muscle tissue (cont'd)	<p><u>Muscle (cont'd)</u></p> <p>Routine stains used for For the demonstration of morphology of muscle fibres (cont'd)</p> <p>Glycogen</p> <p>Lipids</p> <p>Mitochondria and Connective tissue</p> <p>Macrophage marker</p> <p>Demonstration of fibre types</p> <p>Oxidative enzyme of the respiratory chain located in mitochondria</p> <p>Respiratory chain enzyme marker of mitochondrial function</p> <p>Mitochondrial enzyme which predominates in type 1 fibres</p> <p>Enzyme that polymerises glucose to form glycogen</p>	<p>Hand Staining Hand Staining techniques using documented in-house methods</p> <p>Muscle PAS CP-HISTO-NEURO-MUSCLE-STAIN4(2) Muscle Oil Red O CP-HISTO-NEURO-MUSCLE-STAIN2(2) Muscle Gomori CP-HISTO-NEURO-MUSCLE-STAIN8(2) Muscle Acid Phosphatase CP-HISTO-NEURO-MUSCLE-STAIN6(2) Muscle ATPase CP-HISTO-NEURO-MUSCLE-STAIN10(2) NADH CP-HISTO-NEURO-MUSCLE-STAIN3 (2) SDH Succinic dehydrogenase CP-HISTO-NEURO-MUSCLE-STAIN7(2) COX Cytochrome oxidase CP-HISTO-NEURO-MUSCLE-STAIN 9(2) Myophosphorylase CP-HISTO-NEURO-MUSCLE-STAIN5(4)</p>	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Cytopathology (Non-Gynae-) examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Bodily fluids	<u>Cytopathology (Non-Gynae)</u> Examination of body fluids to enable the examination of cellular material in order to identify or exclude morphological and cytological abnormalities	<u>Papanicolaou and May-Grunwald Giemsa staining</u> Using Heraeus centrifuge, cytocentrifuge, Class I safety cabinet, Leica ST5020 staining machine, Leica CV5030 coverslipper. All used in conjunction with manufacturer's instructions and maintenance. CP-CYTO-SR-NG1 CP-CYTO-TECH-STAIN9 CP-CYTO-AUTO7	RLH
Bile fluid Bronchial washings, brushings and alveolar lavage CSF Endoscopic ultrasound guided fine needle aspiration Serous fluids Fine Needle Aspirations		CP-CYTO-TECH-NG-PREP2 CP-CYTO-TECH-NG-PREP4 CP-CYTO-TECH-NG-PREP6	
Miscellaneous fluids Sputum Urine		CP-CYTO-TECH-NG-PREP5 CP-CYTO-TECH-NG-PREP16	
		CP-CYTO-TECH-NG-PREP9 CP-CYTO-TECH-NG-PREP7 CP-CYTO-TECH-NG-PREP3 CP-CYTO-TECH-NG-PREP8 CP-CYTO-TECH-NG-PREP10 CP-CYTO-TECH-NG-PREP12	
Cytology specimens processed into FFPE blocks	<u>Immunohistochemistry</u> Immunohistochemistry see histology	CP-CYTO-TECH-STAIN1(3)	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Cytopathology (Non-Gynae-) examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Fresh tissue sample	<u>Non-Gynaecological ENT one-stop clinic</u> Examination of cellular material in order to identify or exclude morphological and cytological abnormalities using the Diff Quik staining method.	Diff-Quik stain CP-CLIN3 CP-CYTO-TECH-STAIN9	RLH
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis of histology, cervical cytology and non-gynae cytology slides	Interpretive Microscopy using an assorted range of diagnostic bright-field microscopes CP-HIST-IMMUNO-GEN-SOP14 CP-HIST-IMMUNO-IMF6 CP-CLIN2	RLH
HUMAN TISSUE	<u>Electron microscopy examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Tissue samples fixed in formaldehyde or glutaraldehyde and formalin fixed paraffin embedded tissues.	<u>Electron Microscopy</u> Production of electron-micrographs of diagnostic ultrastructural features of tissue samples.	<u>Specimen preparation. Processing of E.M. samples</u> CP-HIST-EM-SPEC3 CP-HIST-EM-SPEC4 CP-HIST-EM-SPEC5 <u>Use of Reichert-Jung Ultracut E ultramicrotome for cutting semi-thin and ultrathin sections.</u> CP-HIST-EM-CUT4 CP-HIST-EM-CUT5 <u>Staining of semi-thin sections.</u> CP-HIST-EM-STAIN2 CP-HIST-EM-STAIN3	RLH



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HUMAN TISSUE (cont'd) Tissue samples fixed in formaldehyde or glutaraldehyde and formalin fixed paraffin embedded tissues (cont'd)	<u>Electron microscopy examination activities for the purpose of clinical diagnosis (cont'd)</u> Production of electron-micrographs of diagnostic ultrastructural features of tissue samples.	In house documented methods incorporating manufacturers' instructions where relevant <u>Examination of specimens and taking of diagnostic electron-micrographs using JEOL JEM1230 transmission electron microscope with SIS Morada digital camera.</u> CP-HIST-EM-MICRO2 CP-HIST-EM-CUT1 CP-HIST-EM-CUT4 CP-HIST-EM-CUT5	QMUL
HUMAN BODY FLUIDS AND TISSUE Blood	<u>Immunology examination activities for the purpose of clinical diagnosis</u> Immunology Allergy Detection of: <ul style="list-style-type: none"> • Total IgE • Allergen Specific IgE • Penicillin G Sp IgE Ab • Penicillin V Sp IgE Ab • Suxamethonium Sp IgE Ab • Ampicillin Sp IgE Ab • Amoxicillin Sp IgE Ab • Bovine Insuline Sp IgE Ab • Human Insuline Sp IgE Ab • Bovine Gelatin Sp IgE Ab • House Dustmite Sp IgE Ab • Cat Dander Sp IgE Ab • Canary Feathers Sp IgE Ab • Reindeer Epith. Sp IgE Ab • Mink Epithelium Sp IgE Ab • Rabbit Serum Sp IgE Ab • Gerbil Epith Sp IgE Ab • Fox Epithelium Sp IgE Ab • Rabbit Urine Sp IgE Ab 	In house documented methods incorporating manufacturers' instructions where relevant Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH



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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 TISSUE (cont'd)</p> <p>Blood (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Allergy (cont'd)</u> Detection of:</p> <ul style="list-style-type: none"> • Parrot Feathers Sp IgE Ab • PlgEon Feather Sp IgE Ab • Deer Epithelium Sp IgE Ab • Horse Dander Sp IgE Ab • Cow Dander Sp IgE Ab • Dog Dander Sp IgE Ab • Dog Epithelium Sp IgE Ab • Goose Feathers Sp IgE Ab • Mouse Epith. Sp IgE Ab • Mouse Urine Sp IgE Ab • Rat Epithelium Sp IgE Ab • Rat Urine Sp IgE Ab • Budgie Feathers Sp IgE Ab • Budgie Serum Sp IgE Ab • Goat Epithelium Sp IgE Ab • Sheep Epith. Sp IgE Ab • Rabbit Epith. Sp IgE Ab • Hamster Epith. Sp IgE Ab • Chicken Feather Sp IgE Ab • Duck Feathers Sp IgE Ab • Rat Epithelium/Serum/Urine) Sp IgE Ab • Turkey Feathers Sp IgE Ab • Feathers Mix 1 Sp IgE Ab • Caged Bird Sp IgE Ab • Egg White Sp IgE Ab • Sesame Seed Sp IgE Ab • Buckwheat Sp IgE Ab • Pea Sp IgE Ab • Peanut Sp IgE Ab • Soya Bean Sp IgE Ab • White Bean Sp IgE Ab • Hazelnut Sp IgE Ab • Brazil Nut Sp IgE Ab • Almond Sp IgE Ab • Pecan Sp IgE Ab 	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Thermo Fisher Phadia 250 (Cont'd) Chemiluminescence</p>	<p>RLH</p>



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HUMAN BODY FLUIDS AND TISSUE (cont'd) Blood (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u> Allergy (cont'd) Detection of: <ul style="list-style-type: none"> • Cashew Nut Sp IgE Ab • Pistachio Nut Sp IgE Ab • Trout Sp IgE Ab • Herring Sp IgE Ab • Clam Sp IgE Ab • Lemon Sp IgE Ab • Grapefruit Sp IgE Ab • Pineapple Sp IgE Ab • Blackberry Sp IgE Ab • Mushroom Sp IgE Ab • Rabbit Meat Sp IgE Ab • Spinach Sp IgE Ab • Lettuce Sp IgE Ab • Cabbage Sp IgE Ab • Paprika Sp IgE Ab • Cinnamon Sp IgE Ab • Coffee Sp IgE Ab • Tea Sp IgE Ab • Poppy Seed Sp IgE Ab • Pumpkin Seed Sp IgE Ab • Crab Sp IgE Ab • Lentil Sp IgE Ab • Apricot Sp IgE Ab • Shrimp Sp IgE Ab • Cherry Sp IgE Ab • Cucumber Sp IgE Ab • Honey Sp IgE Ab • Tomato Sp IgE Ab • Pine Nut Sp IgE Ab • Plaice Sp IgE Ab • Plum Sp IgE Ab • Walnut Sp IgE Ab • Squid Sp IgE Ab • Grape Sp IgE Ab • Pork Meat Sp IgE Ab • Broccoli Sp IgE Ab 	In house documented methods incorporating manufacturers' instructions where relevant Thermo Fisher Phadia 250 (Cont'd) Chemiluminescence	RLH



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<p>HUMAN BODY FLUIDS AND TISSUE (cont'd)</p> <p>Blood (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Allergy (cont'd)</u> Detection of:</p> <ul style="list-style-type: none"> • Aubergine Sp IgE Ab • Peppercorn Sp IgE Ab • Beef Meat Sp IgE Ab • Ginger Sp IgE Ab • Thyme Sp IgE Ab • Chill Pepper Sp IgE Ab • Curry Sp IgE Ab • Nutmeg Sp IgE Ab • Oregano Sp IgE Ab • Turkey Meat Sp IgE Ab • Red Kidney Bean Sp IgE Ab • Oyster Sp IgE Ab • Papaya Sp IgE Ab • Carob Bean Sp IgE Ab • Cows Milk Sp IgE Ab • Cod Sp IgE Ab • Halibut Sp IgE Ab • Lime Sp IgE Ab • Sardine Sp IgE Ab • Chick Pea Sp IgE Ab • Carrot Sp IgE Ab • Anchovy Sp IgE Ab • Green Bean Sp IgE Ab • Rape Pollen Sp IgE Ab • Coriander Sp IgE Ab • Crayfish Sp IgE Ab • Hops Sp IgE Ab • Fig Sp IgE Ab • Watermelon Sp IgE Ab • Orange Sp IgE Ab • Saffron Sp IgE Ab • Linseed Sp IgE Ab • Lupine Seed Sp IgE Ab • Scallop Sp IgE Ab • Black Olive Sp IgE Ab • Raspberry Sp IgE Ab 	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Thermo Fisher Phadia 250 (Cont'd) Chemiluminescence</p>	<p>RLH</p>



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HUMAN BODY FLUIDS AND TISSUE (cont'd) Blood (cont'd)	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Allergy (cont'd)</u> Detection of:</p> <ul style="list-style-type: none"> • Potato Sp IgE Ab • Coconut Sp IgE Ab • Blue Mussel Sp IgE Ab • Wheat Sp IgE Ab • Tuna Sp IgE Ab • Salmon Sp IgE Ab • Omega-5 Gliadin Sp IgE Ab • Haddock Sp IgE Ab • Strawberry Sp IgE Ab • Garlic Sp IgE Ab • Onion Sp IgE Ab • Apple Sp IgE Ab • Rye Sp IgE Ab • Chub Mackerel Sp IgE Ab • Foxtail Millet Sp IgE Ab • Octopus Sp IgE Ab • Barley Sp IgE Ab • Oat Sp IgE Ab • Egg Yolk Sp IgE Ab • N Bos D 8 Cows Milk Casein Sp IgE Ab • Gluten Sp IgE Ab • Corn Sp IgE Ab • Lobster Sp IgE Ab • Cheddar Cheese Sp IgE Ab • Cheese Mould Sp IgE Ab • Chicken Meat Sp IgE Ab • Kiwi Fruit Sp IgE Ab • Celery Sp IgE Ab • Melon Sp IgE Ab • Lamb Meat Sp IgE Ab • Mustard Sp IgE Ab • Rice Sp IgE Ab • Malt Sp IgE Ab • Mango Sp IgE Ab • Banana Sp IgE Ab 	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Thermo Fisher Phadia 250 (Cont'd) Chemiluminescence</p>	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd) Blood (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Allergy (cont'd)</u> Detection of: <ul style="list-style-type: none"> • Chocolate Sp IgE Ab • Pear Sp IgE Ab • Peach Sp IgE Ab • Avocado Sp IgE Ab • Mixed Nuts Sp IgE Ab • Fish Mix Sp IgE Ab • Grain Mix Sp IgE Ab • Food Mix Sp IgE Ab • Curry Spice Mix Sp IgE Ab • Mixed Meat Sp IgE Ab • Vernal Grass Sp IgE Ab • Timothy Grass Sp IgE Ab • Grass Mix Sp IgE Ab • Bee Venom Sp IgE Ab • Horse Fly Sp IgE Ab • Wasp Venom Sp IgE Ab • Cockroach Sp IgE Ab • Mosquito Sp IgE Ab • Abachi Wood Sp IgE Ab • Castor Bean Sp IgE Ab • Silk Sp IgE Ab • Formaldehyde Sp IgE Ab • Latex Sp IgE Ab • Cotton Seed Sp IgE Ab • Sunflower Seed Sp IgE Ab • P. Notatum Sp IgE Ab • Cladosporium Herbarum Sp IgE Ab • A. Fumigatus Sp IgE Ab • A. Alternata Sp IgE Ab • H. Halodes Sp IgE Ab • Mould Mix Sp IgE Ab • Miscellaneous Sp IgE Ab • London Plane Sp IgE Ab • White Pine Sp IgE Ab • Japanese Cedar Sp IgE Ab 	In house documented methods incorporating manufacturers' instructions where relevant Thermo Fisher Phadia 250 (Cont'd) Chemiluminescence	RLH



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<p>HUMAN BODY FLUIDS AND TISSUE (cont'd)</p> <p>Blood (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Allergy (cont'd)</u> Detection of:</p> <ul style="list-style-type: none"> • Grey Alder Sp IgE Ab • Spruce Tree Sp IgE Ab • Elder Tree Sp IgE Ab • Chestnut Pollen Sp IgE Ab • Date Sp IgE Ab • Cypress Tree Sp IgE Ab • Birch Pollen Sp IgE Ab • Hazel Pollen Sp IgE Ab • Oak Tree Pollen Sp IgE Ab • Elm Tree Pollen Sp IgE Ab • Tree Pollen Mix Sp IgE Ab • Golden Rod Sp IgE Ab • Nettle Pollen Sp IgE Ab • Mugwort Pollen Sp IgE Ab • Plantain Pollen Sp IgE Ab • Mixed Weed Sp IgE Ab • Yeast Sp IgE Ab • Cephalosporin Sp IgE Ab • Protamine Sp IgE Ab • Anisakis Sp IgE Ab • Rpru P1 Pr-10 Peach Sp IgE Ab • Rpru P4 Profilin Peach Sp IgE Ab • Rmal D3 Apple Ltp Sp IgE Ab • Cor A14 Hazel Nut Sp IgE Ab • Cor A9 Hazel Nut Sp IgE Ab • Rjug R1 Walnut Sp IgE Ab • Rjug R3 Ltp Walnut Sp IgE Ab • Rphl P12 Timothy Sp IgE Ab • Ngal D4 Hen Egg Lysozyme Sp IgE Ab 	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Thermo Fisher Phadia 250 (Cont'd) Chemiluminescence</p>	<p>RLH</p>



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<p>HUMAN BODY FLUIDS AND TISSUE (cont'd)</p> <p>Blood (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Allergy (cont'd)</u> Detection of:</p> <ul style="list-style-type: none"> • Rhev B8 Latex Profilin Sp IgE Ab • Acarus Siro Sp IgE Ab • Mouse (Epithelium/Serum/Urine) Sp IgE Ab • Chicken Droppings Sp IgE Ab • Meat Mix Sp IgE Ab • Sweet Potato Sp IgE Ab • Parsley Sp IgE Ab • Gliadin Sp IgE Ab • Asparagus Sp IgE Ab • Cow Whey Sp IgE Ab • Basil Sp IgE Ab • Black Pepper Sp IgE Ab • Cauliflower Sp IgE Ab • Sweet Chestnut Sp IgE Ab • Goat Milk Sp IgE Ab • Mandarin Sp IgE Ab • Swordfish Sp IgE Ab • Jackfruit Sp IgE Ab • Beetroot Sp IgE Ab • Catfish Sp IgE Ab • Red Currant Sp IgE Ab • Cochineal Extract (Carmine Red) Sp IgE Ab • Quinoa Sp IgE Ab • Salmon Roe Sp IgE Ab • Spelt Wheat Sp IgE Ab • Pumpkin Sp IgE Ab • Fennel Sp IgE Ab • Blueberry Sp IgE Ab • Date Sp IgE Ab • Cranberry Sp IgE Ab • Mint Sp IgE Ab 	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Thermo Fisher Phadia 250 (Cont'd) Chemiluminescence</p>	<p>RLH</p>



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Blood (cont'd)	<u>Allergy (cont'd)</u> Detection of: <ul style="list-style-type: none"> • Macadamia Nut Sp IgE Ab • Pollock Sp IgE Ab • Tilapia Sp IgE Ab • Fire Ant Sp IgE Ab • Phthalic Anhydride Sp IgE Ab • Maleic Anhydride Sp IgE Ab • Mehtyltetrahydroptalic Anhydride Sp IgE • Mucor Racemosus Sp IgE Ab • Candida Albicans Sp IgE Ab • Pityrosporum Orbiculare Sp IgE Ab • Aspergillus Flavus Sp IgE Ab • Wall Pellitory Sp IgE Ab • Chlorhexadine Sp IgE Ab • Ara H2 Peanut Glycinin Sp IgE Ab Tryptase IgG Aspergillus fumigatus Avian precipitins	Thermo Fisher Phadia 250 (Cont'd) Chemiluminescence	RLH
Blood	<u>Autoimmune Serology</u> Detection of: Anti-Cardiolipin (IgG,A,M Screen) ENA Screen Intrinsic Factor antibodies Thyroid Peroxidase antibodies Tissue Transglutaminase (IgA)	IM ID03 IM A50 IM A70 Dynex DS2 ELISA ELISA – Orgentec IM A33 ELISA – IL/Werfen IM A58 ELISA - Orgentec IM A22 ELISA - Orgentec IM A36 ELISA - Orgentec IM A45	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Blood (cont'd)	<u>Autoimmune Serology</u> Detection of: (cont'd) Acetylcholine Receptor Abs Anti-GAD antibodies Anti-Natalizumab (Tysabri) Abs TSH Receptor antibodies Faecal Calprotectin	Dynex DS2 ELISA ELISA - RSR IM A55 ELISA - RSR IM A60 ELISA – Inhouse Biogen-idec IM A57 ELISA - RSR IM A62 ELISA – ACCUSAY IM A68	RLH
Blood	Detection of: Citrullinated Protein Abs ANCA ELISA [MPO/PR3] Anti-Cardiolipin abs IgG / M Beta-2-Glycoprotein 1 abs IgG / M dsDNA ELISA GBM Antibodies Tissue Transglutaminase (IgG) M2 Antibodies	Thermo Fisher Phadia 250 Chemiluminescence IM A54 IM A63 IM A 61 IM A61 IM A67 IM A59 IM A64 IM A71	RLH
Blood	Liver Euroassay [M2/LC1/SLA/LKM1] ENA Characterisation [Ro/La/RNP/Sm/Jo1/Scl70/Ribo]	<u>Manual Immunoblot</u> Blot - Euroimmun IM A47 Blot - Euroimmun IM A39	RLH
Blood	PLA2 Receptor abs by Biochip	<u>Manual Biochip</u> Biochip - Euroimmun IM A66	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Blood	PLA2 Receptor abs by ELISA	<u>DS2 ELISA</u> ELISA - Euroimmun IM A69	RLH
Blood	Adrenal antibodies	<u>Indirect Immunofluorescence</u> Slides – IL/Werfen IM A07	RLH
	ANA (Hep-2) Screen	Slides – Biodiagnostics IM A06	
	Autoantibody Screen	Slides – IL/Werfen IM A05	
	dsDNA Immunofluorescence	Slides – Biosystems/Launch IM A10	
	Endomysial antibodies (IgA)	Slides – IL/Werfen IM A11	
	IgG ANCA	Slides – IL/Werfen IM A09 AN	
	Islet Cell antibodies	Slides – IL/Werfen IM A29	
	Neuronal Antibodies	Slides – IL/Werfen IM A49	
	Pemphigus/Pemphigoid	Slides – IL/Werfen IM A13	
Blood	Immunodeficiency:	Manual Radial Immunodiffusion	RLH
	C1 Esterase (Level)	RID – Binding Site IM ID04	
	Classical Pathway (CH100)	RID – Binding Site IM ID09	
	Alternate Pathway (AP100)	RID – Binding Site IM ID10	
Blood	C1 Esterase (Function)	<u>Manual ELISA</u> Berichrome C1-inhibitor Kit IM ID05	RLH
Blood	Mannose Binding Ligand	Bioporto MBL Oligomer ELISA IM ID08	



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Blood	Haemophilus B Antibodies	<u>Dynex DS2 ELISA</u> ELISA – Binding Site IM ID06	RLH
	Tetanus antibodies	ELISA – Binding Site IM ID07	
	IgG Subclasses	<u>Binding Site SPA+</u> <u>Turbidimetry</u> Turbidimetry – Binding Site IM ID11	RLH
Blood	<u>Flow Cytometry:</u>		
	Lymphocyte Subsets (CD3,4,8)	<u>BD FACS Canto II</u> <u>Flow Cytometry</u> Using manufacturer's monoclonal antibody kits: IM ID12	RLH
	Immunodeficiency Panel (B,T,NK)	IM ID12	
	B Cell Subpopulation	IM ID13	
	CFSE Lymphocyte proliferation	IM ID15	
	Neutrophil Function [DHR]	IM ID17	
	CD11a / CD18 Expression	IM ID18	



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HUMAN BODY FLUIDS AND TISSUE	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures incorporating manufacturers' instructions where relevant	RLH
Blood	<u>Immunophenotyping</u> Detection and enumeration of GPI-deficient cell clones in patients with Paroxysmal Nocturnal Haemoglobinuria, Aplastic Anaemia and Myelodysplasia. For diagnosis and follow up	<u>BD FACSCanto II flow cytometer</u> Cells deficient in GPI-linked markers are detected and quantified IMP.SOP.012	
Blood, Bone marrow, CSF, Pleural Fluid, Ascites, serous fluid and effusion.	T-cell, B-cell, Myeloid Screening (Leukaemia/Lymphoma and MDS)	Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies are analysed using flow cytometry. IMP.SOP.008	
Blood, Bone marrow, CSF, Pleural Fluid, Ascites, serous fluid and effusion.	Detection and characterisation of B-cell Lymphoproliferative disorders. Assessment of minimal residual disease (MRD)	Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies are analysed using flow cytometry. IMP.SOP.009 IMP.SOP.045	
Blood, Bone marrow, CSF, Pleural Fluid, Ascites, serous fluid and effusion.	Detection and characterisation of T-cell/NK-cell Lymphoproliferative disorders. Assessment of minimal residual disease (MRD)	Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies are analysed using flow cytometry. IMP.SOP.013 IMP.SOP.045	
Blood, Bone marrow, CSF, Pleural Fluid, Ascites, serous fluid and effusion.	Detection and characterisation of plasma cell disorders (Myeloma, Monoclonal Gammopathy of Unknown Significance) and Plasmacytoma. Assessment of minimal residual disease (MRD)	Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies are analysed using flow cytometry. IMP.SOP.011 IMP.SOP.045	



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Immunophenotyping (cont'd)</u>	Documented in-house procedures incorporating manufacturers' instructions where relevant (Cont'd) <u>BD FACSCanto II flow cytometer (Cont'd)</u>	RLH
Blood, Bone marrow, CSF, Pleural Fluid, Ascites, serous fluid and effusion.	Detection and characterisation of acute leukaemia, and enumeration of blasts and monocytes in Myelodysplastic syndrome. Assessment of minimal residual disease (MRD)	Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies are analysed using flow cytometry. IMP.SOP.010 IMP.SOP.045	
Blood, Bone marrow, CSF, Pleural Fluid, Ascites, serous fluid and effusion.	Assessment of intracellular antigens during investigation of acute leukaemia, Lymphoproliferative disorders, and lymphoma	Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies are analysed using flow cytometry. IMP.SOP.014	
HUMAN BODY FLUIDS AND TISSUE	<u>Histocompatibility and immunogenetics examination activities for the purpose of clinical diagnosis</u> <u>Clinical Transplantation</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Blood (EDTA)	DNA Extraction	Geno-M6 EZ1 Advanced XL Qiagen Biorobot CTL-MOL-SOP-019	RLH
DNA	HLA Typing: HLA- A,B,C,DRB1, DRB345, DQA/B1,DPA/B1	<u>LiquiChip (Luminex)</u> Qiagen LiquiChip Workstation Thermal cyclers Kit: LUMINEX LABType® SSO CTL-MOL-SOP-020	RLH
DNA	B*57:01 testing	Kit: LUMINEX LABType® SSO CTL-MOL-SOP-020	RLH
DNA	B27 testing	Kit: LUMINEX LABType® SSO CTL-MOL-SOP-020	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Histocompatibility and immunogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Clinical Transplantation (cont'd)</u>		
DNA	HLA Typing: HLA- A,B,C,DRB345, DRB1,DQA1, DQB1, DPA1, DPB1	<u>PCR SSP</u> Thermal cyclers Roche Lightcycler Kit: Histotype PCR SSP BAG Healthcare CTL-MOL-SOP-029	RLH
DNA	HLA-B*57:01 testing	Kit: LinkSeq HLA-ABCDRDQDP+ 384 Typing Kit CTL-MOL-SOP-016	RLH
DNA	Haemochromatosis (HFE) testing	Kit: Olerup HLA B*57 subtyping kit CTL-MOL-SOP-029 Kit: IDT Primers CTL-MOL-SOP-014	RLH
DNA	HLA Sequence Based Typing: HLA – A,B,C,DRB1,DQB1,DPB1	<u>SBT</u> <u>Sequence Based Typing</u> Thermal cyclers ABI 3730XL capillary analyser Kit: SBT excellerator CTL-MOL-SOP-002	RLH
Serum/ lymphocytes	HLA Class I & Class II antibody detection and identification: HLA- A,B,C,DRB1,DRB3,DRB4,DR B5,DQA1,DQB1,DPA1,DPB1	<u>LiquiChip (Luminex)</u> Qiagen LiquiChip Workstation Kits: One lambda LABScreen Mixed + FlowPRA® Single Antigen. CTL-SER-SOP-039:	RLH
Serum/ lymphocytes	Un-separated, B and B cell depleted Lymphocytotoxic cross matching	<u>Lymphocytotoxicity</u> Reagents: Monoclonal IgG W632+class II L243, Complement. CTL-SER-SOP-036	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Histocompatibility and immunogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Clinical Transplantation (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Serum/ lymphocytes	T and B cell Flowcytometric crossmatching	<u>Flowcytometry</u> Becton Dickinson FACSCANTO Reagents: Dako CD3, CD19, FITC SOP: CTL-SER-SOP-010:	RLH
Serum/ lymphocytes	HLA Class I & Class II antibody detection and identification: HLA- A,B,C,DRB1,DRB3,DRB4,DRB5,DQA1,DQB1,DPA1,DPB1	<u>Lymphocytotoxicity</u> Reagents: Monoclonal IgG W632+class II L243, Complement SOP: CTL-SER-SOP-034:	RLH
HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Cytogenetics examination activities for the purpose of clinical diagnosis</u> <u>Cytogenetics</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Blood (lithium heparin), bone marrow, body fluids	Cell culture and karyotype analysis using G-banding and image capture analysis Preparation and cell harvest for acquired and constitutional cytogenetic abnormalities Karyotyping analysis of G-banded chromosomes Reporting of cytogenetics results	Olympus BX45 Light microscope (PP/3/36), Metasystems IKAROS imaging software CMH-CYTO-SOP-003 CMH-CYTO-SOP-011 CMH-CYTO-SOP-002 CMH-CYTO-SOP-012 CMH-CYTO-SOP-004 CMH-CYTO-SOP-013 CMH-CYTO-SOP-008 CMH-CYTO-SOP-015 CMH-CYTO-POL-002	RLH



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<p>HUMAN BODY FLUIDS AND TISSUE (cont'd)</p> <p>Fixed cells / Formalin Fixed Paraffin Embedded tissue (FFPE)</p>	<p><u>Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Cytogenetics (cont'd)</u></p> <p>Detection of microscopic and submicroscopic gains/losses and rearrangements of DNA</p> <p>Preparation and cell harvest for acquired and constitutional cytogenetic abnormalities</p> <p>Detection of microscopic and submicroscopic gains/losses and rearrangements of DNA</p> <p>Reporting of cytogenetics results</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Zeiss AXIO Imager microscope Metasystems ISIS imaging software</p> <p>CMH-CYTO-SOP-003 CMH-CYTO-SOP-011 CMH-CYTO-SOP-042 CMH-CYTO-SOP-039 CMH-CYTO-SOP-002 CMH-CYTO-SOP-012 CMH-CYTO-SOP-053 CMH-CYTO-SOP-027 CMH-CYTO-SOP-048 CMH-CYTO-SOP-004 CMH-CYTO-SOP-013</p> <p>Fluorescence in situ hybridisation (FISH) Zeiss AXIO Imager microscope Metasystems ISIS imaging software CMH-CYTO-SOP-025 CMH-CYTO-SOP-017 CMH-CYTO-SOP-043 CMH-CYTO-SOP-052</p> <p>CMH-CYTO-POL-002</p>	<p>RLH</p>



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Molecular Genetics examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Blood, Bone marrow, Tissue, Body fluids	<u>Molecular Genetics</u> Nucleic acid extraction and quantification	DNA/RNA extraction using: Maxwell®16 instrument HAEM-MOLEC-SOP-02 HAEM-MOLEC-SOP-60 HAEM-MOLEC-SOP-03 HAEM-MOLEC-SOP-66 DNA/RNA quantification using Nanodrop and Qubit instruments HAEM-MOLEC-SOP-04 HAEM-MOLEC-SOP-65	RLH
DNA	JAK2	JAK2 assay by RQ-PCR using Qiagen Mutascreen kit on Applied Biosystems 7500 HAEM-MOLEC-SOP-19	RLH
DNA	CALR	CALR assay using in-house PCR method on Veriti thermal cycler and Applied Biosystems 3730 HAEM-MOLEC-SOP-54	RLH
DNA	MPL	MPL assay using in-house PCR method on Veriti thermal cycler and Applied Biosystems 3730 HAEM-MOLEC-SOP-55	RLH
RNA	BCR-ABL1	BCR-ABL1 using in house / EAC RQ-PCR method with Qiagen Ipsogen Standards, on Applied Biosystems 7500 and Veriti thermal cycler HAEM-MOLEC-SOP-05 HAEM-MOLEC-SOP-11 HAEM-MOLEC-SOP-12 HAEM-MOLEC-SOP-13 HAEM-MOLEC-SOP-14	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Molecular Genetics (cont'd)</u>		
DNA	FLT3 /NPM1	FLT3 / NPM1 assay using in-house PCR method on Veriti thermal cyclor and Applied Biosystems 3730 HAEM-MOLEC-SOP-20 HAEM-MOLEC-SOP-23	RLH
DNA	FVL / Prothrombin Variant	FVL / Prothrombin Variant assay using in-house RQ-PCR method on Applied Biosystems 7500 HAEM-MOLEC-SOP-09	RLH
DNA	Immunoglobulin Rearrangement (IGH and IGK)	IG assay by PCR using Invivoscribe kit on Veriti thermal cyclor and analysed Applied Biosystems 3730 HAEM-MOLEC-SOP-10	RLH
DNA	T-Cell Receptor Rearrangement (TCRB and TCRG)	TCR assay by PCR using Invivoscribe kit on Veriti thermal cyclor and analysed Applied Biosystems 3730 HAEM-MOLEC-SOP-10	RLH
DNA	EGFR	EGFR Assay using Roche Cobas EGFR kit and analysed on Cobas 4800 HAEM-MOLEC-SOP-52	RLH
DNA	RAS mutations (KRAS and NRAS)	RAS Assay detecting KRAS and NRAS mutations using Entrogen RAS kit and analysed on Applied Biosystems 7500 HAEM-MOLEC-SOP-53	RLH



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<p>HUMAN BODY FLUIDS AND TISSUE (cont'd)</p> <p>DNA</p> <p>DNA</p>	<p><u>Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Molecular Genetics (cont'd)</u></p> <p>Chimerism Analysis</p> <p>Minimal Residual Disease Monitoring in Acute Lymphoblastic Leukaemia (ALL)</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Chimerism assay by PCR using Promega Powerplex 16 HS kit on G-Storm and analysed on Applied Biosystems 3730 HAEM-MOLEC-SOP-16</p> <p>MRD assay by PCR, RQ-PCR and sequencing using published methods, on Veriti / G-Storm, Applied Biosystems 7500 and Applied Biosystems 3730 HAEM-MOLEC-SOP-06 HAEM-MOLEC-SOP-22 HAEM-MOLEC-SOP-24 to HAEM-MOLEC-SOP-31 HAEM-MOLEC-SOP-33 to HAEM-MOLEC-SOP-35</p>	<p>RLH</p> <p>RLH</p>



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Retinoblastoma examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
A) Whole blood, fresh retinoblastoma tumour, paraffin embedded tissue, received DNA samples. B) Amniotic fluid, chorionic villus. C) Hair, buccal cells. D) Whole blood, fresh retinoblastoma tumour.	<u>Retinoblastoma</u>	<u>DNA/RNA extraction</u> Manual DNA/RNA extraction using: Zymo Quick-gDNA MidiPrep Zymo Quick-gDNA MiniPrep Ambion RecoverAll Total Nucleic Acid Isolation Kit RBSOP_078 RBSOP_079 RBSOP_081 RBSOP_094 RBSOP_096 RBINFO_029	RLH
DNA/ RNA obtained from sample types specified above: A	RB1 Mutation Screening for point mutations and small in/dels.	High Resolution Melt (HRM) Confirmation Screening using a Rotorgene (Corbett/Qiagen) Bioline SensiFAST HRM Kit, Qiagen Type-it HRM Kit RBSOP_053 RBSOP_054	RLH
DNA/ RNA obtained from sample types specified above: A, B, C, D	RB1 variant	PCR/RT-PCR Amplification and Sanger Sequencing: Thermal cyclers ABI 3730XL capillary analyser Big Dye Terminator v1.1 Cycle Sequencing Kit RBSOP_090 RBSOP_084 RBSOP_069 RBSOP_087 RBSOP_027 RBSOP_036 RBSOP_099 RBSOP_025 RBSOP_091 RBSOP_088	RLH



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United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Barts Health NHS Trust

Issue No: 003 Issue date: 24 December 2019

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY FLUIDS AND TISSUE (cont'd)</p> <p>DNA/ RNA obtained from sample types specified above: A, B, C</p> <p>DNA/ RNA obtained from sample types specified above: A, B</p>	<p><u>Retinoblastoma examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Retinoblastoma (cont'd)</u></p> <p>RB1 linkage exclusion testing and LOH analysis.</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>PCR Amplification and Fragment Analysis: Thermal cyclers ABI 3730XL capillary analyser RBSOP_071 RBSOP_069 RBSOP_025 RBSOP_042 RBSOP_088 RBSOP_048</p>	RLH
	<p>Screening for dosage mutations in RB1.</p>	<p>Multi-Ligation Probe Analysis (MLPA): Thermal cyclers ABI 3730XL capillary analyser MRC Holland MLPA SALSA P047 Kit RBSOP_059 RBSOP_045</p>	RLH
		<p>Quantitative Fluorescence PCR (QF-PCR): Thermal cyclers ABI 3730XL capillary analyser. Using in house methods incorporating manufacturers' instructions where relevant RBSOP_035 RBSOP_069</p>	RLH



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<p>HUMAN BODY FLUIDS AND TISSUE (cont'd)</p> <p>DNA/ RNA obtained from sample types specified above: A, B</p>	<p><u>Retinoblastoma examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Retinoblastoma (cont'd)</u></p> <p>Mutation in RB1 Promoter</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Bisulphite Modification and Methylation specific PCR: Thermal cyclers ABI 3730XL capillary analyser Zymo EZ DNA Methylation-Gold Kit RBSOP_068 RBSOP_041 RBSOP_058 RBSOP_025</p>	<p>RLH</p>
<p>END</p>			