


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8285</p> <p>Accredited to ISO 15189:2022</p>	<p>Barts Health NHS Trust as the host of NHS East and South East London Pathology Partnership</p> <p>Issue No: 025 Issue date: 30 April 2026</p>	
	<p>Pathology Barts Health NHS Trust Pathology and Pharmacy Building Royal London Hospital 80 Newark Street London E1 2ES</p>	<p>Contact: Heather Dolphin Tel: +44 (0)20 3246 3030 E-Mail: heather.dolphin@nhs.net Website: http://www/bartshealth.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address Department of Pathology The Royal London Hospital Pathology and Pharmacy Building 80, Newark Street London E1 1ES</p>	<p>Specimen reception</p>	<p>RLH</p>
<p>Haematology & Blood Transfusion</p> <p>Hugh Boothe 020 3246 0374</p> <p>Kurtis Lee 020 324 0441</p> <p>Julia Lancut 020 324 6044</p> <p>Juswal Dadhra 020 3246 0409</p> <p>Julia Lancut 020 3246 0432</p> <p>Minal Dave 020 3246 0409</p>	<p>Routine Haematology Special Haematology Routine Coagulation Special Coagulation Blood Transfusion</p>	<p>RLH</p>
<p>Clinical Biochemistry</p> <p>Hugh Boothe 020 3246 0374</p> <p>Greg Dearman 020 3246 0443</p> <p>Shatha Abu-Huleh 02032460407</p> <p>Ashraf Ghahani 02032460407</p>	<p>Automated biochemistry Proteins Immunoassay LCMS HPLC</p>	<p>RLH</p>



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Location details	Activity	Location code
Microbiology	Bacteriology Parasitology Mycology Molecular microbiology	RLH
	Kurt Djemal 020 3246 0309	
	Susan Benson 020 3246 0324	
	David Ball 020 3246 0307	
	Nathan North 020 3246 0306	
	Natalie Marshall 020 3246 0308	
Virology	Virology Infectious diseases serology Molecular virology	RLH
	Kurt Djemal 0203 246 0309	
	Xose Couto Parada 020 3246 0471	
	Spiro Pereira 0203 246 0328	
	Deva Perinpanathan 0203 246 0300	
Cellular Pathology	Histology Cytology Frozen Sections Body Storage and Release (mortuary services)	RLH
	Toby Hunt 020 3246 0185	
	Dean McDonald 020 3246 0218	
	Lee Jeffries 020 3246 0218	
	Stephen Rodgers 020 3246 0184	
	Keziban Rehman 020 3246 0170	
	Lynne Pulham 020 3246 0190	
Immunology	Immunology Allergy Autoimmune serology Immunodeficiency Flow Cytometry	RLH
	Sophie Lloyd Davies 020 3246 0287	



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Location details	Activity	Location code
Clinical Transplantation Delordson Kallon 020 3246 0472	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	Specimen reception SBH
Haematology & Blood Transfusion Neha Thomas 0203 465 7240 Hugh Boothe 020 3246 0374 Kurtis Lee 020 3246 0441 Juswal Dadhra 020 3246 0409 Julia Lancut 0203246 0432 Minal Dave 020 3246 0409	Haematology Coagulation Blood Transfusion	SBH
Clinical Biochemistry Greg Dearman 020 3246 0409	Clinical Biochemistry	SBH
Histopathology Toby Hunt 020 3246 0185 Lee Jeffries 020 3246 0218	Frozen Sections	SBH



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Location details	Activity	Location code
<p>Address Whipps Cross University Hospital Pathology Whipps Cross Road Leytonstone London E11 1NR</p> <p>Local Contact As specified below</p>	Specimen Reception	WCUH
<p>Haematology & Blood Transfusion</p> <p>Hugh Boothe 020 3246 0374</p> <p>Kurtis Lee 020 3246 0441</p> <p>Julia Lancut 020 2346 0555</p>	Haematology Coagulation Blood Transfusion	WCUH
<p>Clinical Biochemistry</p> <p>Greg Dearman 0208 539 5522 EXT 5887</p>	Clinical Biochemistry	WCUH
<p>Address Newham University Hospital Pathology Glen Road Plaistow London E13 8SL</p> <p>Local Contact As specified below</p>	Specimen Reception	NUH
<p>Haematology Blood Transfusion</p> <p>Hugh Boothe 020 3246 0374</p> <p>Kurtis Lee 020 3246 0441</p> <p>Gareth Heywood-Beldon 020 7363 8068</p>	Haematology Coagulation Blood Transfusion	NUH
<p>Clinical Biochemistry</p> <p>Greg Dearman 020 7363 8002</p>	Clinical Biochemistry	NUH



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Location details	Activity	Location code
<p>Address Homerton Healthcare NHS Foundation Trust Homerton University Hospital Homerton Row London E9 6SR</p> <p>Local Contact As specified below</p>	Specimen reception	HH
Haematology	Nandini Kizhakkayil 020 8510 7503	HH
Clinical Chemistry	Greg Dearman 020 7363 8002	HH
Blood Transfusion		HH
<p>Address University Hospital Lewisham High Street Lewisham London SE13 6LH</p> <p>Local Contact As specified below</p>	Specimen reception	UHL
Haematology		UHL
Blood Transfusion		UHL
Clinical Chemistry	Greg Dearman 020 7363 8002	UHL
<p>Address University Hospital Lewisham 1st Floor Waterloo Block Lewisham High Street Lewisham London SE13 6LH</p> <p>Local Contact As specified below</p>		
Cellular Pathology	Dalian Beaver 020 3192 3029	UHL
	Miguel Evaristo 020 3192 3029	
Blood Sciences	Richard McLean 020 3192 6669	UHL
	Cytology Histology	
	Blood Transfusion Haematology Clinical Chemistry	



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Location details		Activity	Location code
Address Queen Elizabeth Hospital Stadium Road Woolwich SE18 4QH	Local Contact As specified below	Specimen reception	QEH
Haematology	Tosin Kelani 0208 836 5707	Haematology	QEH
Blood Transfusion		Blood Transfusion	QEH
Clinical Chemistry	Greg Dearman 020 7363 8002	Clinical Chemistry	QEH
Cellular Pathology	Dalian Beaver 020 8856 5683	Histology	QEH



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Testing performed by the Organisation at the locations specified

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Address Theatre Fridge Level 1, zone 10 Newham University Hospital Glen Road Plaistow London E13 8SL	Local Contact Gareth Heywood- Beldon	Blood Collection Fridge Hemobank 20 remote issue fridge No testing occurs, blood storage only	NUH-BF- 1
Address A&E fridge ground floor zone 1 Newham University Hospital Glen Road Plaistow London E13 8SL	Local Contact Gareth Heywood- Beldon	Blood Collection Fridge Hemobank 20 remote issue fridge No testing occurs, blood storage only	NUH-BF- 2
Address Laboratory issue fridge Ground floor zone 2 Newham University Hospital Glen Road Plaistow London E13 8SL	Local Contact Gareth Heywood- Beldon	Hemobank 80 blood collection issue fridge	NUH-BF- 3
Address Gateway Surgical Centre 3 rd floor Newham University Hospital Glen Road Plaistow London E13 8SL	Local Contact Gareth Heywood- Beldon	Blood Collection Fridge Hemobank 20 remote issue fridge No testing occurs, blood storage only	NUF-BF- 4
Address Laboratory stock fridge Ground floor zone 2 Newham University Hospital Glen Road Plaistow London E13 8SL	Local Contact Gareth Heywood- Beldon	Labcold stock fridge No testing occurs, blood storage only	NUH-BF- 5



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Location details		Activity	Location code
Address A&E Resus Room Level 0 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	Hemobank 80 blood collection issue fridge No testing occurs, blood storage only	RLH-BF-1
Address Adult Theatres Level 4 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	Hemobank 80 blood collection issue fridge No testing occurs, blood storage only	RLH-BF-2
Address CCU Level 4 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	Hemobank 80 blood collection issue fridge No testing occurs, blood storage only	RLH-BF-3
Address ITU Level 12 Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	Hemobank 20 remote issue fridge No testing occurs, blood storage only	RLH-BF-4



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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	Hemobank 20 remote issue fridge No testing occurs, blood storage only	RLH-BF-5
Address Royal London Hospital Paediatric Theatres Level 6 Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	Hemobank 80 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	Hemobank 80 remote issue fridge No testing occurs, blood storage only	RLH-BF-7
Address Blood transfusion dept 4 th floor P&P building Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	Helmer IB120 issue fridge	RLH-BF-9
Address Blood transfusion dept 4 th floor P&P building Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	Helmer HB245 stock fridge	RLH-BF-10



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Location details		Activity	Location code
Address Haematology Day Unit 2nd floor Royal London Hospital Whitechapel Road Whitechapel London E1 1BB	Local Contact Julia Lancut	HELMER fridge IB120; No testing occurs; stock of issued blood products for Haematology Day Unit patients	RLH-BF-11
Address KGV Building Level 1E St Bartholomew's Hospital West Smithfield London EC1A 7BE	Local Contact Neha Thomas	Hemobank 80 remote issue fridge No testing occurs, blood storage only	SBH-BF-01
Address KGV Building Level 1 Theatres St Bartholomew's Hospital West Smithfield London EC1A 7BE	Local Contact Neha Thomas	Hemobank 80 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 Neha Thomas	Hemobank 80 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 Neha Thomas	Hemobank 80 remote issue fridge No testing occurs, blood storage only	SBH-BF-04



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Location details		Activity	Location code
Address Blood transfusion and haematology department Blood transfusion laboratory St Bartholomew's Hospital West Smithfield London EC1A 7BE	Local Contact Neha Thomas	Helmarib111 stock fridge	SBH-BF-05
Address Blood transfusion and haematology department Blood transfusion laboratory St Bartholomew's Hospital West Smithfield London EC1A 7BE	Local Contact Neha Thomas	IBR120-GX	SBH-BF-06
Address A&E Resus Junction 5/6 Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Julia Lancut	Hemobank 20 remote issue 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 Julia Lancut	Hemoibank20 remote issue fridge No testing occurs, blood storage only	WCUH-BF-2
Address Maternity Operating Theatres Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood-Beldon	Hemobank 20 remote issue fridge No testing occurs, blood storage only	WCUH-BF-3



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Location details		Activity	Location code
<p>Address Theatres Fridge Junction 7/8 Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR</p>	<p>Local Contact Gareth Heywood-Beldon</p>	<p>Hemobank 20 remote issue fridge No testing occurs, blood storage only</p>	<p>WCUH-BF-4</p>
<p>Address Plane tree centre Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR</p>	<p>Local Contact Gareth Heywood-Beldon</p>	<p>Hemobank 20 remote issue fridge</p>	<p>WCUH-BF-5</p>
<p>Address Acorn ward Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR</p>	<p>Local Contact Gareth Heywood-Beldon</p>	<p>Hemobank 20 remote issue fridge</p>	<p>WCUH-BF-6</p>
<p>Address Issue blood fridge Haematology and blood transfusion junction 2 Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR</p>	<p>Local Contact Gareth Heywood-Beldon</p>	<p>Helmer Hemobank 80</p>	<p>WCUH-BF-7</p>
<p>Address Haematology and blood transfusion junction 2 Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR</p>	<p>Local Contact Gareth Heywood-Beldon</p>	<p>Labcold blood stock fridge</p>	<p>WCUH-BF-8</p>



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Location details		Activity	Location code
Address Pathology Department Ground Floor Homerton Hospital Homerton Row London E9 6SR	Local Contact Nandini Kizhakkayil	BT Haier Fridge -HXC-358B Stock Fridge	HH-BF-1
Address Pathology Department Ground Floor Homerton Hospital Homerton Row London E9 6SR	Local Contact Nandini Kizhakkayil	Labcold (Model RDBG29640MD) Double door blood issue fridge	HH-BF-2
Address Blood Sciences Laboratory Queen Elizabeth Hospital Stadium Road Woolwich SE18 4QH	Local Contact Julia Lancut Tosin Kelani	Blood storage (stock/issue) Fridge managed by laboratory	QEH-BF-1
Address Ward 21 Haematology/Oncology Queen Elizabeth Hospital Stadium Road Woolwich SE18 4QH	Julia Lancut Tosin Kelani	Blood storage only Fridge managed by laboratory	QEH-BF-2
Address Theatres Queen Elizabeth Hospital Stadium Road Woolwich SE18 4QH	Julia Lancut Tosin Kelani	Blood storage only Fridge managed by laboratory	QEH-BF-3
Address Blood issue room Rapid response laboratory University Hospital Lewisham High Street Lewisham London SE13 6LH	Julia Lancut Richard McLean	Blood product storage (Stock/issue) Fridge managed by laboratory	UHL-BF-1



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Location details		Activity	Location code
Address Main Theatre Paediatric University Hospital Lewisham High Street Lewisham London SE13 6LH	Local Contact Julia Lancut Richard McLean	Blood storage Fridge managed by laboratory	UHL-BF-2
Address ICU University Hospital Lewisham High Street Lewisham London SE13 6LH	Julia Lancut Richard McLean	Blood storage Fridge managed by Laboratory	UHL-BF-3
Address Day Surgery Unit University Hospital Lewisham High Street Lewisham London SE13 6LH	Julia Lancut Richard McLean	Blood storage Fridge managed by Laboratory	UHL-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 SAMPLES	<u>Haematology examination activities for the purposes of clinical diagnosis:</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Routine Haematology			
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-9100 series multiple cell counting technique: Sysmex XN 3100 Sysmex XN-20 & XN-10 Laser light scatter/Flow Cytometry/colourmetric method EHA.SYSMEX.4 EHA.SYSMEX.6	RLH SBH NBH WCUH HH QEH UHL
Venous Whole blood (EDTA)	Reticulocyte count	Sysmex XN 91000, XN 2000 & XN 1000 Laser light scatter/Flow Cytometry/colourmetric method EHA. SYSMEX.4	RLH SBH NUH WCUH QEH UHL HH
Venous Plasma (Citrate)	Citrate platelet count	Sysmex XN10/20 Sheath Flow Detection EHA.SYSMEX.4	QEH UHL
Venous Whole blood (EDTA)	Erythrocyte Sedimentation Rate (ESR)	StaRRsed InterRliner RS (Autocompact) Westergren method aggregation capacity mm/hr EHA.ESR.2	RLH HH
Whole blood (EDTA)	Erythrocyte Sedimentation Rate (ESR)	StaRRsed ST (Inversa) Westergren method aggregation capacity mm/hr EHA.ESR.1	UHL WCUH NUH QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Special Haematology		
Venous Whole blood (EDTA)	Morphological examination of peripheral blood films Red cell/white cell/platelets abnormalities/cellularity	Sysmex SP50 Digital morphology analyser May Grunwald Giemsa stain Microscopy EHA.SYSMEX.1 EHA.SYSMEX.5	RLH HH QEH UHL NUH SBH WCUH
Venous Whole blood (EDTA)	Morphological examination of peripheral blood films	RAL staining machine Automated bath staining unit May Grunwald Giemsa stain Microscopy EHA.SYSMEX.4	RLH SBH
Venous Whole blood (EDTA)	Morphological examination of peripheral blood films Red cell/white cell/platelets abnormalities	May Grunwald-Giemsa staining Manual Microscopy EHA.MORPH.4	RLH WCUH NUH SBH HH
Venous Whole blood (EDTA)	Morphological examination of peripheral blood films Red cell/white cell/platelets abnormalities	Romanowski staining Manual microscopy EHA.MORPH.2	QEH UHL
Venous Whole blood (EDTA)	Malaria films Malaria parasites - PF, PV, PO, PM	Thin film manual stain using: Giemsa Thin film manual stain using: Field's stain A Field's stain B EHA.MTEST.2	RLH WCUH NUH HH QEH UHL
Venous Whole blood (EDTA)	Malaria Parasite Identification. Detection of HRP2 and pan specific LDH antigens of Plasmodium species: P. falciparum, pan-detection for P. malariae, P. ovale and P. vivax	Lateral flow immunochromatography CareUS kit EHA.MTEST.2	RLH WCUH NUH HH QEH UHL



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Special Haematology		
Bone Marrow (Aspirate and Trephine)	Bone Marrow examination for iron storage	Bone Iron Stones/Sideroblasts Perl's Prussian Blue EHA.MTEST.3	RLH
Bone marrow	Morphological examination of bone marrow	Red cell/white cell/platelets abnormalities/cellularity May Grunwald-Giemsa staining Manual Microscopy BH-SP-024	QEH UHL
Urine	Iron storage	Perl's Prussian Blue Manual microscopy EHA.MTEST.3	RLH
Venous Whole blood (EDTA)	Infectious mononucleosis screening for Heterophile Antibodies	Accusay mono one-step antibody test kit (AB/AG agglutination) EHA.MTEST.1	HH QEH UHL RLH WCUH NUH
	Routine Coagulation		
Venous Plasma (Citrate)	Routine clotting screen 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 CN-3000 Photometric end-point clot detection ECO.ROUT.8 ECO.ROUT.9	HH QEH UHL
Venous Plasma (Citrate)	D-dimer	Sysmex CN3000 Latex immunoassay ECO.ROUT.8 ECO.ROUT.9	HH QEH UHL



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Special Coagulation		
Venous Plasma (Citrate)	Factors VIII, IX, XI, XII, II, V, VII and X	Sysmex 2500e Stage assay using multi dilution analysis ECO.HPHILIA.5	RLH
Venous Plasma (Citrate)	Factor VIII	Sysmex CN3000 Endpoint clot detection Factor VIII chromogenic and Factor IX assays ECO.HPHILIA.4	UHL
Venous Plasma (Citrate)	Factor VIII and factor XIII,	Sysmex C2500 Chromogenic assays ECO.HPHILIA.5	RLH
Venous Plasma (Citrate)	α 2-antiplasmin	Sysmex CS2500 Chromogenic assay ECO.HPHILIA.5	RLH
Venous Plasma (Citrate)	Von Willebrand factor antigen (vW:Ag)	Sysmex CS2100 Latex assay ECO.HPHILIA.5	RLH
Venous Plasma (Citrate)	von Willebrand factor activity (vW:GpIbM)	Sysmex CS2100 Latex assay ECO.HPHILIA.5	RLH
Venous Plasma (Citrate)	Anti-Xa activity assay for low molecular weight heparin	Sysmex CS2500 & 5100 Chromogenic kinetic assay ECO.ROUT.8/9	RLH SBH NUH WCUH
Venous Plasma (Citrate)	Anti-Xa activity assay for organan	Sysmex CS2500 & 5100 Chromogenic kinetic assay ECO.ROUT.8/9	RLH
Venous Plasma (Citrate)	Anti-Xa activity assay for rivaroxaban	Sysmex CS2500 & 5100 Chromogenic kinetic assay ECO.ROUT.8/9	RLH NUH WCUH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Special Coagulation (cont'd)		
Venous Plasma: Citrate	Anti-Xa activity assay for rivaroxaban	Sysmex CS2500 & 5100 Chromogenic kinetic assay ECO.ROUT.8/9	RLH NUH WCUH
Venous Plasma (Citrate)	Anit-Xa activity assay for unfractionated heparin	Sysmex CS2500 & 5100 Chromogenic kinetic assay ECO.ROUT.8/9	RLH SBH NUH WCUH
Venous Plasma (Citrate)	Anti-Xa activity assay for edoxaban	Sysmex CS2500 and 5100 Chromogenic kinetic assay ECO.ROUT.8/9	RLH NUH WCUH
Venous Plasma (Citrate)	Inhibitor screen and assay for: Factor VIII inhibitors Factor IX inhibitors Factor XI inhibitors Factor II inhibitors Factor V inhibitors Factor VII inhibitors Factor X inhibitors Factor XIII inhibitors r vWF inhibitors	Sysmex CS2500 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 CS2500 APTT-based screen HAEM-COAG-HAEM-004	RLH
Venous Plasma (Citrate)	Lupus Anticoagulant screen by DRVVT Lupus Anticoagulant screen by dilute APTT	Sysmex CS5100 dAPTT end point clot detection DRVVT HAEM-COAG-LUPUS-001	RLH
Venous Plasma (Citrate)	Antithrombin activity assay	Sysmex CS2500 Turbidimetric immunoassay End point clot detection Latex immunoassay ECO.THROM.1	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Special Coagulation (cont'd)		
Venous Plasma (Citrate)	Free Protein S antigen assay	Sysmex CS2500 Turbidimetric immunoassay End point clot detection Latex immunoassay ECO.THROM.1	RLH
Venous Plasma (Citrate)	Protein C activity assay	Sysmex CS2500 Turbidimetric immunoassay End point clot detection Latex immunoassay ECO.THROM.1	RLH
Venous Plasma (Citrate)	Thrombin Inhibitor assay Dabigatran Argatroban	Sysmex CS2500 Turbidimetric immunoassay End point clot detection Chromogenic assay ECO.HPHILIA.6	RLH
Plasma	Heparin Induced Thrombocytopenia screen (HIT)	Werfen AcuStar Automated chemiluminescent immunoassay ECO.MASSAY.3	QEH
Venous Platelet Rich Plasma (Citrate)	Platelet Function Ristocetin Induced Platelet Aggregation	Helena AggRam Light Absorption Borne aggregometry HAEM-COAG-PLTF-001	RLH



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HUMAN BODY SAMPLES (cont'd)	<p><u>Haematology examination activities for the purposes of clinical diagnosis:</u> (cont'd)</p> <p>Red Cell</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Documented in-house methods to meet the requirements of the Sickle Cell and Thalassemia screening programme as defined in the NHS Sickle Cell and thalassemia screening: Laboratory QA evidence requirements.</p>	
Venous Whole blood (EDTA)	<p>Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants</p> <p>HbF HbA2 HbA1c Hb J Hb Ao Hb D-Eran Hb Lepore Hb E Hb G Hb D Hb Stanleyville II Hb S Hb O-Arab Hb C</p>	<p>Sebia Hydrasys Capillary electrophoresis ERC.AUTO. 6 ERC.AUTO. 2 ERC.AUTO. 5</p>	RLH
Venous Whole blood (EDTA)	<p>Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants</p> <p>HbF HbA2 HbA1c Hb J Hb Ao Hb D-Eran Hb Lepore Hb E Hb G Hb D Hb Stanleyville II Hb S Hb O-Arab, HbC</p>	<p>BioRad Variant II HPLC Beta Thal Dual kit. ERC.AUTO. 6 ERC.AUTO. 2 ERC.AUTO. 5</p>	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Red Cell (cont'd)	Documented in-house methods to meet the requirements of the Sickle Cell and Thalassemia screening programme as defined in the NHS Sickle Cell and thalassemia screening: Laboratory QA evidence requirements.	
Venous Whole blood (EDTA)	Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants HbF HbA2 HbA1c Hb J Hb Ao Hb D-Eran Hb Lepore Hb E Hb G Hb D Hb Stanleyville II Hb S Hb O-Arab Hb C	BioRad Variant II HPLC Short programme ERC.AUTO. 6 ERC.AUTO. 2 ERC.AUTO. 5	QEH UHL
Venous Whole blood (EDTA)	Sickle Cell screening	Streck Sickledex Manual relative insolubility method EHA.MAN.1	RLH HH QEH UHL
Venous Whole blood (EDTA)	G6PD Spot test	Trinity Biotech G6PD screening kit. Manual detection of fluorescence method ERC.HLYsis.2.	RLH
Venous Whole blood (EDTA)	Detection of haemoglobin variants	Sebia Hydragel Acid Haemoglobin (E) Gel ERC.MAN.4	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Haematology examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Red cell (cont'd)			
Venous Whole blood (EDTA)	Detection of haemoglobin variants	Sebia Hydragel Alkaline Haemoglobin (E) Gel ERC.MAN.3	RLH
Venous Whole blood (EDTA)	Detection of haemoglobin F in patients suspected of hereditary persistence of foetal haemoglobin and $\delta\beta$ thalassemia	HPLC Variant II ERC.AUTO.6 ERC.AUTO.2	HH QEH RLH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis:</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Venous Whole blood (Plasma)	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	Bio-Rad cards/gels ID-centrifuge Micro column agglutination immunoassay HAEM-BT-Group-014 HAEM-BT-INVGN-002	RLH SBH WCUH NUH HH
Venous Whole blood (Plasma)	Antibody Screen by detection of antibodies to: 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	Bio-Rad cards/gels ID-centrifuge Micro column agglutination immunoassay HAEM-BT-Group-014 HAEM-BT-INVGN-002	RLH SBH WCUH NUH HH



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Venous Whole blood (Plasma)	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	Grifols/gels ID-centrifuge Micro column agglutination immunoassay QE-BT-MAN002 QE-BT-MAN003 QE-BT-MAN009	UHL QEH
Venous Whole blood (Plasma)	Antibody Screen by detection of antibodies to: 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	Bio-Rad cards/gels ID-centrifuge Micro column agglutination immunoassay HAEM-BT-Group-014 HAEM-BT-INVGN-002	UHL QEH
Venous Whole blood (Plasma)	Blood Group by detection and identification of antigens A A1 B AB O RhD	Grifols Erytra Grifols Gel cards QE-BTAUT008 QE-BT-AUT009 QE-BT-MAN002 QE-BT-MAN003	QEH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Venous Whole blood (EDTA)	Direct Antiglobulin Test (DAT)	Grifols Gel: Monospecific and Polyspecific DG Gel Coombs card DG Gel DC Scan card DG Gel Sol QE-MAN005	QEH UHL
Venous Whole blood (EDTA)	Direct Antiglobulin Test (DAT)	Bio-Rad Micro column agglutination immunoassay HAEM-BT-INVGN-003	RLH SBH WCUH NUH HH
Venous Whole blood (EDTA)	Red Cell Phenotyping for antigens of the following blood group systems: Rh: C, D, E, c, e, Cw Kell: K	Gel Erytra Grifols Gel cards QE-BTAUT008 QE-BT-AUT009 QE-BT-MAN002 QE-BT-MAN003 QE-BT-MAN009	QEH UHL
Venous Whole blood (EDTA)	Elution's	Acid elution followed by Micro column agglutination immunoassay HAEM-BT-INVGN-004	RLH
Venous Whole blood (EDTA)	Antibody titration: Titration of anti-A and Anti-B against A1, A2 and B cells	BioRad Coombs anti-IgG card HAEM-BT-INVGN-009 HAEM-BT-INVGN-011	RLH
Venous Whole blood (EDTA)	Red Cell phenotyping: 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	Bio-Rad Micro column agglutination immunoassay HAEM-BT-INVGN-014	RLH WCUH SBH NUH HH



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HUMAN BODY SAMPLES (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Venous Whole blood: (Plasma)	Crossmatch by IAT Compatibility testing Serological crossmatch Serological compatibility testing	Bio-Rad Micro column agglutination immunoassay HAEM-BT-XM-001	RLH SBH WCUH NUH HH
Donor red blood cells Patient red blood cells Plasma in EDTA	IAT manual Crossmatch	Grifols: DG Gel Coombs card GD Gel Sol NHSBT OR1r NHSBT Weak Anti-D NHSBT Inert AB Serum QE-MAN005	QEH UHL
Venous whole blood: EDTA Cord Blood: EDTA	Foetal Maternal Haemorrhage screen (Kleihauer Test)	Kleihauer Acid Elution Technique EBT.INVEST.4 QE-BT-ANT004	NUH RLH WCUH QEH UHL



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Determination of: ACE	Roche c8000 (c/702) BCHEM-COBAS-SOP-1 Kinetic method using third party reagents Buhlmann as an open channel BB-AP-065	QEH RLH
Serum	Alanine Aminotransferase (ALT)	Enzymatic Method	RLH SBH NUH WCUH
Serum	Albumin	Colorimetric BCG	RLH SBH NUH WCUH QEH UHL
Serum	Alkaline Phosphatase (ALP)	Colorimetric	RLH SBH NUH WCUH QEH UHL
Serum	Alpha – 1 Antitrypsin	Immunoturbidimetric	RLH
Serum	Amikacin	Roche KIMS	RLH UHL
Serum	Ammonia	Enzymatic	RLH WCUH QEH UHL
Serum	Amylase	Enzymatic detection methods BBAP-109	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Determination of: (cont'd)	Roche c8000 (c/702) BCHEM-COBAS-SOP-1	
Serum	Aspartate Aminotransferase (AST)	Enzymatic	RLH SBH NUH WCUH QEH UHL
Serum	Bicarbonate	Enzymatic	RLH SBH WCUH QEH UHL
Serum	C3	Immunoturbidimetric	RLH
Serum	C4	Immunoturbidimetric	RLH
Serum	Caeruloplasmin	Immunoturbidimetric	RLH
Serum	Calcium	Photometric	RLH NUH SBH WCUH QEH UHL
Serum	Carbamazepine	Roche KIMS	RLH
Serum	Chloride	Indirect ISE	RLH NUH SBH WCUH QEH
Serum	Cholesterol	Enzymatic colorimetric	RLH NUH WCUH QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Determination of: (cont'd) C-Reactive Protein (CRP)	Roche c8000 (c/702) BCHEM-COBAS-SOP-1 Immunoturbidimetric	RLH SBH NUH WCUH QEH
Serum	Creatine Kinase (CK)	Enzymatic	RLH SBH NUH WCUH QEH UHL
Serum	Creatinine	Enzymatic	RLH NUH WCUH SBH QEH
Serum	Direct Bilirubin	Wako Vandate oxidation method colorimetric Direct Bilirubin on Cobas 8000 as an open channel BB-AP-074	QEH UHL
Serum	Ethanol	Enzymatic	RLH WCUH QEH UHL
Serum	Fructosamine	Colorimetric	RLH
Serum	Gamma-Glutamyltransferase	Enzymatic colorimetric	RLH SBH NUH WCUH QEH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Determination of: (cont'd)	Roche c8000 (c/702) BCHEM-COBAS-SOP-1	
Serum	Gentamicin	Enzymatic immunoassay	QEH UHL RLH
Serum	Glucose	Enzymatic	RLH NUH SBH WCUH QEH UHL
Serum	HDL Cholesterol	Enzymatic colorimetric	RLH NUH WCUH QEH UHL
Serum	Immunoglobulin A	Immunoturbidimetric	RLH
Serum	Immunoglobulin G	Immunoturbidimetric	RLH
Serum	Immunoglobulin M	Immunoturbidimetric	RLH
Serum	Iron	Colorimetric	RLH QEH UHL
Serum	Lactate	Colorimetric	RLH WCUH QEH
Serum	Lactate Dehydrogenase (LDH)	Enzymatic	RLH SBH NUH WCUH QEH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Determination of: (cont'd)	Roche c8000 (c/702) BCHEM-COBAS-SOP-1	
Serum	Lipase	Enzymatic	RLH NUH WCUH QEH
Serum	Lithium	Colorimetric	RLH QEH UHL
Serum	Magnesium	Colorimetric using xylydyl blue	RLH NUH SBH WCUH QEH UHL
Serum	Paracetamol	Colorimetric	RLH NUH WCUH QEH UHL
Serum	Phenobarbitone	Roche KIMS	RLH
Serum	Phenytoin	Roche KIMS	RLH QEH
Serum	Phosphate	Molybdate UV	RLH NUH SBH WCUH QEH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Determination of: (cont'd)	Roche c8000 (c/702) BCHEM-COBAS-SOP-1	
Serum	Potassium	Indirect ISE	RLH SBH NUH WCUH QEH UHL
Serum	Rheumatoid Factor	Immunoturbidimetric	RLH QEH
Serum	Salicylate	Enzymatic	RLH QEH UHL
Serum	Sodium	Indirect ISE	RLH SBH NUH WCUH QEH UHL
Serum	Theophylline	Roche KIMS	RLH
Serum	Tobramycin	Roche KIMS	RLH
Serum	Total Bilirubin	Colorimetric Diazomethod	RLH SBH NUH WCUH QEH UHL
Serum	Total Protein	Colorimetric	RLH SBH NUH WCUH QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Determination of: (cont'd)	Roche c8000 (c/702) BCHEM-COBAS-SOP-1	
Serum	Transferrin	Immunturbidimetric	RLH QEH
Serum	Triglycerides	Enzymatic colorimetric Uricase	RLH NUH WCUH QEH UHL
Serum	Urate	Enzymatic colorimetric	RLH SBH NUH WCUH QEH UHL
Serum	Urea	Enzymatic Urase	RLH SBH NUH WCUH QEH UHL
Serum	Vancomycin	Roche KIMS	RLH QEH UHL
Serum	Valprorate	Roche KIMS	RLH QEH
CSF	Glucose	Colorimetric	WCUH RLH
CSF	Lactate	Colorimetric	RLH QEH
CSF	Total protein	Turbidimetric method	RLH WCUH QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Determination of: (cont'd)	Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1	
Urine	Albumin	Turbidimetric method	RLH
Urine	Calcium	Photometric	RLH
Urine	Creatinine	Colorimetric assay Jaffé method	RLH WCUH
Urine	Magnesium	Colorimetric using xylydyl blue	RLH
Urine	Phosphate	Molybdate UV BCHEM-COBAS-SOP-1	RLH
Urine	Potassium	Indirect ISE	RLH WCUH QEH UHL NUH
Urine	Protein	Turbidimetric method	RLH WCUH QEH UHL
Urine	Sodium	Indirect ISE	RLH WCUH QEH UHL NUH
Urine	Urea	Kinetic enzymatic BCHEM-COBAS-SOP-1	QEH UHL RLH
Urine	Urate	Kinetic enzymatic BCHEM-COBAS-SOP-1	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Total Bile Acids	Roche c8000 (c/702) –using Dialab enzymatic rate method BCHEM-COBAS-702-METHOD-47	RLH QEH
Data	Calculation of:		
Data	Corrected Calcium	Adjusted calcium mmol/L = $0.02^* (43 - \text{albumin g/L} + \text{measured total calcium mmol/L})$ BCHEM-COBAS-SOP-1	RLH NUH SBH WCUH QEH UHL
Data	Globulin	BB-AP-143	QEH UHL
Data	Non-HDL cholesterol	BB-AP-133	QEH UHL
Data	TIBC	Transferrin x 0.0251 BCHEM-COBAS-SOP-1	RLH
Data	Corrected Phenytoin	Measured phenytoin/ $1 - \alpha(P1/P) + \alpha$ BCHEM-COBAS-SOP-1	RLH
Data	Macro Prolactin	%Recovery = $((\text{Monomeric prolactin}) / \text{Total PRL}) \times 100$ BCHEM-E-UNIT-METHOD-SOP25	RLH QEH
Data	Urine protein:creatinine ratio	BB-AP-148	QEH UHL
Serum Urine	Osmolality	Advanced Micro-Osmometer Freezing point depression BCHEM-OSM-1	RLH NUH SBH HH QEH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of:	Roche Cobas e801 BCHEM-IA-SOP-1	
Serum	Antithyroglobulin antibodies	Competitive	RLH
Serum	Adrenocorticotrophic Hormone (ACTH)	Sandwich Assay	RLH
Serum	BNP (NT-Pro)	Sandwich Assay	RLH QEH
Serum	CA125	Sandwich Assay	RLH
Serum	CA15-3	Sandwich Assay	RLH
Serum	CA19-9	Sandwich Assay	RLH
Serum	Carcinoembryonic Antigen (CEA)	Sandwich Assay	RLH
Serum	Cortisol	Competitive Assay	RLH QEH UHL
Serum	C-Peptide	Sandwich Assay	RLH
Serum	Digoxin	Competitive Immunoassay detection BCHEM-IA-SOP-1	QEH UHL
Serum	Ferritin	Sandwich Assay	RLH QEH UHL
Serum	Follicle Stimulating Hormone (FSH)	Sandwich Assay	RLH
Serum	FT4	Competitive Assay	RLH QEH UHL
Serum	Growth Hormone	Sandwich Assay	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 SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of: (cont'd)		
Serum	Human Chorionic Gonadotrophin (HCG)	Roche Cobas e801 BCHEM-IA-SOP-1 Sandwich Assay	RLH NUH WCUH QEH UHL
Serum	Insulin	Sandwich Assay	RLH
Serum	Luteinizing Hormone (LH)	Sandwich Assay	RLH
Serum	Parathyroid Hormone (PTH)	Sandwich Assay	RLH
Serum	Oestradiol	Competitive Assay	RLH
Serum	Procalcitonin	Sandwich Assay	RLH QEH
Serum	Progesterone	Competitive Assay	RLH
Serum	Prolactin	Sandwich Assay	RLH
Serum	Prostate Specific Antigen (PSA)	Sandwich Assay	RLH
Serum	Folate	Competitive Assay	RLH QEH
Serum	Sex Hormone Binding Globulin (SHBG)	Sandwich Assay	RLH
Serum	Testosterone	Competitive Assay	RLH
Serum	Thyroglobulin	Sandwich Assay	RLH
Serum	Thyroid peroxidase (TPO)	Sandwich Assay	RLH
Serum	Thyroid Stimulating Hormone (TSH)	Sandwich Assay	RLH QEH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Measurement of: (cont'd) Troponin T	Roche Cobas e801 BCHEM-IA-SOP-1 Sandwich Assay	RLH NUH WCUH QEH UHL
Serum	Free T3	Competitive Assay	RLH QEH UHL
Serum	Vitamin B12	Competitive Assay	RLH QEH
	Vitamin D	Competitive Assay	RLH QEH UHL
Serum	Troponin T	Roche Cobas e411 Sandwich Assay BCHEM-IA-SOP-1	SBH
	Measurement of:	Roche Cobas Pro c503 BCHEM-IA-SOP-1	
Serum Plasma	Albumin	Colorimetric (BCG)	HH
Serum Plasma	Alkaline phosphatase (ALP)	Colorimetric	HH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of: (cont'd)	Roche Cobas Pro c503 BCHEM-IA-SOP-1	
Serum Plasma	Alanine aminotransferase (ALT)	Enzymatic (with PLP)	HH
Serum Plasma	Amikacin	Kinetic interaction of microparticles (KIMS)	HH
Plasma	Ammonia	Enzymatic	HH
Serum Plasma	Aspartate aminotransferase (AST)	Enzymatic (with PLP)	HH
Serum Plasma	Bicarbonate	Enzymatic	HH
Serum Plasma	Calcium	Colorimetric	HH
Serum Plasma	Chloride	Ion specific electrode (ISE) (indirect)	HH
Serum Plasma	Cholesterol (total)	Enzymatic colorimetric	HH
Serum Plasma	Creatine kinase (CK)	Enzymatic	HH
Serum Plasma	Creatinine	Enzymatic	HH
Serum Plasma	C-reactive protein (CRP)	Immunoturbidimetric,	HH
Plasma	Ethanol	Enzymatic	HH
Serum Plasma	Gentamicin	Kinetic interaction of microparticles (KIMS)	HH
Serum Plasma	Gamm-glutamyl transferase (GGT)	Enzymatic	HH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of: (cont'd)	Roche Cobas Pro c503 BCHEM-IA-SOP-1	
Plasma	Glucose	Enzymatic	HH
Serum Plasma	High density lipoprotein cholesterol (HDL)	Enzymatic	HH
Serum Plasma	Lactate	Colorimetric	HH
Serum Plasma	(Lactate dehydrogenase (LDH)	Enzymatic	HH
Serum Plasma	Lipase	Enzymatic	HH
Serum Plasma	Magnesium	Colorimetric (xylydyl blue)	HH
Serum Plasma	Paracetamol	Homogenous enzyme immunoassay	HH
Serum Plasma	Phosphate	Molybdate UV	HH
Serum Plasma	Potassium	Ion specific electrode (ISE) (indirect)	HH
Serum Plasma	Sodium	Ion specific electrode (ISE) (indirect)	HH
Serum Plasma	Total bilirubin	Colorimetric (dialzo)	HH
Serum Plasma	Total protein	Colorimetric	HH
Serum Plasma	Triglycerides	Colorimetric (uricase)	HH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of: (cont'd)		
Serum Plasma	Urea	Roche Cobas Pro c503 BCHEM-IA-SOP-1 Enzymatic (urease)	HH
Serum Plasma	Uric acid (urate)	Enzymatic	HH
Serum Plasma	Vancomycin	Kinetic interaction of microparticles (KIMS)	HH
CSF	Glucose	Enzymatic (hexokinase)	HH
CSF	Lactate	Colorimetric	HH
CSF	Total Protein	Turbidimetric	HH
Urine	Creatinine	Colorimetric (enzymatic based on Jaffe)	HH
Urine	Potassium	Ion specific electrode (ISE) (indirect)	HH
Urine	Sodium	Ion specific electrode (ISE) (indirect)	HH
Urine	Total protein	Turbidimetric	HH
Serum Plasma	Human chorionic gonadotrophin (HCG)	Sandwich immunoassay	HH
Serum Plasma	Free T4 (FT4)	Competitive immunoassay	HH
Serum Plasma	Procalcitonin (PCT)	Competitive immunoassay	HH
Serum Plasma	Troponin T	Sandwich immunoassay	HH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of: (cont'd)		
Serum Plasma	Thyroid stimulating hormone (TSH)	Roche Cobas Pro c503 BCHEM-IA-SOP-1	HH
	Proteins		
Serum	Paraprotein	Sebia Capillarys , Electrophoresis BCHEM-PROT-METHOD-SOP26	RLH
Serum	Paraprotein	Sebia Capillarys , Immunotyping BCHEM-PROT-METHOD-SOP27	RLH
Serum	Paraprotein	Sebia Hydrasys, Immunofixation BCHEM-PROT-METHOD-SOP10	RLH
Serum	Paraprotein screen	Sebia Capillarys 3 OCTA using Capillary Zonal Electrophoresis (CZE) BCHAM-PROT-SOP 4	RLH
Serum	Paraprotein quantification	Sebia Capillarys 3 OCTA using Capillary Zonal Electrophoresis (CZE) BCHAM-PROT-SOP 4	RLH
Serum	Paraprotein immunotyping	Sebia Capillarys 3 OCTA using Capillary Zonal Electrophoresis (CZE) and Immunosubtraction BCHAM-PROT-SOP 4	RLH
Urine	Monoclonal Protein Screen	Sebia Hydrasys 2, High Sensitive Urine Gel Electrophoresis BCHEM-PROT-METHOD-SOP19	RLH
Urine	Monoclonal Protein Immunotyping	Sebia Hydrasys 2, Immunofixation BCHEM-PROT-METHOD-SOP10	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Proteins Aldosterone	DiaSorin Liaison Immunoassay BCHEM-LIASON-METHOD-SOP3	RLH
Serum	Insulin Growth Factor-1 (IGF-1)	DiaSorin Liaison Immunoassay BCHEM-LIASON-METHOD-SOP4	RLH
Sweat	Detection and quantification of Chloride (Sweat test)	M926S Digital Sweat Chloride meter Titrimetric method BCHEM-PROT-METHOD-SOP11	RLH
Sweat	Detection and quantification of Chloride (Sweat test)	Chlorocek Chloridometer Coulometric Titration using BB-AP-087	UHL
	LCMS Determination of:	Waters Acquity UPLC-Quattro Premier XE Liquid chromatography-tandem mass spectrometry (LCMS/MS)	
Serum	Androstenedione (A4)	BCHEM-LCMS-METHOD-SOP8	RLH
Serum	Dehydroepiandrosterone Sulphate (DHEAS)	BCHEM-LCMS-METHOD-SOP8	RLH
Serum	Extracted Testosterone (LCMS)	BCHEM-LCMS-METHOD-SOP8	RLH
Serum	11-Deoxycortisol	BCHEM-LCMS-METHOD-SOP8	RLH
Serum	17-Hydroxyprogesterone	BCHEM-LCMS-METHOD-SOP8	RLH
Serum	Dihydrotestosterone (DHT)	BCHEM-LCMS-METHOD-SOP9	RLH
Whole Blood	Cyclosporin A	BCHEM-LCMS-METHOD-SOP2	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	LCMS (cont'd)		
Whole Blood	Tacrolimus	BCHEM-LCMS-METHOD-SOP2	RLH
Whole Blood	Sirolimus	BCHEM-LCMS-METHOD-SOP2	RLH
	Special Chemistry		
Urine	Determination of:	Thermo Scientific Indiko Plus CEDIA Drugs of Abuse BCHEM-INDIKO-5	RLH
	Amphetamine Benzodiazepines Buprenorphine Cocaine EDDP (Methadone metabolite) Opiates THC (Cannabinoids) 6MAM (heroin metabolite)		
Serum	Detection and quantification of Copper	Analyst 800 Atomic Absorption Spectrophotometer In house reagents BCHEM-AAS-METHOD-SOP7	RLH
Serum	Detection and quantification of Selenium	Analyst 800 Atomic Absorption Spectrophotometer In house reagents BCHEM-AAS-METHOD-SOP8	RLH
Serum	Detection and quantification of Zinc	Analyst 800 Atomic Absorption Spectrophotometer In house reagents BCHEM-HPLC-METHOD-SOP6	RLH
Serum	Detection and quantification of Vitamin A	Dionex Ultimate 3000 HPLC Chromsystems Vitamins A & E kit. BCHEM-HPLC-METHOD-SOP9	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Detection and quantification of Vitamin E	Dionex Ultimate 3000 HPLC Chromsystems Vitamins A & E kit. BCHEM-HPLC-METHOD-SOP9	RLH
Urine	Detection and quantification of 5HIAA	Dionex Ultimate 3000 HPLC 150 mm Allsphere ODS column BCHEM-HPLC-METHOD-SOP1	RLH
Urine	Metanephrines Screen for: Metadrenaline Normetadrenaline 3-methoxytyramine	Chromsystems Urine Metadrenalines kit BCHEM-HPLC-METHOD-SOP4	RLH
CSF	Determination of Xanthochromia (haempigments)	Uvikon XL Spectrophotometry BCHEM-UVIKON XL001	RLH
CSF	Determination of Xanthochromia (haempigments)	Perkin Elmer Spectrophotometer Scanning spectrophotometric BCHEM-XANTH-1	QEH
Whole Blood	Detection and quantification of Glycated Haemoglobin (HbA1c)	BioRad D100 HPLC BCHEM-HPLC-METHOD-10	RLH
Faeces	Faecal Immunochemical Test (FIT) Detection of blood	OC-Sensor Pledia Faecal Immunotesting BCHEM-BATCH-METHOD-SOP5	RLH
Serum	Beta-2-microglobulin (B2M)	Binding Site Optilite Turbidimetry BCHEM-PROT-METHOD-SOP42	RLH
Serum	Free Kappa Light Chains	Binding Site Optilite Turbidimetry BCHEM-PROT-METHOD-SOP42	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Free Lambda Light Chains	Binding Site Optilite Turbidimetry BCHEM-PROT-METHOD-SOP43	RLH
Serum	Free Kappa/Free Lambda Ratio	Calculated Test Ratio BCHEM-PROT-METHOD-SOP43	RLH
Serum	Cryoglobulin	Visual technique BB-PP-5	QEH



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HUMAN BODY SAMPLES (cont'd)	<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 manufacturers' operating instructions.	
Urine Wound swabs Genital swabs Throat swabs Oral swabs Skin swabs Eye swabs Ear swabs Nose swabs	Bacteriology Isolation and characterisation of microorganisms of clinical significance	Automated inoculation onto selective and non-selective culture media using: BioMérieux Copan WASP EMI.SOP.4-COPAN	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 Bronchoalveolar lavage	Isolation and characterisation of microorganisms of clinical significance	Microscopy, manual gram stain and manual culture EMI.FLUI.1 EMI.SWAB.2 EMI.SOP.1 EMI.URIN.5 EMI.FLUI.5 EMI.RESP.4 EMI.RESP.1 EMI.GENI.1 EMI.GENI.2 EMI.SWAB.2	RLH
Rectal Swabs Wound swabs Throat swabs Skin swabs Nose swabs	Identification of bacteria and antibiotic susceptibility testing	Microscopy, manual gram stain and manual culture	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Rectal Swabs Wound swabs Throat swabs Skin swabs Nose swabs	Detection of: MRSA	Culture onto selective media and Oxoid PBP2a EMI.SWAB.1	RLH
Rectal Swabs Wound swabs Throat swabs Skin swabs Nose swabs	MSSA	Culture onto selective media and Oxoid PBP2a EMI.SWAB.1	RLH
Rectal Swabs Wound swabs Throat swabs Skin swabs Nose swabs	VRE	Culture onto selective media EMI.SWAB.1	RLH
Rectal Swabs Wound swabs Throat swabs Skin swabs Nose swabs	CRO	Culture onto selective media EMI.SWAB.1	RLH
Inoculated GC Selective agar	Isolation of <i>Neisseria gonorrhoeae</i>	Microscopy, manual gram stain and manual culture EMI.GENI.2	RLH
Whole blood	Detection of microbial growth and general isolation of microorganisms of clinical significance	BioMérieux Virtuo (fluorescence detection) followed by isolation onto selected media EMI.BCULT.4	RLH
Faeces Rectal swab	Isolation and characterisation of <i>Salmonella spp.</i> <i>Shigella spp.</i> <i>Campylobacter spp.</i> <i>E coli 0157</i> <i>Vibrio spp.</i> <i>Yersinia spp.</i>	Microscopy, manual gram stain and manual culture EMI.FAEC.6	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Bacterial culture isolates produced by the laboratory	Identification of bacteria	Bruker MALDI-ToF-MS EMI.SOP.9	RLH
Yeast culture isolated produced by the laboratory	Identification of yeasts	Bruker MALDI-ToF-MS EMI.SOP.9	RLH
Bacterial culture isolates produced by the laboratory	Antibiotic susceptibility testing	EUCAST disc testing EMI.SENSI.3	RLH
Vaginal swabs	Identification of Group B streptococci	Microscopy, manual gram stain and manual culture E&O chromogenic agar EMI.SWAB.1	RLH
Tissue Dialysis fluid Ascitic Fluid Pleural fluid Other Body fluids CSF	Examination for white blood cells, red blood cells, differential and detection of bacteria and fungi.	Manual method Gram stain and Bright field microscopy Differential stain using Romanowsky and phase microscopy EMI.SOP.16 EMI.FLUI.1	RLH
Urine	Detection, identification and quantification of red blood cells, white cells and epithelial cells of clinical significance in urine	Sysmex UF5000 Flow cytometry EMI.URIN.4	RLH
Urine	Detection, identification and quantification of red blood cells, white cells, and epithelial cells of clinical significance in urine	Manual: Phase contrast microscopy MICR.B.SOP004	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Sputum Bronchoalveolar lavage Tissue Dialysis fluid Ascitic fluid Pleural fluid Other Body fluids CSF Cystic Fibrosis Sputum	Isolation and characterisation of <i>Mycobacteria sp.</i>	Becton Dickenson MGIT EMI.TB.1 Manual culture E&O solid media slopes EMI.TB.1	RLH
Sputum Bronchoalveolar lavage Tissue Dialysis fluid Ascitic fluid Pleural fluid Other Body fluids CSF Cystic Fibrosis Sputum	Isolation and characterisation of <i>Mycobacteria sp.</i>	Manual culture E&O solid media slopes EMI.TB.1	RLH
Sputum Bronchoalveolar lavage Tissue Dialysis fluid Ascitic Fluid Pleural fluid Other Body fluids CSF Cystic Fibrosis Sputum	Isolation and characterisation of <i>Mycobacteria sp.</i>	Manual auramine phenol stain and fluorescent microscopy Confirmation of auramine positive slides by Ziehl-Neelsen stain and microscopy EMI.TB.1	RLH
Whole blood	Isolation and characterisation of <i>Mycobacteria sp.</i>	Becton Dickenson FX40 EMI.TB.1	RLH
CSF Serum	Detection of Cryptococcal antigens	Alpha lab lateral flow device EMI.FLUI.4	RLH
Bronchoalveolar lavage Serum	Detection of Galactomannan	BioRad Platella TM Aspergillus EIA kit EMI.MYCO.2	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Faeces	Detection of cryptosporidium	Manual Cold Ziehl Neelsen stain and microscopy EMI.SOP.16 EMI.FAEC.5	RLH
Faeces	Detection of cryptosporidium	Manual Auramine stain and fluorescent microscopy EMI.FAEC.7	RLH
Faeces	Detection and identification of ova, cysts and parasites	Manual parasep concentration and microscopy EMI.SOP.16 EMI.FAEC.5	RLH
Faeces	Molecular detection of <i>Cryptosporidium parvum/hominis</i> <i>Giardia lamblia</i> <i>Entamoeba histolytica</i>	BD Max PCR EMI.FAEC.1	RLH
Faeces	Detection of <i>Clostridioides difficile</i> GDH	Dynex DS2 ProLab GDH EIA kit EMI.FAEC.1	RLH
Faeces	Detection of <i>Clostridioides difficile</i> toxin	Quik Chek Complete lateral flow device EMI.FAEC.1	RLH
Faeces	Detection of <i>Clostridioides difficile</i> toxin genes	BD Max PCR EMI.FAEC.1	RLH
Faeces	Helicobacter Antigen	Dynex DS2 Premier Platinum HpSA PLUS antigen test kit EMI.FAEC.2	RLH
Skin Nail Hair Respiratory sample Bodily fluids Tissue samples	Isolation and characterisation of fungi of clinical significance	Microscopic examination of colonies using calcofluor white and fluorescent microscopy brightfield microscopy using EMI.MYCO.1	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Skin Nail Hair Respiratory sample Bodily Fluids Tissue samples	Isolation and characterisation of fungi of clinical significance	Microscopic examination of colonies using Lactophenol blue and light microscopy	RLH
Serum	Detection of Beta D Glucan	Toxinometer MT6500 Wako-Fujifilm BDG test EMI.SER.4	RLH
Serum	Detection of Strongyloides antibodies	Dynex DS2 Bordier Strongyloides ratti EIA kit EMI.SER.1	RLH
Bacterial or yeast isolates Sterile fluids Sterile tissues Bacterial/fungal Isolates Paediatric plasma Blood culture	DNA extraction	AusDiagnostics MT-Prep 24 MT Prep Viral/Pathogen nucleic acids extraction B Kit EVI.AUTO.EQUIP.11	RLH
Sputum Bronchoalveolar lavage CSF EBUS	Detection <i>Mycobacterium tuberculosis</i> and Rifampicin resistance	Cepheid GeneXpert MTB/RIF Ultra cartridge EMI.TB.4	RLH
Sputum	Detection of <i>Mycobacterium tuberculosis</i> complex with Rifampicin and Isoniazid resistance markers	BD MAX MDR TBEMI.TB.4	RLH
Faeces	Detection of: <i>Salmonella spp</i> <i>Shigella spp</i> Enteroinvasive <i>E.coli</i> Campylobacter spp. (<i>C.coli</i> and <i>C.jejuni</i>) Shiga-toxins 1 and 2 (STEC or VTEC <i>Shigella dysenteriae</i>	BD Max Enteric Bacterial Panel Extended Enteric Bacterial Panel EMI.FAEC.7	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Faeces	Detection of: <i>Giardia lamblia</i> <i>Cryptosporidium parvum/homnis</i> <i>Entamoeba histolytica</i>	BD Max Enteric Parasite Panel EMI.FAEC.7	RLH
DNA Extracts, PCR Purified Products (Post bead clean up) Sequencing Libraries	Detection and identification 16S rRNA	Nanopore sequencing on DNA extracts from clinical samples for identification of bacterial organisms using EZ2 DNA extraction platform and ONT MinION sequencers EMI.MOL.2 EMI.MOL8	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u>	Documented Procedures as indicated based on manufacturer instructions and/ or validated in-house developed assays	
	Infectious Diseases Serology	Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening (IDPS) Programme as defined in the laboratory QA evidence requirements (targets marked *).	
	Detection of:	Abbott Diagnostics ARCHITECT i2000SR Abbott Chemiluminescent Microparticle Immunoassay VIRO.SER.SOP.008	
Serum (or Plasma)	Cytomegalovirus IgG antibody	CMV IgG Elecsys E2G 300 V2	RLH
Serum (or Plasma)	Cytomegalovirus IgG avidity	CMV IgG Avidity Elecsys E2G 100 V2	RLH
Serum (or Plasma)	Cytomegalovirus IgM antibody	CMV IgM Elecsys E2G 300	RLH
Serum (or Plasma)	Epstein Barr Virus EBNA IgG antibody	EBV EBNA IgG Elecsys E2G 300	RLH
Serum (or Plasma)	Epstein Barr Virus VCA IgG antibody	EBV VCA IgG Elecsys E2G 300	RLH
Serum (or Plasma)	Epstein Barr Virus VCA IgM antibody	EBV IgM Elecsys E2G 300	RLH
Serum (or Plasma)	Hepatitis A IgM antibody	Anti-HAV G2 Elecsys E2G 300	RLH
Serum (or Plasma)	Hepatitis A IgG antibody	Anti-HAV IgM Elecsys E2G 300	RLH
Serum (or Plasma)	Hepatitis B core Total antibody *	Anti-HBc G2 Elecsys E2G 300 V2	RLH
Serum (or Plasma)	Hepatitis B core IgM antibody *	Anti-HBc IgM Elecsys E2G 300	RLH
Serum (or Plasma)	Hepatitis B envelope antigen	HBeAg Elecsys E2G 300	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated based on manufacturer instructions and/ or validated in-house developed assays	
	Detection of:	Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening (IDPS) Programme as defined in the laboratory QA evidence requirements (targets marked *).	
		Roche Cobas e801 Preanalytical modules p471 and p612 Electrochemiluminescence Immunoassay EVI.SER.SOP.2	
Serum (or Plasma)	Hepatitis B envelope total antibody	Anti-HBe Elecsys E2G 300	RLH
Serum (or Plasma)	Hepatitis B surface antigen*	HBsAg G2 Elecsys E2G 300 V2	RLH
Serum (or Plasma)	Hepatitis B surface antibody*	Anti-HBs G2 Elecsys E2G 300 V2	RLH
Serum (or Plasma)	Hepatitis B surface antigen (confirmatory)*	HBsAg G2 Auto Confirm Elecsys cobas e V2	RLH
Serum (or Plasma)	Hepatitis B surface antigen (qualitative)*	HBsAg G2 quant G2 Elecsys E2G 100 V2)	RLH
Serum (or Plasma)	Hepatitis C IgG antibody	Anti-HCV G2 Elecsys E2G 300 V2	RLH
Serum (or Plasma)	Human Immunodeficiency Virus 1/2 antibody/antigen *	HIV duo Elecsys E2G 300 V2	RLH
Serum (or Plasma)	Human T-Lymphotropic Virus 1/2 antibody	HTLV Elecsys E2G 300 V2	RLH
Serum (or Plasma)	Rubella Virus IgG antibody	Rubella IgG Elecsys E2G 300	RLH
Serum (or Plasma)	Rubella Virus IgM antibody	Rubella IgM Elecsys E2G 300	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented Procedures as indicated based on manufacturer instructions and/ or validated in-house developed assays Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening (IDPS) Programme as defined in the laboratory QA evidence requirements (targets marked *). Roche Cobas e801 Preanalytical modules p471 and p612 Electrochemiluminescence Immunoassay EVI.SER.SOP.2	
Serum (or Plasma)	Treponema pallidum (Syphilis) total antibody *	Syphilis Elecsys E2G 300 V2	RLH
Serum (or Plasma)	Toxoplasma IgG antibody	Toxo IgG Elecsys E2G 300	RLH
Serum (or Plasma)	Toxoplasma IgM antibody	Toxo IgM Elecsys E2G 300	RLH
Serum	Rapid Plasma Reagin (RPR)	Arlington Scientific® RPR Card Test for Syphilis on the AIX 1000 Automated Test System	RLH
	Detection of:	DiaSorin LIAISON® analyser Immuno Chemiluminescence Immunoassay VIRO.SER.SOP.001	
Serum (or Plasma)	Varicella Zoster Virus (VZV) IgG antibody	Liaison® VZV IgG HT	RLH
Serum (or Plasma)	Measles Virus IgG antibody	LIAISON® Measles IgG	RLH
Serum (or Plasma)	Measles Virus IgM antibody	LIAISON® Measles IgM	RLH
Serum (or Plasma)	Mumps Virus IgG antibody	LIAISON® Mumps IgG	RLH
Serum (or Plasma)	Mumps Virus IgM antibody	LIAISON® Mumps IgM	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u> Detection of:	Documented Procedures as indicated based on manufacturer instructions and/ or validated in-house developed assays DiaSorin LIAISON® analyser Immuno Chemiluminescence Immunoassay VIRO.SER.SOP.001 Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening (IDPS) Programme as defined in the laboratory QA evidence requirements (targets marked *).	
Serum (or Plasma)	Hepatitis B Virus core total antibody (confirmation of screening assay) *	LIAISON® Anti-HBc	RLH
Serum (or Plasma)	Parvovirus B19 IgM antibody	Liaison® Biotrin Parvovirus B19 1gM	RLH
Serum (or Plasma)	Parvovirus B19 IgG antibody	Liaison® Biotrin Parvovirus B19 IgG Plus	RLH
Serum (or Plasma)	Treponema pallidum total antibody *	LIAISON® Treponema Screen	RLH
Serum (or Plasma)	Borrelia burgdorferi IgG antibody	LIAISON® Borrelia IgG	RLH
Serum (or Plasma)	Borrelia burgdorferi IgM antibody	LIAISON® Borrelia IgM II	RLH
Serum (or Plasma)	Hepatitis D total antibody	LIAISON® XL murex Anti-HDV	RLH
Serum (or Plasma)	Hepatitis E IgM antibody	LIAISON® Murex Anti-HEV IgM	RLH
Serum (or Plasma)	Hepatitis E IgG antibody	LIAISON® Murex Anti-HEV IgG	RLH
Serum Whole blood (EDTA)	Detection of HSV1 and HSV2 antibodies	Focus Diagnostics /Sterilab HerpeSelect® 1 and 2 Immunoblot IgG VIRO.SER.SOP.007	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented Procedures as indicated based on manufacturer instructions and/ or validated in-house developed assays	
Faeces	Qualitative detection of: Adenovirus DNA Enterovirus RNA Sapovirus RNA Astrovirus RNA Norovirus GI RNA Norovirus GII RNA Rotavirus RNA	AusDiagnostics Hi-Plex (MT-processor and MT-analyser) AusDiagnostics Enteric Viruses 8-well kit (REF 25037) VIRO.MOL.SOP.002	RLH
EDTA plasma	HIV-1 Genotypic antiretroviral Resistance testing	In-house Whole Genome Sequencing Assay using Illumina® Miseq/Miniseq	RLH
EDTA plasma	HBV Genotyping and Resistance Testing	In-house Whole Genome Sequencing Assay using Illumina® Miseq/Miniseq	RLH
EDTA plasma	HCV Genotyping and Resistance Testing	In-house Whole Genome Sequencing Assay using Illumina® Miseq/Miniseq	RLH
CSF	Qualitative detection of: Herpes simplex virus 1 Herpes simplex virus 2 Varicella zoster virus Epstein Barr Virus Cytomegalovirus Human herpesvirus 6 Human herpesvirus 7 Enterovirus (includes types A, B, C and D) Human parechovirus Human adenovirus	AusDiagnostics Hi-Plex (MT-processor and MT-analyser) AusDiagnostics Viral panel 12-well kit (REF 27095) VIRO.MOL.SOP.001	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Virology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented Procedures as indicated based on manufacturer instructions and/ or validated in-house developed assays	
Genital Swabs Throat Swabs Rectal Swabs Urine	Detection of Chlamydia trachomatis DNA Neisseria gonorrhoea DNA	Roche Cobas 8800 EVI.AUTO.SOP.6 KIT COBAS 6800/8800 CT/NG 480T IVD	RLH
Genital Swabs Throat Swabs Rectal Swabs Urine	Trichomonas vaginalis DNA Mycoplasma genitalium DNA	KIT COBAS 8800 TV/MG 384T IVD	
Genital Swabs	High Risk Human Papilloma Virus DNA	KIT COBAS 8800 HPV 480T IVD	RLH
Genital Swabs CSF	Herpes Simplex Virus Type 1 DNA	In house kit	RLH
Genital Swabs CSF	Herpes Simplex Virus Type 2 DNA	In house kit	RLH
Genital Swabs	Varicella Zoster Virus DNA	In house kit	RLH
Plasma: EDTA	Hepatitis B Virus DNA (Viral Load)	KIT COBAS 8800 HBV 96T IVD	RLH
Plasma: EDTA	Hepatitis C Virus RNA (Viral Load)	KIT COBAS 8800 HCV 96T CE- IVD	RLH
Plasma: EDTA CSF	Human Immunodeficiency Virus Type 1 RNA (Viral Load)	KIT COBAS 8800 HIV-1 96T IVD	RLH
Plasma: EDTA CSF	Epstein Barr Virus DNA (Viral Load)	KIT COBAS 8800 EBV 192T IVD	RLH
Plasma: EDTA CSF	Human Cytomegalovirus DNA (Viral Load)	KIT COBAS 8800 CMV 96T IVD	RLH
Plasma: EDTA Urine	BK virus DNA (Viral Load)	KIT COBAS 8800 BKV 192T IVD	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis</u>	Documented Procedures as indicated based on manufacturer instructions and/ or validated in-house developed assays	
Genital swab Urine (positive for <i>M. genitalium</i>)	Detection of mutations in the 23S r-RNA gene associated with resistance to azithromycin (macrolide antibiotic) (A2058G, A2059G, A2058T, A2058C, E.coli numbering)	Cepheid GeneXpert RT- PCRResistancePlus® MG FleXible kit VIRO.MOL.SOP.022	RLH
Rectal Swab (in Cobas PCR Media)	Detection of Chlamydia trachomatis Lymphogranuloma venereum (LGV) DNA	ELITechGroup ELITe InGenius Viasure C. trachomatis (LGV) RT-PCR kit EVI.AUTO.7	RLH
Biopsy tissue (wet) Blood (plasma, serum) Human body fluids Cellular material	Purification of nucleic acid material	QIAGEN QIA Symphony SP/AS QIA Symphony Virus/Bacteria mini kit VIRO.MOL.SOP.016	RLH
CSF Biopsy tissue (wet) Blood (wholeblood, plasma, serum) Human body fluids Cellular material	Purification of nucleic acid material	QIAGEN BioRobot™ EZ1 and EZ1 Advanced XL EZ1 virus mini kit, EZ1 DNA blood 350µl kit, EZ1 DNA tissue kit VIRO.MOL.SOP.025	RLH
	Detection and/or quantification of Virus:	QIAGEN Rotorgene QIAgen Quantitect Multiplex PCR kit	
EDTA plasma	Hepatitis E virus RNA	In house kit EVI.AUTO.12	RLH
Saliva Human body fluids Cellular material	Measles Virus RNA	In house kit EVI.SEMIA.9	RLH
EDTA plasma	Quantification of HIV-2 RNA	Rotor-gene MDx 5plex	EDTA plasma



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Tissue: biopsy, excision, resection and post-mortem</p> <p>Tissues from: Breast Gastrointestinal Skin Urological Bronchial/lung/thoracic Endocrine including thyroid, parathyroid, adrenal Lymphoreticular including lymph nodes, spleen and bone marrow trephines (processing only) Liver Bone and soft tissues, Gynaecological Head and neck</p> <p>Specialties include: Ear, Nose and Throat Oral Pathology Skin Breast Gynaecological Renal Gastro-intestinal Endocrine Paediatric Lymphopoietic Urology</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Specimen dissection Downdraft benches Categorisation of routine samples as per RCPATH guidelines – A, B, C & D specimens</p> <p>CP-HIST-SR-CU11 CP-HIST-SR-CU9 CP-HIST-TECH-AUTO17 CHQ-DP-008 CHQ-DP-009 CHQ DP 0010 CHQ-RP-0013 SOP H011 SOP H012</p>	<p>RLH QEH UHL</p>



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin Fixed Tissue		Decalcification Manual method Decalcifier 1 CP-HIST-SR-DECAL1 CHQ-DP-0010 SOP H013	RLH QEH UHL
Formalin Fixed Tissue		Tissue processing Sakura VIP6AI tissue processor CP-HIST-TECH-AUTO47 CP-HIST-TECH-P&E7 CHQ-MP-0065 SOP H046	RLH UHL
Formalin Fixed Tissue		Sakura VIP6 tissue processor CP-HIST-TECH-AUTO47 CP-HIST-TECH-P&E7 CHQ-MP-0065 SOP H046	QEH UHL
Formalin Fixed Tissue		Embedding Sakura Tissue Tek 5 & 6 embedding consoles Paratrimmers Leica Slide writer	RLH QEH UHL
Formalin Fixed Paraffin Embedded tissue (FFPE)		Microtomy Rotary microtomes: Solmedia Histo-line MR3000 Shandon Finesse 325 Leica RM2235 Leica Histocore Biocut Microm H350s, Microm HM200 and Sakura Accu-cut SRM200CW Histocore Autocut CHQ-MP-006 CP-HIST-TECH-AUTO4 TECH-AUTO57 CP-HIST-TECH-CUT-3 SOP H035	RLH QEH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Frozen tissue		Routine Cryotomy Leica cryostat CM1950 CP-HIST-TECH-FS1-8 CP-HIST-TECH-FS20-24 CP-HIST-SBH-SOP7	RLH SBH
Fresh muscle tissue		Routine Cryotomy Leica CM1950 CP-HIST-TECH-FS1 CP-HIST-NEURO-MUSCLE-SOP3	RLH
Formalin fixed paraffin embedded (FFPE), fresh and frozen tissue	Routine morphological staining for the detection of basophilic and eosinophilic structures	Automated H&E staining Sakura Tissue-Tek Prisma Plus automated slide stainer and Tissue-Tek film automated coverslipper CP-HIST-TECH-SORT4 CHQ-MP-0067 SOP H062 SOP H007	RLH QEH UHL
Fresh tissue	Routine morphological staining for the detection of: Basophilic and eosinophilic structures	Manual Heamatoxylin and Eosin (H&E) Stain SOP L011	UHL
Formalin Fixed Paraffin Embedded Tissue ((FFPE) sections on glass slides	Morphological assessment and interpretation/diagnosis	Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	UHL
FFPE (Formalin fixed paraffin embedded) tissue sections and frozen tissue	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Coverslipping of stained slides Tissue-Tek film automated coverslipper CP-HIST-TECH-SORT4 CHQ-MP-0067 SOP H062 SOP H007	RLH QEH UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> Special stains for the detection of:	In house documented methods incorporating manufacturer's instructions where relevant Automated staining Artisan Automated stainer CP-HIST-TECH-AUTO2 CP-HIST-TECH-AUTO29	
FFPE slides	Hemosiderin	Iron stain AR15811-2	RLH
FFPE slides	Amyloid	Congo Red (AR16192-2)	RLH
FFPE slides	Haematopoietic cells	Giemsa (AR1649-2)	RLH
FFPE slides	Connective tissues	Masson's Trichrome (AR17392-2)	RLH
FFPE slides	Fungi & Pneumocystis jiroveci (carinii)	Grocott AR17611-2)	RLH
FFPE slides	Reticulin fibres	Reticulin (AR17911-2)	RLH
FFPE slides	Glomerular Basement membrane	Jones Basement Membrane (AR1801102)	RLH
FFPE slides	Spirochetes	Warthin Starry (AR18192-2)	RLH
FFPE slides	Acid mucins	Alcian Blue CP-HIST-TECH-SORT4	RLH
FFPE slides	Acid & Neutral mucins	Alcian Blue Periodic Schiff's CP-HIST-TECH-SORT4	RLH
	Special stains for the detection of:	Automated staining of special stains on Sakura Tissue Tek Prisma	
FFPE slides	Carbohydrates	Periodic Acid Schiff's CP-HIST-TECH-SORT4	RLH
FFPE slides	Helicobacter pylori	Giemsa CP-HIST-TECH-SORT4	RLH
FFPE slides	Acid and Neutral Mucopolysaccharides	Alcian Blue/Periodic Acid Schiff	QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
FFPE slides	Acid and Neutral Mucopolysaccharides	Automated staining of special stains on Sakura Tissue Tek Prisma CHQ-MP-0067 Diastase Alcian Blue/Periodic Acid Schiff	QEH
FFPE slides	Helicobacter/Microorganisms	Giemsa	QEH
FFPE slides	Neutral Mucopolysaccharides, glycogen and fungus	Periodic Acid Schiff (PAS) & Diastase PAS (D/PAS)	QEH
FFPE slides	Special stains for the detection of: Elastic fibres & connective tissue	<u>Manual staining</u> Miller's Elastic Van Geison (EVG) CP-HIST-TECH-STAIN6	RLH
FFPE slides	Gram positive and negative bacteria	Gram CP-HIST-TECH-STAIN10	RLH
FFPE slides	Connective Tissue	HVG CP-HIST-TECH-STAIN13	RLH
FFPE slides	Melanin	Masson Fontana CP-HIST-TECH-STAIN14	RLH
FFPE slides	Removal of melanin pigment	Melanin Bleach CP-HIST-TECH-STAIN16	RLH
FFPE slides	Fibrin	MSB CP-HIST-TECH-STAIN17	RLH
FFPE slides	Hepatitis B Copper associated protein	Orcein CP-HIST-TECH-STAIN18	RLH
Frozen tissue	Lipids	Oil-Red-O CP-HIST-TECH-STAIN19	RLH
FFPE slides	Glycogen	DPAS/DABPAS CP-HIST-TECH-STAIN21	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Special stains for the detection of: (cont'd)	<u>Manual staining</u>	
FFPE slides	Copper	Rhodanine CP-HIST-TECH-STAIN24	RLH
FFPE slides	Calcium salts	von Kossa CP-HIST-TECH-STAIN27	RLH
FFPE slides	Mycobacterium leprae	Wade Fite CP-HIST-TECH-STAIN28	RLH
FFPE slides	<i>Mycobacterium spp. including tuberculosis</i>	Ziehl Neelsen CP-HIST-TECH-STAIN30	RLH
FFPE slides	Acid Mucopolysaccharides	Alcian Blue CHQ-SP-003	QEH
FFPE slides	Amyloid	Congo Red CHQ-SP-005	QEH
FFPE slides	Elastic fibres and connective tissue	Elastic/Haematoxylin Van Gieson (EVG/HVG) CHQ-SP-007 CHQ-SP-014	QEH
FFPE slides	Bile pigments	Fouchet van Gieson CHQ-SP-008	QEH
FFPE slides	Fungi including Pneumocystis jiroveci (carinii)	Grocott Hexamine Silver CHQ-SP-013	QEH
FFPE slides	Mucin; Cryptococcus	Mucicarmin CHQ-SP-0020	QEH
FFPE slides	Gram +ve & -ve microorganisms	Gram CHQ-SP-0011	QEH
FFPE slides	Connective samples and fibrin	Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) CHQ-SP-0019	QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Special stains for the detection of: (cont'd)	<u>Manual staining</u>	
FFPE slides	Melanin, Argentaffin cells and Lipofuchsin	Masson Fontana CHQ-SP-0016	QEH
FFPE slides	Connective tissue	Masson's Trichrome CHQ-SP-0017	QEH
FFPE slides	Haemosiderin and ferric iron	Perl's Prussian Blue CHQ-SP-0024	QEH
FFPE slides	Reticulin fibres	Reticulin- Gordon & Sweets CHQ-SP-0010	QEH
FFPE slides	Copper-associated protein and Hepatitis B-affected cells	Shikata's Orcein CHQ-SP-0022	QEH
FFPE slides	Mast cells	Toluidine Blue CHQ-SP-0028	QEH
FFPE slides	Tubercle bacilli	Ziehl Neelsen (ZN) CHQ-SP-0021	QEH
FFPE slides	Melanin bleach	Mallory Melanin Bleach CHQ-SP-0015	QEH
FFPE slides	Leprosy bacilli	Wade-Fite CHQ-SP-0029	QEH
FFPE slides	Acid mucins	Alcian blue HSS01	UHL
FFPE slides	Acid and Neutral Mucopolysaccharides	Alcian Blue/Periodic Acid Schiff	UHL
FFPE slides	Acid and Neutral Mucopolysaccharides	Diastase alcian blue/periodic acid Schiff	UHL
FFPE slides	Amyloid	Congo Red	UHL
FFPE slides	Elastic fibres	Elastic Van Gieson (Millers)	UHL
FFPE slides	Elastic fibres	Elastin Mayers	UHL



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Special stains for the detection of: (cont'd)	<u>Manual staining</u>	
FFPE slides	Helicobacter pylori	Modified Giemsa	UHL
FFPE slides	Spirochaetes and protozoa	Full Giemsa	UHL
FFPE slides	Reticulin fibres	Gordon and Sweets	UHL
FFPE slides	Gram positive and negative bacteria	Gram Twort	UHL
FFPE slides	Bacteria	Gram stain	UHL
FFPE slides	Pathogenic Fungi	Grocott Hexamine silver	UHL
FFPE slides	Connective tissue, fibrin	Martius Scarlett Blue (MSB)	UHL
FFPE slides	Melanin	Masson Fontana	UHL
FFPE slides	Melanin	Melanin Bleach	UHL
FFPE slides	Hepatitis B surface antigen	Orcein	UHL
FFPE slides	Fungi, glycogen, mucins	Periodic acid Schiff reaction (PAS)	UHL
FFPE slides	Fungi, glycogen, mucins	Periodic acid Schiff Diastase reaction (PASD)	UHL
FFPE slides	Iron	Perls Prussian Blue	UHL
FFPE slides	Mast cells	Toluidine Blue	UHL
FFPE slides	Collagen,muscle,RBCs	Weigerts Haematoxylin van Gieson	UHL
FFPE slides	Tubercle bacilli	Ziehl Neelsen	UHL
FFPE slides	Placental trophoblasts cells	b.HCG	UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following:	Roche Benchmark Ultra Immunostainer I004 SOP I004	
FFPE slides	Subset of B and T lymphocytes	BCL2	UHL
FFPE slides	Subset of Epithelial cell types	BerEp4	UHL
FFPE slides	Parafollicular cells in thyroid and medullary thyroid carcinomas	Calcitonin	UHL
FFPE slides	Mesothelium, sex cord stromal tumours	Calretinin	UHL
FFPE slides	Low molecular weight cytokeratin	CAM5.2	UHL
FFPE slides	T cell marker	CD3	UHL
FFPE slides	Subset of B cells and T cells	CD5	UHL
FFPE slides	Subset of B cells, some epithelial cells	CD10	UHL
FFPE slides	Granulocytes, Reed-Sternberg cells	CD15 (LeuM1)	UHL
FFPE slides	B cells	CD20 (L26)	UHL
FFPE slides	Follicular dendritic cells	CD21	UHL
FFPE slides	Follicular dendritic cells, some B cells	CD23	UHL
FFPE slides	Activated B/T cells, Reed Sternberg cell, embryonal carcinoma	CD30	UHL
FFPE slides	Endothelial cells, macrophages	CD31	UHL
FFPE slides	Endothelial cells, variety of other neoplasm	CD34	UHL
FFPE slides	Pan leukocyte marker	CD45 (LCA)	UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Immunostainer I004 SOP I004	
FFPE slides	Neuroendocrine, Schwann cells, NK cells	CD56	UHL
FFPE slides	Macrophages	CD68	UHL
FFPE slides	B cells, plasma cells	CD79a	UHL
FFPE slides	GIST, mast cells, seminoma	CD117	UHL
FFPE slides	Plasma cells, squamous epithelium	CD138	UHL
FFPE slides	Marker of intestinal differentiation	CDX2	UHL
FFPE slides	Expressed by some adenocarcinomas	CEA	UHL
FFPE slides	Tissues of neuroendocrine origin Neuroendocrine marker	Chromogranin A	UHL
FFPE slides	High molecular weight cytokeratins	CK5/6	UHL
FFPE slides	Specific low molecular weight cytokeratin	CK7	UHL
FFPE slides	Specific low molecular weight cytokeratin	CK19	UHL
FFPE slides	Specific low molecular weight cytokeratin	CK20	UHL
FFPE slides	Expressed by CMV infected cells	CMV	UHL
FFPE slides	Striated and smooth muscle cells	Desmin	UHL
FFPE slides	GIST tumours	Dog-1	UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Immunostainer I004 SOP I004	
FFPE slides	Adhesion molecule, lost in lobular Ca breast	E Cadherin	UHL
FFPE slides	Subset of Normal and neoplastic epithelium	EMA	UHL
FFPE slides	Expressed by some breast and gynae carcinomas	ER	UHL
FFPE slides	Fibro histiocytic marker	Factor XIIIa	UHL
FFPE slides	Mesothelial cells, some thyroid tumours	HBME-1	UHL
FFPE slides	HHV-8 infected cells in Kaposi's sarcoma lesions, primary effusion lymphoma, Castleman's disease	HHV8	UHL
FFPE slides	Immature melanocytes, Melanoma, others	HMB45	UHL
FFPE slides	Expressed by cells infected with Herpes simplex	HSV	UHL
FFPE slides	Sex chord stromal tumours	Inhibin	UHL
FFPE slides	Subset of B cells and plasma cells	Kappa	UHL
FFPE slides	Proliferating cells	KI67	UHL
FFPE slides	B cell follicles	Lambda	UHL
FFPE slides	Melanocytes and melanoma	Melan A	UHL
FFPE slides	Pan-cytokeratin marker	MNF116	UHL
FFPE slides	Marker of high risk HPV	P16	UHL
FFPE slides	Over-expressed by some tumours	P53	UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Immunostainer I004 SOP I004	
FFPE slides	Squamous epithelium, basal cells	P63	UHL
FFPE slides	Expressed by Placenta, germ cell tumours	PLAP	UHL
FFPE slides	Expressed by prostatic epithelium, some salivary tumours	PSA	UHL
FFPE slides	Expressed by melanocytes, Schwann cells, myoepithelial	S100	UHL
FFPE slides	Smooth muscle cells, myoepithelial cells	SMA	UHL
FFPE slides	Neuroendocrine cells	Synaptophysin	UHL
FFPE slides	Thyroglobulin containing cells (thyroid)	Thyroglobulin	UHL
FFPE slides	Thyroid, adenocarcinoma lung	TTF-1	UHL
FFPE slides	Cells of mesenchymal origin	Vimentin	UHL
FFPE slides	Mesothelium, Ovarian serous carcinoma	WT-1	UHL
FFPE slides	Breast, Urothelia carcinoma	GATA-3	UHL
FFPE slides	Ovarian epithelial carcinoma	PAX-8	UHL
FFPE slides	Mesothelioma	D2-40	UHL
FFPE slides	Lung adenocarcinoma	Napsin	UHL
FFPE slides	Treponema pallidum	Anti-spirochaete	UHL
FFPE slides	Langerhans cells	CD1a	UHL
FFPE slides	Melanoma	Maat1/Melan A	UHL



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
FFPE slides	Immunohistochemistry to detect the following: (cont'd) Epithelial tumours	Roche Benchmark Ultra Immunostainer I004 SOP I004 Pancytokeratin	UHL
FFPE slides	Immunohistochemistry to detect the following: Glandular, transitional, and squamous epithelia	Roche Benchmark Ultra Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9 AE1/AE3	RLH
FFPE slides	Glandular epithelia	Cam 5.2	RLH
FFPE slides	Glandular epithelia	CK5/6	RLH
FFPE slides	Glandular epithelia	Ventana basal cell cocktail (34βE12+p63)	RLH
FFPE slides	Glandular epithelia	P40	RLH
FFPE slides	Glandular epithelia	P63	RLH
FFPE slides	Intestinal epithelial	CDX-2	RLH
FFPE slides	Gastrointestinal epithelia	CK20	RLH
FFPE slides	Glandular, transitional epithelial	CK7	RLH
FFPE slides	RS cells	CD30	RLH
FFPE slides	N killer (NK) cells, NK like T-cells, neural cell adhesion molecule	CD56	RLH
FFPE slides	Intermediate filament	Desmin	RLH
FFPE slides	Adhesion molecule predominantly in epithelial SAMPLES	SMA	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	Astrocytes, Schwann cells, satellite cells, enteric glial cells and some groups of ependymal cells	GFAP	RLH
FFPE slides	Cell-cell adhesion in epithelial cells	E-Cadherin	RLH
FFPE slides	Melanosomes	HMB45	RLH
FFPE slides	Proliferation marker	Ki-67	RLH
FFPE slides	Melanocytes	Melan A	RLH
FFPE slides	Expressed in melanocytes, and myoepithelial cells	SOX-10	RLH
FFPE slides	Mismatch repair (MMR) protein MSH6	MSH6	RLH
FFPE slides	Mismatch repair protein	MLH1	RLH
FFPE slides	Cervical Ca	P16	RLH
FFPE slides	Tumour suppressor gene	P53	RLH
FFPE slides	Programmed death-1 molecule	PD-1	RLH
FFPE slides	Oestrogen receptor	Oestrogen receptor	RLH
FFPE slides	Progesterone receptor	Progesterone receptor	RLH
FFPE slides	Protein involved in the mismatch repair pathway)	PMS2	RLH
FFPE slides	T lymphocytes	CD2	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	T cells	CD3	RLH
FFPE slides	T-cells and a subset of mature B-cells	CD5	RLH
FFPE slides	T cytotoxic lymphocytes	CD8	RLH
FFPE slides	T helper lymphocytes	CD4	RLH
FFPE slides	Langerhans cells	CD1a	RLH
FFPE slides	CD10 molecule to detect common acute lymphoblastic leukaemia antigen (CALA) and follicular lymphoma	CD10	RLH
FFPE slides	Intronless gene which encodes a member of the SOX family of transcription factors	Sox 11	RLH
FFPE slides	B lymphocytes	CD20	RLH
FFPE slides	Follicular dendritic cells	CD21	RLH
FFPE slides	B cells	CD23	RLH
FFPE slides	Blood vessels and haematopoietic cells	CD31	RLH
FFPE slides	Blood vessels, haematopoietic cells, and GIST tumours	CD34	RLH
FFPE slides	Detect cells of lymphoid or myeloid origin	CD45	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	Melanoma, neuroendocrine	S100	RLH
FFPE slides	Megakaryocytes	CD61	RLH
FFPE slides	Macrophages	CD68 (KP-1)	RLH
FFPE slides	Normal and neoplastic plasma cells	CD138	RLH
FFPE slides	Receptor expressed on the surface of monocytes (low expression) and macrophages (high expression)	CD163	RLH
FFPE slides	Anaplastic large cell lymphoma	ALK-1	RLH
FFPE slides	Simian virus 40	SV-40	RLH
FFPE slides	Follicular lymphomas and diffuse large cell lymphomas	BCL-2	RLH
FFPE slides	Transcriptional regulator gene	BCL-6	RLH
FFPE slides	Mantle cell lymphoma	Cyclin D1	RLH
FFPE slides	Human herpesvirus type 8 (HHV-8)	HHV-8	RLH
FFPE slides	IgD	IgD (polyclonal)	RLH
FFPE slides	IgM	IgM (polyclonal)	RLH
FFPE slides	IgG	IgG (polyclonal)	RLH
FFPE slides	Beta-Catenin	Beta-Catenin	RLH
FFPE slides	Inhibin a peptide hormone	Inhibin α	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	Wilms tumour gene product	WT-1	RLH
FFPE slides	Ovarian carcinoma	CA-125	RLH
FFPE slides	Medullary carcinoma	Calcitonin (polyclonal)	RLH
FFPE slides	Mesothelial cells	Calretinin	RLH
FFPE slides	Mesothelioma marker	BAP1	RLH
FFPE slides	Colon Mucosa	CEA (Monoclonal)	RLH
FFPE slides	Neuroendocrine tumours	Chromogranin A	RLH
FFPE slides	Neuroendocrine cells	Synaptophysin	RLH
FFPE slides	Neuronal cell adhesion molecules	CD56	RLH
FFPE slides	Plasma cells	Kappa	RLH
FFPE slides	Plasma cells	Lambda	RLH
FFPE slides	Plasma cells, some B-cells in the light zone of germinal centres, and a subset of T-cells (T-cells in germinal centres and interfollicular areas)	MUM1	RLH
FFPE slides	Detection of GIST tumours	DOG1	RLH
FFPE slides	Epithelial membrane antigen	EMA	RLH
FFPE slides	Epithelial antigen	Ber-EP4	RLH
FFPE slides	Epithelial Related Antigen	MOC-31	RLH
FFPE slides	Dermatofibroma	Factor 13a	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	Breast and urothelial carcinoma	GATA3	RLH
FFPE slides	Apocrine cells	GCDFP-15	RLH
FFPE slides	Hepatocellular carcinoma	Hepatocyte Specific Antigen	RLH
FFPE slides	Trophoblasts	hCG (polyclonal)	RLH
FFPE slides	Syncytiotrophoblasts	PLAP	RLH
FFPE slides	Smooth muscle cells	SMMHC	RLH
FFPE slides	Rhabdomyosarcoma	Myogenin	RLH
FFPE slides	Neuroendocrine tumours	Neurofilament Protein	RLH
FFPE slides	Seminoma and embryonal carcinoma	Oct-4	RLH
FFPE slides	Prostate adenocarcinoma	P504S	RLH
FFPE slides	Renal cell carcinoma	PAX-8	RLH
FFPE slides	B lymphocytes	PAX5	RLH
FFPE slides	Prostate adenocarcinoma	PSA	RLH
FFPE slides	Cortical thymocytes, ALL	TdT	RLH
FFPE slides	Thyroglobulin	Thyroglobulin	RLH
FFPE slides	Thyroid Transcription Factor-1	TTF-1	RLH
FFPE slides	Intermediate filament	Vimentin	RLH
FFPE slides	Wilms tumour	WT1	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	Anaplastic lymphoma kinase (ALK) protein	ALK (D5F3)	RLH
FFPE slides	Cytokeratin 19	CK19	RLH
FFPE slides	Mesothelioma / Lymphatic endothelium	D2-40	RLH
FFPE slides	Hairy Cell lymphoma	DBA44	RLH
FFPE slides	Class 1 MHC	B2 Microglobulin	RLH
FFPE slides	Succinic dehydrogenase enzyme	SDHB	RLH
FFPE slides	Granulocytes	Myeloperoxidase	RLH
FFPE slides	Melanoma marker	S100	RLH
FFPE slides	NK cells	T1A1	RLH
FFPE slides	Mantle cell marker	SOX 11	RLH
FFPE slides	PD L1	PD-L1 (SP263)	RLH
FFPE slides	Cmyc	C-Myc	RLH
FFPE slides	Thyroid transcription factor-1	TTF-1	RLH
FFPE slides	Wilms tumour gene product	WT-1	RLH
FFPE slides	HER 2	HER2 (4B5)	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following:	Roche Benchmark Ultra immunostainer CHQ-IP-0015	
FFPE slides	Embryonic cell in normal tissues and germ cell tumours	Alpha Fetoprotein	QEH
FFPE slides	Cytokeratins (acidic, basic)	AE1/AE3	QEH
FFPE slides	HGPIN, prostate adenocarcinoma	AMACR (Racemase)	QEH
FFPE slides	T lymphocytes, follicular lymphoma, basal cell carcinoma	Bcl2 oncoprotein	QEH
FFPE slides	Epithelial cell types	Ber Ep4	QEH
FFPE slides	Mesothelial cells	Calretinin	QEH
FFPE slides	Glandular cells	CAM 5.2	QEH
FFPE slides	T cells	CD3	QEH
FFPE slides	Mature T cells, T cell lymphomas	CD5	QEH
FFPE slides	Mature B cells, CALLA	CD10	QEH
FFPE slides	Granulocytes, Reed-Sternberg cells	CD15	QEH
FFPE slides	B cells	CD20	QEH
FFPE slides	Reed-Sternberg cells, plasma cells, ALCL	CD30	QEH
FFPE slides	Endothelial cells	CD31	QEH
FFPE slides	Haematopoetic cells, vascular endothelium	CD34	QEH
FFPE slides	Natural killer cells, neuroendocrine tissues	CD56	QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra immunostainer CHQ-IP-0015	
FFPE slides	Macrophages, monocytes, myeloid cells	CD68	QEH
FFPE slides	B cells	CD79alpha	QEH
FFPE slides	Ewing Sarcoma, atypical fibroxanthoma	CD99	QEH
FFPE slides	Mast cells, GIST	CD117/CKIT	QEH
FFPE slides	Plasma cells	CD138	QEH
FFPE slides	Intestinal epithelial cells, colorectal + other adenocarcinomas	CDX2	QEH
FFPE slides	CEA glycoproteins	CEA	QEH
FFPE slides	Tissues of neuroendocrine origin	Chromogranin	QEH
FFPE slides	CytoMieglo Virus	CMV	QEH
FFPE slides	Mantle cell lymphoma	Cyclin D1	QEH
FFPE slides	Epithelial samples from glandular to stratified squamous	Cytokeratin (MNF116)	QEH
FFPE slides	Stratified squamous epithelium, basal cells, mesotheliomas	Cytokeratin 5/6	QEH
FFPE slides	Normal and neoplastic epithelia	Cytokeratin 7	QEH
FFPE slides	Epithelial and carcinoma cells	Cytokeratin 19	QEH
FFPE slides	Adenocarcinomas, columnar epithelial cells	Cytokeratin 20	QEH
FFPE slides	Striated and smooth muscle cells	Desmin	QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra immunostainer CHQ-IP-0015	
FFPE slides	Lymphatic vessels	D2-40	QEH
FFPE slides	Gastrointestinal stromal tumour	DOG-1	QEH
FFPE slides	Normal ductal epithelial cells, ductal carcinoma	E-Cadherin	QEH
FFPE slides	Normal and neoplastic epithelium	EMA	QEH
FFPE slides	Endothelial cell	Factor XIIIa	QEH
FFPE slides	Thyroid tumours	Galectin 3	QEH
FFPE slides	Mammary gland carcinomas	GATA-3	QEH
FFPE slides	Mammary gland carcinomas	Mammaglobin	QEH
FFPE slides	Placental trophoblasts	HCG	QEH
FFPE slides	Kaposi's sarcoma	HHV-8	QEH
FFPE slides	Melanoma, melanocyte differentiation	HMB45	QEH
FFPE slides	Sex cord stromal tumours	Inhibin	QEH
FFPE slides	Proliferating Cells	Ki 67	QEH
FFPE slides	B cells, T cells, monocytes, macrophages	LCA	QEH
FFPE slides	Melanoma marker	Melan-A	QEH
FFPE slides	Adenocarcinoma	MOC-31	QEH
FFPE slides	Rhabdomyosarcoma	MyoD1	QEH
FFPE slides	Alveolar cells, lung adenocarcinoma	Napsin A	QEH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra immunostainer CHQ-IP-0015	
FFPE slides	Nuclei of cells expressing oestrogen	Oestrogen Receptors	QEH
FFPE slides	High grade dysplasia of cervix	p16	QEH
FFPE slides	Dysplasia in Barrett's oesophagus	p53	QEH
FFPE slides	Prostate basal cells, myoepithelial cells	p63	QEH
FFPE slides	Prostatic glandular epithelium	PAP	QEH
FFPE slides	Ovarian tumour, renal cell carcinoma	PAX-8	QEH
FFPE slides	Germ cell tumours	PLAP	QEH
FFPE slides	Nuclei of cells expressing Progesterone	Progesterone Receptors	QEH
FFPE slides	Prostate secretory and ductal epithelium	PSA	QEH
FFPE slides	Renal cell carcinoma	RCC	QEH
FFPE slides	Schwann cells, nerve processes, neural and melanocytic neoplasms	S100	QEH
FFPE slides	Smooth muscle cells, myoepithelial cells	Smooth Muscle Actin (SMA)	QEH
FFPE slides	Smooth muscle cells, myoepithelial cells	Smooth Muscle Myosin (SMMS-1)	QEH
FFPE slides	Melanocytes	SOX-10	QEH
FFPE slides	Neuroendocrine cells	Synaptophysin	QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry to detect the following: (cont'd)	Roche Benchmark Ultra immunostainer CHQ-IP-0015	
FFPE slides	Thyroid and lung epithelial cells	TTF1	QEH
FFPE slides	Mesothelial cells, serous carcinoma	WT-1	QEH
FFPE slides	Mismatch Repair Genes in Hereditary Nonpolyposis Colonic Cancer (HNPCC)	MMR Panel (MSH2, MSH6, MLH1, PMS2)	QEH
FFPE slides	lung squamous cell carcinomas	P40	QEH
FFPE slides	skin basal cell carcinomas	CK14	QEH
FFPE slides	breast and prostate carcinoma	Androgen receptor	QEH
FFPE slides	Prostate intraepithelial neoplasia	34Be12+p6 DS	QEH
FFPE slides	Fibromatosis	Beta- Catenin	QEH
FFPE slides	B Cells	CD23	QEH
FFPE slides	Endothelial Cells	ERG	QEH
FFPE slides	Breast Human Epidermal Growth Factor Receptor 2	HER2	QEH
FFPE slides	Hepatocarcinoma	HSA	QEH
FFPE slides	Melanoma	Melan A +Ki67 DS	QEH
FFPE slides	Prostate Adenocarcinoma	NKX3.1	QEH
FFPE slides	Lobular Carcinoma	P120 Catenin	QEH
FFPE slides	Prostate Adenocarcinoma	PIN4	QEH
FFPE slides	Colonic tumour marker	SAT-B2	QEH
FFPE slides	Treponema pallidum	Spirochete	QEH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
FFPE slides	Immunohistochemistry to detect the following: (cont'd) Breast tumour HER 2 status	Roche Benchmark Ultra immunostainer CHQ-IP-0015 INFORM HER2 Dual ISH DNA Probe Cocktail Assay	RLH
	Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers:	Automated staining Roche Benchmark Ultra CP-HIST-NEURO-MUSCLE-SOP1 CP-HIST-NEURO-MUSCLE-SOP2 CP-HIST-NEURO-MUSCLE-SOP3 CP-HIST-NEURO-MUSCLE-SOP4 CP-HIST-NEURO-MUSCLE-IMMUNO 2 CP-HIST-IMMUNO-GEN-SOP2	
Fresh muscle tissue	Sarcolemmal membrane of skeletal muscle	Dystrophin 1	RLH
Fresh muscle tissue	Sarcolemmal membrane of skeletal muscle	Dystrophin 2	RLH
Fresh muscle tissue	Sarcolemmal membrane of skeletal muscle	Dystrophin 3	RLH
Fresh muscle tissue	Cytoskeletal protein	Spectrin	RLH
Fresh muscle tissue	Heavy chain component of the laminin-2 complex	Merosin	RLH
Fresh muscle tissue	Sarcolemmal membrane of skeletal muscle	Alpha Sarcoglycan	RLH
Fresh muscle tissue	Sarcolemmal membrane	Beta Sarcoglycan	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers:	In house documented methods incorporating manufacturer's instructions where relevant Automated staining Roche Benchmark Ultra: CP-HIST-NEURO-MUSCLE-SOP1 CP-HIST-NEURO-MUSCLE-SOP2 CP-HIST-NEURO-MUSCLE-SOP3 CP-HIST-NEURO-MUSCLE-SOP4 CP-HIST-NEURO-MUSCLE-IMMUNO 2 CP-HIST-IMMUNO-GEN-SOP2	
Fresh muscle tissue	Sarcolemmal membrane, dystrophy marker	Delta Sarcoglycan	RLH
Fresh muscle tissue	Sarcolemmal membrane, dystrophy marker	Gamma Sarcoglycan	RLH
Fresh muscle tissue	Dystrophin associated glycoprotein	Beta Dystroglycan	RLH
Fresh muscle tissue	Dystrophin-related protein	Utrophin	RLH
Fresh muscle tissue	Plasma membrane protein	Dysferlin 1 (Hamlet 1)	RLH
Fresh muscle tissue	Contractile muscle specific protein	Fast Myosin	RLH
Fresh muscle tissue	Muscle fibre sub-typing	Slow Myosin	RLH
Fresh muscle tissue	Immature muscle fibres	Neonatal Myosin	RLH
Fresh muscle tissue	Major histocompatibility class I molecules	HLA ABC	RLH
Fresh muscle tissue	Macrophages	CD68 (KP-1)	RLH
Fresh muscle tissue	T-cell marker	CD3	RLH
Fresh muscle tissue	T-Helper cells	CD4	RLH
Fresh muscle tissue	Cytotoxic T-cells	CD8	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers:	In house documented methods incorporating manufacturer's instructions where relevant Automated staining Roche Benchmark Ultra CP-HIST-NEURO-MUSCLE-SOP1 CP-HIST-NEURO-MUSCLE-SOP2 CP-HIST-NEURO-MUSCLE-SOP3 CP-HIST-NEURO-MUSCLE-SOP4 CP-HIST-NEURO-MUSCLE-IMMUNO 2 CP-HIST-IMMUNO-GEN-SOP2	
Fresh muscle tissue	B-cell marker	CD20	RLH
Fresh muscle tissue	Structural protein of sarcomeric Z discs and sarcolemma in human skeletal and cardiac muscle	Myotilin	RLH
Fresh muscle tissue	Neopeptide formed by poly (C9) in the terminal complement complex	MAC (C5b-9)	RLH
Fresh muscle tissue	The p62 protein	P62	RLH
Fresh muscle tissue	Ubiquitin protein	Ubiquitin	RLH
Fresh muscle tissue	Routine stains used for the demonstration of morphology of muscle fibres Basophilic and eosinophilic structures	Manual staining techniques Muscle H&E Stain CP-HISTO-NEURO-MUSCLE-STAIN1	RLH
Fresh muscle tissue	Glycogen	Muscle PAS CP-HISTO-NEURO-MUSCLE-STAIN4	RLH
Fresh muscle tissue	Lipids	Muscle Sudan black CP-HISTO-NEURO-MUSCLE-STAIN13	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Routine stains used for the demonstration of morphology of muscle fibres	Manual staining techniques	
Fresh muscle tissue	Mitochondria and Connective tissue	Muscle Gomori CP-HISTO-NEURO-MUSCLE-STAIN8	RLH
Fresh muscle tissue	Macrophage marker	Muscle Acid Phosphatase CP-HISTO-NEURO-MUSCLE-STAIN6	RLH
Fresh muscle tissue	Demonstration of fibre types	Muscle ATPase CP-HISTO-NEURO-MUSCLE-STAIN10	RLH
Fresh muscle tissue	Oxidative enzyme of the respiratory chain located in mitochondria	NADH CP-HISTO-NEURO-MUSCLE-STAIN3	RLH
Fresh muscle tissue	Respiratory chain enzyme marker of mitochondrial function	SDH Succinic dehydrogenase CP-HISTO-NEURO-MUSCLE-STAIN7	RLH
Fresh muscle tissue	Mitochondrial enzyme which predominates in type 1 fibres	COX Cytochrome oxidase CP-HISTO-NEURO-MUSCLE-STAIN 9	RLH
Fresh muscle tissue	Enzyme that polymerises glucose to form glycogen	Myo phosphorylase CP-HISTO-NEURO-MUSCLE-STAIN5	RLH



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Body Fluids Fine needle aspirates Breast/cyst/nipple discharge Sputum Urine CSF Oesophageal washings and brushings Conventional Bronchial Brushings Biliary duct brushings Pancreatic duct brushings Duodenal brushings Liver Skin scrape Ovarian cyst endometrium Serous fluids Bronchial washings Bronchial Alveolar lavage</p>	<p><u>Cytopathology examination activities for the purpose of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Non Gynae Preparation Centrifuge Cytocentrifugation T2000 LBC Processor Sakura Tissue-Tek Prisma Plus Film coverslipper</p> <p>CP.CYTO.SOP.17 CP.CYTO.SOP.14 CP.CYTO.SOP.15 CP.CYTO.SOP.11 CP.CYTO.SOP.10 CP.CYTO.SOP.3 CP.CYTO.SOP.16 CP.CYTO.SOP.13 CP.CYTO.SOP.4 CP.CYTO.SOP.9</p>	<p>RLH UHL</p>
<p>Fin Body fluids Fine needle aspirates Breast/cyst/nipple discharge Sputum Urine CSF Oesophageal washings and brushings Conventional Bronchial Brushings Biliary duct brushings Pancreatic duct brushings Duodenal brushings Liver Skin scrape Ovarian cyst endometrium Serous fluids Bronchial washings Bronchial Alveolar lavage</p>	<p>Demonstration of: Cells (nuclei and cytoplasm) and micro-organisms</p>	<p>Manual staining</p> <p>Papanicolaou stain for Non-Gynae Specimens</p> <p>May-Grunwald & Giemsa stain for air dried slides</p> <p>H&E stain CP-HIST-IMMUNO-GEN-SOP14 CP-HIST-IMMUNO-IMF6 CP-CLIN2</p>	<p>RLH</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Body fluids Fine needle aspirates Breast/cyst/nipple discharge Sputum Urine CSF Oesophageal washings and brushings Conventional Bronchial Brushings Biliary duct brushings Pancreatic duct brushings Duodenal brushings Liver Skin scrape Ovarian cyst endometrium Serous fluids Bronchial washings Bronchial Alveolar lavage</p>	<p><u>Cytopathology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro organisms</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Automated staining Gemini staining machine</p> <p>Papanicolaou stain for Non-Gynae Specimens</p> <p>May-Grunwald & Giemsa stain for air dried slides</p> <p>Cytogiem stain</p> <p>H&E stain</p> <p>May-Grunwald & Giemsa stain for air dried slides</p> <p>SOP C003 SOP C025 SOP C041</p>	<p>UHL</p>
<p>All cytology samples</p>	<p>Morphological assessment and interpretation/diagnosis.</p>	<p>Microscopy Light microscopy SOP C005 SOP C002 SOP C033 SOP C005 SOP C002 SOP C012</p>	<p>RLH UHL</p>
<p>Synovial aspirate</p>	<p>Detection and identification of Crystals</p>	<p>Preparation and examination Polarising microscope SOP C005 SOP C002</p>	<p>UHL</p>



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Detection of: 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 Insulin Sp IgE Ab Human Insulin Sp IgE Ab Bovine Gelatine Sp IgE Ab House Dust mite 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 Parrot Feathers Sp IgE Ab Pigeon 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	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Detection of: (cont'd) 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 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	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Detection of: (cont'd)	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	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 Aubergine Sp IgE Ab Peppercorn Sp IgE Ab Beef Meat Sp IgE Ab Ginger Sp IgE Ab Thyme Sp IgE Ab Chilli 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 Cow's Milk Sp IgE Ab Cod Sp IgE Ab Halibut Sp IgE Ab Lime Sp IgE Ab Sardine Sp IgE Ab Chickpea 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		



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Detection of: (cont'd) 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 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	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Detection of: (cont'd) 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 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 Herbarium Sp IgE Ab A. Fumigatus Sp IgE Ab A. Alternata Sp IgE Ab H. Halodes Sp IgE Ab Mould Mix Sp IgE Ab	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Detection of: (cont'd) Miscellaneous Sp IgE Ab London Plane Sp IgE Ab White Pine Sp IgE Ab Japanese Cedar Sp IgE Ab 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 Rhev B8 Latex Profilin Sp IgE Ab Acarus Siro Sp IgE Ab Mouse (Epithelium/Serum/Urine) Sp IgE Ab Chicken Droppings Sp IgE Ab	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Detection of: (cont'd) 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 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 Aspergillus Flavus Sp IgE Ab	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Detection of: (cont'd)	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	Pityrosporum Orbiculare 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	IM ID03 IM A50 IM A70	
	Autoimmune Serology		
	Detection of:		
Blood	Anti-Cardiolipin (IgG,A,M Screen)	Dynex DS2 ELISA – Orgentec IM A33	RLH
Blood	Intrinsic Factor antibodies	Dynex DS2 ELISA - Orgentec IM A22	RLH
Blood	Tissue Transglutaminase (IgA)	Dynex DS2 ELISA - Orgentec IM A45	RLH
Blood	Acetylcholine Receptor Abs	Dynex DS2 ELISA - RSR IM A55	RLH
Blood	Anti-GAD antibodies	Dynex DS2 ELISA - RSR IM A60	RLH
Blood	Anti-Natalizumab (Tysabri) Abs	Dynex DS2 ELISA – Inhouse Biogen-idec IM A57	RLH



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Barts Health NHS Trust as the host of NHS East and South East London Pathology Partnership

Issue No: 025 Issue date: 30 April 2026

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Autoimmune Serology (cont'd)		
	Detection of: (cont'd)		
Blood	TSH Receptor antibodies	Dynex DS2 ELISA - RSR IM A62	RLH
Blood	Infliximab drug level	Dynex DS2 ELISA – PROMonitor IM A73	RLH
Blood	Infliximab antibody level	Dynex DS2 ELISA – PROMonitor IM A74	RLH
Blood	Adalimumab drug level	Dynex DS2 ELISA – Promonitor IM A81	RLH
Blood	Adalimumab antibody level	Dynex DS2 ELISA – Promonitor IM A82	RLH
Blood	Islet cell antibodies (GAD/IA2/ZnT8)	Dynex DS2 ELISA – RSR IM A75	RLH
Blood	Anti C1q Antibodies	Dynex DS2 ELISA IM A85	RLH
Blood	Pancreatic Faecal Elastase	Dynex DS2 FELA – ELISA IM A65 IM A82	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Detection of:	Thermo Fisher Phadia 250 Chemiluminescence	
Blood	Citrullinated Protein Abs	IM A54	RLH
Blood	ANCA ELISA [MPO/PR3]	IM A63	RLH
Blood	Anti-Cardiolipin abs IgG / M	IM A 61	RLH
Blood	Beta-2-Glycoprotein 1 abs IgG / M	IM A61	RLH
Blood	dsDNA ELISA	IM A67	RLH
Blood	GBM Antibodies	IM A59	RLH
Blood	Tissue Transglutaminase (IgG)	IM A64	RLH
Blood	M2 Antibodies	IM A71	RLH
Blood	Connective tissue disease screen	IM A91	RLH
	Immunophenotyping		
Blood	Scleroderma / Polymyositis Panel [Jo-1, PL-7, PL-12, SRP, Mi-2, Ku, PM-Scl100 & Scl-70]	Semi-automated D Tek Blue Diver Blot - CLS IM A77	RLH
Blood	Extended Liver Panel [M2/nPDC; gp210; sp100; LKM1; LC1; SLA and F-Actin]	Semi-automated D Tek Blue Diver Blot - CLS IM A78	RLH
Blood	ANA 12 Extended ENA Panel [Sm; RNP (68kD/A/C); Sm/RNP; SSA/Ro 60kD; SSB (La); Jo-1; Scl-70; PM-Scl-100; Ku; CENP-A/B; PCNA & Mi-2]	Semi-automated D Tek Blue Diver Blot - CLS IM A79	RLH
Blood	Myositis panel [Jo-1, PL-7, PL-12, EJ, SRP, MDA-5, TIF18, Ro52, SAE1, SAE2 + NXP2.]	Semi-automated D Tek Blue Diver Blot-CLS IM A88	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u> Immunophenotyping (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood	PLA2 Receptor abs	DS2 ELISA Euroimmun IM A69	RLH
Blood	Adrenal antibodies	Indirect Immunofluorescence Slides – IL/Werfen IM A07	RLH
Blood	ANA (Hep-2) Screen	Indirect Immunofluorescence Slides – Biodiagnostics IM A06	RLH
Blood	dsDNA Immunofluorescence	Indirect Immunofluorescence Slides – Biosystems/Launch IM A10	RLH
Blood	Endomysial antibodies (IgA)	Indirect Immunofluorescence Slides – IL/Werfen IM A11	RLH
Blood	IgG ANCA	Indirect Immunofluorescence Slides – IL/Werfen IM A09 AN	RLH
Blood	Islet Cell antibodies	Indirect Immunofluorescence Slides – IL/Werfen IM A29	RLH
Blood	Neuronal Antibodies	Indirect Immunofluorescence Slides – IL/Werfen IM A49	RLH
Blood	Myocardial antibodies	Indirect Immunofluorescence Slides – IL/Werfen IM A80	RLH
Blood	Pemphigus/Pemphigoid	Indirect Immunofluorescence Slides – IL/Werfen IM A13	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunodeficiency		
Blood	C1 Esterase level	Binding Site Optilite Turbidimetry IM ID04	RLH
Blood	C1 Esterase (Function)	Sysmex CN2500 Siemens Berichrom C1 inhibitor kit IMID05	RLH
Blood	Mannose Binding Ligand	Thermo Fisher MBL Oligomer ELISA IM ID08	RLH
Blood	Haemophilus B Antibodies	DS2 ELISA Binding Site: VaccZyme™ Human Anti-Haemophilus influenzae type b Enzyme Immunoassay Kit IM ID06	RLH
Blood	Tetanus antibodies	DS2 ELISA Binding Site: VaccZyme™ Anti-Tetanus Toxoid IgG Enzyme Immunoassay Kit IM ID07	RLH
Blood	<i>Salmonella typhi</i> Ab	DS2 ELISA Binding site: VaccZyme™ Human Anti-Salmonella typhi Vi IgG Enzyme Immunoassay Kit IM ID22	RLH
Blood	IgG Subclasses	Turbidimetry Binding Site: Optilite® IgG1 Kit Optilite® IgG2 Kit Optilite® IgG3 Kit Optilite® IgG4 Kit IM ID11	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
	Flow Cytometry	BD FACS LyricFlow Cytometry Monoclonal antibody kits:	
Whole blood	Lymphocyte Subsets (CD3,4,8)	BD FACS LyricFlow Cytometer BD Multitest™ CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC IM ID12	RLH
Whole blood	Immunodeficiency Panel (B, T, NK)	BD FACS LyricFlow Cytometer BD Multitest™ 6-color TBNK CD3 FITC / CD16 PE + CD56 PE / CD45 PerCP-Cy™5.5 / CD4 PE-Cy™7 / CD19 APC / CD8 APC-Cy™7IM ID12	RLH
Whole blood	B Cell Subpopulation	BD FACS LyricFlow Cytometer Manual assay using the following reagents: BD: APC Mouse IgG1, κ Isotype Control. BD: CD19 (SJ25C1). BD: PE Mouse Anti-Human CD21. BD: APC Mouse Anti-Human CD38. BD: PE Mouse Anti-Human CD21. BD: APC Mouse Anti-Human IgM. BD: FITC Mouse Anti-Human IgM. Dako: Mouse IgG1/FITC Isotype. Dako: Monoclonal Mouse Anti-Human CD27/FITC Clone M-T271 IM ID13	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Whole blood	Neutrophil Function [DHR]	BD FACS LyricFlow Cytometer Manual assay using the following reagents: Sigma Aldrich: Dihydrorhodamine 123 Sigma Aldrich: Phorbol 12-myristate 13-acetateIM ID17	RLH
Whole blood	Detection and enumeration of GPI-deficient cell clones in patients with Paroxysmal Nocturnal Haemoglobinuria, Aplastic Anaemia and Myelodysplasia. For diagnosis and follow up	BD FACS LyricFlow Cytometer Cells deficient in GPI-linked markers are detected and quantified IMP.SOP.012	RLH
Whole blood Bone marrow CSF Pleural Fluid Ascites, serous fluid and effusion.	T-cell, B-cell, Myeloid Screening (Leukaemia/Lymphoma and MDS)	BD FACS LyricFlow Cytometer Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies IMP.SOP.008	RLH
Whole 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)	BD FACS LyricFlow Cytometer Cells labelled with fluorescent validated CE-IVD and RUO monoclonal. IMP.SOP.009 IMP.SOP.045	RLH
Whole 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)	BD FACS LyricFlow Cytometer Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies IMP.SOP.013 IMP.SOP.045	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Whole 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)	BD FACS LyricFlow Cytometer Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies. IMP.SOP.011 IMP.SOP.045	RLH
Whole 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)	BD FACS LyricFlow Cytometer Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies are analysed using flow cytometry. IMP.SOP.010 IMP.SOP.045	RLH
Whole blood Bone marrow CSF Pleural Fluid Ascites, serous fluid and effusion.	Assessment of intracellular antigens during investigation of acute leukaemia, Lymphoproliferative disorders, and lymphoma	BD FACS LyricFlow Cytometer Cells labelled with fluorescent validated CE-IVD and RUO monoclonal antibodies are analysed using flow cytometry. IMP.SOP.014	RLH
Whole blood Bone Marrow Body Fluids	Smear staining for suspected Leukaemia / Lymphoma - morphological examination	RAL staining machine. IMP.SOP.051	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histocompatibility and immunogenetics examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Whole blood (EDTA) Buccal swab Spleen	Clinical Transplantation DNA Extraction	DNA Extraction EZ1 Advanced XL Qiagen Biorobot EZ1&2 DNA Blood kits CTL.GEN.SOP.100	RLH
Whole blood (EDTA)	DNA Extraction	Manual DNA extraction QIAamp DNA Blood Mini Kit CTL.GEN.SOP.100	RLH
Genomic DNA extracted in house from the above sample type or received as a primary sample from external source	Human Leukocyte Antigen (HLA) typing Class I/II: A, B, C, DRB1, DRB345, DQA/B1, DPA/B1	PCR - SSO Luminex® 100/200 analyser Luminex XY™ plate handling platform Luminex SD™ sheath fluid delivery system EZ1&2 DNA Blood kits Lifecodes® HLA-SSO Typing Kits MATCH IT! DNA analysis software CTL.MOL.SOP.100	RLH
Genomic DNA extracted in house from the above sample type or received as a primary sample from external source	B*57:01 testing	PCR - SSO Luminex® 100/200 analyser Luminex XY™ plate handling platform Luminex SD™ sheath fluid delivery system Verti and Verti Pro thermocyclers Lifecodes® HLA-SSO Typing Kit MATCH IT! DNA Analysis software CTL-MOL-SOP-100	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histocompatibility and immunogenetics examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Genomic DNA extracted in house from the above sample type or received as a primary sample from external source	Clinical Transplantation (cont'd) Human Leukocyte Antigen (HLA) typing Class I/II: A, B, C, DRB345, DRB1, DQA1, DQB1, DPA1, DPB1	PCR - SSP Roche Lightcycler LinkSeq HLA-ABCDRDQDP+384 Typing Kit Suretyper analysis Software CTL.MOL.SOP.120	RLH
Genomic DNA extracted in house from the above sample type or received as a primary sample from external source	Human Leukocyte Antigen (HLA) typing Class I/II: A, B, C, DRB345, DRB1, DQA1, DQB1, DPA1, DPB1	Next Generation Sequencing (NGS) Qubit Veriti Pro thermocycler Illumina MiniSeq Illumina MiSeq GenDx NGSgo-MX11-1 kit NGSgo-AmpXv2 kit NGSgo-LibrX kit NGSgo-IndX kit NGS Engine analysis software CTL.MOL.SOP.110	RLH
Genomic DNA extracted in house from the above sample type or received as a primary sample from external source	Haemochromatosis (HFE) testing	PCR-SSP IDT Primers Gel tank Verti thermocycler Syngene GBOX gel imager CTL.MOL.SOP.130	RLH
Serum	Human Leukocyte Antigen (HLA) typing Class I/II: A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1, DPB1	Luminex® 100/200 analyser Luminex XY™ plate handling platform Luminex SD™ sheath fluid delivery system One lambda LABScreen Single Antigen kits HLA Fusion analysis software CTL.SER.SOP.100	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Histocompatibility and immunogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Clinical Transplantation (cont'd) Human Leukocyte Antigen (HLA) typing Class I/II: A,B,C,DRB1,DRB3,DRB4,DRB5, DQA1,DQB1,DPA1,DPB1	Luminex® 100/200 analyser Luminex XY™ plate handling platform Luminex SD™ sheath fluid delivery system LIFECODES LifeScreen Deluxe (LMX) kit LIFECODES LSA Class I kit LIFECODES LSA Class II kit MATCH IT! Antibody analysis software CTL.SER.SOP.100	RLH
Blood (cells & serum)	Detection of IgG HLA specific antibodies to donor T and B lymphocytes	Becton Dickinson FACSLyric Dako CD3 Dako CD19 Dako FITC CTL.SER.SOP.110	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Cytogenetics examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Blood (lithium heparin) Bone marrow Body fluids	Cell culture and karyotype analysis using G-banding and image capture analysis	Olympus BX45 Light microscope (PP/3/36), Metasystems IKAROS imaging software	RLH
Blood (lithium heparin) Bone marrow Body fluids	Preparation and cell harvest for acquired and constitutional cytogenetic abnormalities	CMH-CYTO-SOP-003 CMH-CYTO-SOP-011 CMH-CYTO-SOP-002 CMH-CYTO-SOP-012 CMH-CYTO-SOP-004 CMH-CYTO-SOP-013	
Blood (lithium heparin) Bone marrow Body fluids	Karyotyping analysis of G-banded chromosomes	CMH-CYTO-SOP-008 CMH-CYTO-SOP-015	
	Reporting of cytogenetics results	CMH-CYTO-POL-002	
Fixed cells / Formalin Fixed Paraffin Embedded tissue (FFPE)	Detection of microscopic and sub microscopic gains/losses and rearrangements of DNA	Zeiss AXIO Imager microscope Metasystems ISIS imaging software	RLH
	Preparation and cell harvest for acquired and constitutional cytogenetic abnormalities	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	
	Detection of microscopic and sub microscopic gains/losses and rearrangements of DNA	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	



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HUMAN BODY SAMPLES (cont'd)	<u>Molecular Genetics examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Blood Bone marrow Tissue Body fluids	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	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	CALR	In house PCR method Veriti thermal cyclers CALR assay Applied Biosystems 3730 HAEM-MOLEC-SOP-54	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	MPL	In house PCR method Veriti thermal cyclers MPL assay Applied Biosystems 3730 HAEM-MOLEC-SOP-55	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	BCR-ABL1	In house / EAC RQ-PCR method with Qiagen Ipsogen Standards Veriti thermal cyclers BCR-ABL1 assay Applied Biosystems 7500 HAEM-MOLEC-SOP-05 HAEM-MOLEC-SOP-11 HAEM-MOLEC-SOP-12 HAEM-MOLEC-SOP-13 HAEM-MOLEC-SOP-14	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	FLT3 /NPM1	In-house PCR method Veriti thermal cyclers FLT3 / NPM1 assay Applied Biosystems 3730 HAEM-MOLEC-SOP-20 HAEM-MOLEC-SOP-23	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	Immunoglobulin Rearrangement (IGH and IGK)	IG assay by PCR Veriti thermal cyclers Invivoscribe kit Applied Biosystems 3730 Applied Biosystems 3730 HAEM-MOLEC-SOP-10	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	T-Cell Receptor Rearrangement (TCRB and TCRG)	TCR assay by PCR Veriti thermal cyclers Invivoscribe kit Applied Biosystems 3730 HAEM-MOLEC-SOP-10	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	Chimerism Analysis	Chimerism assay by PCR Thermal cyclers Promega Powerplex 16 HS kit Applied Biosystems 3730 HAEM-MOLEC-SOP-16	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	Minimal Residual Disease Monitoring in Acute Lymphoblastic Leukaemia (ALL)	MRD assay by PCR MRD assay by RQ-PCR Sequencing using published methods Veriti thermal cyclers Applied Biosystems 7500 Applied Biosystems 3730 HAEM-MOLEC-SOP-06 HAEM-MOLEC-SOP-22 HAEM-MOLEC-SOP-24 HAEM-MOLEC-SOP-25 HAEM-MOLEC-SOP-26 HAEM-MOLEC-SOP-27 HAEM-MOLEC-SOP-28 HAEM-MOLEC-SOP-29 HAEM-MOLEC-SOP-30 HAEM-MOLEC-SOP-31 HAEM-MOLEC-SOP-33 HAEM-MOLEC-SOP-34 HAEM-MOLEC-SOP-35	RLH



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HUMAN BODY SAMPLES (cont'd)	<u>Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources	MYD88	Qiagen Qbiomarker Thermal cycler MYD88 assay Applied Biosystems 7500. CMH-SOP-014 MYD88	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources FFPE	BRAF	Biocartis Idylla™ System Idylla™ BRAF Mutation Test	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources FFPE	EGFR	Biocartis Idylla™ System Idylla™ EGFR Mutation Test	RLH
Genomic DNA and RNA extracted in-house from the sample types listed and/or received as primary samples from external sources	Detection of fusion genes and mutations in haematological malignancies	Next Generation Sequencing using: In house methodology Library Preparation using Hamilton Star Liquid Handler and with massively paralleled sequencing on a NextSeq 550 Oncomine myeloid research assay Bioinformatic data analysis using: commercial software (Ion Chef and IonS5 sequencer) and databases CMH-SOP-010 CMH-SOP-011 CMH-SOP-012 CMH-SOP-013	RLH



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources</p>	<p><u>Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection and mutations in Cancer samples</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Next Generation Sequencing using: In house methodology Library Preparation using Hamilton Star Liquid Handler and with massively paralleled sequencing on a NextSeq 550 Ion Ampliseq Cancer hotspot panel v2 Bioinformatic data analysis using: commercial software (Ion Chef and IonS5 sequencer) and databases CMH-SOP-010 CMH-SOP-011 CMH-SOP-012 CMH-SOP-013</p>	<p>RLH</p>
<p>Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources</p>	<p>ABL1 (exons 4, 5, 6, 7); EGFR (exons 3, 7, 15, 18, 19, 20, 21); GNAS (exons 8, 9); KRAS (exons 2, 3, 4); PTPN11 (exons 3, 13); AKT1 (exons 3, 6); ERBB2 (exons 19, 20, 24); GNAQ (exon 5); MET (exons 2, 11, 14, 16, 19); RB1 (exons 4, 6, 10, 11, 14, 17, 18, 20, 21, 22); ALK (exons 23, 25); ERBB4 (exons 3, 4, 6, 7, 8, 9, 15, 23); HNF1A (exons 3, 4); MLH1 (exon 12); RET (exons 10, 11, 13, 15, 16); APC (exon 16); EZH2 (exon 16); HRAS (exons 2, 3); MPL (exon 10); SMAD4 (exons 4, 5, 6, 8, 9, 10, 11, 12); ATM (exons 8, 9, 12, 17, 26, 34, 35, 36, 39, 50, 54, 55, 56, 59, 61, 63); FBXW7 (exons 5, 8, 9, 10, 11); IDH1 (exon 1); NOTCH1 (exons 26, 27, 34); SMARCB1 (exons 2, 4, 5, 9); BRAF (exons 11, 15); FGFR1 (exons 4, 7); JAK2</p>	<p>Next Generation Sequencing using: In house methodology Library Preparation using Hamilton Star Liquid Handler and with massively paralleled sequencing on a NextSeq 550 Ion Ampliseq Cancer hotspot panel v2 Bioinformatic data analysis using: commercial software (Ion Chef and IonS5 sequencer) and databases CMH-SOP-010 CMH-SOP-011 CMH-SOP-012 CMH-SOP-013</p>	<p>RLH</p>



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

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Issue No: 025 Issue date: 30 April 2026

Testing performed by the Organisation at the locations specified

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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources</p>	<p><u>Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>JAK3 (exons 4, 13, 16); NRAS (exons 2, 3, 4); SRC (exons 3, 5, 6, 9, 11); CDKN2A (exon 2); FGFR3 (exons 7, 9, 14, 16, 18); IDH2 (exon 1); PDGFRA (exons 12, 14, 15, 18); STK11 (exons 1, 4, 5, 6, 8); CSF1R (exons 7, 22); FLT3 (exons 11, 14, 16, 20); KDR (exons 6, 7, 11, 19, 21, 26, 27, 30, 30); PIK3CA (exons 2, 5, 7, 8, 10, 14, 19, 21); TP53 (exons 2, 4, 5, 5, 6, 7, 8, 10); CTNNB1 (exon 3); GNA11 (exon 5); KIT (exons 2, 9, 10, 11, 13, 14, 15, 17, 18); PTEN (exons 1, 3, 5, 6, 7, 8); VHL (exons 1, 2, 3);</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Next Generation Sequencing using: In house methodology Library Preparation using Hamilton Star Liquid Handler and with massively paralleled sequencing on a NextSeq 550 Ion Ampliseq Cancer hotspot panel v2 Bioinformatic data analysis using: commercial software (Ion Chef and IonS5 sequencer) and databases CMH-SOP-010 CMH-SOP-011 CMH-SOP-012 CMH-SOP-013</p>	<p>RLH</p>
<p>Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources</p>	<p>IGH Somatic Hypermutation screening</p>	<p>IGH Somatic Hypermutation assay Veriti thermal cycler Invivoscribe kit Applied Biosystem 3730. HAEM-MOLEC-SOP-68</p>	<p>RLH</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>A) Whole blood, fresh retinoblastoma tumour, paraffin embedded tissue, received DNA samples.</p> <p>B) Amniotic fluid, chorionic villus.</p> <p>C) Hair, buccal cells.</p> <p>D) Whole blood, fresh retinoblastoma tumour.</p>	<p><u>Retinoblastoma examination activities for the purpose of clinical diagnosis</u></p> <p>Dual DNA and RNA extraction</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Manual dual DNA and RNA extraction using: Zymo Quick-gDNA MidiPrep Zymo Quick-gDNA MiniPrep Ambion Recover All Total Nucleic Acid Isolation Kit TriReagent QI Amp RNA blood mini kit RB.SOP.078 RB.SOP.079 RB.SOP.081 RB.SOP.096 RB.SOP.077 RB.SOP.095 RB.INFO.029</p>	<p>RLH</p>
<p>Genomic DNA extracted in-house from the sample types listed and received as primary samples from external sources (A)</p>	<p>RB1 Mutation Screening for point mutations and small indels.</p>	<p>Rotorgene Q High Resolution Melt (HRM) Confirmation Screening using a Bioline SensiFAST HRM Kit, Qiagen Type-it HRM Kit RB.DOC.053 RB.SOP.054 RB.SOP.086</p>	<p>RLH</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>Genomic DNA and RNA extracted in house from the sample types listed above and/or received as primary samples from external sources (A,B,C) RNA extracted inhouse from the sample types listed above or received as primary sample type from an external source (A)</p>	<p><u>Retinoblastoma examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>RB1 variant</p>	<p>In house documented methods incorporating manufacturer's instructions where relevant</p> <p>Sanger sequencing Inhouse designed PCR/RT-PCR Amplification Thermal cycler ABI 3730XL Capillary electrophoresis instruments Analysis and interpretation of variants by: Big Dye Terminator v1.1 Cycle Sequencing Kit RB.DOC.090 RB.DOC.084 RB.SOP.069 RB.SOP.087 RB.SOP.027 RB.SOP.036 RB.SOP.099 RB.SOP.025 RB.SOP.091 RB.SOP.088</p>	<p>RLH</p>
<p>Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources: (A, B, C)</p>	<p>RB1 linkage exclusion testing and LOH analysis.</p>	<p>PCR Amplification and Fragment Analysis Thermal cyclers ABI 3730XL capillary analyser RB.DOC.071 RB.SOP.069 RB.SOP.025 RB.SOP.042 RB.SOP.088 RB.DOC.048</p>	<p>RLH</p>
<p>Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources (A, B, D)</p>	<p>Screening for dosage mutations in RB1.</p>	<p>Multiplex Ligation-dependant Probe Amplification (MLPA) Thermal cycler MRC Holland MLPA SALSA P047 Kit ABI 3730XL capillary analyser RB.SOP.059 RB.DOC.045 RB.DOC.060</p>	<p>RLH</p>



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HUMAN BODY SAMPLES (cont'd)	<u>Retinoblastoma examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturer's instructions where relevant	
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources (A, B, D)	Screening for dosage mutations in RB1.	Quantitative Fluorescence PCR (QF-PCR)In In-house methods using fragment analysis for trisomy screen Thermal cyclers ABI 3730XL capillary analyser. RB.DOC.035 RB.SOP.069	RLH
Genomic DNA extracted in-house from the sample types listed and/or received as primary samples from external sources (A)	Hypermethylation in RB1 Promoter	Methylation Specific - Multiplex Ligation-dependant Probe Amplification (MS-MLPA) Thermal cyclers Agarose gel electrophoresis Zymo EZ DNA Methylation-Gold Kit ABI3500XL analyser RB.DOC.068 RB.SOP.041 RB.SOP.058 RB.SOP.025	RLH
END			