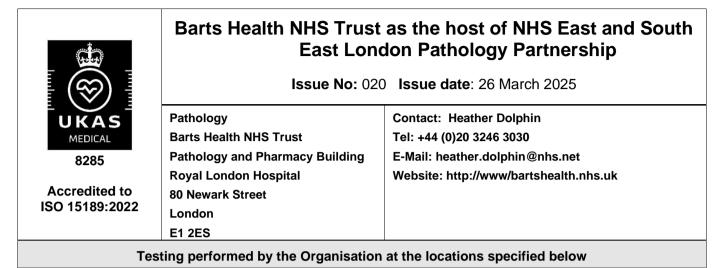
Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



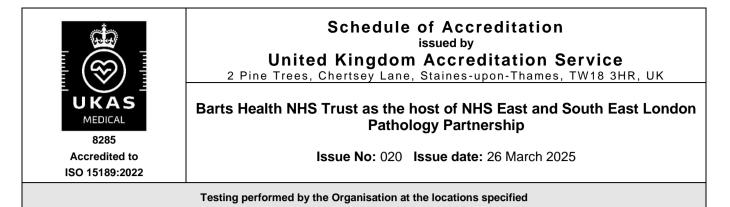
Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Department of Pathology The Royal London Hospital Pathology and Pharmacy Building 80, Newark Street London E1 1ES	Local Contact As specified below		RLH
Haematology & Blood Transfusion	Karl Jewell 020 3246 0374 Kurtis Lee 020 324 0441 Patricia Richards 020 324 6044 Juswal Dadhra 020 3246 0409 Julia Lancut 020 3246 0432 Minal Dave 020 3246 0409	Routine Haematology Special Haematology Routine Coagulation Special Coagulation Blood Transfusion	RLH
Clinical Biochemistry	Karl Jewell 020 3246 0374 Greg Dearman 020 3246 0443	Automated biochemistry Proteins Immunoassay LCMS HPLC	RLH

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



Location details		Activity	Location code
Immunology	Chris Scott 020 3246 0287	Immunology Allergy Autoimmune serology Immunodeficiency Flow Cytometry	RLH
Clinical Transplantation	Delordson Kallon 020 3246 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		SBH
Haematology & Blood Transfusion	Neha Thomas 0203 465 7240 Karl Jewell 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

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Location details		Activity	Location code
Histopathology	Toby Hunt 020 3246 0185	Frozen Sections	SBH
	Lee Jeffries 020 3246 0218		
Address Whipps Cross University Hospital Pathology Whipps Cross Road Leytonstone London E11 1NR	Local Contact As specified below	Specimen Reception	WCUH
Haematology & Blood Transfusion	Karl Jewell 020 3246 0374 Kurtis Lee	Haematology Coagulation Blood Transfusion	WCUH
	020 3246 0441 Patricia Richards 020 2346 0555		
Clinical Biochemistry	Greg Dearman 0208 539 5522 EXT 5887	Clinical Biochemistry	WCUH
Address Newham University Hospital Pathology Glen Road Plaistow London E13 8SL	Local Contact As specified below	Specimen Reception	NUH
Haematology Blood Transfusion	Karl Jewell 020 3246 0374	Haematology Coagulation Blood Transfusion	NUH
	Kurtis Lee 020 3246 0441		
	Gareth Heywood-Beldon 020 7363 8068		

	Schedule of Accreditation		
	United Kingdom Accreditation Service		
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UKAS	Barts Health NHS Trust as the host of NHS East and South East London Pathology Partnership		
8285	3 , 3 , 1		
Accredited to	Issue No: 020 Issue date: 26 March 2025		
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Testing performed by the Organisation at the locations specified			

Location details		Activity	Location code
Clinical Biochemistry	Greg Dearman 020 7363 8002	Clinical Biochemistry	NUH
Address Homerton Healthcare NHS Foundation Trust Homerton University Hospital Homerton Row London E9 6SR	Local Contact As specified below	Specimen reception	нн
Haematology	Nandini KIZHAKKAYIL	Haematology	нн
Clinical Chemistry	02085107503	Clinical Chemistry	
Blood Transfusion		Blood Transfusion	
Address University Hospital Lewisham High Street Lewisham London SE13 6LH	Local Contact As specified below	Specimen reception	UHL
Haematology		Haematology	UHL
Blood Transfusion		Blood Transfusion	UHL
Clinical Chemistry		Clinical Chemistry	UHL
Address University Hospital Lewisham 1 st Floor Waterloo Block Lewisham High Street Lewisham London SE13 6LH	Local Contact As specified below		
Cellular Pathology	Dalian Beaver 02031923029 Miguel Evaristo 02031923029	Cytology Histology	UHL
Blood Sciences	Richard McLean 02031926669.	Blood Transfusion Haematology Clinical Chemistry	UHL

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Testing performed by the Organisation at the locations specified			

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		Clinical Chemistry	QEH
Cellular Pathology	Dalian Beaver 02088565683	Histology	QEH

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	Testing performed by the Organisation at the locations specified

Site activities performed away from the locations listed above:

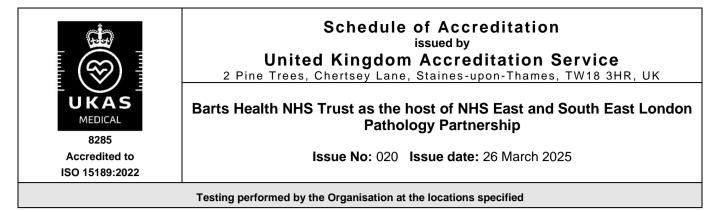
Location details		Activity	Location code
Address Theatre Fridge Level 1, zone 10 Newham University Hospital Glen Road Plaistow London E13 8SL	Local Contact Gareth Heywood- Beldon	Blood Collection Fridge Hemobank 20 remote issue fridge No testing occurs, blood storage only	NUH-BF- 1
Address A&E fridge ground floor zone 1Newham 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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	United Kingdom Accreditation Service
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	Testing performed by the Organisation at the locations specified

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 1Royal 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



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

Issue No: 020 Issue date: 26 March 2025

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

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

Issue No: 020 Issue date: 26 March 2025

Location details		Activity	Location code
Address Theatres Fridge Junction 7/8 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-4
Address Plane tree centre Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood- Beldon	Hemobank 20 remote issue fridge	WCUH- BF-5
Address Acorn ward Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood- Beldon	Hemobank 20 remote issue fridge	WCUH- BF-6
Address Issue blood fridge Haematology and blood transfusion junction 2 Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood- Beldon	Helmer Hemobank 80	WCUH- BF-7
Address Haematology and blood transfusion junction 2 Whipps Cross University Hospital Whipps Cross Road Leytonstone London E11 1NR	Local Contact Gareth Heywood- Beldon	Labcold blood stock fridge	WCUH- BF-8



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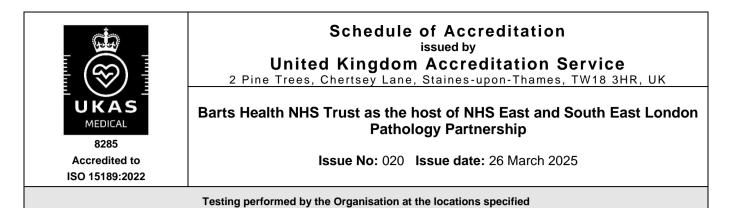
Barts Health NHS Trust as the host of NHS East and South East London **Pathology Partnership**

Issue No: 020 Issue date: 26 March 2025

Location details		Activity	Location code
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
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 Patricia Richards 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	Patricia Richards Tosin Kelani	Blood storage only Fridge managed by laboratory	QEH-BF- 2
Address Theatres Queen Elizabeth Hospital Stadium Road Woolwich SE18 4QH	Patricia Richards 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	Patricia Richards Richard McLean	Blood product storage (Stock/issue) Fridge managed by laboratory	UHL-BF- 1

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	Barts Health NHS Trust as the host of NHS East and South East London Pathology Partnership
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Location details		Activity	Location code
Address Main Theatre Paediatric University Hospital Lewisham High Street Lewisham London SE13 6LH	Patricia Richards Richard McLean	Blood storage Fridge managed by laboratory	UHL-BF- 2
Address ICU University Hospital Lewisham High Street Lewisham London SE13 6LH	Patricia Richards Richard McLean	Blood storage Fridge managed by Laboratory	UHL-BF- 3
Address Day Surgery Unit University Hospital Lewisham High Street Lewisham London SE13 6LH	Patricia Richards Richard McLean	Blood storage Fridge managed by Laboratory	UHL-BF- 4



Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Haematology examination activities for the purposes of clinical diagnosis: Routine Haematology	In house documented methods incorporating manufacturer's instructions where relevant	
Venous whole blood: EDTA	Full Blood Count	Sysmex XN-9100 series multiple cell counting technique: Sysmex XN 3100Sysmex XN-20 & XN-10 EHA.SYSMEX.4 EHA.SYSMEX.6	RLH SBH NBH WCUH HH QEH UHL
	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 Haemoglobin Concentration (MCHC)		
Venous whole blood: EDTA	Reticulocyte count	Sysmex XN 91000, XN 2000 & XN 1000 EHA. SYSMEX.4	RLH SBH NUH WCUH QEH UHL HH
Venous Plasma: Citrate	Citrate platelet count	Sheath Flow Detection using Sysmex XN10/20 EHA.SYSMEX.4	QEH UHL
Venous whole blood: EDTA	Erythrocyte Sedimentation Rate	StaRRsed InteRRliner RS (Autocompact) Westergren method aggregation capacity mm/hr EHA.ESR.2	RLH HH WCUH NUH

DETAIL OF ACCREDITATION

	Schedule of Accreditation
	United Kingdom Accreditation Service
	2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK
UKAS MEDICAL 8285	Barts Health NHS Trust as the host of NHS East and South East London Pathology Partnership
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Materials/Products te	ested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)		Haematology examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
		Routine Haematology (cont'd)		
Venous whole blood: EDTA	:	Erythrocyte Sedimentation Rate	StaRRsed ST (Inversa) Westergren method aggregation capacity mm/hr EHA.ESR.1	UHL
Venous whole blood: EDTA	:	Peripheral blood staining and morphology	Automated – Sysmex SP50 using May Grunwald Giemsa stain EHA.SYSMEX.1	RLH HH
Venous whole b EDTA	blood:	Examination of Peripheral blood film, detection of normal and abnormal morphologies, white blood cell differential	Blood film examination by light microscopy EHA.MORPH.4	RLH WCUH NUH SBH HH
Venous whole b EDTA	olood:	Examination of Peripheral blood film, detection of normal and abnormal morphologies, white blood cell differential	Blood film examination using Romanowski staining Haematek 3000 Light microscopy EHA.MORPH.2	QEH UHL
Venous whole b EDTA	blood:	Morphological Detection and Identification of Malaria Parasites	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 b EDTA	blood:	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	CareUS kit	RLH WCUH NUH HH QEH UHL
Venous whole b EDTA	olood:	Peripheral blood slide staining for morphology	RAL staining machine, automated bath staining unit EHA.SYSMEX.4	RLH NUH SBH

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Special Haematology		
Bone Marrow (Aspirate and Trephine)	Bone Marrow examination Hemosiderin	Perl's iron manual stain HAEM-HAEM-MORPH-017	RLH
Bone marrow	To identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis	Light microscopy using MGG and Iron stain BH-SP-024	QEH UHL
Urine	Hemosiderin	Perl's iron manual stain HAEM-HAEM-MORPH-017	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 CS5100, CS2500 & CN- 3000 Photometric end-point clot detection ECO.ROUT.8/9	RLH SBH WCUH NUH HH
Venous Plasma: Citrate	D-dimer	Sysmex CS5100 Latex immunoassay ECO.ROUT.8/9	RLH
Venous Plasma: Citrate	D-dimer	Sysmex CS2500tex immunoassay ECO.ROUT.8/9	NUH WCUH SBH



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

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Venous Plasma: Citrate	D-dimer	Sysmex CN ECO.ROUT.8/9	нн
	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 and factor XIII,	Sysmex C2500Chromogenic assays ECO.HPHILIA.5	RLH
Venous Plasma: Citrate	α2-antiplasmin	Sysmex CS2500 Chromogenic assay ECO.HPHILIA.5	RLH
Venous Plasma: Citrate		Sysmex CS2100 ECO.HPHILIA.5	RLH
	Von Willebrand factor antigen (vW:Ag)	Latex assay	RLH
	von Willebrand factor activity (vW:RCo)	Platelet agglutination assay	RLH
	von Willebrand factor activity (vW:GpIbM)	Latex assay	RLH
Venous Plasma: Citrate	Anti-Xa Activity (Heparin) and direct Xa inhibitors Assay	Sysmex CS2500 & 5100 Chromogenic kinetic assay ECO.ROUT.8/9	RLH NUH WCUH
Venous Plasma: Citrate	Anti-Xa activity assay for apixaban	Sysmex CS2500 & 5100 Chromogenic kinetic assay ECO.ROUT.8/9	RLH NUH WCUH
Venous Plasma: Citrate	Anti-Xa activity assay for fondaparinux	Sysmex CS2500 & 5100 Chromogenic kinetic assay ECO.ROUT.8/9	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 FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Special Coagulation (cont'd)		
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 orgaran	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
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	Prekallikrein assay, high molecular weight Kininogen (HMWK)	Sysmex CS2500 One stage end-point assay ECO.HPHILIA.5	RLH
Venous Plasma: Citrate	 Inhibitor screen and assay For factor VIII inhibitors For factor IX inhibitors For factor XI inhibitors For factor II inhibitors For factor V inhibitors For factor VII inhibitors For factor X inhibitors For factor X inhibitors For factor X inhibitors For factor XIII inhibitors For factor XIII inhibitors For factor XIII 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

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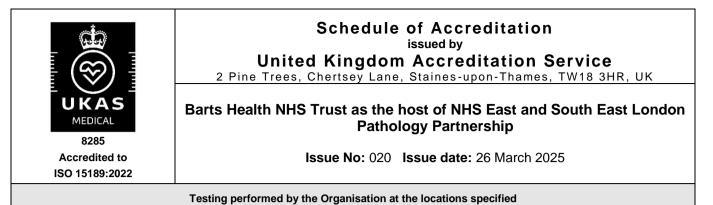
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Special Coagulation (cont'd)		
Venous Plasma: Citrate	 Lupus Anticoagulant screen 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	 Thrombophilia Assays Antithrombin activity assay Free Protein S antigen assay 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 Thrombocytopaenia (HIT)	Automated chemiluminescent immunoassay using Werfen AcuStar BH-CP-035 BH-CP-036	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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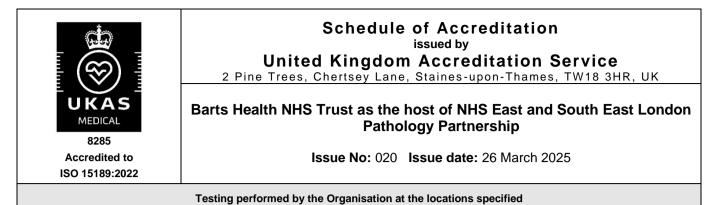
Materials/Products	tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)		Haematology examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
		<u>Red Cell</u>	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 EDTA	blood:	 Haemoglobinopathy screen for the detection of: HbF HbA2 HbA1c Hb J Hb Ao Hb D-Eran Hb Lepore Hb E Hb G Hb D Hb Sanleyville II Hb S Hb O-Arab Hb C 	Sebia Hydrasys HPLC, capillary electrophoresis BioRad Variant II Beta Thal Dual kit. HAEM-RED-HBO-AUTO-06 HAEM-RED-HBO-AUTO-08 BH-SP-016	RLH QEH UHL
Venous whole EDTA	blood:	Sickle Cell screening	Manual relative insolubility method using Streck Sickledex EHA.MAN.1	rlh hh Qeh Uhl
Venous whole EDTA	blood:	G6PD Spot test	Manual detection of fluorescence method using Trinity Biotech G6PD screening kit. HAEM-RED-HBO- HAEMOLYSIS-14	RLH
Venous whole EDTA	blood:	Detection of haemoglobin variants	Sebia Hydragel Acid Haemoglobin (E) Gel HAEM-RED-HBO-AUTO-05	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 FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Venous whole blood: EDTA	Detection of haemoglobin variants	Sebia Hydragel Alkaline Haemoglobin (E) Gel HAEM-RED-HBO-AUTO-04	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 HAEM-RED-HBO-AUTO-08	HH



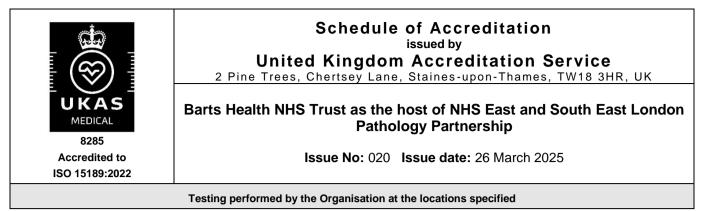
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis:	In house documented methods incorporating manufacturer's instructions where relevant	
Venous whole blood: EDTA	 Blood Group by detection and identification of antigens: A Rh D Positive A Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative A B Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens Antibody screening and identification: Rh blood group antibodies: Anti-Cw, C, c, E, e and D. Kell blood group antibodies: Anti-Kell, k, Kpa and Kpb. Kidd blood group antibodies: Anti-Jka and Jkb. Duffy blood group antibodies: Anti-Fya, and Fyb. Lutheran blood group antibodies: Anti-Lua and Lub. MNS blood group antibodies: Anti-Lea and Leb P blood group antibodies: Anti-P1 	Manual Bio-Rad cards/gels,ID-centrifuge Micro column agglutination immunoassay HAEM-BT-Group-014 HAEM-BT-INVGN-002	RLH SBH WCUH NUH HH



Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis:	In house documented methods incorporating manufacturer's instructions where relevant	
Venous whole blood: EDTA	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative B Rh D Negative B Rh D Negative O Rh D Negative Including the presence of A2 antigens Antibody screening and identification:	Manual Grifols/gels,ID-centrifuge Micro column agglutination immunoassay QE-BT-MAN002 QE-BT-MAN003 QE-BT-MAN009	UHL QEH
	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		
Venous whole blood: EDTA	Blood Grouping: A A1 B AB O RhD	Gel techniques using Grifols: Erytra (automated) Gel cards (manual) QE-BTAUT008 QE-BT-AUT009 QE-BT-MAN002 QE-BT-MAN003	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 FLUIDS (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Venous whole blood: EDTA	Direct Antiglobulin Test	Gel techniques using Grifols, Automated and Manual: 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	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 techniques using Grifols: Erytra (automated) Gel cards (manual) 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	Manual titration method using BioRad Coombs anti-IgG card HAEM-BT-INVGN-009 HAEM-BT-INVGN-011	RLH
Venous whole blood: EDTA	Red Cell phenotyping for antigens of the following blood group systems: Rh: C, D, E, c, e, and Cw Kell: K, k and Kpa Duffy: Fya and Fyb Kidd: Jka and Jkb MNS: M, N, S and s Lewis: Lea and Leb	Red Cell Phenotyping HAEM-BT-INVGN-014	RLH WCUH SBH NUH HH



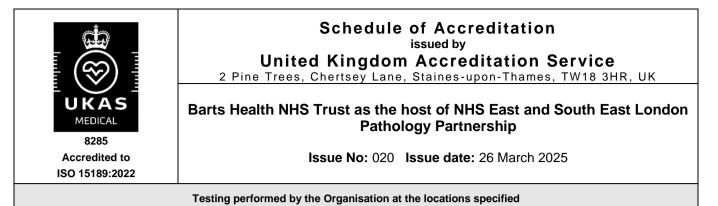
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Venous whole blood: EDTA	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	Manual gel technique using 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)	Estimation of FMH by Kleihauer EBT.INVEST.4 QE-BT-ANT004	NUH RLH WCUH QEH UHL
Venous whole blood: EDTA Cord Blood: EDTA	Alkali Denaturation Test	Manual Tube technique using NaOH. EBT.INVEST.6HAEM	NUH RLH WXH HH

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Clinical Biochemistry examination activities for the purposes of clinical diagnosis:	In house documented methods incorporating manufacturer's instructions where relevant	
Serum	Determination of:	Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1	
	ACE	Kinetic method using third party reagents Buhlmann as an open channel BB-AP-065	QEH
	Alanine Aminotransferase (ALT)	Enzymatic Method	RLH SBH NUH WCUH
	Albumin	Colorimetric BCG	RLH SBH NUH WCUH QEH UHL
	Alkaline Phosphatase (ALP)	Colorimetric	RLH SBH NUH WCUH QEH UHL
	Alpha – 1 Antitrypsin	Immunoturbidimetric	RLH
	Amikacin	Roche KIMS	RLH UHL
	Ammonia	Enzymatic	RLH WCUH QEH UHL
	Amylase	Enzymatic detection methods BBAP-109	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 FLUIDS (cont'd)	Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Determination of: (cont'd)	Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1	
	Aspartate Aminotransferase (AST)	Enzymatic	RLH SBH NUH WCUH QEH UHL
	Bicarbonate	Enzymatic	RLH SBH WCUH QEH UHL
	C3	Immunoturbidimetric	RLH
	C4	Immunoturbidimetric	RLH
	Caeruloplasmin	Immunoturbidimetric	RLH
	Calcium	Photometric	RLH NUH SBH WCUH QEH UHL
	Carbamazepine	Roche KIMS	RLH QEH
	Chloride	Indirect ISE	RLH NUH SBH WCUH
	Cholesterol	Enzymatic colorimetric	RLH NUH WCUH QEH



Materials/Products tested	Type of test/Properties	Standard specifications/	Location
	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Determination of: (cont'd)	Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1	
	C-Reactive Protein (CRP)	Immunoturbidimetric	RLH SBH NUH WCUH
	Creatine Kinase (CK)	Enzymatic	RLH SBH NUH WCUH QEH UHL
	Creatinine	Enzymatic	RLH NUH WCUH SBH
	Digoxin	Roche KIMS	RLH
	Direct Bilirubin	Wako Vandate oxidation method colorimetric Direct Bilirubin on Cobas 8000 as an open channel BB-AP-074	QEH UHL
	Ethanol	Enzymatic	RLH WCUH QEH UHL
	Fructosamine	Colorimetric	RLH QEH
	Gamma-Glutamyltransferase	Enzymatic colorimetric	RLH SBH NUH 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 FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> activities for the purposes of	In house documented methods incorporating manufacturer's	Code
	clinical diagnosis: (cont'd)	instructions where relevant	
Serum (cont'd)	Determination of: (cont'd)	Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1	
	Gentamicin	Enzymatic immunoassay	QEH UHL
	Glucose	Enzymatic	RLH NUH SBH WCUH QEH UHL
	HDL Cholesterol	Enzymatic colorimetric	RLH NUH WCUH QEH UHL
	Immunoglobulin A	Immunoturbidimetric	RLH
	Immunoglobulin G	Immunoturbidimetric	RLH
	Immunoglobulin M	Immunoturbidimetric	RLH
	Iron	Colorimetric	RLH QEH UHL
	Lactate	Colorimetric	RLH WCUH
	Lactate Dehydrogenase (LDH)	Enzymatic	RLH SBH NUH WCUH QEH UHL
	Lipase	Enzymatic	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 FLUIDS (cont'd)	Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Determination of: (cont'd)	Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1	
	Lithium	Colorimetric	RLH QEH UHL
	Magnesium	Colorimetric using xylidyl blue	RLH NUH SBH WCUH QEH UHL
	Paracetamol	Colorimetric	RLH NUH WCUH QEH UHL
	Phenobarbitone	Roche KIMS	RLH
	Phenytoin	Roche KIMS	RLH QEH
	Phosphate	Molybdate UV	RLH NUH SBH WCUH QEH UHL
	Potassium	Indirect ISE	RLH SBH NUH WCUH QEH UHL
	Rheumatoid Factor	Immunoturbidimetric	RLH QEH

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measured/Range of measurement	Equipment/Techniques used	Code
<u>Clinical Biochemistry examination</u> <u>activities for the purposes of</u> <u>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	
Salicylate	Enzymatic	RLH QEH UHL
Sodium	Indirect ISE	RLH SBH NUH WCUH QEH UHL
Theophylline	Roche KIMS	RLH QEH UHL
Tobramycin	Roche KIMS	RLH
Total Bilirubin	Colorimetric Diazomethod	RLH SBH NUH WCUH QEH UHL
Total Protein	Colorimetric	RLH SBH NUH WCUH
Transferrin	Immunoturbidimetric	RLH
Triglycerides	Enzymatic colorimetric Uricase	RLH NUH WCUH QEH UHL
	activities for the purposes of clinical diagnosis: (cont'd)Determination of: (cont'd)SalicylateSodiumTheophyllineTobramycinTotal BilirubinTotal ProteinTransferrin	activities for the purposes of clinical diagnosis: (cont'd)incorporating manufacturer's instructions where relevantDetermination of: (cont'd)Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1SalicylateEnzymaticSodiumIndirect ISETheophyllineRoche KIMSTobramycin Total BilirubinRoche KIMSTotal ProteinColorimetric DiazomethodTransferrinImmunoturbidimetric

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Materials/Products tested	Type of test/Properties	Standard specifications/	Location
	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Determination of: (cont'd)	Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1	
	Cryoglobulin	Visual technique BB-PP-5	QEH
	Urate	Enzymatic colorimetric	RLH SBH NUH WCUH QEH UHL
	Urea	Enzymatic Urase	RLH SBH NUH WCUH QEH UHL
	Vancomycin	Roche KIMS	RLH QEH UHL
	Valprorate	Roche KIMS	RLH QEH
CSF	Glucose	Colorimetric	WCUH
CSF	Lactate	Colorimetric	RLH QEH
CSF	Total protein	Turbidimetric method	RLH WCUH QEH
Fluids	Lactate dehydrogenase (LDH)	Rate enzymatic detection BB-AP-134	QEH
Fluids	Sodium	Ion selective electrode (indirect) detection BB-AP-139	QEH UHL



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum (cont'd)	Determination of: (cont'd)	Roche c8000 (c/702) Automated Roche photometric Chemistry methods. BCHEM-COBAS-SOP-1	
Urine	Albumin	Turbidimetric method	RLH QEH
Urine	Amylase	Enzymatic detection methods BBAP-109	QEH UHL
Urine	Calcium	Photometric	RLH
Urine	Creatinine	Colorimetric assay Jaffé method	QEH RLH WCUH
Urine	Magnesium	Colorimetric using xylidyl blue	RLH QEH UHL
Urine	Phosphate	BCHEM-COBAS-702-METHOD- 62 Molybdate UV	RLH QEH UHL
Urine	Potassium	Indirect ISE	RLH WCUH QEH UHL
Urine	Protein	Turbidimetric method	RLH WCUH QEH UHL
Urine	Sodium	Indirect ISE	RLH WCUH QEH UHL
Urine	Urea	Kinetic enzymatic BB-AP-147	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 FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> activities for the purposes of clinical diagnosis: (cont'd)	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:	Calculated Tests	
Data	Corrected Calcium	Adjusted calcium mmol/L = 0.02* (43 -albumin g/L + 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	LDL cholesterol	BB-AP-119	QEH UHL
Data	TIBC	Transferrin x 0.0251 BCHEM-COBAS-SOP-1	RLH
Data	Corrected Phenytoin	Measured phenytoin/ 1-α(P1/P)+ α BCHEM-COBAS-SOP-1	RLH
Data	Macro Prolactin	%Recovery = ((Monomeric prolactin)/Total PRL) X100 BCHEM-E-UNIT-METHOD- SOP25	RLH QEH
Data	Urine Protein:creatinine ratio	BB-AP-148	QEH UHL
Data	Urine Albumin:creatinine ratio	BB-AP-137	QEH

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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Serum Urine	Osmolality	Advanced Micro-Osmometer Freezing point depression BCHEM-OSM-1 BCHEM-OSMO-METHOD- SOP62	RLH NUH WCUH SBH HH QEH UHL
	Measurement of:	Roche e801Standard Automated Roche ECL Immunoassay methods BCHEM-IA-SOP-1	
Serum	Antithyroglobulin antibodies	Competitive	RLH
Serum	Adrenocorticotrophic Hormone (ACTH)	Sandwich Assay	RLH
Serum	Alpha Feto Protein (AFP)	1Sandwich Assay	RLH QEH
Serum	BNP (NT-Pro)	Sandwich Assay	RLH QEH
Serum	CA125	Sandwich Assay	RLH QEH
	Measurement of:	Roche - Standard Automated Roche ECL Immunoassay methods BCHEM-IA-SOP-1	
Serum	CA15-3	Sandwich Assay	RLH QEH
Serum	CA19-9	Sandwich Assay	RLH QEH
Serum	Carcinoembrionic Antigen (CEA)	Sandwich Assay	RLH 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 FLUIDS (cont'd)	Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of:	Roche e801Standard Automated Roche ECL Immunoassay methods BCHEM-IA-SOP-1	
Serum	Cortisol	Competitive Assay	RLH QEH UHL
Serum	C-Peptide	Sandwich Assay	RLH
Serum	Digoxin	Competitive Immunoassay detection BB-AP-172	QEH UHL
Serum	Ferritin	Sandwich Assay	RLH QEH UHL
Serum	Follicle Stimulating Hormone (FSH)	Sandwich Assay	RLH QEH
Serum	FT4	Competitive Assay	RLH QEH UHL
Serum	Growth Hormone	Sandwich Assay	RLH
Serum	Human Chorionic Gonadotrophin (HCG)	Sandwich Assay	RLH NUH WCUH QEH UHL
Serum	Insulin	Sandwich Assay	RLH
Serum	Luteinizing Hormone (LH)	Sandwich Assay	RLH QEH
Serum	Parathyroid Hormone (PTH)	Sandwich Assay	RLH QEH

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HUMAN BODY FLUIDS (cont'd)	Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of:	Roche e801Standard Automated Roche ECL Immunoassay methods BCHEM-IA-SOP-1	
Serum	Oestradiol	Competitive Assay	RLH QEH
Serum	Procalcitonin	Sandwich Assay	RLH
Serum	Progesterone	Competitive Assay	RLH QEH UHL
Serum	Prolactin	Sandwich Assay	RLH QEH
Serum	Prostate Specific Antigen (PSA)	Sandwich Assay	RLH QEH
Serum	Folate	Competitive Assay	RLH
Serum	Sex Hormone Binding Globulin (SHBG)	Sandwich Assay	RLH QEH
Serum	Testosterone	Competitive Assay	RLH QEH
Serum	Thyroglobulin	Sandwich Assay	RLH
Serum	Thyroid peroxidase (TPO)	Sandwich Assay	RLH QEH
Serum	Thyroid Stimulating Hormone (TSH)	Sandwich Assay	RLH QEH UHL
Serum	Troponin T	Sandwich Assay	RLH NUH WCUH QEH UHL

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HUMAN BODY FLUIDS (cont'd)	Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Measurement of:	Roche e801Standard Automated Roche ECL Immunoassay methods BCHEM-IA-SOP-1	
Serum	Free T3	Competitive Assay	RLH QEH UHL
Serum	Vitamin B12	Competitive Assay	RLH
	Vitamin D	Competitive Assay	RLH QEH UHL
Serum	Troponin T	Roche – e411 Standard Automated Roche ECL Immunoassay methods Sandwich Assay BCHEM-IA-SOP-1	SBH
	Therapeutic drug monitoring	Roche Cobas c303 BCHEM-COBAS-SOP-1	
Serum	Amikacin	Kinetic interaction of microparticles (KIMS) – homogenous immunoassay	НН
Serum	Gentamicin	Homogeneous Enzyme immunoassay	нн
Serum	Vancomycin	Kinetic interaction of microparticles (KIMS)	нн
	General chemistry and toxicology	Roche Cobas c303 BCHEM-COBAS-SOP-1SOP	
Serum	Acetaminophen	Homogenous enzyme immunoassay	нн
Serum	Albumin	Colorimetric detection (BCG)	нн
Serum	Alkaline Phosphatase (ALP)	Colorimetric detection	нн



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

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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	General chemistry and toxicology (cont'd)	Roche Cobas c303 BCHEM-COBAS-SOP-1SOP	
Serum	Alanine transaminase (with PLP*)	Enzymatic detection	НН
Plasma (lithium heparin)	Ammonia	Enzymatic detection	нн
Serum	Aspartate transaminase (with PLP*)	Enzymatic detection	НН
Serum	Total Bilirubin	Colorimetric diazo detection	нн
Serum	Bicarbonate	Enzymatic detection	нн
Serum	Calcium	Colorimetric detection	нн
Serum	Cholesterol	Enzymatic colorimetric detection	нн
Serum	Creatinine	Enzymatic detection	нн
Urine	Urine creatinine	Kinetic Jaffe colorimetric detection	НН
Serum	Creatinine Kinase (CK)	Enzymatic detection	нн
Serum	C-Reactive Protein	Particle-enhanced Immunoturbidimetric	нн
Serum	Gamma-Glutamyl aminotransferase (GGT)	Enzymatic colorimetric detection	НН
Plasma (fluoride oxalate)	Glucose	UV detection Enzymatic detection	НН
CSF(fluoride oxalate)	Glucose	UV detection Enzymatic detection	НН
Serum	High density lipoprotein	Homogeneous enzymatic colorimetric detection	НН
Serum	Lactate Dehydrogenase (LDH)	UV detection	нн
Plasma (fluoride oxalate)	Lactate	Colorimetric endpoint detection	НН



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis</u> : (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	General chemistry and toxicology (cont'd)	Roche Cobas c303 BCHEM-COBAS-SOP-1SOP	
CSF (fluoride oxalate)	Lactate	Colorimetric endpoint detection	нн
Serum	Lipase	Enzymatic colorimetric detection	нн
Serum	Magnesium	Colorimetric endpoint detection	нн
Serum	Phosphate	Molybdate UV detection	нн
Serum	Total protein	Colorimetric detection	нн
Urine	Urine total protein	Turbidimetric detection	нн
Serum	Triglycerides	Enzymatic colorimetric	нн
Serum	Uric acid	Enzymatic colorimetric	нн
Serum	Urea	Enzymatic colorimetric	нн
Serum Urine	Sodium	Indirect ISE (Ion Selective Electrode)	нн
Serum Urine	Potassium	Indirect ISE (Ion Selective Electrode)	нн
Serum	Chloride	Indirect ISE (Ion Selective Electrode)	нн
	Immunoassay	Roche Cobas e402 BCHEM-IA-SOP-1	
Serum	Beta human chorionic gonadotropin (B-HCG)	Sandwich ECLIA detection	нн
Serum	Free thyroxine 4 (FT4)	Competitive ECLIA detection	нн
Serum	Troponin T (TNT)	Sandwich ECLIA detection	нн
Serum	Thyroid stimulating hormone (TSH)	Sandwich ECLIA detection	НН

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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis</u> : (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunoassay	Roche Cobas e402 BCHEM-IA-SOP-1	
Serum	Procalcitonin (PCT)	Sandwich ECLIA detection	нн
	<u>Proteins</u>		
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
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
Serum	Aldosterone	DiaSorin Liaison immunoassay analyser BCHEM-LIASON-METHOD- SOP3	RLH
Serum	Insulin Growth Factor-1 (IGF-1)	DiaSorin Liaison immunoassay analyser BCHEM-LIASON-METHOD- SOP4	RLH
Sweat	Chloride	M926S Digital Sweat Chloride meter- titrimetric method BCHEM-PROT-METHOD-SOP11	RLH
Sweat	Conductivity	Wescor Macroduct Collection system Wescor 3100 Sweat Check Sweat conductivity analyser	UHL

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Materials/Products tested	Type of test/Properties	Standard specifications/	Location
	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY FLUIDS (cont'd)	Clinical Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Sweat	Chloride	Coulometric Titration using Chlorochek Chloridometer 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
Whole Blood	Tacrolimus	BCHEM-LCMS-METHOD-SOP2	RLH
Whole Blood	Sirolimus	BCHEM-LCMS-METHOD-SOP2	RLH
Urine	Determination of:	CEDIA Drugs of Abuse assay on the Thermo Scientific Indiko Plus Clinical Chemistry analyser BCHEM-INDIKO-5	RLH
	Amphetamine Benzodiazepines Buprenorphine Cocaine EDDP (Methadone metabolite) Opiates THC (Cannabinoids) 6MAM (heroin metabolite)		

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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	HPLC		
	Measurement of:	AAS on the Analyst 800 Atomic Absorption Spectrophotometer	
Serum	Copper	BCHEM-AAS-METHOD-SOP7	RLH
Serum	Selenium	BCHEM-AAS-METHOD-SOP8	RLH
Serum	Zinc	BCHEM-HPLC-METHOD-SOP6	RLH
	Measurement of:	Dionex Ultimate 3000 HPLC- using Chromsystems Vitamins A & E kit.	
Serum	Vitamin A	BCHEM-HPLC-METHOD-SOP9	RLH
Serum	Vitamin E	BCHEM-HPLC-METHOD-SOP9	RLH
	Measurement of:	Dionex Ultimate 3000 HPLC System	
Urine	5HIAA	Using 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	Xanthochromia	Spectrophotometry on Uvikon XL BCHEM-UVIKON XL001	RLH
CSF	Xanthochromia	Scanning spectrophotometric Perkin Elmer Spectrophotometer BB-MP-017	QEH
Whole Blood	HbA1c	HPLC on BioRad D100 BCHEM-HPLC-METHOD-10	RLH

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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis:</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Faeces	Faecal Occult Blood	Faecal Immunotesting on OC- Sensor Pledia 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
Serum	Free Lambda Light Chains	Binding Site Optilite, turbidimetry BCHEM-PROT-METHOD- SOP43	RLH
Serum	Free Kappa/Free Lambda Ratio	Calculated Test BCHEM-PROT-METHOD- SOP43	RLH

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HUMAN BODY FLUIDS AND TISSUES	Microbiology examination activities for the purpose of clinical diagnosis	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
	Bacteriology		
Urine Wound swabs Genital swabs Throat swabs Oral swabs Skin swabs Eye swabs Ear swabs Nose swabs	Isolation and characterisation of microorganisms of clinical significance	Automated inoculation of plates using: Culture media BioMérieux Copan WASP MICR.EQUIP046	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 Faeces	Isolation and characterisation of microorganisms of clinical significance	Manual inoculation of plates culture media EMI.FLUI.1 EMI.SWAB.2 EMI.SOP.1 MICR.B.SOP004 MICR.B.SOP013 MICR.B.SOP007 MICR.B.SOP015 MICR.B.SOP016 MICR.B.SOP001	RLH
Rectal Swabs Wound swabs Throat swabs Skin swabs Nose swabs	Antibiotic resistance screening: CRO MRSA MSSA VRE	Culture, identification, and susceptibility testing as described above. Culture media Oxoid PBP2a EMI.SWAB.1	RLH
Inoculated plates for Neisseria gonorrhoeae	Isolation of <i>Neisseria</i> gonorrhoeae	MICR.B.SOP016	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 FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd) <u>Bacteriology</u> (cont'd)	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Blood	Isolation and characterisation of microorganisms of clinical significance	Automated culture BioMérieux Virtuo BioMérieux Blood cultures MICR.B.SOP012	RLH
Faeces Rectal swab	Culture and identification of: Salmonella spp. Shigella spp. Campylobacter spp. E coli 0157 Vibrio spp. Yersinia spp.	Manual culture using culture media and identification using manual biochemical tests MICR.B.SOP010	RLH
Bacterial and yeast isolates cultured in-house	Identification of microorganisms of clinical significance	Bruker MALDI-ToF-MS (matrix-assisted laser desorption/ionization time-of-flight mass spectrometry)MICR.E.SOP015	RLH
Bacterial isolates	Susceptibility testing	EUCAST disc testing EMI.SENSI.3	RLH
Vaginal swabs	Group B streptococci screen	E&O chromogenic agar EMI.SWAB.1	RLH
Tissue Dialysis fluid Ascitic Fluid Pleural fluid Other Body fluids CSF	White and red cell count, white cell differentiation and microscopic detection of bacteria and fungi.	Gram stain and differential stain by Romanowsky method examined with bright field microscopy Cell count by phase microscopy MICR.M.SOP006 EMI.FLUI.1	RLH
Urine	Detection, identification and quantification of red blood cells, white cells and epithelial cells of clinical significance in urine	Automated: Urine microscopy and particle recognition by Sysmex UF5000 Flow cytometer MICR.E.SOP025	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 FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd) <u>Bacteriology</u> (cont'd)	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
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
Urine	Pneumococcal Antigen	TRU Pneumococcal kit Rapid immuno-chromatographic assay EMI.URIN.3	RLH
Sputa Bronchoalveolar lavage Tissue Dialysis fluid Ascitic fluid Pleural fluid Other Body fluids CSF Cystic Fibrosis Sputa	Isolation and detection of Mycobacteria	Automated culture BD MGIT machine and BD MGIT liquid culture bottles EMI.TB.1 <u>Manual culture</u> E&O solid media slopes EMI.TB.1	RLH
Sputa Bronchoalveolar lavage Tissue Dialysis fluid Ascitic Fluid Pleural fluid Other Body fluids CSF Cystic Fibrosis Sputa	Detection of Mycobacteria	UV microscope to examine manual stained Auramine slides Bright field microscope to examine manual stained Ziehl- Neelsen slides EMI.TB.1	RLH
Whole blood	Detection of Mycobacteria	BD FX40 blood culture system blood culture bottles EMI.TB.1	RLH
CSF Sera	Detection of Cryptococcal antigens	Alpha lab lateral flow device MICR.B.SOP018	RLH
Bronchoalveolar lavage Sera	Detection of Galactomannan	Platella TM Aspergillus EIA kit (Bio-Rad) EMI.MYCO.2	RLH

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd) <u>Bacteriology</u> (cont'd)	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Faeces	Detection of cryptosporidium	Light microscope to examine manual-stained Cold Ziehl Neelsen slides UV microscope to examine manual stained Auramine slides MICR.M.SOP006 MICR.B.SOP011	RLH
Faeces	Detection of ova, cysts, and parasites	Parasep and light microscopy for the concentration method MICR.M.SOP006 MICR.B.SOP011	RLH
Faeces	Molecular detection of Cryptosporidium parvum/hominis, <i>Giardia lamblia</i> and <i>Entamoeba</i> <i>histolytica</i>	PCR by BD Max MICR.B.SOP056	RLH
Faeces	Detection of <i>Clostridioides difficile</i> GDH	Prolab GDH EIA test kit using Dynex DS2 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	PCR by BDMax EMI.FAEC.1	RLH
Faeces	Helicobacter Antigen	Premier Platinum HpSA PLUS antigen test kit using DYNEXDS2 EMI.FAEC.2	RLH
Skin Nail Hair Respiratory sample Bodily Fluids Tissue samples	Isolation and identification of fungal pathogens	Calcofluor White and UV microscope Culture media Lactophenol blue for identification Light microscope EMI.MYCO.1	RLH

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd) Bacteriology (cont'd)	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Sera	Detection of Beta D Glucan	Wako-Fujifilm BDG test and toxinometer MICR.B.SOP60	RLH
Sera	Detection of Strongyloides antibodies	Bordier Strongyloides ratti ELISA DS2 MICR.B.SOP062	RLH
Bacterial or yeast isolates Sterile fluids Sterile tissues Bacterial/fungal Isolates Paediatric plasma Blood culture	Extraction of DNA for the molecular detection of bacteria or yeasts or fungi	Operation and use of the AusDiagnostics MT-Prep 24 automated nucleic acid purification system with the MT Prep Viral/Pathogen nucleic acids extraction B Kit VIRO.MOL.EQUIP.002	RLH
DNA extracted in-house	Detection of 16S and 18S ribosomal DNA	PCR for product amplification QuantStudio 5 and Veriti Pro and Gel electrophoresis using the Gel tank MICR.EXT007 MICR.MOL.SOP018	RLH
DNA sequence data	Analysis of DNA sequence data generated externally	Identification of bacteria and fungi using 16S and 18S PCR assays MICR.MOL.SOP018	RLH
Sputa Bronchoalveolar lavage CSF EBUS	Molecular assay for Mycobacterium tuberculosis detection and Rifampicin resistance	Cepheid GeneXpert MTB/RIF Ultra cartridge (Cepheid) MICR.B.SOP053	RLH
Decontaminated sputa	<i>Mycobacterium tuberculosis</i> complex with Rifampicin and Isoniazid resistance markers Molecular detection of bacterial pathogens:	BD MAX MIC.MOL.SOP022	RLH

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
	Bacteriology (cont'd)		
Faeces	Enteric bacteria panel: Salmonella spp Shigella spp Enteroinvasive E.coli Campylobacter spp. (C,coli and C.jejuni) Shiga-toxins 1 and 2 (STEC or VTEC Shigella dysenteriae	BD Max MICR.B.SOP056	RLH
Faeces	Enteric parasite panel: Giardia lamblia Cryptosporidium parvum/homnis Entamoeba histolytica	BD Max MICR.B.SOP056	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 FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purposes of clinical diagnosis	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:	ARCHITECT i2000SR analyser Abbott Diagnostics Chemiluminescent Microparticle Immunoassay using standard kits for this analyser 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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purposes of clinical diagnosis (cont'd)	Documented Procedures as indicated based on manufacturer instructions and/ or validated in- house developed assays	
	Infectious Diseases Serology (cont'd)	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 e801 analytical unit and preanalytical modules p471 and p612 using ECLIA - Electrochemiluminiscence 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 FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purposes of clinical diagnosis (cont'd)	Documented Procedures as indicated based on manufacturer instructions and/ or validated in- house developed assays	
	Infectious Diseases Serology (cont'd)	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 e801 analytical unit and preanalytical modules p471 and p612 using ECLIA - Electrochemiluminiscence 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 (or Plasma)	Parvovirus B19 IgG antibody		RLH
Serum Plasma	Antibodies to Treponema palladium TPHA	Fortress TPHA Haemagglutination assay VIRO.SER.SOP.005	RLH
	Detection of:	LIAISON® analyser – DiaSorin Immuno Chemiluminescence Immunoassay using standard kits VIRO.SER.SOP.001	
Serum (or Plasma)	Varicella Zoster Virus (VZV) IgG antibody		RLH
Serum (or Plasma)	Hepatitis B Virus core total antibody (confirmation of screening assay) *		RLH
Serum (or Plasma)	Measles Virus IgG antibody		RLH

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purposes of clinical diagnosis (cont'd)	Documented Procedures as indicated based on manufacturer instructions and/ or validated in- house developed assays	Code
	Detection of:	LIAISON® analyser – DiaSorin Immuno Chemiluminescence Immunoassay using standard kits VIRO.SER.SOP.001	
Serum (or Plasma)	Measles Virus IgM antibody		RLH
Serum (or Plasma)	Mumps Virus IgG antibody		RLH
Serum (or Plasma)	Mumps Virus IgM antibody		RLH
Serum (or Plasma)	Parvovirus B19 IgM antibody		RLH
Serum (or Plasma)	Treponema pallidum total antibody *		RLH
Serum (or Plasma)	Borrelia burgdorferi IgG antibody		RLH
Serum (or Plasma)	Borrelia burgdorferi IgM antibody		RLH
Serum (or Plasma)	Hepatitis D total antibody		RLH
Serum (or Plasma)	Hepatitis E IgM antibody		RLH
Blood. Serum (and EDTA)	HSV1 and HSV2 antibodies by immunoblot	HerpeSelect® 1 and 2 Immunoblot IgG (from Focus Diagnostics /Sterilab) VIRO.SER.SOP.007	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 FLUIDS AND TISSUES (cont'd)	Virology examination activities for the purposes of clinical diagnosis (cont'd)	Documented Procedures as indicated based on manufacturer instructions and/ or validated in- house developed assays	
CSF	Qualitative detection of CSF viruses: 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
Respiratory secretions including those collected by a swab for viral sampling	Qualitative detection of Respiratory viruses: Influenza A Virus RNA Influenza B Virus RNA SARS CoV-2 RNA ORF1 Seasonal Coronavirus RNA Respiratory Syncytial Virus RNA Rhinovirus RNA Enterovirus RNA Human Bocavirus DNA Parainfluenza Virus 1 RNA Parainfluenza Virus 2 RNA Parainfluenza Virus 3 RNA Parainfluenza Virus 4 RNA Parechovirus RNA Human Adenovirus DNA Human Metapneumovirus RNA	AusDiagnostics Hi-Plex (MT- processor and MT-analyser) AusDiagnostics Respiratory Viruses 16-well kit (REF 20602) EVI.SEMIA.2	RLH
Stool including those collected by a swab for viral sampling	Qualitative detection of Enteric viruses: Adenovirus DNA Enterovirus RNA Saprovirus 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

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purposes of clinical diagnosis	Documented Procedures as indicated based on manufacturer instructions and/ or validated in- house developed assays	
Nose and throat swabs Nasopharyngeal aspirate Bronchoalveolar lavages Endotracheal tube aspirate Sputum CSF Eye swabs Stool swabs, Urine	SARs CoV-2 detection E and ORF 1a sequences	Roche Cobas 6800 and 8000 real-time PCR systems using Cobas SARS-cov-2 assay for use with Cobas 6800 and 8800 systems	RLH
Genital Swabs Throat Swabs Rectal Swabs Urine	Chlamydia trachomatis DNA Neisseria gonorrhoea DNA Trichomonas vaginalis DNA Mycoplasma genitalium DNA	COBAS® 6800 and 8800 Systems- Roche Molecular Diagnostics. Standard kits for these analysers. VIRO.MOL.SOP.009	RLH
Genital Swabs	High Risk Human Papilloma Virus DNA Herpes Simplex Virus Type 1 DNA Herpes Simplex Virus Type 2 DNA Varicella Zoster Virus DNA	COBAS® 6800 and 8800 Systems- Roche Molecular Diagnostics. Standard kits for these analysers. VIRO.MOL.SOP.009	RLH
Plasma: EDTA	Hepatitis B Virus DNA (Viral Load) Hepatitis C Virus RNA (Viral Load) Human Immunodeficiency Virus Type 1 RNA (Viral Load) Epstein Barr Virus DNA (Viral Load) Human Cytomegalovirus DNA (Viral Load)	COBAS® 6800 and 8800 Systems- Roche Molecular Diagnostics. Standard kits for these analysers. VIRO.MOL.SOP.009	RLH
Plasma: EDTA Urine	BK virus DNA (Viral Load)	COBAS® 6800 and 8800 Systems- Roche Molecular Diagnostics. Standard kits for these analysers. VIRO.MOL.SOP.009	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 FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities</u> for the purposes of clinical diagnosis (cont'd)	Documented Procedures as indicated based on manufacturer instructions and/ or validated in- house developed assays	
CSF	Human Immunodeficiency Virus Type 1 RNA (Viral Load) Epstein Barr Virus DNA (Viral Load) Human Cytomegalovirus DNA (Viral Load) Herpes Simplex Virus Type 1 DNA Herpes Simplex Virus Type 2 DNA Varicella Zoster Virus DNA	COBAS® 6800 and 8800 Systems- Roche Molecular Diagnostics. Standard kits for these analysers. VIRO.MOL.SOP.009	RLH
Nose and throat swabs Nasopharyngeal aspirate Bronchoalveolar lavages Endotracheal tube aspirate Sputum CSF Eye swabs Stool swabs Urine	SARs CoV-2 detection E and N2	Cepheid GeneXpert real-time PCR using XpertXpress SARS- coV-2 test	RLH
Genital swab Urine (positive for <i>M.</i> <i>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 real-time PCR using resistancePlus® MG FleXible kit VIRO.MOL.SOP.022	RLH
Biopsy tissue (wet) Blood (plasma, serum) Human body fluids Cellular material (including those collected with a swab suitable for viral sampling)	Purification of nucleic acid material	QIAsymphony SP/AS instruments - QIAGEN Ltd. QIAsymphony Virus/Bacteria mini kit VIRO.MOL.SOP.016	RLH

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Molecular examination activities for the purposes of clinical diagnosis (cont'd)	Documented Procedures as indicated based on manufacturer instructions and/ or validated in- house developed assays	
Purification of nucleic acid material	Qiagen BioRobot™ EZ1 and EZ1 Advanced XL - QIAGEN Ltd. EZ1 virus mini kit, EZ1 DNA blood 350µl kit, EZ1 DNA tissue kit VIRO.MOL.SOP.025	RLH
Detection and/or quantification of Virus:	Rotor gene QIAGEN Ltd QIAgen Quantitect Multiplex PCR kit QIAgen Quantitect Multiplex RT- PCR kit	
Quantitative detection of HIV-2 Type 2 RNA (viral) load	VIRO.MOL.SOP.013	RLH
Hepatitis E virus RNA	VIRO.MOL.SOP.017	RLH
Measles Virus RNA	VIRO.MOL.SOP.010	RLH
	Molecular examination activities for the purposes of clinical diagnosis (cont'd) Purification of nucleic acid material Detection and/or quantification of Virus: Quantitative detection of HIV-2 Type 2 RNA (viral) load Hepatitis E virus RNA	measured/Range of measurementEquipment/Techniques usedMolecular examination activities for the purposes of clinical diagnosis (cont'd)Documented Procedures as indicated based on manufacturer instructions and/ or validated in- house developed assaysPurification of nucleic acid materialQiagen BioRobot™ EZ1 and EZ1 Advanced XL - QIAGEN Ltd. EZ1 virus mini kit, EZ1 DNA blood 350µl kit, EZ1 DNA tissue kit VIRO.MOL.SOP.025Detection and/or quantification of Virus:Rotor gene QIAGEN Ltd QIAgen Quantitect Multiplex PCR kit QIAgen Quantitect Multiplex RT- PCR kitQuantitative detection of HIV-2 Type 2 RNA (viral) loadVIRO.MOL.SOP.013Hepatitis E virus RNAVIRO.MOL.SOP.017



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HUMAN BODY TISSUE	Histopathological examination activities for the purposes of clinical diagnosis	In house documented methods incorporating manufacturer's instructions where relevant	
Tissue: biopsy, excision, resection and post- mortem 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 Specialties include: Ear, Nose and Throat Oral Pathology Skin Breast Gynaecological Renal Gastro-intestinal Endocrine Paediatric	clinical diagnosis The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	instructions where relevant Macroscopic and Microscopic examination	RLH QEH UHL
Lymphopoietic Urology			

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
		Macroanalysis and dissection Manual method with categorisation of routine samples as per RCPath guidelines – A, B, C & D specimens	RLH QEH UHL
		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	
Formalin Fixed Tissue		Decalcification Manual method using acid decalcifiers (Decalcifier 1) CP-HIST-SR-DECAL1 CHQ-DP-0010 SOP H013	RLH QEH UHL
Formalin Fixed Tissue		Processing Sakura VIP6AI tissue processor	RLH UHL
		Sakura VIP6 tissue processor	QEH UHL
		Sakura VIP6A	RLH
		CP-HIST-TECH-AUTO47 CP-HIST-TECH-P&E7 CHQ-MP-0065 SOP H046	

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin Fixed Paraffin Embedded Tissue (FFPE)		Microtomy Rotary microtomes: Leica 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
Formalin fixed paraffin embedded (FFPE), fresh and frozen tissue	Routine morphological staining for the detection of basophilic and eosinophilic structures	Automated H&E staining using 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	Basophilic and eosinophilic structures	Manual Heamatoxylin and Eosin Stain SOP L011	UHL
Frozen tissue	Intraoperative frozen sections	Leica cryostat CM1950 CP-HIST-TECH-FS1-8 CP-HIST-TECH-FS20-24 CP-HIST-SBH-SOP7	RLH SBH
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



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Special stains for the detection of:	Automated staining Staining of special stains on the 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	RLH
FFPE slides	Acid & Neutral mucins	Alcian Blue Periodic Schiff's	RLH
FFPE slides	Carbohydrates	Periodic Acid Schiff's	RLH
FFPE slides	Helicobacter pylori	Giemsa	RLH
		Automated staining of special stains on Sakura Tissue Tek Prisma CHQ-MP-0067	
FFPE slides	Acid and Neutral Mucopolysaccharides	Alcian Blue/Periodic Acid Schiff	QEH
FFPE slides	Acid and Neutral Mucopolysaccharides	Diastase Alcian Blue/Periodic Acid Schiff	QEH



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Special stains for the detection of: (cont'd)	Automated staining of special stains on Sakura Tissue Tek Prisma CHQ-MP-0067	
FFPE slides	Helicobacter/Microorganisms	Giemsa	QEH
FFPE slides	Neutral Mucopolysaccharides, glycogen and fungus	Periodic Acid Schiff (PAS) & Diastase PAS (D/PAS)	QEH
	Manual Special Stains		
FFPE slides	Elastic fibres & connective tissue	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
FFPE slides	Copper	Rhodanine CP-HIST-TECH-STAIN24	RLH



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Manual Special Stains (cont'd)		
FFPE slides	Calcium salts	von Kossa CP-HIST-TECH-STAIN27	RLH
FFPE slides	Mycobacterium leprae	Wade Fite CP-HIST-TECH-STAIN28	RLH
FFPE slides	Mycobacterium spp. including tuberculosis	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	Mucicarmine CHQ-SP-0020	QEH
FFPE slides	Gram +ve & -ve microogranisms	Gram CHQ-SP-0011	QEH
FFPE slides	Connective tissue and fibrin	Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) CHQ-SP-0019	QEH
FFPE slides	Melanin, Argentaffin cells and Lipofuchsin	Masson Fontana CHQ-SP-0016	QEH
FFPE slides	Connective tissue	Masson's Trichrome CHQ-SP-0017	QEH



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Manual Special Stains (cont'd)		
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
FFPE slides	Helicobacter pylori	Modified Giemsa	UHL
FFPE slides	Spirochaetes and protozoa	Full Giemsa	UHL
FFPE slides	Reticulin fibres	Gordon and Sweets	UHL



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Manual Special Stains (cont'd)		
FFPE slides	Gram postive 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
	Immunohistochemistry - detection of:	Automated Benchmark Ultra Roche Immunostainer I004 (SOP I004)	
FFPE slides	Subset of B and T lymphocytes	BCL2	UHL
FFPE slides	Subset of Epithelial cell types	BerEp4	UHL



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Benchmark Ultra Roche Immunostainer I004 (SOP I004)	
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
FFPE slides	Neuroendocrine, Schwann cells, NK cells	CD56	UHL



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Benchmark Ultra Roche Immunostainer I004 (SOP I004)	
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	СК7	UHL
FFPE slides	Specific low molecular weight cytokeratin	СК19	UHL
FFPE slides	Specific low molecular weight cytokeratin	СК20	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
FFPE slides	Adhesion molecule, lost in lobular Ca breast	E Cadherin	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 TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Benchmark Ultra Roche Immunostainer 1004 (SOP 1004)	
FFPE slides	Subset of Normal and neoplastic epithelium	ЕМА	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,	HMB45	UHL
FFPE slides	Melanoma, others 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	Карра	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
FFPE slides	Squamous epithelium, basal cells	P63	UHL



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Benchmark Ultra Roche Immunostainer I004 (SOP I004)	
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	Maart1/Melan A	UHL
FFPE slides	Epithelial tumours	Pancytokeratin	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 TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	Code
	Immunohistochemistry - detection of:	Automated Immunohistochemistry using Ventana BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	Glandular, transitional, and squamous epithelia	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	СК20	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 tissue	SMA	RLH
FFPE slides	Astrocytes, Schwann cells, satellite cells, enteric glial cells and some groups of ependymal cells	GFAP	RLH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Immunohistochemistry using Ventana BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
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 Programmed death-1 molecule	P53 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
FFPE slides	T cells	CD3	RLH
FFPE slides	T-cells and a subset of mature B- cells	CD5	RLH



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Immunohistochemistry using Ventana BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
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	B cells	CD79a	RLH
FFPE slides	B cells	CD79a	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
FFPE slides	Melanoma, neuroendocrine	S100	RLH

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Immunohistochemistry using Ventana BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
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 tissue 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 TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Immunohistochemistry using Ventana 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	CalretininBAP1	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	Карра	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	ЕМА	RLH
FFPE slides	Epithelial antigen	Ber-EP4	RLH
FFPE slides	Epithelial Related Antigen	MOC-31	RLH



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	Code
	Immunohistochemistry - detection of: (cont'd)	Automated Immunohistochemistry using Ventana BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	Dermatofibroma	Factor 13a	RLH
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

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated Immunohistochemistry using Ventana BenchMark ULTRA Automated IHC/ISH slide staining system CP-HIST-IMMUNO-AUTO9	
FFPE slides	Wilms tumour	WT1	RLH
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	С-Мус	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 TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of:	Automated immunohistochemistry using Ventana 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 TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated immunohistochemistry using Ventana 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	CytoMeglo Virus	CMV	QEH
FFPE slides	Mantle cell lymphoma	Cyclin D1	QEH
FFPE slides	Epithelial tissue 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 TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated immunohistochemistry using Ventana 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	ЕМА	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



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated immunohistochemistry using Ventana Benchmark Ultra immunostainer CHQ-IP-0015	
FFPE slides	Alveolar cells, lung adenocarcinoma	Napsin A	QEH
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



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated immunohistochemistry using Ventana Benchmark Ultra immunostainer CHQ-IP-0015	
FFPE slides	Melanocytes	SOX-10	QEH
FFPE slides	Neuroendocrine cells	Synaptophysin	QEH
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



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Materials/Products tested	Type of test/Properties	Standard specifications/	Location
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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Immunohistochemistry - detection of: (cont'd)	Automated immunohistochemistry using Ventana Benchmark Ultra immunostainer CHQ-IP-0015	
FFPE slides	Prostate Adenocarcinoma	PIN4	QEH
FFPE slides	Colonic tumour marker	SAT-B2	QEH
FFPE slides	Treponema pallidum	Spirochete	QEH
FFPE slides	DDISH	INFORM HER2 Dual ISH DNA Probe Cocktail Assay	RLH
Fresh muscle tissue	Examination of muscle tissue in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Cryotomy using Bright cryostat OFT-5000 CP-HIST-TECH-FS1 CP-HIST-NEURO-MUSCLE- SOP3	RLH
	Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers:	Automated staining using benchmark ultra: CP-HIST-NEURO-MUSCLE- SOP1 CP-HIST-NEURO-MUSCLE- SOP2 CP-HIST-NEURO-MUSCLE- SOP3 CP-HIST-NEURO-MUSCLE- IMMUNO 1 CP-HIST-NEURO-MUSCLE- IMMUNO CP-HIST-NEURO-MUSCLE- IMMUNO CP-HIST-NEURO-MUSCLE- IMMUNO3 CP-HIST-IMMUNO-GEN-SOP2	
Fresh muscle tissue	Sarcolemmal membrane of skeletal muscle	Dystrophin 1	RLH

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	Code
	Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers:	Automated staining using benchmark ultra: CP-HIST-NEURO-MUSCLE- SOP1 CP-HIST-NEURO-MUSCLE- SOP2 CP-HIST-NEURO-MUSCLE- SOP3 CP-HIST-NEURO-MUSCLE- IMMUNO 1 CP-HIST-NEURO-MUSCLE- IMMUNO CP-HIST-NEURO-MUSCLE- IMMUNO CP-HIST-NEURO-MUSCLE- IMMUNO3 CP-HIST-IMMUNO-GEN-SOP2	
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
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

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers:	Automated staining using benchmark ultra: CP-HIST-NEURO-MUSCLE- SOP1 CP-HIST-NEURO-MUSCLE- SOP2 CP-HIST-NEURO-MUSCLE- SOP3 CP-HIST-NEURO-MUSCLE- IMMUNO 1 CP-HIST-NEURO-MUSCLE- IMMUNO CP-HIST-NEURO-MUSCLE- IMMUNO CP-HIST-NEURO-MUSCLE- IMMUNO3 CP-HIST-IMMUNO-GEN-SOP2	
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
Fresh muscle tissue	B-cell marker	CD20	RLH

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	Code
	Antibodies used for enzyme profile, markers for dystrophin myopathy and inflammatory markers:	Automated staining using benchmark ultra: CP-HIST-NEURO-MUSCLE- SOP1 CP-HIST-NEURO-MUSCLE- SOP2 CP-HIST-NEURO-MUSCLE- SOP3 CP-HIST-NEURO-MUSCLE- IMMUNO 1 CP-HIST-NEURO-MUSCLE- IMMUNO 1 CP-HIST-NEURO-MUSCLE- IMMUNO CP-HIST-NEURO-MUSCLE- IMMUNO3 CP-HIST-IMMUNO-GEN-SOP2	
Fresh muscle tissue	Structural protein of sarcomeric Z discs and sarcolemma in human skeletal and cardiac muscle	Myotilin	RLH
Fresh muscle tissue	Neoepitope 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
	Routine stains used for the demonstration of morphology of muscle fibres	Manual staining techniques	
Fresh muscle tissue	H&E stain	H&E Stain Muscle H&E CP-HISTO-NEURO-MUSCLE- STAIN1	RLH
Fresh muscle tissue	Glycogen	Muscle PAS CP-HISTO-NEURO-MUSCLE- STAIN4	RLH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Routine stains used for the demonstration of morphology of muscle fibres (cont'd)	Manual staining techniques	
Fresh muscle tissue	Lipids	Muscle Sudan black CP-HISTO-NEURO-MUSCLE- STAIN13	RLH
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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUE	Cytopathology examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturer's instructions where relevant	
Body fluids	Examination of body fluids to enable the examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Papanicolaou and May-Grunwald Giemsa staining using Heraeus centrifuge, cytocentrifuge, Class I safety cabinet, Sakura Tissue- Tek Prisma Plus film coverslipper, T2000 LBC Processor	RLH
		CP.CYTO.SOP.17 CP.CYTO.SOP.14 CP.CYTO.SOP.15 CP.CYTO.SOP.11 CP.CYTO.SOP.10	
Bronchial washings, brushings and alveolar lavage		CP.CYTO.SOP.3 CP.CYTO.SOP.16 CP.CYTO.SOP.13	RLH
CSF		CP.CYTO.SOP.4	RLH
Endoscopic ultrasound guided fine needle asp		CP.CYTO.SOP.9	RLH
Serous fluids		CP.CYTO.SOP.8	RLH
Fine Needle Aspirations		CP.CYTO.SOP.9	RLH
Sputum		CP.CYTO.SOP.9	RLH
Urine		CP.CYTO.SOP.7	RLH
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis of histology, cytology slides	Interpretive Microscopy using an assorted range of diagnostic bright-field microscopes	RLH
		CP-HIST-IMMUNO-GEN-SOP14 CP-HIST-IMMUNO-IMF6 CP-CLIN2	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Cytopathology examination</u> activities for the purpose of <u>clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
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	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Diagnostic cytology (non-gynae) Manual procedures for preparation and reporting using Cytospin, T2000, Gemini staining machine, Tissue Tek coverslipper and light microscope.	UHL
	Demonstration of : Cells (nuclei and cytoplasm) and micro organisms	Papanicolaou and May-Grunwald Giemsa stains using Gemini stainer SOP C003	UHL
	Staining for cellular architecture and nuclear detail Identification of Basophilic and eosinophilic structures	Cytogiem stain using Gemini stainer SOP.C025	UHL
	H&E staining for cellular architecture and nuclear detail Identification of Basophilic and eosinophilic structures	H&E stain using Gemini stainer SOP C041	UHL

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Cytopathology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant Interpretive Microscopy using an assorted range of diagnostic bright-field microscopes SOP C005 SOP C002 SOP C033 SOP C005	
		SOP C005 SOP C002 SOP C012	
Synovial Aspirate (Synovial Fluid for Cytology)	Detection and identification of Crystals	Preparation and examination of joint fluids using polarising microscopy SOP C005 SOP C002	UHL

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturer's instructions where relevant	
Blood	Detection of:	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	Total IgE Allergen Specific IgE Penicillin G Sp IgE Ab Penicillin V Sp IgE Ab Suxamethonium Sp IgE Ab Ampicillin Sp IgE Ab Bovine Insulin Sp IgE Ab Bovine Gelatine Sp IgE Ab Human Insulin Sp IgE Ab Bovine Gelatine Sp IgE Ab Cat Dander Sp IgE Ab Cat Dander Sp IgE Ab Reindeer Epith. Sp IgE Ab Reindeer Epith. Sp IgE Ab Gerbil Epith Sp IgE Ab Fox Epithelium Sp IgE Ab Rabbit Vrine Sp IgE Ab Parrot Feathers Sp IgE Ab Deer Epithelium Sp IgE Ab Dog Dander Sp IgE Ab Dog Dander Sp IgE Ab Cow Dander Sp IgE Ab Boy IgE Ab Dog Dander Sp IgE Ab Bog Epithelium Sp IgE Ab Dog Epithelium Sp IgE Ab Bog Epithelium Sp IgE Ab		

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood (cont'd)	Detection of: (cont'd)	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	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 Peanut 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 Pecan Sp IgE Ab Pecan Sp IgE Ab Cashew Nut Sp IgE Ab Pistachio Nut Sp IgE Ab Trout Sp IgE Ab Clam Sp IgE Ab Grapefruit Sp IgE Ab Blackberry Sp IgE Ab Blackberry Sp IgE Ab Rabbit Meat Sp IgE Ab Spinach Sp IgE Ab Cabbage Sp IgE Ab		

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Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
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 Squid Sp IgE Ab Grape Sp IgE Ab Pork Meat Sp IgE Ab Broccoli Sp IgE Ab Aubergine Sp IgE Ab Beef Meat Sp IgE Ab Ginger Sp IgE Ab Chilli Pepper Sp IgE Ab Curry Sp IgE Ab Oregano Sp IgE Ab Thyme Sp IgE Ab Oregano Sp IgE Ab Turkey Meat Sp IgE Ab Red Kidney Bean Sp IgE Ab Cow's Milk Sp IgE Ab Cow's Milk Sp IgE Ab Cod Sp IgE Ab Cot Sp IgE Ab Cod Sp IgE Ab Con Sp IgE Ab Corean Sp IgE Ab Cod Sp IgE Ab Cod Sp IgE Ab Cod Sp IgE Ab Con Sp IgE Ab		
	measured/Range of measurement	measured/Range of measurementEquipment/Techniques usedImmunology examination activities for the purpose of clinical diagnosis (cont'd)In house documented methods incorporating manufacturer's instructions where relevantDetection of: (cont'd)Thermo Fisher Phadia 250 Cherny Sp IgE Ab Cucumber Sp IgE Ab Pine Nut Sp IgE Ab Pine Nut Sp IgE Ab Pine Nut Sp IgE Ab Bacid Sp IgE Ab Broccoli Sp IgE Ab Curry Sp IgE Ab Curry Sp IgE Ab Drike Sp IgE Ab Curry Sp IgE Ab Curry Sp IgE Ab Curry Sp IgE Ab Drikey Meat Sp IgE Ab Curry Sp IgE Ab Curry Sp IgE Ab Drikey Meat Sp IgE Ab Coregano Sp IgE Ab Code Sp IgE Ab Coriander Sp IgE Ab Carrot Sp IgE Ab <b< td=""></b<>

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood (cont'd)	Detection of: (cont'd)	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	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 Potato Sp IgE Ab Potato Sp IgE Ab Blue Mussel Sp IgE Ab Blue Mussel Sp IgE Ab Tuna Sp IgE Ab Salmon Sp IgE Ab Salmon Sp IgE Ab Salmon Sp IgE Ab Garlic Sp IgE Ab Strawberry Sp IgE Ab Garlic Sp IgE Ab Apple Sp IgE Ab Chub Mackerel Sp IgE Ab Foxtail Millet Sp IgE Ab Foxtail Millet Sp IgE Ab Barley Sp IgE Ab Oat Sp IgE Ab Oat Sp IgE Ab Cotopus Sp IgE Ab Barley Sp IgE Ab Cotopus Sp IgE Ab Cotopus Sp IgE Ab Barley Sp IgE Ab Cotopus Sp IgE Ab Cotopus Sp IgE Ab Dat Sp IgE Ab Cotopus Sp IgE Ab Corn Sp IgE Ab Cheese Mould Sp IgE Ab Chicken Meat Sp IgE Ab Chicken Meat Sp IgE Ab Chicken Meat Sp IgE Ab Chicken Meat Sp IgE Ab		

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood (cont'd)	Detection of: (cont'd)	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	Melon Sp IgE Ab Lamb Meat Sp IgE Ab Mustard Sp IgE Ab Rice Sp IgE Ab Malt Sp IgE Ab Banana Sp IgE Ab Banana Sp IgE Ab Pear Sp IgE Ab Pear Sp IgE Ab Avocado Sp IgE Ab Avocado Sp IgE Ab Fish Mix Sp IgE Ab Food Mix Sp IgE Ab Grain Mix Sp IgE Ab Curry Spice Mix Sp IgE Ab Mixed Meat Sp IgE Ab Vernal Grass Sp IgE Ab Bee Venom Sp IgE Ab Bee Venom Sp IgE Ab Horse Fly Sp IgE Ab Cockroach Sp IgE Ab Silk Sp IgE Ab Silk Sp IgE Ab Silk Sp IgE Ab Formaldehyde Sp IgE Ab Silk Sp IgE Ab Cotton Seed Sp IgE Ab Cotton Seed Sp IgE Ab Abachi Wood Sp IgE Ab Cotton Seed Sp IgE Ab Abachi Sp IgE Ab Formaldehyde Sp IgE Ab Cotton Seed Sp IgE Ab A Alternata Sp IgE Ab A. Alternata Sp IgE Ab Mould Mix Sp IgE Ab		

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood (cont'd)	Detection of: (cont'd)	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	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 Oak Tree Pollen Sp IgE Ab Elm Tree Pollen Sp IgE Ab Golden Rod Sp IgE Ab Nettle Pollen Sp IgE Ab Mugwort Pollen Sp IgE Ab Plantain Pollen Sp IgE Ab Yeast Sp IgE Ab Cephalosporin 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 Rjug R1 Walnut Sp IgE Ab Rjug R3 Ltp Walnut Sp IgE Ab Rhev B8 Latex Profilin Sp IgE Ab Anouse (Epithelium/Serum/Urine) Sp IgE Ab Chicken Droppings Sp IgE Ab		

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood (cont'd)	Detection of: (cont'd)	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	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 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 Blueberry Sp IgE Ab Blueberry Sp IgE Ab Fennel Sp IgE Ab Blueberry Sp IgE Ab Date Sp IgE Ab Mint Sp IgE Ab Fire Ant Sp IgE Ab Fire Ant Sp IgE Ab Phthalic Anhydride Sp IgE Ab Maleic Anhydride Sp IgE Ab Maleic Anhydride Sp IgE Ab Maleic Anhydride Sp IgE Ab		

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood (cont'd)	Detection of: (cont'd)	Thermo Fisher Phadia 250 Chemiluminescence IM ID01 IM ID02	RLH
	Pityrosporum Orbiculare Sp IgE Ab		
	Aspergillus Flavus Sp IgE Ab Wall Pellitory Sp IgE Ab Chlorhexadine Sp IgE Ab Ara H2 Peanut Glycinin Sp IgE Ab		
	Tryptase IgG Aspergillus fumigatus Avian precipitins	IM ID03 IM A50 IM A70	
	Autoimmune Serology	Dynex DS2 ELISA	
	Detection of:		
Blood	Anti-Cardiolipin (IgG,A,M Screen)	ELISA – Orgentec IM A33	RLH
Blood	Intrinsic Factor antibodies	ELISA - Orgentec IM A22	RLH
Blood	Tissue Transglutaminase (IgA)	ELISA - Orgentec IM A45	RLH
Blood	Acetylcholine Receptor Abs	ELISA - RSR IM A55	RLH
Blood	Anti-GAD antibodies	ELISA - RSR IM A60	RLH
Blood	Anti-Natalizumab (Tysabri) Abs	ELISA – Inhouse Biogen-idec IM A57	RLH
Blood	TSH Receptor antibodies	ELISA - RSR IM A62	RLH
Faeces	Faecal Calprotectin	ELISA – ACCUSAY IM A68	RLH

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Autoimmune Serology (cont'd)	Dynex DS2 ELISA	
	Detection of: (cont'd)		
Blood	Infliximab drug level	ELISA – PROMonitor IM A73	RLH
Blood	Infliximab antibody level	ELISA – PROMonitor IM A74	RLH
Blood	Adalimumab drug level	ELISA – Promonitor IM A81	RLH
Blood	Adalimumab antibody level	ELISA – Promonitor IM A82	RLH
Blood	Islet cell antibodies (GAD/IA2/ZnT8)	ELISA – RSR IM A75	RLH
Blood	Anti C1q Antibodies	ELISA IM A85	RLH
Blood	Pancreatic Faecal Elastase	FELA – ELISA IM A65 IM A82	RLH
Blood	MBL	ELISA IM ID08	RLH
Blood	C1 Esterase level	Binding Site Optilite turbidimetry IM ID04	RLH



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HUMAN BODY FLUIDS AND TISSUE	Immunology examination activities for the purpose of clinical diagnosis	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
	Detection of:	Semi-automated D Tek Blue Diver	
Blood	Scleroderma / Polymyositis Panel [Jo-1, PL-7, PL-12, SRP, Mi-2, Ku, PM-Scl100 & Scl-70]	Blot - CLS IM A77	RLH
Blood	Extended Liver Panel [M2/nPDC; gp210; sp100; LKM1; LC1; SLA and F-Actin]	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]	Blot - CLS IM A79	RLH
Blood	Myositis panel [Jo-1, PL-7, PL-12, EJ, SRP, MDA-5, TIF18, Ro52, SAE1, SAE2 + NXP2.]	Blot-CLC IM A88	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood	PLA2 Receptor abs by ELISA	DS2 ELISA - Euroimmun IM A69	RLH
	Detection of:	Indirect Immunofluorescence	
Blood	Adrenal antibodies	Slides – IL/Werfen IM A07	RLH
Blood	ANA (Hep-2) Screen	Slides – Biodiagnostics IM A06	RLH
Blood	Autoantibody Screen	Slides – IL/Werfen IM A05	RLH
Blood	dsDNA Immunofluorescence	Slides – Biosystems/Launch IM A10	RLH
Blood	Endomysia antibodies (IgA)	Slides – IL/Werfen IM A11	RLH
	Detection of:	Indirect Immunofluorescence	
Blood	IgG ANCA	Slides – IL/Werfen IM A09 AN	RLH
Blood	Islet Cell antibodies	Slides – IL/Werfen IM A29	RLH
Blood	Neuronal Antibodies	Slides – IL/Werfen IM A49	RLH
Blood	Myocardial antibodies	Slides – IL/Werfen IM A80	RLH
Blood	Pemphigus/Pemphigoid	Slides – IL/Werfen IM A13	RLH
	Immunodeficiency:	Manual Radial Immunodiffusion	
Blood	C1 Esterase (Function)	Siemens Berichrom C1 inhibitor kit on Sysmex CN2500 IMID05	RLH

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Blood	Mannose Binding Ligand	Thermo Fisher MBL Oligomer ELISA IM ID08	RLH
Blood	Haemophilus B Antibodies	DS2 ELISA – Binding Site IM ID06	RLH
Blood	Tetanus antibodies	DS2 ELISA – Binding Site IM ID07	RLH
Blood	Salmonella typhi Ab	DS2 ELISA-binding site IM ID22	RLH
Blood	IgG Subclasses	Turbidimetry – Binding Site IM ID11	RLH

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis	Documented in-house procedures incorporating manufacturer's instructions where relevant	
	Flow Cytometry:	BD FACS LyricFlow Cytometry Using manufacturer's monoclonal antibody kits:	
Blood	Lymphocyte Subsets (CD3,4,8)	IM ID12	RLH
Blood	Immunodeficiency Panel (B,T,NK)	IM ID12	RLH
Blood	B Cell Subpopulation	IM ID13	RLH
Blood	Neutrophil Function [DHR]	IM ID17	RLH
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
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 are analysed using flow cytometry. IMP.SOP.008	RLH
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 antibodies are analysed using flow cytometry. IMP.SOP.009 IMP.SOP.045	RLH
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 are analysed using flow cytometry. IMP.SOP.013 IMP.SOP.045	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis	Documented in-house procedures incorporating manufacturer's instructions where relevant	
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 are analysed using flow cytometry. IMP.SOP.011 IMP.SOP.045	RLH
Blood, Bone marrow, CSF, Pleural Fluid, Ascites, serous fluid and effusion.	Detection and characterisation of acute leukaemia, and enumeration of blasts and monocytes in Myelodysplastic syndrome. Assessment of minimal residual disease (MRD)	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
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
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 FLUIDS AND TISSUE (cont'd)	Histocompatibility and immunogenetics examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturer's instructions where relevant	
	Clinical Transplantation		
Blood (EDTA) Buccal swab Spleen	DNA Extraction	DNA Extraction EZ1 Advanced XL Qiagen Biorobot CTL.GEN.SOP.100	RLH
Blood (EDTA)	DNA Extraction	Manual DNA extraction using the QIAamp DNA Blood Mini Kit CTL.GEN.SOP.100	RLH
DNA	HLA	Luminex® 100/200 analyser Luminex XY™ plate handling platform Luminex SD™ sheath fluid delivery system	
DNA	HLA Typing: HLA– A,B,C,DRB1, DRB345, DQA/B1,DPA/B1	Thermal cyclers Kit: Lifecodes® HLA-SSO Typing Kits CTL.MOL.SOP.100	RLH
DNA	B*57:01 testing	Kit: Lifecodes® HLA-SSO Typing Kits CTL-MOL-SOP-100	RLH
DNA	B27 testing	Kit: Lifecodes® HLA-SSO Typing Kits CTL-MOL-SOP-100	RLH
DNA	HLA Typing: HLA– A,B,C,DRB345, DRB1,DQA1, DQB1, DPA1, DPB1	Thermal cyclers Roche Lightcycler Kit: LinkSeq HLA-ABCDRDQDP+ 384 Typing Kit CTL.MOL.SOP.120	RLH

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Histocompatibility and immunogenetics examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
	Clinical Transplantation (cont'd)		
DNA	HLA Typing: HLA– A,B,C,DRB345, DRB1,DQA1, DQB1, DPA1, DPB1	Next Generation Sequencing (NGS) using the Qubit, Veriti Pro thermocycler, Illumina MiniSeq and MiSeq, and in-house method Kits: GenDx NGSgo-MX6-1, NGSgo-AmpXv2, NGSgo-LibrX, NGSgo-IndX CTL.MOL.SOP.110	RLH
DNA	Haemochromatosis (HFE) testing	Kit: IDT Primers CTL.MOL.SOP.130	RLH
	HLA Class I & Class II antibody detection and identification:	Luminex® 100/200 analyser Luminex XY™ plate handling platform Luminex SD™ sheath fluid delivery system	
Serum	HLA- A,B,C,DRB1,DRB3,DRB4,DRB5, DQA1,DQB1,DPA1,DPB1	Kits: One lambda LABScreen Single Antigen. CTL.SER.SOP.100	RLH
Serum	HLA- A,B,C,DRB1,DRB3,DRB4,DRB5, DQA1,DQB1,DPA1,DPB1	Kit: LIFECODES LifeScreen Deluxe (LMX) LIFECODES LSA Class I LIFECODES LSA Class II CTL.SER.SOP.100	RLH
Serum/ lymphocytes	T and B cell Flowcytometric crossmatching	Becton Dickinson FACSLyric Reagents: Dako CD3, CD19, FITC SOP: CTL.SER.SOP.110	RLH



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Cytogenetics examination activities for the purpose of clinical diagnosis	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	
	Reporting of cytogenetics results	CMH-CYTO-POL-002	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUE (cont'd)	Molecular Genetics examination activities for the purpose of clinical diagnosis	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
DNA	CALR	CALR assay using in-house PCR method on Veriti thermal cycler and Applied Biosystems 3730 HAEM-MOLEC-SOP-54	RLH
DNA	MPL	MPL assay using in-house PCR method on Veriti thermal cycler and Applied Biosystems 3730 HAEM-MOLEC-SOP-55	RLH
RNA	BCR-ABL1	BCR-ABL1 using in house / EAC RQ-PCR method with Qiagen Ipsogen Standards, on Applied Biosystems 7500 and Veriti thermal cycler HAEM-MOLEC-SOP-05 HAEM-MOLEC-SOP-11 HAEM-MOLEC-SOP-12 HAEM-MOLEC-SOP-13 HAEM-MOLEC-SOP-14	RLH
DNA	FLT3 /NPM1	FLT3 / NPM1 assay using in- house PCR method on Veriti thermal cycler and Applied Biosystems 3730 HAEM- MOLEC-SOP-20 HAEM-MOLEC-SOP-23	RLH

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
DNA	FVL / Prothrombin Variant	FVL / Prothrombin Variant assay using in-house RQ-PCR method on Applied Biosystems 7500 HAEM-MOLEC-SOP-09	RLH
DNA	Immunoglobulin Rearrangement (IGH and IGK)	IG assay by PCR using Invivoscribe kit on Veriti thermal cycler and analysed Applied Biosystems 3730 HAEM-MOLEC-SOP-10	RLH
DNA	T-Cell Receptor Rearrangement (TCRB and TCRG)	TCR assay by PCR using Invivoscribe kit on Veriti thermal cycler and analysed Applied Biosystems 3730 HAEM-MOLEC-SOP-10	RLH
DNA	Chimerism Analysis	Chimerism assay by PCR using Promega Powerplex 16 HS kit analysed on Applied Biosystems 3730 HAEM-MOLEC-SOP-16	RLH
DNA	Minimal Residual Disease Monitoring in Acute Lymphoblastic Leukaemia (ALL)	MRD assay by PCR, RQ-PCR and sequencing using published methods, on Veriti Applied Biosystems 7500 and Applied Biosystems 3730 HAEM- MOLEC-SOP-06 HAEM-MOLEC-SOP-22 HAEM-MOLEC-SOP-24 to HAEM-MOLEC-SOP-31 HAEM-MOLEC-SOP-35	RLH
DNA	MYD88	MYD88 assay using Qiagen Qbiomarker MYD88 assay on Applied Biosystems 7500. CMH-SOP-014 MYD88	RLH



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Materials/Products tested	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY FLUIDS AND TISSUE (cont'd)	Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
DNA and FFPE	BRAF EGFR	Biocartis Idylla™ System Idylla™ BRAF Mutation Test Idylla™ EGFR Mutation Test	RLH
DNA and RNA	Next generation sequencing for detection of fusion genes and mutations in haematological malignancies	Oncomine myeloid research assay. Ion Chef and IonS5 sequencer. CMH-SOP- 010 to CMH-SOP-013	RLH
DNA	Next generation sequencing for detection and mutations in Cancer samples	Ion Ampliseq Cancer hotspot panel v2. Ion Chef and IonS5 sequencer. CMH-SOP-010 to CMH-SOP-013	RLH
DNA	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		

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Molecular Genetics examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
DNA	Next generation sequencing for detection and mutations in cancer samples(cont'd) 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);	Ion Ampliseq Cancer hotspot panel v2. Ion Chef and IonS5 sequencer. CMH-SOP-010 to CMH-SOP-013	RLH
DNA	IGH Somatic Hypermutation screening	IGH Somatic Hypermutation assay using Invivoscribe kit on Veriti thermal cycler, with sequencing analysed on Applied Biosystem 3730. HAEM-MOLEC-SOP-68	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 FLUIDS AND TISSUE (cont'd)	Retinoblastoma examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturer's instructions where relevant	
 A) Whole blood, fresh retinoblastoma tumour, paraffin embedded tissue, received DNA samples. B) Amniotic fluid, chorionic villus. C) Hair, buccal cells. D) Whole blood, fresh retinoblastoma tumour. 		DNA/RNA extraction: Manual DNA/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.091 RB.SOP.096 RB.SOP.095 RB.INFO.029	RLH
DNA obtained from sample types specified above: A	RB1 Mutation Screening for point mutations and small indels.	High Resolution Melt (HRM) Confirmation Screening using a Rotorgene (Qiagen) Bioline SensiFAST HRM Kit, Qiagen Type-it HRM Kit RB.DOC.053 RB.SOP.054 RB.SOP.086	RLH
DNA/ RNA obtained from sample types specified above: A, B, C, RNA obtained from sample type A	RB1 variant	PCR/RT-PCR Amplification and Sanger Sequencing: Thermal cyclers ABI 3730XL capillary analyser 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.036 RB.SOP.025 RB.SOP.091 RB.SOP.088	RLH

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Retinoblastoma examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
DNA obtained from sample types specified above: A, B, C	RB1 linkage exclusion testing and LOH analysis.	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	RLH
DNA obtained from sample types specified above: A, B, D	Screening for dosage mutations in RB1.	Multi-Ligation Probe Analysis (MLPA): Thermal cyclers ABI 3730XL capillary analyser MRC Holland MLPA SALSA P047 Kit RB.SOP.059 RB.DOC.045 RB.DOC.060	RLH
		Quantitative Fluorescence PCR (QF-PCR): Thermal cyclers ABI 3730XL capillary analyser. Using in house methods incorporating manufacturer's instructions where relevant RB.DOC.035 RB.SOP.069	RLH
DNA obtained from sample types specified above: A,	Hypermethylation in RB1 Promoter	Bisulphite Modification and Methylation specific PCR: Thermal cyclers Agarose gel electrophoresis Zymo EZ DNA Methylation-Gold Kit RB.DOC.068 RB.SOP.041 RB.SOP.058 RB.SOP.025	RLH
END			