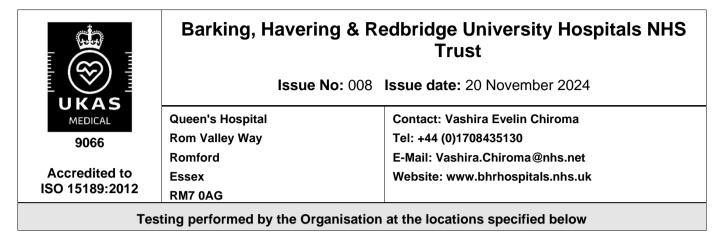
Schedule of Accreditation

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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 Queen's Hospital Rom Valley Way Romford Essex RM7 0AG	Local contact Ali Aisha (Haematology, Coagulation) Dhanaraj Krishnamurthy (Biochemistry) 01708 503710	Haematology Coagulation Molecular Haematology Blood Transfusion Biochemistry	QH
	Local contact Graham Thwaites 01708 435250	Routine Histopathology Special stains Immunohistochemistry and Molecular Diagnostic Cytopathology	QH
	Local contact Feny Johny William 01708 435577	Microbiology	QH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Location details		Activity	Location code
Address King George Hospital Barley Lane Goodmayes Essex IG3 8YB	Local contact Ali Aisha (Haematology, Coagulation) Dhanaraj Krishnamurthy (Biochemistry) 01708 503710	Haematology Coagulation Immunology Haemoglobinopathies Blood Transfusion Biochemistry	KGH
	Local contact Denise Digby 01708 435577	Microbiology Serology	KGH
	Local contact Feny Johny William 01708 435577	Prenatal Screening	KGH

	Schedule of Accreditation issued by United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK
	Barking, Havering & Redbridge University Hospitals NHS Trust
9066 Accredited to ISO 15189:2012	Issue No: 008 Issue date: 20 November 2024
	Testing performed by the Organisation at the locations specified

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Address Labour Ward Queen's Hospital Rom Valley Way Romford Essex RM7 0AG	Local contact Xiaohui Tang 01708 435158	Satellite blood fridge: storage of blood and products only	QH
Address NICU Queen's Hospital Rom Valley Way Romford Essex RM7 0AG	Local contact Xiaohui Tang 01708 435158	Satellite blood fridge: storage of blood and products only Hot lab	QH QHHL
Address Emergency Department Queen's Hospital Rom Valley Way Romford Essex RM7 0AG	Local contact Xiaohui Tang 01708 435158	Satellite blood fridge: storage of blood and products only Hot lab	QH QHHL
Address Theatres Queen's Hospital Rom Valley Way Romford Essex RM7 0AG	Local contact Xiaohui Tang 01708 435158	Satellite blood fridge: storage of blood and products only	QH
Address Theatres King George Hospital Barley Lane Goodmayes Essex IG3 8YB	Local contact Xiaohui Tang 01708 435158	Satellite blood fridge: storage of blood and products only	КСН



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of clinical diagnosis and monitoring:	Manufacturer's instructions and documented in-house methods	
	<u>montoning.</u>	Roche c8000	
Serum	Carbamazepine	Immunoassay SOP-10772	QH
Serum	Phenytoin	SOP-6472 (KIMS)	QH
Serum	Theophylline	SOP-10278 (KIMS)	QH
Serum	Digoxin	Immuno-inhibition assay SOP-10476	QH/ KGH
Serum	Valproic acid	Enzymatic immunoassay SOP-10279	QH
Serum/ Plasma	Lithium	Colorimetric assay SOP-10632	QH/KGH
Serum/ Plasma	Bicarbonate	Enzymatic colourimetric assay SOP-10410	QH/KGH
Serum/ Plasma	ACE	Enzymatic assay SOP-10767	KGH
Serum/ Plasma	С3	Immuno-turbidimetric assay SOP-10371	QH/KGH
Serum/ Plasma	C4	Immuno-turbidimetric assay SOP-10312	QH/KGH
Plasma	Alcohol	Enzymatic assay SOP-10409	QH
Plasma	Ammonia	Enzymatic assay SOP-10638	QH/KGH
Serum/ Plasma	Haptoglobin	Immuno-turbidimetric assay SOP-10563	QH
Serum/ Plasma	Albumin	Colorimetric assay SOP-10358	QH/KGH

DETAIL OF ACCREDITATION



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods Roche c8000	
Serum/ Plasma	Alkaline-phosphatase	Colorimetric assay SOP-10629	QH/KGH
Serum/ Plasma	ALT	Enzymatic Colorimetric assay SOP-10377	QH/KGH
Serum/ Plasma	Amylase	Enzymatic Colorimetric assay SOP-10379	QH/KGH
Serum/ Plasma	AST	Enzymatic Colorimetric assay SOP-10380	QH/KGH
Serum/ Plasma	Bilirubin-total	Colorimetric assay SOP-10642	QH/KGH
Serum/ Plasma	Calcium	Colorimetric assay SOP-10313	QH/KGH
Serum/ Plasma	Chloride	Ion-Selective Electrode SOP-10284	QH/KGH
Serum/ Plasma	Cholesterol	Enzymatic colorimetric assay SOP-10391	QH/KGH
Serum/ Plasma	HDL cholesterol	Enzymatic Colorimetric assay SOP-10983	QH/KGH
Serum/ Plasma	Creatine kinase	Enzymatic Colorimetric assay SOP-10419	QH/KGH
Serum/ Plasma	Creatinine	Enzymatic assay SOP-11853	QH/KGH
Serum/ Plasma	CRP	Immuno-turbidimetric assay SOP-6662	QH/KGH
Serum/ Plasma	Gamma GT	Enzymatic Colorimetric assay SOP-10518	QH/KGH
Serum/ Plasma	Glucose	Enzymatic colorimetric assay SOP-10519	QH/KGH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods Roche c8000	
Serum/ Plasma	GTT	Enzymatic assay SOP-3472	QH/KGH
Serum/ Plasma	Immunoglobulins: IgA IgG IgM	Immuno-turbidimetric assay SOP-9396 SOP-9392 SOP-9391	QH/KGH
Serum/ Plasma	Iron	Colorimetric assay SOP-10566	QH/KGH
Plasma	Lactate	Colorimetric assay SOP-10522	QH/KGH
Serum/ Plasma	LDH	Enzymatic Colorimetric assay SOP-10523	QH/KGH
Serum/ Plasma	Magnesium	Colorimetric assay SOP-10524	QH/KGH
Serum/ Plasma	Paracetamol	Colorimetric assay SOP-10734	QH/KGH
Serum/ Plasma	Phosphate	Colorimetric assay SOP-10527	QH/KGH
Serum/ Plasma	Potassium	Ion-Selective Electrode SOP-10284	QH/KGH
Serum/ Plasma	Protein-total	Colorimetric assay SOP-10534	QH/KGH
Serum/ Plasma	Rheumatoid factor	Immuno-turbidimetric assay SOP-10759	QH/KGH
Serum/ Plasma	Salicylate	Enzymatic colorimetric assay SOP-10530	QH/KGH
Serum/ Plasma	Sodium	Ion-Selective Electrode SOP-10284	QH/KGH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods Roche c8000	
Serum/ Plasma	Triglycerides	Enzymatic colorimetric assay SOP-10589	QH/KGH
Serum/ Plasma	UIBC	Colorimetric assay SOP-10538	QH/KGH
Serum/ Plasma	Urate	Enzymatic colorimetric assay SOP-10593	QH/KGH
Serum/ Plasma	Urea	Enzymatic colorimetric assay SOP-10539	QH/KGH
Serum	Conjugated bilirubin	Colorimetric assay SOP-10373	QH/KGH
Urine	Albumin	Immuno-turbidimetric assay SOP6428	QH/KGH
Urine	Sodium	Ion selective electrode SOP-10284	QH/KGH
Urine	Potassium	Ion selective electrode SOP-10284	QH/KGH
Urine	Protein	Turbiimetric assay SOP 10535	QH/KGH
Urine	Urate	Enzymatic colorimetric assay SOP- 10593	QH/KGH
Urine	Calcium	Colorimetric assay SOP-10313	QH/KGH
Urine	Creatinine	Enzymatic assay SOP-11853	QH/KGH
Urine	Magnesium	Colorimetric assay SOP-10524	QH/KGH
Urine	Phosphate	Colorimetric assay SOP-10527	QH/KGH
CSF	Glucose	Enzymatic colorimetric assay SOP-10519	QH/KGH
CSF	Lactate	Colorimetric assay SOP-10522	QH/KGH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods Roche c8000	
CSF	Protein	Turbidimetric assay SOP-10535	QH/KGH
Serum/Plasma	B12	Competitive Immunoassay SOP-10791	QH/KGH
Serum/Plasma	CA125	Sandwich assay SOP-10514	QH/KGH
Serum/Plasma	CEA	Sandwich assay SOP-10737	QH/KGH
Serum	Cortisol	Competitive Immunoassay SOP-10516	QH/KGH
Serum	FSH	Sandwich assay SOP-10553	QH/KGH
Serum	Ferritin	Sandwich assay SOP-10549	QH/KGH
Serum	Free T3	Competitive Immunoassay SOP-10558	QH/KGH
Serum	Free T4	Competitive Immunoassay SOP-11003	QH/KGH
Serum	HCG	Sandwich assay SOP-10398	QH/KGH
Serum	LH	Sandwich assay SOP-10399	QH/KGH
Serum	Macro prolactin	PEG precipitation treatment of sample followed by Sandwich assay SOP-1242, 10441	QH/KGH
Serum	Progesterone	Competitive Immunoassay SOP-10787	QH/KGH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods Roche c8000	
Serum	Prolactin	Sandwich assay SOP-10428	QH/KGH
Serum	PSA	Sandwich assay SOP-10491	QH/KGH
Serum	Folate	Competitive Immunoassay SOP-10998	QH/KGH
Serum	Testosterone	Competitive Immunoassay SOP-10445	QH/KGH
Serum	Troponin T HS	Sandwich assay SOP-10736	QH/KGH
Serum	тѕн	Sandwich assay SOP-10448	QH/KGH
Serum/ Plasma	CA153	Sandwich assay SOP-10468	QH
Serum	Oestradiol	Competitive Immunoassay SOP-10422	QH/KGH
Serum	CA19-9	Sandwich assay SOP-10469	QH
Serum	Beta 2 microglobulin	Immunoturbidmetric assay SOP-10365	QH
Serum	РТН	Sandwich assay SOP-10488	QH/KGH
Plasma	NT pro BNP	Sandwich assay SOP-10363	QH/KGH
Serum	Vitamin D	Competitive immunoassay SOP 11852	QH/KGH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods Roche c8000	
Serum	PGLF		QH
Serum	Soluble fms like tyrosine kinase		QH
Serum	Bile acids		QH
Serum	FASP screening AFP		KGH
Serum	FASP screening total HCG		KGH
		Roche Cobas Bio c702	
Serum/Plasma	Procalcitonin	ECLIA	QH/KGH
Serum/Plasma	Amakacin Vancomycin	KIMS	QH/KGH
Serum/Plasma	Gentamicin	CEDIA	QH/KGH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods	
Serum	Serum protein Immunofixation: Paraprotein confirmation and typing	Sebia Hydrasys Immunofixation electrophoresis SOP-1866	KGH
Serum	Serum protein electrophoresis and immunosubtraction: Paraprotein confirmation, typing and quantitation	Sebia Capillarys Capillary electrophoresis and immunosubtraction electrophoresis SOP-3714	KGH
Serum/Urine	Osmolality	OSMO1 Freezing point depression SOP-1632	QH/KGH
Urine	Bence-Jones protein	Sebia Hydrasys Immunofixation electrophoresis SOP-4003	KGH
CSF	Xanthochromia	Uvikon Spectrophotometer SOP-3672	QH
Sweat	Sweat chloride	Sherwood M926S Chloride Analyser Direct reading, digital chloride meter SOP-1208	QH
Faeces	Detection of occult haemoglobin	Iummunoturbidomitry using OC Sensor and SOP Pathology 7441	KGH
Serum/Plasma	Free kappa lights chains Free lambda light chains	Immunoturbidimetric Binding Site Optilite	KGH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

	Type of test/Properties		
Materials/Products tested	measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods	
	Calculated assays	Calculated using in-house documented methods SOP-7106 and using:	
Data	eGFR	Calculated using the CKD-EPI eGFR creatinine calculation	QH/KGH
Data	Adjusted calcium	Calcium and albumin	QH/KGH
Data	Acute kidney injury	Current creatinine and creatinine baseline National Algorithm	QH/KGH
Data	Globulin	Total protein and albumin	QH/KGH
Data	Cholesterol /HDL ratio	Cholesterol and HDL	QH/KGH
Data	LDL cholesterol	Cholesterol, HDL and triglycerides	QH/KGH
Data	Non HDL cholesterol	HDL and cholesterol	QH/KGH
Data	Transferrin saturation	Iron and TIBC	QH/KGH
Data	ТІВС	Iron and UIBC	QH/KGH
Data	24hr BJP	Urine BJP and Urine volume	QH/KGH
Data	Albumin creatinine ratio	Urine albumin and urine creatinine	QH/KGH
Data	Protein creatinine ratio	Urine total protein and urine creatinine	QH/KGH
Data	24hr calcium excretion	Urine calcium and urine volume	QH/KGH
Data	24hr protein	Urine protein and urine volume	QH/KGH
Data	24hr magnesium	Urine magnesium and urine volume	QH/KGH
Data	24hr phosphate	Urine phosphate and urine volume	QH/KGH
Data	24hr potassium	Urine potassium and urine volume	QH/KGH
Data	24hr sodium	Uirne sodium and urine volume	QH/KGH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities (cont'd)	Documented in-house methods	
	Calculated assays	Calculated using in-house documented methods SOP-7106 and using:	
Data	24hr uric acid	Urine uric acid and urine volume	QH/KGH
Data	Creatinine clearance	Serum creatinine, urine creatinine and urine volume	QH/KGH
Data	Calcium creatinine clearance ratio	Urine calcium,, urine creatinine, serum creatinine and serum calcium SOP-4485	QH/KGH
Data	SFL1:PLGF ratio	SFLT and PGLF	QH
Data	Free kappa/lambda ratio	In Serum/Plasma	KGH
Data	Free Androgen Index		QH/KGH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Pre-natal screening examination activities for the purpose of clinical diagnosis	Manufacturer's instructions and documented in-house methods	
		Documented -in-house methods to meet the requirements of the Fetal Anomaly Screening Programme as defined in the July 2018 'FASP screening: laboratory QA evidence requirements'	
Serum Serum Serum	PAPP-A Free beta HCG Kryptor PLGF	B.R.A.H.M.S Kryptor Time resolved amplified cryptate emission immunoassay SOP-4441 SOP-3866	KGH
Serum Serum	Unconjugated estirol Inhibin-A	SOP-3858 SOP-3856	
		Beckman Access 2 Immunoassay	
Serum	Inhibin-A	SOP-3856	KGH
Serum	Unconjugated estriol	SOP-3858	KGH
	Calculated assays	Calculated assays calculated using in-house documented methods and using:	KGH
Data	PAPP-A MoM	Viewpoint software using FMF algorithm SOP-8173	
Data	Free beta HCG MoM	Viewpoint software using FMF algorithm SOP-8173	
Data	Second trimester adjusted risk for Trisomy 21	SSD software SOP-3859	
Data	Inhibin-A MoM	Lifecycle software using FMF	
Data	Unconjugated estriol MoM	algorithm Lifecycle software using FMF algorithm	
Data	AFP MoM	SSD software	



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008

o: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Prenatal screening examination activities (cont'd)	Documented in-house methods	
	Calculated assays (cont'd)		
Data	Second trimester total bHCG MoM	SSD software	
		Roche Cobas Pure Using following methods: Spectrophotometric BCG	QHHL
Serum/Plasma	Albumin	Enzymatic Spectrophotometric (IFCC)	
	ALT Amylase Cholesterol CK Creatinine Triglyceride Urea Glucose	Enzymatic Spectrophotometric (Hexokinase)	
	Calcium	Spectrophotometric NM-BAPTA	
	Chloride Potassium Sodium	Indirect ISE	
	CRP	Immunoturbidimetric	
	Magnesium Phosphate	Spectrophotometric endpoint Spectrophotometric Molybdate	
	Total Bilirubin Total Protein	Diazo Spectrophotometric Biuret Spectrophotometric	
	Troponin T TSH	ECLIA Sandwich Immunoassay	
	Free T4	ECLIA Competitive Immunoassay	



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

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 purpose of clinical diagnosis	Manufacturer's instructions and documented in-house methods	
EDTA whole blood	Full blood count: Red blood cells White blood cells Hb MCH MCH MCC HCT RDW Neutrophils Lymphocytes Basophils Eosinophils Platelets Reticulocytes concentration and % MPV Immature granuloctyes, nucleated red cells concentration and % RetHb Immature platelet fraction Optical platelet count	Sysmex XN10 (XN9100) and XN10 (XN3100) & (XN-1000) analysers using flow cytometry, sodium lauryl sulphate for haemoglobin measurement and hydrodynamic focussing/direct current detection for RBC and plateletsSOP 5637	QH/ KGH/ QHHL



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented in-house methods	
EDTA whole blood	Full blood count: Red blood cells White blood cells Hb MCH MCHC MCV HCT RDW Neutrophils Lymphocytes Monocytes Basophils Eosinophils Platelets Reticulocytes Conc & % MPV Immature Granulocytes Nucleated Red cells Conc & % nRBCs RetHb Immature platelet fraction Optical platelet count	XN-20 (XN9100) Uses Flow Cytometry, Sodium Lauryl Sulphate for Haemoglobin measurement and Hydrodynamic focusing/Direct current detection for RBCs and Platelets and WPC for flagging Immature WBCs (Blasts/abnormal lymphocytes) SOP 5637	QH
EDTA whole blood	Erythrocyte sedimentation rate automated	Starrsed Interliner automated ESR analyser SOP-331	QH
		Starrsed RL automated ESR analyser SOP-331	KGH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

	Type of test/Properties		
Materials/Products tested	measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination</u> <u>activities (</u> cont'd)	Documented in-house methods	
EDTA whole blood	Peripheral blood film assessment	Sysmex SP-50 Manual blood film preparation and automated May-Grunwald-Giemsa staining using Sysmex SP-50 and SOP11168 RAL stainer-semi automated for manually prepared films using MCDh stain and SOP 10897	QH/KGH
		Examination of peripheral blood films using Cella Vision DI-60 SOP-12446	QH
EDTA whole blood	Sickle solubility test	Precipitation of reduced HbS SOP-341	QH/KGH
EDTA whole blood	Malaria screen test to detect malaria parasites thin film, thick film, parasitaemia	Giemsa staining and manual film examination SOP-380	QH/KGH
EDTA whole blood	Malaria antigen (rapid diagnostic test) for malarial parasites	CareUs Test kit Rapid immune-chromatographic technique SOP-380	QH/KGH
EDTA whole blood	Detection of malarial parasites, P. falciparum, P. vivax, P. malariae & P. ovale	Apacor Rapydtest CareStart ICT SOP 11840	QH/KGH
Serum, plasma or EDTA whole blood	Infectious mononucleosis screening / Detection of heterophile antibody	Accusay Mono test. Solid- phase immunoassay SOP-378	QH/KGH
Whole blood/ EDTA/ Heparin anticoagulant	G6PD screen	Trinity Biotech kit Visual fluorescence SOP-382	QH
EDTA whole blood/ anticoagulant blood	G6PD assay	Uvikon XL spectrophotometer Quantitative ultraviolet kinetic determination Pointe Scientific G6PD quantitative measurement using SOP-344	QH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Is

o: 008 Issue date: 20 November 2024

		1	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination</u> <u>activities</u> (cont'd)	Documented in-house methods	
Serum	Heparin induced thrombocytopenia test (HIT)	Stago STic Expert HIT RDT SOP-337	QH
		Documented -in-house methods to meet the requirements of the Sickle Cell and Thalassaemia screening programme as defined in the July 2018 version of 'Sickle Cell and Thalassaemia: laboratory QA evidence requirements'	QH
Bone marrow	Bone marrow aspirate and bone marrow film assessment	May Grunwald- Giemsa staining SOP-377	QH
		<u>Automated</u> Sysmex SP-50 stainer RAL stainer	
Bone marrow, urine deposits, whole EDTA blood	Perl's Prussian blue	Perl's Prussian blue stain and optical microscopy SOP-379	QH
EDTA whole blood	HbA1c	Menarini 9210 Boronate affinity chromatography SOP-7067	QH
EDTA whole blood	Haemoglobinopathy screen: Hb A Hb A2 Hb F Hb S Hb E Hb C Hb D Hb H Hb A2 variant	Bio-Rad Variant II Bio-Rad β-Thalassemia short programme kit using High performance liquid chromatography SOP-6267	KGH
EDTA whole blood	Acid gel electrophoresis	Acid gel electrophoresis SOP-191	KGH
EDTA whole blood	CAM electrophoresis	Alkaline electrophoresis SOP-192	КСН



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

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 (cont'd)	Documented in-house methods	
Citrated plasma	Coagulation Coagulation Screen: Prothrombin time INR EVM (50:50 mix) . INR RVV using thromborel S	Sysmex CS5100 analyser Clot detection SOP-393 SOP-782 SOP-783 SOP1008	QH
Citrated plasma Citrated plasma Citrated plasma	reagent APTT EVM (50:50 mix) Thrombin time Clauss fibrinogen		
Citrated plasma	Direct Oral AntiCoagulants (DOACS)	Sysmex CS5100 analyser SOP-9111	QH
Citrated plasma	D-Dimers	Immuno-turbidometric assay SOP-545	
Citrated plasma	Coagulation Screen: Prothrombin time INR EVM (50:50 mix) INR RVV using thromborel S reagent	Sysmex CS2500 analyser Clot detection SOP-3393 393 SOP-782 782 SOP783 SOP1008	QHHL
Citrated plasma Citrated plasma Citrated plasma Citrated plasma	APTT EVM (50:50 mix) Thrombin time Clauss fibrinogen D-Dimers	Immuno-turbidometric assay SOP-545	QH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

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 (cont'd)	Documented in-house methods	
Citrated plasma	<u>Coagulation</u> (cont'd) Factor Assays: (1 stage assays) II V VII VIII IX X XI XII	Sysmex CS5100 analyser Clot detection SOP-9142	QH
Citrated plasma	Anti-Xa assay	SOP-9111	QH
Citrated plasma	Von Willibrand factor antigen	Sysmex CS5100 analyser Immuno-turbidometric assay SOP-9165	QH
Citrated plasma Citrated plasma Citrated plasma Citrated plasma	Factor XIII Anti-thrombin III antigen Protein C (PC) Free protein S antigen (FPS Ag)	Sysmex CS5100 analyser Chromogenic assay: SOP-9142 SOP-9144 SOP-9145 SOP-9143	QH
Citrated platelet poor plasma	Lupus anticoagulants: Dilute Russell Viper venom screen) Dilute Russell Viper venom confirm Dilute APTT Dilute APTT confirm	Sysmex CS5100 analyser Clot detection SOP-9147	QH
Citrated plasma	PT and APTT	Manual method using CoaDATA Semi Automated Opto mechanical Coagulometer and SOP-11279	QH/KGH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

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 (cont'd)	Documented in-house methods	
	Molecular Haematology		
Whole blood	Genomic DNA extraction for use in PCR techniques	Boekel Thermal mixer SOP-156	QH
		HAIN FluoroCycler 12 and HAIN GenoXtract automated extractor using Hain Fluorotype Kits and Hain GenoXtract Blood Extraction Kit using SOPs Pathology 11092, 11091, 11093	QH
Genomic DNA from EDTA whole blood	Factor V Leiden mutation G1691A		
Genomic DNA from EDTA whole blood	Prothrombin gene mutation G20210A		
Genomic DNA from EDTA whole blood	HFE C282Y and H63D gene mutation assay (haemachromatosis)		
Genomic DNA from EDTA whole blood	HLA-B27	Techne TC-4000 PCR and electrophoresis SOP-159 SOP-160	QH
	Immunology examination activities for the purpose of clinical diagnosis	Manufacturers instructions and documented in-house methods using:	
SST	Autoimmune antibody screen. Antibodies to: Parietal cell Smooth muscle Mitochondrial Liver/ kidney Microsomal	HTZ Beeline 220 Sample and slide preparation followed by optical microscopy. Indirect immunofluorescence technique. SOP-9183	KGH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008

Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities (cont'd)	Documented in-house methods	
		<u>Phadia 250</u> ELIA - Fluorescent enzyme immunoassay:	KGH
SST	Connective tissue screen: U1RNP (RNP 70, A, C) SSA (Ro) SSB(La) CENP ScI-70 Jo1 Fibrillarin RNA Pol III Rib-P Pm-Scl PCNA Mi2 Sm Native purified dsDNA	SOP-6010	
SST	Anti-cardiolipin antibodies: IgG & IgM	SOP-6021`	
SST	Anti-glomerular basement membrane (GBM) antibodies	SOP-6008	
SST	Anti-tissue transglutaminase (tTG) antibodies	SOP-6011	
SST	Anti- proteinase3 (PR3) and myeloperoxidase (MPO) antibodies	SOP-6007	
SST	Anti-cyclic citrullated protein (CCP) antibodies	SOP-6020	
Serum	Thyroid Antibody (TPO)	Phadia 250 ELIA - Fluorescent enzyme immunoassay SOP-12778	КСН



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities (cont'd)	Documented in-house methods	
		Phadia 250 analyser ELIA Immunoassay :	
SST	Anti-thyroid peroxidase (TPO) antibodies	SOP-6024	KGH
Serum	Specific IgE allergens: fx1 fx2 fx5 mx1 gx3 tx8 f1 f2 f4 f13 f14 f81 e1 e5 d1 m3	SOP-8425	KGH
Serum	Total IgE	SOP-8425	KGH
Faeces	Calprotectin	Phadia 250 analyser ELIA Fluoroenzyme immunoassay SOP-8570	KGH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

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	Manufacturers instructions and documented in-house methods using:	
EDTA whole blood / plasma/ EDTA cord blood	ABO and RhD Blood group	Automated Immucor NEO IRIS analyser Microtitre plate method SOP5401 SOP-764	QH
		Automated Immucor Echo Lumena analyser Microtitre plate method SOP-2008 SOP-764	КСН
		<u>Manual</u> Tube technique SOP-751	QH/KGH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012

Issue No: 008 Issue date: 20 November 2024

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)	Documented in-house methods	
EDTA plasma	Red cell antibody screen: Rhesus blood group antibodies: anti-C anti-C anti-C anti-E anti-E anti-e Kell System blood group antibodies: anti-K anti-K anti-Kpa Kidd blood group antibodies: anti-JKb Duffy blood group antibodies: anti-Fya anti Fyb Lutheran blood group antibodies: anti-Lua anti-Lub MNS blood group antibodies: anti-N anti-S anti-S anti-S	Automated Immucor Neo IRIS analyser Gel solid phase capture method SOP-5401 DiaMed microtube gel technique SOP-753	QH



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

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)	Documented in-house methods	
EDTA plasma	Red cell antibody screen: Rhesus blood group antibodies: anti-Cw anti-C anti-C anti-D anti-E anti-e Kell System blood group antibodies: anti-K anti-K anti-Kpa Kidd blood group antibodies: anti-JKa anti-JKb Duffy blood group antibodies: anti-Fya anti-Fya anti-Fya anti-Fya anti-Fyb Lutheran blood group antibodies: anti-Lua anti-Lub MNS blood group antibodies: anti-N anti-N anti-S anti-S anti-S	Automated Immucor Echo Lumena analyser Gel solid phase capture method SOP-2008 Manual DiaMed microtube gel technique SOP-753	KGH
EDTA whole blood	Red cell antibody identification	Immucor Neo IRIS analyser Biorad Gel microcolumn method SOP-767	QH
		Immucor Echo Lumina analyser Bio-Rad Gel microcolumn method SOP-767	КСН



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

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)	Documented in-house methods	
EDTA whole blood	Direct anti-globulin test (DAT)	<u>Automated</u> Immucor Neo IRIS analyser SOP-5401 Bio-Rad gel techniqueSOP 2509	QH
EDTA whole blood	Direct anti-globulin test (DAT)	<u>Automated</u> Immucor Echo Lumena analyser SOP 2008 DAT by DiaMed gel technique SOP-2509	КСН
EDTA whole blood	Red cell RhK phenotyping	Bio-Rad Gel microcolumn card Rh /K Phenotype microtyping cards SOP-755	QH/KGH
		<u>Tube technique</u> SOP-755	QH
		Automated Immucor NEO IRIS analyser SOP-5041	QH
EDTA whole blood	Red cell compatibility test: IAT (indirect agglutination test) Cross match Immediate spin Electronic issue	Bio-Rad Gel technique SOP-770	QH/KGH
EDTA whole blood	Kleihauer test	Guest Fetal red cell detection kit Acid elution method SOP-762	QH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of	Standard specifications/	Location
	measurement	Equipment/Techniques used	Code
HUMAN BODY TISSUE	Histopathological examination activities for the purpose of clinical diagnosis	In house documented procedures using manual methods or equipment in conjunction with manufacturers' instruction as specified	
Fixed and fresh tissue from excisional and incisional biopsies and surgical resection specimens	Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Tissue samples		Specimen Dissection Manual method: SOP-678 SOP-679 SOP-680 SOP-681 SOP-682 SOP-698 SOP-698 SOP-803 SOP-1982 SOP-9435 SOP-9581 SOP-9581 SOP-9594 SOP-1983 SOP-2718 SOP-2718	QH
Unfixed tissue samples		Frozen sections Leica CM1950 Cryostat SOP-799 SOP-6904	QH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

	Type of test/Properties		
Materials/Products tested	measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods	
Formalin fixed tissue samples and blocks Clots (Cellblocks)		Tissue processing and embedding Leica ASP 300 Tissue Processor Tissue-Tek VIP 6 IPC Cassette Printer: SOP-806 SOP-6101 SOP-1147 SOP-696 SOP-804	QH
Formalin fixed tissue samples and blocks		Microtomy SOP-695	QH
Formalin fixed paraffin embedded tissue sections on glass slides.	H&E staining for tissue architecture and nuclear detail	Dako Coverstainer Automated Staining methods SOP-9006 SOP-602	QH
		Leica ST5020 SOP-808	
		CV5030 Coverslipper SOP-1265	
Formalin fixed paraffin embedded tissue sections on glass slides	Special Staining for the identification of:	Leica ST5020 Automated staining SOP-808	QH
		CV5030 Coverslipper SOP-1265	
	Acid and neutral mucins	Alcian Blue (PAS), with and without Diastase Digestion SOP-816	
	Neutral mucins, glycogen and PAS + / - substances	Periodic Acid Schiffs (PAS) with and without Diastase Digestion SOP-833	
	Helicobacter pylori	Giemsa SOP-822	



Accredited to ISO 15189:2012

Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

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)	Documented in-house methods	
Formalin fixed paraffin embedded tissue sections on glass slides	Manual Special Staining for the identification of:	Manual stains using stains:	QH
	Acid mucins	Alcian Blue pH 2.5 SOP-814	
	Fibrin / Connective tissue	Martius, Scarlet, Blue SOP-603	
	Mallory bodies / Connective Tissue	Chromotrope Analine Blue (CAB) SOP-817	
	Amyloid	Congo Red (Highman's) SOP-818	
	Elastin fibres and Collagen	Elastic Van Gieson SOP-820	
	Bile	Fouchet SOP-821	
	Gram positive and negative bacteria	Gram Stain SOP-823	
	Fungi	Grocott (Gomori Methanamine Silver) SOP-826	
	Collagen	Haematoxylin Van Gieson SOP-827	
	Argentaffin, chromaffin and some lipofuscins	Masson Fontana SOP-829	
	Connective tissue	Masson Trichrome SOP-830	
	Elastin fibres, HepB and copper associated protein	Stains Orcein (Shikata's method) SOP-832	



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

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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)	Documented in-house methods	
Formalin fixed paraffin embedded tissue sections on glass slides (cont'd)	<u>Manual Special Staining</u> (cont'd)	Manual stains	QH
giass sinces (cont d)	Iron	Stains Perls Prussian Blue SOP-834	
	Reticulin fibres	Stains Reticulin Gordon & Sweet SOP-836	
	Mycobacterium	Stains Ziehl Neelson (ZN) SOP-839	
	Haemopoetic tissue	Stains Haematological Giemsa SOP-2839	



Accredited to ISO 15189:2012

Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

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)	Documented in-house methods	
Formalin fixed paraffin embedded tissue sections on glass slides	Immunohistochemistry for the identification of:	Dako Onmis Automated Immunohistochemistry: SOP-801 SOP-598 SOP-599 SOP-979	QH
	Epithelial Cells	AE1/AE 3	
	α-1-fetoprotein	AFP	
	β-catenin protein	B-Catenin	
	bcl-2 oncogene	BCL-2	
	Centroblasts / centrocyts and some T cells	BCL-6	
	Epithelial cells	BerEP4	
	Ductal epithelium	CA19.9	
	Luminal cells in a variety of tissue	Ca 125	
	Simple epithelia	Cam 5.2	
	Peripheral nerve ganglion / mesothelial cells	CALRETININ	
	T cells	CD 3 (T)	
	T-helper cells / thymocytes	CD 4	
	T cells and B cell subset	CD 5	
	T cell subset	CD 8	
	Various haemopoetic cells/ enterocytes, endometrial stromal cells myofibroblasts	CD 10	
	Reed Sternburg cells	CD 15	



Accredited to ISO 15189:2012

Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	measurement <u>Histopathological examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis</u> (cont'd)	Documented in-house methods	
Formalin fixed paraffin embedded tissue sections on glass slides (cont'd)	Immunochemistry (cont'd)	Dako Omnis	QH
glass slides (cont d)	B cells	CD 20	
	Follicular dentritic cells / mature B cells	CD 21	
	B cells	CD 23	
	Reed Sternburg cells	CD 30	
	Endothelial cells	CD 31	
	Endothelial cells	CD 34	
	Plasma cells	CD38	
	Lymphocytes	CD 45 (LCA)	
	Platelets	CD 61	
	Macrophages	CD 68 (PGM1)	
	B cells	CD 79a	
	Mast cells	CD 117	
	Plasma cells	CD 138	
	Macrophages	CD163	
	Intestinal epithelia nuclei	CDX2	
	Intestinal epithelial cells	CEA (MONO)	
	Neuroendocrine cells	CHROMOGRANIN A	
	Various epithelial cells	CK5/6	
	Epithelial tissue	СК 7	



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house methods	
Formalin fixed paraffin embedded tissue sections on glass slides (cont'd)	Immunochemistry (cont'd)	Dako Omnis	QH
giass sinces (contra)	Sqamous epithelia	CK 14	
	Simple epithelia	CK 18	
	Epithelia	CK 19	
	Intestinal epithelia	CK 20	
	Mantle cell lymphoma / melanoma	CYCLIN DI	
	GIST	DOG-1	
	Epstein Barr Virus	EBV (LMP)	
	Epithelial membrane cells	E-Cadherin	
	Epithelial cells	EMA	
	Endothelial cells	FACTOR 13A	
	Breast and bladder tumours	GATA3	
	Breast marker	GCDFP-15	
	Astrocytes / ependymal cells	GFAP	
	Erythrocytes	Glycophorin C	
	Trophoblastic cells	hCG	
	Hepatocytes	HEPPA 1	
	Melanocytes	HMB45	
	Epithelial cells	HMWCK (34BE12)	
	Testis	Inhibin a	



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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house methods	
Formalin fixed paraffin embedded tissue sections on glass slides (cont'd)	Immunochemistry (cont'd)	Dako Omnis	QH
glass slides (cont d)	Plasma cells	КАРРА	
	Germinal centre B cells	Ki67	
	Plasma cells	LAMBDA	
	Breast	MAMAGLOBIN	
	Melanocytes	MELAN A	
	Lynch syndrome indicator	MLH1	
	Epithelial cells	MNF116	
	Lynch Syndrome	MSH2	
	Lynch Syndrome	MSH6	
	Plasma cells / B cells	MUM 1	
	Neurons	NF	
	Neuroendocrine cells	NSE	
	Oestrogen receptor cells	Oestrogen Receptor	
	Stem / germ cells	Oct ¾	
	Squamous epithelium	P40	
	Ovarian and colonic adenocarcinoma	P53	
	Squamous epithelium	P63	
	Follicular and mantle zone B cells	PAX 5	
	Syncytiotrophoblasts	PLAP	



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

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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)	Documented in-house methods	
Formalin fixed paraffin embedded tissue sections on glass slides (cont'd)	Immunochemistry (cont'd)	Dako Omnis	QH
	Lynch syndrome	PMS2	
	Prosate epithlelium	PSAP	
	Renal tuble epithelium	RCC	
	Scwann Cells, adipocytes	S100	
	Smooth muscle	SMA	
	Neuroendocrine cells, ganglion cells	Synaptophysin	
	Thymocytes	Tdt	
	Thyroid	Thyroglobulin	
	Lymphatic endothelium	D240	
	Skeletal muscle differentiation	Myogenin	
	Neutraphil elastase proteins	Neutralphil elastase	
	Mesencymal tissue	Vimentin	
	Fallopian tube epithelia	WT-1 PSMA TTF1	



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

	Type of test/Properties	Standard anapilizations /	Location
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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house methods	
Formalin fixed paraffin embedded tissue sections on glass slides (cont'd)	Immunochemistry (cont'd)	Dako Autostainer Link 48 automated immunohistochemistry using SOP-801	QH
	Presence of PD-L1 in NSCLC	PD-L1 (clone 22C3)	
	Progesterone receptor cells	Progesterone receptor	
	Prostatic adenocarcinoma	P504S	
	Lung / Follicular epithelia thyroid	TTF1	
Formalin fixed paraffin embedded tissue sections on glass slides	Immunohistochemistry for the detection of:	Ventana Benchmark Ultra SOP-3102 SOP-4348	QH
	ALK protein	ALK (clone D5F3)	
	HER 2	Automated immunohistochemistry HER2 (4B5)	
	Muscle cells	DESMIN	
	Lung	Napsin	
	Kidney, FT, ovarian	PAX8	
	Cervical epithelium for HPV	P16	
	Smooth muscle	SMMHC	
	Melanoma	SOX10	
		CD56	
		NKX3.1	



Accredited to

Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

ISO 15189:2012

Issue No: 008 Issue date: 20 November 2024

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)	Documented in-house methods	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscope Olympus BX50F4 Microscopy (qualitative analysis) and In-house procedures: SOP-7800	QH
Fixed human tissue preparations	Detection of mutations KRAS BRAF EGFR NRAS/BRAF	PCR using Biocartis Idylla system and SOP Pathology 10068	QH
HUMAN BODY TISSUE (cont'd)	Cytopathological examination activities for the purpose of clinical diagnosis	In house documented procedures using manual methods or equipment in conjunction with manufacturers' instruction as specified	
	Non-Gynaecological cytology		
	Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities		QH
Body fluids: Bronchial washings Cerebrospinal fluid (CSF) Cytological fluids (including FNAs) Sputum Urine Breast specimen Respiratory samples for differential cell count Gastro – Intestinal tract specimens		Preparation/centrifugation using: SOP-2130 SOP-2131 SOP-2133 SOP-2134 SOP-2135 SOP-2136 SOP-7176 SOP-8442	QH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	Cytopathological examination activities (cont'd)	Documented in-house methods	
Respiratory samples, cytological fluids, FNA, gastrointestinal tract samples & urines	<u>Non-Gynae Cytology</u> (cont'd)	Hologic T2000 processor In house procedures using Liquid based cytology processing: SOP-2325	QH
Urine		Hologic T5000 processor in-house procedures using liquid based cytology processing SOP-3981	
		Leica multistainer Leica ST 5020 : Papanicolaou staining May-Grunwald Giemsa staining SOP-1764	QH
	Morphological assessment and interpretation/diagnosis	Microscopes: Olympus BX45TF Olympus BX46F Olympus BX45 Microscopy (qualitative analysis) SOP-2343 SOP-2140	QH
Clots	Thrombin plasma clot formation	Cytology Sample Preparation SOP-2132	QH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Accredited to ISO 15189:2012 Issue No: 008 Issue date: 20 November 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUE	Microbiology examination activities for the purpose of clinical diagnosis	In house documented methods based on related UK Standards for Microbiology investigations (PHE SMIs) and using:	
Whole Blood	Culture & detection of microorganisms for the purpose of clinical diagnosis	BD BACTEC FX200 and 400 at QH. BD BACTEC FX200 at KGH. SOP-14047	QH/KGH
CSF, blood cultures	S.pneumonieae	Wellcogen S.pneumonieae test kit. Latex particle agglutination. SOP-4851 SOP-5165 SOP-1579	QH
CSF & Drain fluids, CSF shunts, Fluids & tissues	Microscopy, culture & detection of microorganisms for the purpose of clinical diagnosis	SOP-1620 SOP-1580 SOP-4851 SOP-5165	QH
HVS & cervical swabs, faeces, all wound swabs including CVP tips and GUM –pre inoculated media	Microscopy, Culture & detection of microorganisms for the purpose of clinical diagnosis	SOP-1469: Genital / HVS bench SOP-1316: Wounds SOP-3239: Faeces SOP-4098: GU Clinical	QH
Hair, nails & skin	Detection of dermatophytes for the purpose of clinical diagnosis	Microscopy and culture using SOP-1627 SOP-1625	QH
MRSA swabs & pre- admission swabs, Neonatal screens, ESBL and CRE screens.	Microscopy, Culture & detection of microorganisms for the purpose of clinical diagnosis	SOP-1467 SOP-4182 SOP-4181	QH
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	SOP-1157 and SOP-2243 in conjunction with equipment manual using Sysmex UF5000 by flourescence flow cytometry	QH
Urine	Culture of microorganisms for the purpose of clinical diagnosis	SOP-8735 using Previ Isola media processor	QH



Schedule of Accreditation issued by

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

Barking, Havering & Redbridge University Hospitals NHS Trust

Issue No: 008 Issue date: 20 November 2024

	Type of test/Properties	Standard specifications/	Location
Materials/Products tested	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY FLUIDS AND TISSUE (cont'd)	Microbiology examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods	
Whole blood Human body fluids and	Acid Alcohol Fast bacilli – Culture & detection	BD BACTEC MGIT 960	QH
tissue		Colorimetric sensor and detection technology detects microorganisms by tracking CO2 production. SOP-1919 SOP-1913 SOP-5678	
Respiratory secretions	Microscopy, Culture & detection of microorganisms for the purpose of clinical diagnosis	SOP-1920	QH
Faeces	C.difficile antigen & toxin detection:		QH
		Launch DS2 analyser Using Techlab C.diff Chek 60 GDH test kit by Enzyme immunoassay SOP-3236	QH
		Manual Techlab C.diff quik Check Complete test kit. Toxin detection using Immunochromatographic method SOP-3113	QH
		Manual Techlab Tox A/B Quik Check kit. SOP-3114	QH
Bacterial isolate	Antigen detection E. coli 0157	Prolex E.coli O157 latex test kit Latex particle agglutination test. SOP-3235	QH
Faeces	Rotavirus & adenovirus antigen detection	CertestRota Adeno test kit. Immunochromatographic method SOP-10212	QH



Schedule of Accreditation issued by

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

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Issue No: 008 Issue date: 20 November 2024

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)	Microbiology examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods	
Bacterial isolate	Identification of pathogens of clinical significance		QH
		Manual biochemical methods SOP-1565 SOP-2469 SOP-5607 SOP-1546 SOP-2187 SOP-2495 SOP-2496 SOP-2485 SOP-2485 SOP-2485 SOP-2484 SOP-2538 SOP-2487 SOP-2538 SOP-1557 SOP-1557 SOP-1558 SOP-3234 SOP-5536 SOP-2532 SOP-1549 SOP-2484 SOP-1564 SOP-7003 SOP-2484 SOP-2492 SOP-2492 SOP-2530 SOP-3543	QH
		Antibody/ antigen agglutination methods SOP-2534 SOP-2534 SOP-2494	QH
Fungal isolates	Identification of Candida albicans	Microscope Leitz laborlux using microscopy SOP-2491: Germ tube	QH



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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)	Microbiology examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods	
Whole blood Human body fluids and	Microscopic analysis	Microscope Leitz laborlux using microscopy	QH
tissue		Stains used in the identification of bacteria SOP-1487: Gram Stain	
Faeces	Detection Ova Cysts and Parasites	Parasep concentration and microscopy SOP-1525 SOP-3238: Modified auramine phenol stain for cryptosporidia	QH
Bacterial isolate	Antibiotic susceptibility testing on clinically significant bacterial isolates	Performed by disc susceptibility and MIC by E Test gradiant dilution using EUCAST methology SOP-11299	QH
Screening samples	Screening for antibiotic resistance	Performed by disc susceptibility using SOP-4182 SOP-7013	QH
Urine	Urinary antigen detection		
	Legionella pneumophila	Binax NOW Legionella urinary antigen card kit Immunochromatographic method SOP-2824	KGH
	Streptococcus pneumonieae	Pneumococcal Antigen using Binax NOW Streptococcus pneumonieae urinary antigen card (kit) SOP-2825	KGH
Nasopharyngeal aspirate	Antigen detection - respiratory Syncytical Virus	Binax NOW RSV test kit Immunochromatographic method SOP-2972	KGH



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Issue No: 008 Issue date: 20 November 2024

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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Microbiology examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods	
	Antibody and or antigen detection:	Biomerieux Vidas analyser Enzyme-linked fluorescent immunoassays	KGH
Blood / Serum	Hepatitis B surface Antigen	SOP-1960	
Blood / Serum	HIV quick Duo	SOP-1974	
Blood / Serum	CMV IgG	SOP-1993	
Blood / Serum	Anti HAV Total	SOP-2025	
Blood / Serum	Mumps IgG	SOP-2086	
Blood / Serum	Rubella IgM	SOP-2090	
Blood / Serum	Toxoplasma competition	SOP-2179	
Blood / Serum	Varicella Zoster IgG	SOP-2180	
Blood / Serum	Anti-HCV	SOP-4950	
Faeces	Antigen detection - Helicobacter pylori antigen	Launch DS2 analyser Using Premier Platinum HpSA Plus test kit by Enzyme immunoassay (EIA) SOP-2828	КСН
Blood	Antibody detection of Measles	VIDAS Using NovaLisa Measles IgG test kit by Enzyme immunoassay (EIA) SOP-5919	KGH
Plasma	Detection of Quantiferon TB (Interferon γ Release Assay (IGRA)	Quantiferon Plus Gold TB ELISA kit and SOP 11491 and 11503	QH



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Issue No: 008 Issue date: 20 November 2024

Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Microbiology examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods	
Detection of DNA for Neisseria gonorrhoeae	Aptima GC assay	KGH
Detection of Chlamydia trachomatis, Neisseria gonnorhoeae	Aptima Combo 2 CT/GC assay	
Mycoplasma genitalium	Aptima Mycoplasma genitalium assay	
	Hologic Panther	
	SOP 13794, 13907	
Screening Detection of SARS- CoV-2 (COVID-19) RNA; specific S gene	BD MAX Using Real time PCR detection and kit CerTest Viasure SARS-CoV-2 S gene SOP 12579	КСН
Identification of bacterial and yeast isolates	Bruker MALDI Biotyper sirius automated identification of bacteria and yeasts using Sepsityper SOP-13779	QH
	Microbiology examination activities for the purposes of clinical diagnosis (cont'd)Detection of DNA for Neisseria gonorrhoeaeDetection of Chlamydia trachomatis, Neisseria gonnorhoeaeMycoplasma genitaliumScreening Detection of SARS- CoV-2 (COVID-19) RNA; specific S geneIdentification of bacterial and	measured/Range of measurementStandard specifications/ Equipment/Techniques usedMicrobiology examination activities for the purposes of clinical diagnosis (cont'd)In house documented methodsDetection of DNA for Neisseria gonorrhoeaeAptima GC assayDetection of Chlamydia trachomatis, Neisseria gonnorhoeaeAptima Combo 2 CT/GC assayMycoplasma genitaliumAptima Mycoplasma genitalium assayScreening Detection of SARS- CoV-2 (COVID-19) RNA; specific S geneBD MAX Using Real time PCR detection and kit CerTest Viasure SARS-CoV-2 S gene SOP 12579Identification of bacterial and yeast isolatesBruker MALDI Biotyper sirius automated identification of bacteria and yeasts using Sepsityper



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	<u>Microbiology examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis</u> (cont'd)	Documented -in-house methods to meet the requirements of the Infectious diseases in pregnancy (IDPS) screening programme as defined in the July 2018 Infectious diseases in pregnancy screening: laboratory QA evidence requirements (targets indicated with *)	
	Antibody and or antigen detection:	Abbott Alinity analyser Detection of antibody and or antigens using Chemiluminescent Microparticle Immunoassay (CIMA) technology:	КСН
Blood / Serum	Hepatitis B surface antigen*	Alinity HBs Ag Titre SOP-13748	
Blood / Serum	Syphilis TP*	Alinity Syphilis TP SOP-13755	
Blood / Serum	Rubella IgG	Alinity Rubella IgG SOP-13753	
Blood / Serum	Anti-HBe	Alinity Anti HBe SOP-13742	
Blood / Serum	Anti-HBclgM	Alinity Anti-HBc-IgM SOP-13744	
Blood / Serum	Anti-HBc	Alinity Anti HBc II SOP -13741	
Blood / Serum	HAVAb IgM	Alinity Hep-A IgM SOP-13749	
Blood / Serum	Anti-HCV	Alinity Anti-HCV SOP-13745	
Blood / Serum	HBeAg	Alinity HBe Ag SOP-13747	
Blood / Serum	Anti-HBs	AlinityAnti HBs SOP-13743	
Blood / Serum	CMV IgM	Alinity CMV IgM SOP-13746	



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HUMAN BODY FLUIDS AND TISSUE (cont'd)	Microbiology examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods	
	Antibody and or antigen detection: (cont'd)		
Blood	Antibody detection - Mycoplasma	Serodia-Myco II test kit Indirect agglutination using gelatine particles SOP-1921	KGH
Blood	Antigen detection Anti- Streptolysin O	Biokit Latex particle agglutination kit SOP-1912	KGH
Blood	Antibody detection of HIV1 & HIV2	Geenius HIV 1 / 2 Confirmatory Assay Indirect solid phase enzyme immunoassay (EIA) SOP-8640	КСН
	END		1