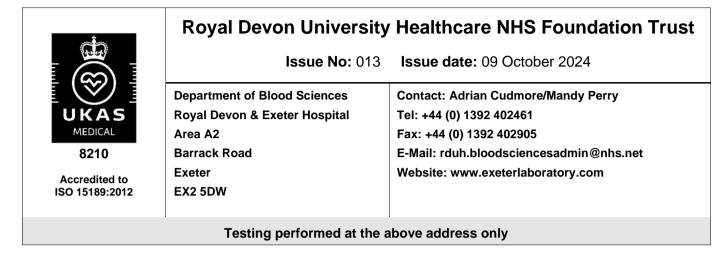
Schedule of Accreditation

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Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity
Department of Blood Sciences Royal Devon & Exeter Hospital Template A Barrack Road Exeter	Contact: Adrian Cudmore 01392 402936	Clinical Chemistry including Fetal Anomaly Screening Programme
EX2 5DW	Adrian Cudmore 01392 402936	General Haematology including Sickle cell and thalassaemia screening
	Adrian Cudmore 01392 402936	Blood transfusion including storage & issue of blood and blood products
	Adrian Cudmore 01392 402936	Special Haematology including Molecular Haematology
	Adrian Cudmore 01392 402936	Immunology

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UKAS	Royal Devon University Healthcare NHS Foundation Trust
8210 Accredited to ISO 15189:2012	Issue No: 013 Issue date: 09 October 2024

Site activities performed away from the locations listed above:

Location details	Activities
Phlebotomy department Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	Venepuncture and collection of blood for diagnostic purposes
Haematology Wards Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	Fridge for storage & issue of blood and blood products only
Maternity Ward Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	Fridge for storage & issue of blood and blood products only
Main theatre Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	2 Fridges for storage & issue of blood and blood products only
Orthopaedic centre Royal Devon and Exeter NHS Foundation Trust Barrack Road Exeter EX2 5DW	Fridge for storage & issue of blood and blood products only
Tiverton Hospital Kennedy Way EX16 6NT	Fridge for storage & issue of blood and blood products only
Sidmouth Hospital Herdons Lane All Saints Road EX10 8EW	Fridge for storage & issue of blood and blood products only
Nightingale Hospital Moor Lane EX2 7JG	Blood fridge for storage & issue of blood and blood products only



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

8210 Accredited to ISO 15189:2012 Royal Devon University Healthcare NHS Foundation Trust

Issue No: 013 Issue date: 09 October 2024

Testing performed at main address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	Biochemistry examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.
		CC/SOP/0284
Serum from venous and capillary collection	Albumin	Colourimetric, BCG
Serum from venous and capillary collection	Alkaline phosphatase	Colourimetric, IFCC
Serum from venous and capillary collection	Alanine aminotransferase	Kinetic, IFCC without PP activation
Serum from venous and capillary collection	Protein (total)	Kinetic, IFCC without PP activation
Serum from venous and capillary collection	Iron	Colourimetric, Biuret
Serum from venous and capillary collection	Magnesium	Colourimetric, Xylidyl Blue
Serum from venous and capillary collection	Cortisol	Competitive ECLIA
Serum from venous and capillary collection	Folate	Competitive ECLIA
Serum from venous and capillary collection	FT3	Competitive ECLIA
Serum from venous and capillary collection	FT4	Competitive ECLIA
Serum from venous and capillary	Oestradiol	Competitive ECLIA
collection Serum from venous and capillary collection	Progesterone	Competitive ECLIA
Serum from venous and capillary collection	Testosterone	Competitive ECLIA
Serum from venous and capillary collection	Vitamin D total	Competitive ECLIA



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology
		Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies
		CC/SOP/0284
Serum from venous and capillary collection	HDL-Cholesterol	Enzymatic Colourimetric, CHER
Serum from venous and capillary collection	Cholesterol (total)	Enzymatic Colourimetric, ID/MS standardisation
Serum from venous and capillary collection	γ-Glutamyltransferase	Enzymatic Colourimetric, IFCC
Serum from venous and capillary collection	Triglycerides	Enzymatic Colourimetric, Wahlefeld
Serum from venous and capillary	Transferrin	Immunoturbidiometric
collection Serum from venous and capillary	IgA	Immunoturbidiometric, Tina-quant
collection Serum from venous and capillary	IgG	Immunoturbidiometric, Tina-quant
collection Serum from venous and capillary	IgM	Immunoturbidiometric, Tina-quant
collection Serum from venous and capillary	Chloride	Indirect ISE
collection Serum from venous and capillary	Urea	Kinetic, Urease
collection Serum from venous and capillary	hsCRP	Particle enhanced
collection Serum from venous and capillary	Active B12	Immunotubidimetric assay, Latex Sandwich ECLIA
collection Serum from venous and capillary	CA 125	Sandwich ECLIA
collection Serum from venous and capillary	Ferritin	Sandwich ECLIA
collection Serum from venous and capillary	IGF-1	Sandwich ECLIA
collection Serum from venous and capillary	FSH	Sandwich ECLIA
collection Serum from venous and capillary collection	LH	Sandwich ECLIA



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.
		CC/SOP/0284
Serum from venous and capillary collection	Prolactin	Sandwich ECLIA
Serum from venous and capillary collection	PSA (total)	Sandwich ECLIA
Serum from venous and capillary	SHBG	Sandwich ECLIA
collection Serum from venous and capillary	TSH	Sandwich ECLIA
collection Serum from venous and capillary	Creatine kinase	UV-Test, IFCC
collection Serum from venous and capillary	Anti-SARS-CoV-2	Sandwich ECLIA
collection Serum from venous and capillary	Anti-SARS-CoV-2 S	Sandwich ECLIA (double antigen)
collection Serum from venous and capillary	Creatinine	Enzymatic, Creatininase
collection and urine Serum from venous and capillary	Sodium	Indirect ISE
collection and urine Serum from venous and capillary collection and urine	Urate	Enzymatic Colourimetric, Uricase
Venous Serum	Bilirubin (total)	Colourimetric, Diazo
Venous Serum	Ethanol	Enzymatic, Alcohol Dehydrogenase
Venous Serum	Paracetamol	Colourimetric, Arylacylamidase
Venous Serum	Bile acids	Colourimetric, HSD



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.
		CC/SOP/0284
Venous Serum	Lactate	Colourimetric, LOD
Venous Serum	Calcium (total)	Colourimetric, NM-BAPTA
Venous Serum	Lithium	Colourimetric, Porphyrin
Venous Serum	Anti-Thyroglobulin	Competitive ECLIA
Venous Serum	Anti-TPO	Competitive ECLIA
Venous Serum	Cyclosporin	Competitive ECLIA
Venous Serum	Digoxin	Competitive ECLIA
Venous Serum	Tacrolimus	Competitive ECLIA
Venous Serum	Vitamin B12	Competitive ECLIA
Venous Serum	Amylase	Enzymatic Colourimetric, IFCC
Venous Serum	Ammonia	Enzymatic, Glutamate dehydrogenase
Venous Serum	Angiotensin converting enzyme	Enzymatic, KK-ACK



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

Royal Devon University Healthcare NHS Foundation Trust

Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies
		CC/SOP/0284
Venous serum	Complement C3	Immunotubidometric, Tina-quant
Venous serum	Complement C4	Immunotubidometric, Tina-quant
Venous serum	Carbamazepine	KIMS
Venous serum	Phenytoin	KIMS
Venous serum	Thophylline	KIMS
Venous serum	Vancomycin	KIMS
Venous serum	Phosphate	Molybdate UV, Molybdate
Venous serum	CRP	Particle enhanced Immunotubidimetric assay, Tina- quant
Venous serum	AFP	Sandwich ECLIA
Venous serum	АМН	Sandwich ECLIA
Venous serum	Beta-HCG	Sandwich ECLIA
Venous serum	CA 15-3	Sandwich ECLIA
Venous serum	CA 19-9	Sandwich ECLIA
Venous serum	CEA	Sandwich ECLIA
Venous serum	Free beta hCG	Sandwich ECLIA



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

Royal Devon University Healthcare NHS Foundation Trust

Issue No: 013 Issue date: 09 October 2024

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.
		CC/SOP/0284
Venous Serum	hGH	Sandwich ECLIA
Venous Serum	hs Troponin T hs	Sandwich ECLIA
Venous Serum	IgE	Sandwich ECLIA
Venous Serum	PAPP-A	Sandwich ECLIA
Venous Serum	PIGF	Sandwich ECLIA
Venous Serum	proBNP	Sandwich ECLIA
Venous Serum	PTH	Sandwich ECLIA
Venous Serum	sFlt-1	Sandwich ECLIA
Venous Serum	Anti-CCP	Sandwich ECLIA (IgG-Capture)
Venous Serum	Lactate dehydrogenase	UV-Test, IFCC
Venous Serum	Bicarbonate	Enzymatic, PEP
Venous Serum	Bilirubin (direct)	Enzymatic, Vanidate Oxidation
Venous Serum	Tobramycin	Enzyme Immunoassay
Venous Serum	Gentamycin	Enzyme Immunoassay, CEDIA
Venous Serum	Methotrexate	Enzyme Immunoassay, EMIT



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.
		CC/SOP/0284
Venous serum	Salicylate	Enzyme Mediated Colourimetric, Hydroxylase
Venous serum	Ceruloplasmin	Immunoturbidometric
Venous serum	Rheumatoid factor	Immunoturbidometric
Venous serum	Free kappa light chains	Immunoturbidometric, Freelite
Venous serum	Free lambda light chains	Immunoturbidometric, Freelite
Venous serum	Alpha-1-antitrypsin	Immunoturbidometric, Tina-quant
Venous serum	Beta-2 microglobulin	Immunoturbidometric, Tina-quant
Venous Serum and urine	Amylase	Enzymatic Colourimetric, IFCC
Venous Serum and urine	Potassium	Indirect ISE
Venous Serum and plasma	Insulin	Sandwich ECLIA
Venous Serum, plasma and urine	C-peptide	Sandwich ECLIA
CSF	Lactate	Colourimetric, LOD
CSF, urine	Protein	Turbidimetric
CSF, urine, venous serum	Glucose	UV-Test, Hexokinase
Urine	Calcium	Colourimetric, NM-BAPTA
Urine	Magnesium	Colourimetric, Xylidyl Blue



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		Roche Cobas 8000 modular system - Spectrophotometric, immunoassay, indirect ion selective electrode methodologies.
		CC/SOP/0284
Urine	MicroAlbumin	Immunoturbidometric, Tina-quant
Urine	Amphetamines	KIMS
Urine	Benzodiazepines	KIMS
Urine	Cannabinoids	KIMS
Urine	Cocaine	KIMS
Urine	Methadone	KIMS
Urine	Opiates	KIMS
Urine	Urea	Kinetic, Urease
Urine	Phosphate	Molybdate UV, Molybdate
		By calculation
Urine	Creatinine Clearance	CC/SOP/0119
Venous serum	Adjusted Calcium	
Venous serum	sFlt-1/PIGF	
Venous serum	Acute Kidney Injury	Calculated using renal registry national algorithm
Venous serum	GFR	MDRD EPI calculation
Venous serum	Urine-C-peptide creatinine ratio	



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		By calculation
Venous serum	Non-HDL cholesterol	CC/SOP/0119
Urine	Albumin/creatinine ratio	
Venous serum	Free lambda/kappa ratio	
Venous serum	Free kappa/lambda ratio	
Venous serum	Schwartz eGFR	
		Dynex DS2 Automated ELISA system
Venous serum	Adalimumab antibody (total)	CC/SOP/0279
Venous serum	Adalimumab drug levels	CC/SOP/0262
Venous serum	GAD antibody	BS/SOP/0033
Venous serum	IA2 antibody	BS/SOP/0035
Venous serum	Infliximab antibody (total)	CC/SOP/0261
Venous serum	Infliximab drug levels	CC/SOP/0260
Venous serum	Ustekinumab drug levels	CC/SOP/907
Venous serum	Vedolizumab antibody (free)	CC/SOP/903
Venous serum	Vedolizumab drug levels	CC/SOP/0262
Venous serum	Zinc Transporter 8 antibody	BS/SOP/0037
Faeces	Faecal Calprotectin	Mast OC Sensor Pledia Mast OC Pledia Calprotectin SOP v01



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

Royal Devon University Healthcare NHS Foundation Trust

Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
		HM-Jack ARC using immunotubidimetry detection by integrated sphere turbidimetry
Faeces	FIT (faecal immunochemical test)	CC/SOP/0309
Venous serum and urine	Osmolarity	Osmo 1 Single Sample Micro- osmometer CC/SOP/0025
Sweat	Chloride	Manual method Chloride meter (Coulometry) CC/SOP/0053



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Haematology examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
	Full Blood Count including the following parameters:	Sysmex XN9100
	Heemeelebin	Electrical impedance, laser light scatter & dye bonding
EDTA whole blood from venous or capillary collection	Haemoglobin	HASOPXN9100
EDTA whole blood from venous or capillary collection	White cell count	
EDTA whole blood from venous or capillary collection	Platelet count	
EDTA whole blood from venous or capillary collection EDTA whole blood from venous or capillary collection	Red blood cell count Haematocrit	
EDTA whole blood from venous collection	MCV	
EDTA whole blood from venous collection	МСН	
EDTA whole blood from venous collection	RDW	
EDTA whole blood from venous collection EDTA whole blood from venous	Neutrophil count	
collection EDTA whole blood from venous	Monocyte count	
collection EDTA whole blood from venous	Eosinophil count	
collection EDTA whole blood from venous collection	Basophil count	
EDTA whole blood from venous collection	RET-He	
Bone marrow	Manual differential	Stained using RAL stainer HASOP RAL stainer
EDTA whole blood	Manual differential	Automated stainer SP-50 HASOPSP-50



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Haematology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Urine	Urinary Haemosiderin	Manual staining HASOPS-0014
CSF	Morphology	Shandon Cytospin Manual staining Microscopy HASOPM-0001
Bone marrow	Bone marrow morphology	Manual staining HASOP RAL Stainer
Bone marrow	Iron	Manual staining HASOPS-0008
EDTA whole blood	Components of haemoglobinopathy screen for the detection of haemoglobin variants/thalassaemia (Including antenatal screening programme):	Capillary electrophoresis HASOPTHAL
	HbA2	
	HbF	
	HbS	
EDTA whole blood	Automated cell count – Haematopoietic Progenitor Cell Count (HPC)	Sysmex based flow cytometric assay HASOPHPC
EDTA whole blood	Detection of HRP2 and pLDH antigens for the identification of Malaria parasites	CareUS test using an immunoassay by laminar flow HASOPM-0032



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Haematology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
EDTA whole blood	Malaria Blood films	Blood Film review using Giesma (thin film) and Field's (thick film) stains HASOPS-0009
EDTA whole blood	Detection of <i>Plasmodium</i> mitochondrial DNA	Loop-mediated amplification using the ILLumiGene assay HASOPO-0012
EDTA whole blood	Blood film for Morphology	Blood smears stained with May- Grunwald and Giemsa stains HASOPSP-50 HASOP RAL Stainer
EDTA whole blood	Erythrocyte Sedimentation Rate (ESR)	Manual method using Becton Dickinson Seditainer Tubes HASOPM-0004
EDTA whole blood	Sickle Cell Solubility (SDX)	Sickledex test kit using a turbidometric assay HASOPM-0020
EDTA Plasma and serum	Glandular Fever screen	Monogen test using latex agglutination HASOPM-0007
EDTA whole blood from venous or capillary collection	HbA1c (Glycated Haemoglobin)	Sebia Capillarys Tera Capillary electrophoresis HASOPGHB



Schedule of Accreditation issued by ited Kingdom Accreditation Servi

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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Haematology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Citrated whole blood	Coagulation screening:	IL TOPS analyser using Turbidimetric assay HASOPC-0024
Citrated whole blood	Routine coagulation screen	
Citrated whole blood	Prothrombin time	
Citrated whole blood	INR	
Citrated whole blood	APTR	
Citrated whole blood	Thrombin Time	Clot detection HASOPC-0018
Citrated whole blood	Liquid Heparin	One stage chromogenic assay HASOPC-0040
Citrated whole blood	Clauss Fibrogen	Clot detection HASOPC-0024
Citrated whole blood	Coagulation Factors 2, 5, 7,8, 9, 10,11 and 12	One stage factor assay HASOPC-0035
Citrated whole blood	Coagulation Factor Inhibititor Assay	Bethesda Assay HASOPC-0017
Citrated whole blood	Von Willebrand Factor Antigen	Immunoturbidometric assay for vWF Antigen HASOPC-0026
Citrated whole blood	Von Willebrand Factor Activity	Immunoturbidometric assay for vWF Activity HASOPC-0027



Schedule of Accreditation issued by ited Kingdom Accreditation Servi

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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Haematology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Citrated whole blood	Thrombophilia screen:	ACL 550 analyser
Citrated whole blood	Lupus Anticoagulant	Direct Russels Viper Venom time HASOPC-0014
Citrated whole blood	Antithrombin	Chromogenic assay HASOPC-0011
Citrated whole blood	Free Protein S	Latex Agglutination HASOPC-0013
Citrated whole blood	Protein C	Chromogenic assay HASOPC-0025
Citrated whole blood	Direct oral anticoagulants: • Apixaban • Rivaroxaban	DOAC assay HASOPC-0048



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Blood Transfusion examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Blood grouping (ABO and RhD) and antibody screening	BioRad IH500 analyser using column agglutination technology TRLP0103
Antibody identification: Detection of antibodies to the following antigen: D, C, c, E, e, Cw, V, K, k, Kpa, Kpb, Eva Evb Jka Jkb Lea Jeb P1 M	Manual technique using BioRad column agglutination technique TRLP0020
N, S, s, Lua, Lub, Xga	BioRad IH500 analyser using column agglutination technology TRLP0056
Blood grouping (ABO and RhD)	Manual direct agglutination tube technique TRLP0009
Manual ABO/D for Newborns	Manual techniques using BioRad column agglutination technology TRLP0010
Direct Antiglobulin Test: detection of IgG, IgA, IgM, C3d, C3c on the surface of red cells	Manual technique using BioRad column agglutination technology
	Automated method using BioRad IH500 column agglutination TRLP0017
Red cell antigen phenotyping: detection of antigen types: C, c, E, e, K	Automated method using BioRad IH500 column agglutination TRLP0084
	 measured/Range of measurement Blood Transfusion examination activities for the purpose of clinical diagnosis Blood grouping (ABO and RhD) and antibody screening Antibody identification: Detection of antibodies to the following antigen: D, C, c, E, e, Cw, V, K, k, Kpa, Kpb, Fya, Fyb, Jka, Jkb, Lea, Leb, P1, M, N, S, s, Lua, Lub, Xga Blood grouping (ABO and RhD) Manual ABO/D for Newborns Direct Antiglobulin Test: detection of IgG, IgA, IgM, C3d, C3c on the surface of red cells Red cell antigen phenotyping: detection of antigen types:



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
EDTA whole Blood	Detection of A subgroup	A1 test: manual using tube technology TRLP0080
EDTA whole Blood	Feto-maternal haemorrhage	Manual test using Guest Medical acid elution technique TRLP0019
EDTA whole Blood	Weak/Partial D testing	Manual technique using BioRad column agglutination technology TRLP0031
EDTA whole Blood Plasma	Antibody titration	Manual technique using BioRad column agglutination technology
		Automated method using BioRad IH500 column agglutination TRLP0043
EDTA whole Blood Plasma	Crossmatch- Compatibility testing of patient plasma with donor cells	Manual serological crossmatch using BioRad column agglutinin IAT TRLP0029
		Electronic Crossmatch TRLP0098
		Manual Neonatal serological Crossmatching using BioRad column agglutination TRLP0041



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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Blood	Cryoglobulins	Manual methodology HASOPP-0005
Serum	Protein analysis and monoclonal band quantification: gamma globulins, beta-2 globulins, beta-1 globulins, alpha-2 globulins, alpha-1 globulins albumin	Sebia Capillarys 2 using capillary zone electrophoresis HASOPP-0008
Urine	Bence-Jones protein	Sebia Hydrasys 2 using agarose gel electrophoresis HASOPP-0007 HASOPP-0009
Blood, urine	Paraprotein typing: IgG, IgM, IgA, IgD, IgE, kappa, Iambda	Sebia Hydrasys 2 using agarose gel electrophoresis immunofixation HASOPP-0007
Serum	Anti-nuclear antibodies screen	IL Quantalyser 2 using immunofluorescence Hep2 method IMSOPI21, IMSOPI27, IMSOPI68, IMSOPI69
Serum	Smooth muscle antibodies Mitochondrial antibodies Liver and kidney microsomal antibodies	LKS method



Schedule of Accreditation issued by ited Kingdom Accreditation Servi

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

Royal Devon University Healthcare NHS Foundation Trust

Accredited to ISO 15189:2012 Issue No: 013 Issue date: 09 October 2024

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Serum	IgG antibodies against the GBM (glomerular basement membrane) antigen	Phadia 250 ELISA IMSOPI33, IMSOPI70
Serum	IgG antibodies against MPO (myeloperoxidase) antigen	IMSOPI35, IMSOPI70
Serum	IgG class autoantibodies directed against PR3 (proteinase 3) antigen	IMSOPI36, IMSOPI70
Serum	Autoimmune test – Beta 2 glycoprotein 1 (B2GP-1); components for IgM and IgG	IMSOPI42, IMSOPI70
Serum	ENA screen and ENA profile	MSOPI71
Serum	Tissue Transglutaminase	IMSOPI42
Serum	Cardiolipins; components for IgG and IgM	IMSOPI29, IMSOPI70
Serum	IgG antibodies directed Double stranded DNA (dsDNA)	IMSOPI30, IMSOPI70
Serum	TSH Receptor Antibodies	IMSOPI76
Serum	Intrinsic Factor Antibodies	IMSOPI73
Serum	IgG antibodies directed to M2	IMSOPI70
Serum	Specific IgE to:	IMSOPI66, IMSOPI70
	Almond Aspergillus fumigatus Blue Mussel Brazil nut Cashew nut Cat epithelium and dander	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Serum	Specific IgE to:	Phadia 250 ELISA
Serum	Cheddar cheese Coconut Common wasp Dog dander Egg white Egg yolk Feather mix: • Goose • Chicken • Duck • Turkey • Fish (cod) • Gluten Grass pollen mix: • Cocksfoot • Meadow fescue • Rye • Timothy • Meadow Hazel nut Honey bee Horse dander	Phadia 250 ELISA IMSOPI66, IMSOPI70
	House dust mite Kiwi Latex Macadamia nut Milk	
	 Mould mix: Penicillium chrysogenum Clodosporium herbarum Aspergillus fumigatus Alternaris alternata 	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Serum (cont'd)	Specific IgE to: (cont'd)	Phadia 250 ELISA
	Peanut Pecan nut Pine nut pignols Pistashio nut Rabbit epithelium Sesame seed Shrimp Soya bean Strawberry Specific IgE to: Tomato Tree pollen mix: • Box elder • Silver birch • Oak • Elm • Walnut Walnut Walnut Weed pollen mix: • Ambrosia artemisiifolia • Artemisia vulgaris • Plantago lanceolata • Chenopedium album	IMSOPI66, IMSOPI70
	END	