Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Blood Sciences Laboratory Pathology Laboratory Stoke Mandeville Hospital Stoke Mandeville	Local contact: Venkat Nadella	Haematology Biochemistry Blood Transfusion Immunology	A
Blood Sciences Laboratory Pathology Laboratory Wycombe Hospital, Queen Alexandra Road, High Wycombe, Bucks	Local contact: Venkat Nadella	Haematology Biochemistry Blood Transfusion	В

Site activities performed away from the locations listed above:

Location details	Activity
Stoke Mandeville Hospital – New Wing	Storage of Blood products
Stoke Mandeville Hospital – Maternity	Storage of Blood products
Stoke Mandeville Hospital – Cancer Care and Haematology Day Unit	Storage of Blood products
Wycombe Hospital – Cancer Care and Haematology Day Unit	Storage of Blood Products

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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 Blood Juine Blood Juine Blood Juine Blood Juine Blood Juine Blood Juine Blood Juine Blood Juine		Equipment/Techniques used In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: Photometric assays Location A = Abbott Architect C8000/C16000 Location B = Abbott Architect C8000 BS-SOP-B7	Code A,B A,B A,B A,B A,B A,B A,B A,B A,B A,B

DETAIL OF ACCREDITATION

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HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology: Enzymatic Colourimetric assays Location A = Abbott Architect C8000/C16000 Location B = Abbott Architect C8000 BS-SOP-B7	

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Human Body Fluids (cont'd) Serum or Plasma unless otherwise stated:	Biochemistry examination activities for the purpose of clinical diagnosis: (cont'd)	Abbott Architect C8000/C16000 Stoke Mandeville Abbott Architect C16000 x 1 and C8000 x 2 and ISR 2000 x 2 and standalone ISR2000 Wycombe Hospital Abbott Architect Chemistry/ISR2000 Enzymatic Colourimetric and in-house method: BS SOP B7	
Blood Blood Blood Blood Blood Blood Blood, CSF Blood, CSF	ACE Salicylate Ammonia Ethanol (repeat test) Glucose Lactate Glucose Lactate (repeat test) Total Protein		B A,B A,B A,B A,B A,B A,B A,B
Blood, urine Blood Blood Blood Blood Blood, urine Blood Blood	Albumin Bilirubin Bilirubin Direct Bilirubin Indirect - calculated Iron Lithium Total Protein Total Globulins - calculated Bile Acids	Colourimetric assays Location A = Abbott Architect C8000/C16000 Location B = Abbott Architect C8000 BS-SOP-B7	A,B A,B A,B A,B A,B A,B A,B A,B A

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HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
		Immunoturbidimetric assays Location A = Abbott Architect C8000/C16000 Location B = Abbott Architect C8000 BS-SOP-B7	
Blood Blood Urine	C-Reactive Protein Transferrin Microalbumin		A,B A,B A,B
		Particle-enhanced turbidimetric inhibition immunoassay – (PETINA) Location A = Abbott Architect C8000/C16000 Location B = Abbott Architect C8000 BS-SOP-B7	
Blood Blood Blood Blood	Digoxin Gentamicin Vancomycin Teicoplanin		A,B A,B A,B A
		Ion selective electrode (ISE) Indirect assays Location A = Abbott Architect C8000/C16000 Location B = Abbott Architect C8000 BS-SOP-B7	
Blood, urine Blood, urine Blood, urine	Chloride Potassium Sodium		A,B A,B A,B

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
Blood Blood Blood Blood	Phenytoin Theophylline Carbamazepine Sodium Valproate	Enzyme Immunoassay Location A = Abbott Architect C8000/C16000 Location B = Abbott Architect C8000 BS-SOP-B7	A,B A,B A A
		Chemiluminescent Microparticle Immunoassay (CMIA) – non- competitive Location A = Abbott Architect ISR 2000 Location B = Abbott Architect ISR2000 BS-SOP-B8	
Blood Blood Blood Blood Blood	NT Pro-BNP Alpha Fetoprotein Anti TPO Beta hCG Carcino Embryonic Antigen		A,B A,B A,B A,B A,B
Blood Blood Blood Blood Blood Blood Blood Blood Blood Blood Blood	(CEA) CA125 CA153 CA 199 Ferritin Folate Free T3 Free T4 FSH Luteinising Hormone Oestradiol Macroprolactin – PEG dilution	BS-SOP-B10	A,B B A,B A,B A,B A,B A,B A,B A,B A,B
Blood Blood	Cortisol Progesterone		A,B A,B

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Biochemistry examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
		Chemiluminescent Microparticle Immunoassay (CMIA) – non- competitive Location A = Abbott Architect ISR 2000 Location B = Abbott Architect ISR2000 BS-SOP-B8	
Blood	Prolactin		A,B
Blood Blood Blood Blood Blood	Procalcitonin Total Prostate Specific Antigen Testosterone Thyroid Stimulating Hormone Free Androgen Index- calculation		A A,B A,B A,B A,B
Blood Blood Blood Blood	High Sensitivity Troponin I Vitamin B12 Vitamin D SHBG		A,B A,B A,B A
Blood	Intact Parathyroid Hormone	Chemiluminescent Microparticle Immunoassay (CMIA)-non- Sandwich assay Location A = Abbott Architect ISR 2000 Location B = Abbott Architect ISR2000 BS-SOP-B8	A,B
CSF	Xanthochromia	UVIKON XS double beam UV/Visible Spectrophotometer BS-SOP-B3	A
Sweat	Sweat Conductivity	Westcor SweatChek BS-SOP-B6	В
Sweat	Sweat chloride	Chlorocheck BS-SOP-B6	В

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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	Biochemistry examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
Blood, urine	Osmolality	Vitech Scientific Osmo1 BS-SOP-B15	A,B
Faeces	Calprotectin	Diasorin Liaison ELISA BS-SOP-B6	A
Blood	HbA1c	BioRad D100 HPLC BS-SOP-B4	A
Blood Urine Urine	Serum immunofixation Urine electrophoresis Urine fixation	Helena SAS-3 & SAS-4 Agarose gel electrophoresis BS-SOP-IV18 BS-SOP-IV43 BS-SOP-IV44 BS-SOP-IV45 BS-SOP-IV46	A A A
Dive		Helena V8 Capillary zone electrophoresis BS-SOP-IV18 BS-SOP-IV43 BS-SOP-IV44 BS-SOP-IV45 BS-SOP-IV46 BS-SOP-IV47	
Blood Blood Blood	Serum electrophoresis Serum immunodisplacement Paraprotein quantitation		A A A

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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	Haematology examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
		Differential laser light scatter using Sysmex XN automated analysers Location A = XN20 & XN10 Location B = XN20 & XN10 BS-SOP-H10	
Whole Blood (EDTA)	Haemoglobin		A,B
Whole Blood (EDTA)	White Blood Cell Count		A,B
Whole Blood (EDTA)	Red Blood Cell Count		A,B
Whole Blood (EDTA)	Haematocrit		A,B
Whole Blood (EDTA)	Mean Corpuscular Volume		A,B
	(MCV)		
Whole Blood (EDTA)	Mean Corpuscular		A,B
	Haemoglobin (MCH)		
Whole Blood (EDTA)	Mean Corpuscular Haemoglobin Concentration		A,B
Whole Blood (EDTA)	(MCHC) Platelet Count		A,B
Whole Blood (EDTA)			
Whole Blood (EDTA)	Red Cell Distribution Width		A,B
Whole Blood (EDTA)	(standard deviation) Red Cell Distribution Width (coefficient variation)		A,B
Whole Blood (EDTA)	Platelet distribution width		A,B
Whole Blood (EDTA)	Mean Platelet Volume		A,B
Whole Blood (EDTA)	Platelet large cell ratio		A,B
Whole Blood (EDTA)	Platelet Citrate count		A,B
Whole Blood (EDTA)	Nucleated Red Blood Cell		A,B
	Count		
Whole Blood (EDTA)	Neutrophil Absolute Count and		A,B
Whole Blood (EDTA)	Lymphocyte Absolute Count and %		A,B
Whole Blood (EDTA)	Monocyte Count Absolute Count and %		A,B
Whole Blood (EDTA)	Eosinophil Absolute Count and %		A,B
Whole Blood (EDTA)	Basophil Absolute Count and %		A,B

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HUMAN BODY FLUIDS	<u>Haematology examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
		Differential laser light scatter using Sysmex XN automated analysers Location A = XN20 & XN10 Location B = XN20 & XN10 BS-SOP-H10	
Whole Blood (EDTA) Whole Blood (EDTA)	Immature Granulocyte Count Reticulocyte Count Absolute Count and %		A,B A,B
Whole Blood (EDTA)	Immature Reticulocyte		A,B
Whole Blood (EDTA)	Reticulocyte Haemoglobin equivalent		A,B
Whole Blood (EDTA)	Immature Platelet Fraction		
Whole Blood (EDTA)	Erythrocyte Sedimentation Rate (ESR)	Vitech Starrsed analyser automated ESR BS-SOP-H12	A,B
Whole Blood (EDTA)	Erythrocyte Sedimentation Rate (ESR)	Westergren method using Monvette pipettes BS-SOP-H11	A,B
Whole Blood (EDTA)	Detection of Morphological Structure.	Microscopy manual blood film examination BS-SOP-H23	A,B
		Transfer of blood films between laboratories BS-SOP-H24	
Bone Marrow	Detection of Morphological Structure	Manual Bone Marrow Film Staining (Perls Iron Stain) & Microscopy BS-SOP-H8 BS-SOP-H18	A,B

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HUMAN BODY FLUIDS	Haematology examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
Whole Blood (EDTA)	Detection and identification of malarial parasites: Plasmodium falciparum Plasmodium vivax Plasmodium ovale Plasmodium malariae Trypanosomes Microfilariae	Staining and Microscopy Morphological examination Blood Borne Parasite Thin film (Giemsa stain) Thick film (Field's stain) BS-SOP-H8	A,B
		Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia (SCT) screening programme(s) as defined in the laboratory QA evidence requirement	
Whole Blood (EDTA)	Detection and identification of abnormal Haemoglobins A1, A2 and F and confirmation of Haemoglobin C, S, D and E	BioRad Variant II HPLC BS -SOP-H2	A
Whole Blood (EDTA)	Sickle solubility	Clin-tech sickle test screening kit BS-SOP-H10	A

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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	<u>Coagulation examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
		Sysmex CS-5100/CS2500 analysers	
Citrated Plasma	INR/Prothrombin time (PT)	Siemens Dade Innovin Reagent BS-SOP-C19 (PT/INR)	A,B
Citrated Plasma	Derived Fibrinogen	Master curve provided by Siemens during PT determinations BS-SOP-C19 (Derived fibrinogen)	A,B
Citrated Plasma	Clauss Fibrinogen	Siemens (Dade Behring) Thrombin assay BS-SOP-C06 (Clauss Fibrinogen)	A,B
Citrated Plasma	Thrombin time	Siemens Thromboclotin BS-SOP-C13 (Thrombin time)	A,B
Citrated Plasma	D-dimer	Siemens Innovance D-Dimer (PETINA) BS-SOP-C07(D dimer)	A,B
Citrated Plasma	Antithrombin III	Siemens Berichrom Antithrombin III Assay - quantitative kinetic test BS-SOP-C22	A
Citrated Plasma	Factor assays (VIII, IX, XI, XII) Factor IX	Siemens (Dade Behring) BS-SOP-C18 (Factor IX assay)	А
Citrated Plasma	Factor XI	Siemens (Dade Behring) BS-SOP-C27 (Factor XI)	А
Citrated Plasma	Factor VIII	Siemens One-Stage Factor VIII Assay - measured with APTT assay BS-SOP-C17	A

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Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Coagulation examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
	Sysmex CS-5100/CS2500 analysers	
Lupus anticoagulant	Siemens (Dade) Actin FSL APTT reagent & DRVV BS-SOP-C05 (LA)	A
	Sysmex CS-5100 analysers	А
Low Molecular Weight Heparin	Biophen Heparin LRT - chromogenic anti-Xa method BS-SOP-C09 (LMWH)	A
Protein C	Sysmex Berichrom Protein C Assay - chromogenic BS-SOP-C26 (Protein C)	A
Protein S	Sysmex Innovance Free PS Antigen Assay – turbidimetric BS-SOP-C23 (Protein S)	A
Apixaban	Biophen Heparin LRT Assay (Anti- Xa) - chromogenic anti-Xa method BS-SOP-C10 (Apixaban)	A
Rivaroxaban	Chromogenic anti-Xa method BS-SOP-C11 (Rivaroxaban)	А
Dabigatran	Hyphen BioMed Hemoclot Thrombin Inhibitors assay BS-SOP-C20 (Dabigatran)	A
	measured/Range of Coagulation examination activities for the purpose of clinical diagnosis Lupus anticoagulant Low Molecular Weight Heparin Protein C Protein S Apixaban Rivaroxaban	The assured/Range of measurementIn house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:Lupus anticoagulantSiemens (Dade) Actin FSL APTT reagent & DRVV BS-SOP-C05 (LA)Low Molecular Weight HeparinBiophen Heparin LRT - chromogenic anti-Xa method BS-SOP-C26 (Protein C)Protein CSysmex Berichrom Protein C Assay - chromogenic BS-SOP-C23 (Protein S)ApixabanBiophen Heparin LRT Assay (Anti- Xa) - chromogenic anti-Xa method BS-SOP-C11 (Rivaroxaban)RivaroxabanChromogenic anti-Xa method BS-SOP-C11 (Rivaroxaban)DabigatranHyphen BioMed Hemoclot Thrombin Inhibitors assay

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HUMAN BODY FLUIDS	<u>Transfusion examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u>	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:
Whole Blood (EDTA) Whole Blood (EDTA)	A Rh D Positive B Rh D Positive	Automated- Ortho Vision using Column Gel Technology BS-SOP-BT3
Whole Blood (EDTA)	AB Rh D Positive	

Type of test/Properties

	methodology:	
A Rh D Positive B Rh D Positive AB Rh D Positive O Rh D Positive A Rh D Negative B Rh D Negative AB Rh D Negative O Rh D Negative	Automated- Ortho Vision using Column Gel Technology BS-SOP-BT3	A,B A,B A,B A,B A,B A,B A,B A,B
	Ortho diagnostics Biovue IgG cards Biovue Neutral cards Resolve panel C (antibody panels) BioRad IgG grouping and DAT cassettes Indirect antiglobulin test Enzyme method Exclusion method (antibody panels) Manual method BS-SOP-BT25	
Rh - C,D,E,c,e,Cw Kell – K, Kpa ,k Duffy – Fya, Fyb MNSs – M, N, S, s Kidd – Jka, Jkb Lewis – Lea + Leb Lutheran – Lua P - P1		A,B A,B A,B A,B A,B A,B A,B A,B
Direct Antiglobulin Test (DAT)	Ortho Vision System DAT/IDAT cassettes Manual method BS-SOP-BT11	A,B
Rh/K Phenotype (CcEeK)	Ortho Vision System BS-SOP-BT58	A,B
	B Rh D Positive AB Rh D Positive O Rh D Positive A Rh D Negative B Rh D Negative O Rh D Negative O Rh D Negative With the set of th	A Rh D Positive Automated- Ortho Vision using Column Gel Technology BS-SOP-BT3 A Rh D Positive B Rh D Positive A Rh D Negative B Rh D Negative O Rh D Negative Ortho diagnostics Biovue IgG cards Biovue Neutral cards Resolve panel C (antibody panels) BioRad IgG grouping and DAT cassettes Indirect antiglobulin test Enzyme method Exclusion method (antibody panels) Manual method BS-SOP-BT25 Rh - C,D,E,c,e,CW Kell – K, Kpa ,k Duffy – Fya, Fyb MNSs – M, N, S, s Kidd – Jka, Jkb Lewis – Lea + Leb Lutheran – Lua P – P1 Direct Antiglobulin Test (DAT) Ortho Vision System DAT/IDAT cassettes Manual method BS-SOP-BT11 Rh/K Phenotype (CcEeK) Ortho Vision System

Location

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HUMAN BODY FLUIDS	Transfusion examination activities for the purpose of clinical diagnosis	In house documented procedures incorporating manufacturers' instructions where relevant using the following instrumentation and methodology:	
Whole Blood (EDTA)	Serological compatibility testing	Manual method BS-SOP-BT12	A,B
Blood film	Foetal Kleihauer	Manual method acid elution BS-SOP-BT8	A,B
Whole Blood (EDTA)	Antibody panels	Manual method using Ortho Biovue IgG and neutral cards	A,B
		BioRad IgG and neutral cards	
Whole Blood (EDTA)	Red Cell phenotype	Manual method using Ortho IgG or neutral cards	A,B
		Tube methods	
END			<u>.</u>