

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>9785</b> <b>Accredited to ISO 15189:2012</b>	<b>Liverpool University Hospitals NHS Foundation Trust</b>	
	<b>Issue No: 005   Issue date: 08 February 2024</b>	
	<b>Blood Sciences</b> Clinical support services building Liverpool University Hospitals NHS Foundation Trust Mount Vernon Street Liverpool L7 8YE	<b>Contact: Ines Santos</b> <b>Tel: +44 (0)151 706 4374</b> <b>E-Mail: Ines.Santos@liverpoolft.nhs.uk</b> <b>Website: www.liverpoolcl.nhs.uk</b>
<b>Testing performed by the Organisation at the locations specified below</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<b>Address</b> Liverpool University Hospitals NHS Foundation Trust Mount Vernon Street Liverpool L7 8YE  <b>Local contact</b> Ines SantosAs above	Haematology Blood Transfusion  Clinical Biochemistry Antenatal & Newborn Screening	A
<b>Address</b> Broadgreen Hospital / Liverpool Heart and Chest Hospital Thomas Drive Liverpool L7 3PE  <b>Local contacts</b> Ines SantosAs above	Haematology Blood Transfusion  Transfusion  Haematology Clinical Biochemistry	B
<b>Address</b> Liverpool Women's Hospital. Crown Street Liverpool L8 7SS  <b>Local contacts</b> Ines Santos As above	Haematology Blood Transfusion  Transfusion  Haematology	C



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**Site activities performed away from the locations listed above:**

Location details	Activity
Accident and Emergency Liverpool University Hospitals NHS Foundation Trust Mount Vernon Street Liverpool L7 8YE	Blood storage & issue Fridge managed by Haematology
Main Theatres Liverpool University Hospitals NHS Foundation Trust Mount Vernon Street Liverpool L7 8YE	Blood storage & issue Fridge managed by Haematology
Surgical ITU/wards Broadgreen Hospital /Liverpool Heart and Chest Hospital Thomas Drive Liverpool L7 3PE	Blood storage & issue Fridge managed by Haematology
Delivery Suite Liverpool Women's Hospital Crown Street Liverpool L8 7SS	Blood storage & issue Fridge managed by Haematology
Theatres Liverpool Women's Hospital Crown Street Liverpool L8 7SS	Blood storage & issue Fridge managed by Haematology



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**DETAIL OF ACCREDITATION**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Serum	Quantitative determination of:	<b>Roche Cobas 8000</b> (colorimetric) using	
	Urea	BS-CORE-SOP-10	A, B
	Bicarbonate	BS-CORE-SOP-123	A, B
	Glucose	BS-CORE-SOP-65	A, B
	Calcium	BS-CORE-SOP-110	A, B
	Creatinine (enzymatic)	BS-CORE-SOP-40	A, B
Serum	Phosphate	BS-CORE-SOP-122	A, B
Serum	Albumin	BS-CORE-SOP-25	A, B
Serum	Total protein	BS-CORE-SOP-102 & BS-CORE-SOP-124	A, B
Serum	Magnesium	BS-CORE-SOP-29	A, B
Serum	AST	BS-CORE-SOP-51	A
	ALT	BS-CORE-SOP-112	A, B
	GGT	BS-CORE-SOP-61	A, B
	Amylase	BS-CORE-SOP-100	A, B
	CK	BS-CORE-SOP-64	A
Serum	ALP	BS-CORE-SOP-16	A, B
	LDH	BS-CORE-SOP-109	A
	Total Bilirubin	BS-CORE-SOP-119	A, B



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Serum	Quantitative determination of: (cont'd)	<b>Roche Cobas 8000</b> (colorimetric) using	
	Lithium	BS-CORE-SOP-38	A
	Urate	BS-CORE-SOP-18	A
	Iron	BS-CORE-SOP-57	A, B
	Salicylate	BS-CORE-SOP-19	A
	Paracetamol	BS-CORE-SOP-22	A
	Total cholesterol	BS-CORE-SOP-9	A, B
	Triglycerides	BS-CORE-SOP-4	A, B
	HDL cholesterol	BS-CORE-SOP-3	A, B
Urine	Urea	BS-CORE-SOP-10	A
	Creatinine (Jaffe)	BS-CORE-SOP-41	A
	Albumin	BS-CORE-SOP-125	A
	Protein	BS-CORE-SOP-124	A
	Magnesium	BS-CORE-SOP-29	A
	Amylase	BS-CORE-SOP-100	A
	Urate	BS-CORE-SOP-18	A
	Calcium	BS-CORE-SOP-110	A
	Phosphate	BS-CORE-SOP-122	A
	Glucose	BS-CORE-SOP-65	A, B
Cerebrospinal fluid	Protein	BS-CORE-SOP-124	A, B
	Glucose	BS-CORE-SOP-65	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Serum	Quantitative determination of: (cont'd)	<b>Roche Cobas 8000</b> (colorimetric) using	
	Direct bilirubin	BS-CORE-SOP-107	A
	ACE	BS-CORE-SOP-31	A
	Ammonia	BS-CORE-SOP-53	A
	Lactate	BS-CORE-SOP-108	A
	LDH	BS-CORE-SOP-109	A
	Bile acid	BS-CORE-SOP-50	A
	Quantitative determination of:	<b>Roche Cobas 8000</b> (Immunoturbidimetry) using:	
	CRP	BS-CORE-SOP-39	A, B
	Transferrin	BS-CORE-SOP-37	B
	IgA	BS-CORE-SOP-44	A
	IgG	BS-CORE-SOP-45	A
	IgM	BS-CORE-SOP-46	A
	C3	BS-CORE-SOP-62	A
	C4	BS-CORE-SOP-54	A
	B2 Microglobulin	BS-CORE-SOP-87	A
Urine/Serum	$\alpha$ 1-antitrypsin	BS-CORE-SOP-52	A
	Caeruloplasmin	BS-CORE-SOP-55	A
	Haptoglobin	BS-CORE-SOP-113	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Urine/serum	Quantitative determination of:	<b>Roche Cobas 8000</b> (Ion selective electrode ISE) using:	
	Sodium	BS-CORE-SOP-12	A, B
	Potassium	BS-CORE-SOP-30	A, B
	Chloride	BS-CORE-SOP-121	A, B
Serum	Quantitative determination of:	<b>Roche Cobas 8000</b> c501 module (Agglutination immunoassay) using:	
	Phenytoin	BS-CORE-SOP-8	A
	Theophylline	BS-CORE-SOP-11	A
	Carbamazepine	BS-CORE-SOP-13	A
	Quantitative determination of:	<b>Roche Cobas 8000</b> c501 module (enzymatic) using:	
	Ethanol	BS-CORE-SOP-5	A
	Quantitative determination of:	<b>Roche Cobas 8000</b> c501 module (enzyme immunoassay) using:	
	Gentamicin	BS-CORE-SOP-93	A
	Tobramycin	BS-CORE-SOP-101	A
	Vancomycin	BS-CORE-SOP-120	A
	Teicoplanin	BS-CORE-SOP-36	A
	Amikacin	BS-CORE-SOP-103	A
	valproate	BS-CORE-SOP-20	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	Quantitative determination of:	<b>Roche Cobas 8000</b> e602/601 module (electrochemiluminescence) using:	
	Troponin T (HS)	BS-CORE-SOP-118	A, B
	NTproBNP	BS-CORE-SOP-17	A
	CK-MB	BS-CORE-SOP-56	A, B
	Vitamin B12	BS-CORE-SOP-66	A, B
	Folate	BS-CORE-SOP-114	A, B
	Ferritin	BS-CORE-SOP-117	A, B
	Cortisol	BS-CORE-SOP-89	A
	Progesterone	BS-CORE-SOP-1	A
	Estradiol	BS-CORE-SOP-14	A
	Testosterone (male)	BS-CORE-SOP-24	A
	DHEAS	BS-CORE-SOP-81	A
	SHBG	BS-CORE-SOP-23	A
	LH	BS-CORE-SOP-2	A
	FSH	BS-CORE-SOP-106	A
	TSH	BS-CORE-SOP-95	A, B
	FT4	BS-CORE-SOP-96	A, B
	FT3	BS-CORE-SOP-97	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>  Quantitative determination of: (cont'd)	In-house documented procedures based on equipment manuals as relevant  <b>Roche Cobas 8000</b> e602/601 module (electrochemiluminescence) using:	
	Prolactin	BS-CORE-SOP-15	A
	ACTH	BS-CORE-SOP-80	A
	PTH	BS-CORE-SOP-88	A
	Insulin	BS-CORE-SOP-90	A
	c-peptide	BS-CORE-SOP-115	A
	PSA	BS-CORE-SOP-72	A
	CA-125	BS-CORE-SOP-67	A
	CA-15-3	BS-CORE-SOP-69	A
	CA-19-9	BS-CORE-SOP-70	A
	AFP	BS-CORE-SOP-26	A
	HCG	BS-CORE-SOP-63	A
	CEA	BS-CORE-SOP-71	A
	Thyroglobulin	BS-CORE-SOP-76	A
	P1NP	BS-CORE-SOP-82	A
	CTx	BS-CORE-SOP-116	A
	Anti TSH receptor Abs	BS-CORE-SOP-79	A
	Anti TPO Abs	BS-CORE-SOP-78	A
Serum	Detection of SARS-CoV-2 IgG and IgM antibody against nucleocapsid (N) antigen	Elecsys anti-SARS-CoV-2 assay on Roche Cobas e602, SOP BS-CORE-SOP-144	A





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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	Quantitative determination of: (cont'd)	<b>Roche Cobas 8000</b> e602/601 module (electrochemiluminescence) using:	
	Anti-thyroglobulin Abs	BS-CORE-SOP-77	A
	Digoxin	BS-CORE-SOP-7	A
		<b>Roche Cobas 8000</b> e801 (electrochemiluminescence) using:	
Serum	SFLT	BS-CORE-SOP-141	A
	PLGF	BS-CORE-SOP-140	A
Cerebrospinal fluid	Detection of xanthochromia	Uvikon XS spectrophotometer using BS-CORE-SOP-68	A
Serum and urine	Osmolality	OsmoPro model using: BS-CORE-SOP-138	A
Serum	Blood gas analysis	Siemens Rapidpoint 500e POCT-SOP-43	A
Whole blood	Detection of Ketones	Nova statstrip ketone meter using: POCT-SOP-11	A
Urine	Detection of HCG	Biosign Urine pregnancy test using: POCT-SOP-3	A
Urine	pH measurement	Hannah ph meter using: BS-NONA-SOP-21	A
	Quantitative determination of:	IDS isys chemiluminescence using:	
Plasma	Aldosterone	BS-NONA-SOP-27	A
Plasma	Renin	BS-NONA-SOP-1	A
Faeces	Faecal Immunochemical Testing (FIT)	Pledia OC Sensor by latex agglutination using: BS-CORE-SOP-69	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Serum	Quantitative determination of: GH	IDS isys chemiluminescence using: BS-NONA-SOP-27	A
Serum	IGF-1	BS-NONA-SOP-29	A
Faeces	Quantitative determination of: Faecal calprotectin	DS2 automated ELISA using: Biohit extraction ELISA BS-NONA-SOP-40	A
	Quantitative determination of:	Berthold gamma counter using:	
	Quantitative determination of:	Agilent 6490 LC-MS/MS using:	
Urine and serum	Tyrosine	BS-NONA-SOP-30	A
Urine and serum	Homogentisic Acid	BS-NONA-SOP-30	A
Urine and serum	Phenylalanine	BS-NONA-SOP-30	A
Urine and serum	Hydroxyphenyllactate	BS-NONA-SOP-30	A
Urine and serum	Hydroxyphenylpyruvate	BS-NONA-SOP-30	A
Serum	1-25 OH Vitamin D	BS-NONA-SOP-76	A
	Quantitative determination of:	Thermo Vanquish Core HPLC System using:	
Plasma	Homocysteine	BS-NONA-SOP-25	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Whole blood	Quantitative determination of: Thiamine (Vitamin B1)	Thermo Vanquish Core HPLC System using)	A
Serum	Vitamin A	BS-NONA-SOP-54	A
	Vitamin E	BS-NONA-SOP-23	A
Plasma	Quantitative determination of: Glycated haemoglobin	TOSOH HLC-723G8 using: BS-NONA-SOP-44	A
Whole blood	Quantitative determination of: Cyclosporin	Waters Xevo TQD LC-MS/MS using: BS-NONA-SOP-63	A
Whole blood	Sirolimus	BS-NONA-SOP-64	A
Whole blood	Tacrolimus	BS-NONA-SOP-63	A
Urine	Quantitative determination of: Urine Metadrenalines (metadrenaline, normetadrenaline, and 3-methoxytyramine)	Waters Acquity UPLC-TQS LC-MS/MS using: BS-NONA-SOP-9	A
Serum	Quantitative determination of: 25-OH Vitamin D	LC-MS/MS by Thermo Cascadion using: BS-NONA-SOP-43	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	Quantitative determination of:	Waters Alliance 2795-Quattro Premier LC-MS/MS using:	
Urine	Urine free cortisol	BS-NONA-SOP-56	A
Serum	17-OHP	BS-NONA-SOP-8	A
Serum	Female Testosterone	BS-NONA-SOP-42	A
Serum	Androstenedione	BS-NONA-SOP-42	A
Urine	5HIAA	BS-NONA-SOP-24	A
	Quantitative determination of:	Thermo ICAP ICPMS using:	
Serum	Aluminium	BS-NONA-SOP-12	A
Serum	Copper	BS-NONA-SOP-47	A
Whole blood	Lead	BS-NONA-SOP-13	A
Whole blood	Manganese	BS-NONA-SOP-14	A
Whole blood	Nickel	BS-NONA-SOP-55	A
Serum	Selenium	BS-NONA-SOP-47	A
Serum	Zinc	BS-NONA-SOP-47	A
Whole blood	Cobalt	BS-NONA-SOP-55	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Whole blood	Quantitative determination of: Chromium	Thermo ICAP ICPMS using: BS-NONA-SOP-55	A
Urine	Copper	BS-NONA-SOP-47	A
Serum	Quantitative determination of: Peg prolactin (precipitation of macroprolactin)	Thermo ICP-MS Inductively Coupled Mass Spectrometry (ICPMS) BS-NONA-SOP-53	A
Serum/urine	Quantitative determination of: Sodium	Roche 9180 electrolyte analyser using: BS-CORE-SOP-12	A
Serum/urine	Potassium	BS-CORE-SOP-13	A



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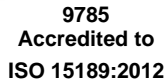
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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	<u>Calculated tests</u>		
	Anion Gap	BS-CORE-SOP-80	A, B
	eGFR	BS-CORE-SOP-86	
	AKI alerts	BS-CORE-SOP-91	
	Adjusted Calcium	BS-CORE-SOP-85	
	Globulins	BS-CORE-SOP-84	
	Non-HDL cholesterol	BS-CORE-SOP-92	
	LDL cholesterol	BS-CORE-SOP-92	
	Cholesterol/HDL ratio	BS-CORE-SOP-92	
	TIBC	BS-CORE-SOP-94	
	Fe % saturation	BS-CORE-SOP-92	
	urine calcium/creatinine ratio	BS-CORE-SOP-99	A
	Urine protein/creatinine ratio	BS-CORE-SOP-99	
	urine albumin/creatinine ratio	BS-CORE-SOP-99	
	Creatine clearance	BS-CORE-SOP-99	
	Urine Sodium/24hrs	BS-CORE-SOP-99	
	Urine Potassium/24 hrs	BS-CORE-SOP-99	
	Urine Chloride/24 hrs	BS-CORE-SOP-99	
	Urine Urea/24 hrs	BS-CORE-SOP-99	
	Urine Creatinine/24 hrs	BS-CORE-SOP-99	



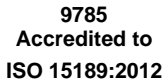
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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	A
	<u>Calculated tests</u> (cont'd)		
	Urine Albumin/24 hrs	BS-CORE-SOP-99	
	Urine Protein/24hrs	BS-CORE-SOP-99	
	Urine Magnesium/24hrs	BS-CORE-SOP-99	
	Urine Amylase/24hrs	BS-CORE-SOP-99	
	Urine Urate/24hrs	BS-CORE-SOP-99	
	Urine Calcium/24hrs	BS-CORE-SOP-99	
	Urine Phosphate/24hrs	BS-CORE-SOP-99	
	Creatine clearance	BS-CORE-SOP-99	
	Urine Sodium/24hrs	BS-CORE-SOP-99	
	Urine Potassium/24 hrs	BS-CORE-SOP-99	
	Urine Chloride/24 hrs	BS-CORE-SOP-99	
	Urine Urea/24 hrs	BS-CORE-SOP-99	
	Urine Creatinine/24 hrs	BS-CORE-SOP-99	
	Urine Albumin/24 hrs	BS-CORE-SOP-99	
	Urine Protein/24hrs	BS-CORE-SOP-99	
	Urine Magnesium/24hrs	BS-CORE-SOP-99	
	Urine Amylase/24hrs	BS-CORE-SOP-99	
	Urine Urate/24hrs	BS-CORE-SOP-99	
	Urine Calcium/24hrs	BS-CORE-SOP-99	



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Blood Plasma	Blood Group by detection and identification of antigens:  A B O Rhesus D status	Automated using Ortho Autovue Innova/Ultra (column agglutination) using: BS-TRAN-SOP-34	C
Blood Plasma	Automated Antibody Screen Rh: anti-C <sup>w</sup> , anti-C, anti-c, anti-D, anti-E, anti-e Kell: anti-K, anti-k, anti-Kp <sup>a</sup> Kidd: anti-Jk <sup>a</sup> , anti-Jk <sup>b</sup> Duffy: anti-Fy <sup>a</sup> , anti-Fy <sup>b</sup> Lutheran: anti-Lu <sup>a</sup> , anti-Lu <sup>b</sup> MNS: anti-M, anti-N, anti-S, anti-s Lewis: anti-Le <sup>a</sup> , anti-Le <sup>b</sup> P: anti-P <sub>1</sub>	Automated using Ortho Autovue Innova/Ultra (column agglutination) using:  BS-TRAN-SOP-34	C
Blood Plasma	Blood Group by detection and identification of antigens:	Manual method using column agglutination technology on BIO-RAD DiaClon ABO/D + reverse grouping cards using:  BS-TRAN-SOP-44	A, B, C
	Antibody Screen - manual Rh: anti-Cw, anti-C, anti-c, anti-D, anti-E, anti-e Kell: anti-K, anti-k, anti-Kpa Kidd: anti-Jka, anti-Jkb Duffy: anti-Fya, anti-Fyb Lutheran: anti-Lua, anti-Lub MNS: anti-M, anti-N, anti-S, anti-s Lewis: anti-Lea, anti-Leb P: anti-P1	Manual method using column agglutination technology on BIO-RAD LISS/Coombs cards using:  BS-TRAN-SOP-41	A, B, C



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: Column agglutination technology using the Diamed system using:	
EDTA Whole Blood	Direct Antiglobulin Test (Manual)	BS-TRAN-SOP-43	A, B, C
	Direct Antiglobulin Test (Automated)	Automated using Ortho Vision (Column Agglutination Technology) using: BS-TRAN-SOP-43	A, B, C
EDTA Whole Blood	Electronic Issue	BS-TRAN-SOP-6	A, B, C
EDTA plasma	Serological Crossmatch	BS-TRAN-SOP-45	
EDTA plasma	Manual Antibody panels – Antigen of the following systems: Rh – C,D,E,c,e,C <sup>w</sup> Kell – K,k,Kp <sup>a</sup> Duffy – Fy <sup>a</sup> , Fy <sup>b</sup> MNSs – M,N,S,s Kidd – Jk <sup>a</sup> , Jk <sup>b</sup> Lutheran – Lu <sup>a</sup> , Lu <sup>b</sup> Lewis – Le <sup>a</sup> , Le <sup>b</sup> P – P <sub>1</sub>	Column agglutination technology on BIO-RAD LISS/Coombs cards using: BS-TRAN-SOP-41	A, B
EDTA plasma	Automated Antibody panels – Antigen of the following systems: Rh – C,D,E,c,e,C <sup>w</sup> Kell – K,k,Kp <sup>a</sup> Duffy – Fy <sup>a</sup> , Fy <sup>b</sup> MNSs – M,N,S,s Kidd – Jk <sup>a</sup> , Jk <sup>b</sup> Lutheran – Lu <sup>a</sup> , Lu <sup>b</sup> Lewis – Le <sup>a</sup> , Le <sup>b</sup> P – P <sub>1</sub>	Biovue IAT (Column agglutination technology) using: BS-TRAN-SOP-42	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
EDTA plasma	Antenatal 3 cell antibody screen – Antigens of the following system: Rh – C,E,c,e, Kell – K,k,Kp <sup>a</sup> Duffy – Fy <sup>a</sup> , Fy <sup>b</sup> MNSs – M,N,S,s Kidd – Jk <sup>a</sup> , Jk <sup>b</sup> Lutheran – Lu <sup>a</sup> , Lu <sup>b</sup> Lewis – Le <sup>a</sup> , Le <sup>b</sup> P –P <sub>1</sub>	Ortho Vision utilising Column agglutination technology using:  BS-TRAN-SOP-23	A,
EDTA Whole Blood	Automated Rh/K typing	Ortho Vision utilising Column agglutination technology using:  BS-TRAN-SOP-117	A,B
EDTA plasma	IgG Anti A & B titres for ABO incompatible renal transplants	ABO titres using Diamed system using:  BS-TRAN-SOP-10	A



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HUMAN BODY FLUIDS (cont'd)	<u>Provision of stem cell preparations and related products for the purpose of stem cell transplantation</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
EDTA whole blood	CD 34 stem cell enumeration	FACS Canto using ISHAGE strategy:  RBS-BMT-SOP-70	A
EDTA whole blood	CD3 cell enumeration	FACS Canto flow cytometer:  RBS-BMT-SOP-71	A
	<u>Molecular genetic analysis for genetic mutations and variants</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
EDTA whole blood	Screening for BCR-ABL	Manual RT-PCR on thermocycler TECHNE/ThermoHybaid PxE 0.5 machine and real-time PCR using the Light Cycler 480 PCR Gel electrophoresis  Haematology Molecular Biology BCR-ABL gene identification using multiplex PCR  BS-MOLB-SOP-14	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular genetic analysis for genetic mutations and variants</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
EDTA whole blood	BCR-ABL quantitation	Real-time PCR using the Light Cyclor 480:  Haematology Molecular Biology general use of LightCycler 480 PCR machine (BS-MOLB-SOP-20) Haematology Molecular Biology e1a2 BCR-ABL LightCycler PCR (BS-MOLB-SOP-13)	A
EDTA Whole blood	Detection of NPM1 mutation	Real-time PCR using the Light Cyclor 480  NPM1 mutation by QIAGEN Ipsogen NPM1 MutScreen kit (BS-MOLB-SOP-21)	A
EDTA blood, bone marrow aspirate EDTA	Detection of c-KIT Mutation	Real-time PCR using the Light Cyclor 480 Haematology Molecular Biology c-KIT mutation by real-time quantitative PCR (BS-MOLB-SOP-24)	A
EDTA Whole blood	Detection of BCR-ABL Kinase Domain Mutation	Manual nested RT-PCR on thermocycler TECHNE/ ThermoHybaid Px E 0.5 machine and Sanger Sequencing HD-MBO-SOP-5	A
EDTA Whole blood	Immunoglobulin heavy chain variable gene	PCR machine – Eppendorf mastercycler  HD-MBO-SOP-29  PCR Gel electrophoresis – GeneFlow MultiSUB Choice Horizontal Gel Unit 15 x 15cm	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular genetic analysis for genetic mutations and variants</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
EDTA Whole blood	FI1L1-PDGFR	Manual RT-PCR on thermocycler TECHNE/ThermoHybaid PxE 0.5 machine PCR Gel electrophoresis  FIP1L1-PDGFR fusion transcript detection by RT-PCR  BS-MOLB-SOP-16	A
EDTA Whole blood	FLT3-ITD	Manual PCR on thermocycler TECHNE/ThermoHybaid PxE 0.5 machine PCR Gel electrophoresis and Sanger sequencing  FLT-3 ITD identification using genomic DNA  BS-MOLB-SOP-22	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular genetic analysis for genetic mutations and variants</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	A
Bone Marrow (including fixed cells), peripheral blood	Targeted detection of mutations and gene fusions associated with myeloid disorders	<p>Oncomine Myeloid NGSPanel sequencing on Ion Torrent using: BS-MOLB-SOP-64</p> <p>Haematology molecular Biology genomic DNA and Vilo cDNA preparation BS-MOLB-SOP-66</p> <p>Quantification by Qubit 2.0 fluorometer (SOP BS-MOLB-SOP-67</p> <p>Oncomine Myeloid Research Assay Library Preparation BS-MOLB-SOP-64</p> <p>Sequencing using Ion Torrent Genexus, Next Generation Sequencing Platform. BS-MOLB-SOP-64</p> <p>Oncomine Myeloid NGS data analysis and reporting using Ion Reporter and Oncomine Variant Annotator BS-MOLB-SOP-68</p>	



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HUMAN BODY FLUIDS (cont'd)  DNA from bone marrow or peripheral blood	<u>Molecular genetic analysis for genetic mutations and variants</u> (cont'd)  Detection of hotspot mutation in MYD88 (L265P)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:  Allele Specific PCR and agarose gel electrophoresis using:  Qiagen Allprep DNA Mini Kit or QIAamp Mini kit for DNA extraction: HD-MBO-SOP-25 BS-MOLB-SOP-34  NanoDrop 8000 using spectrophotometry technology HD-MBO-SOP-20  Agarose Gel electrophoresis and GeneFlow MultiSUB Choice Horizontal Gel Unit 15 x 15cm HD-MBO-SOP-27  BS-MOLB-FOR-20	A





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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Whole blood EDTA Body fluids	Full Blood Count (FBC) analysis of the following parameters:  WBC RBC HGB HCT MCV MCH MCHC RDW PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count	Sysmex XN automated analysers; hydrodynamic focusing, fluorescent staining, differential laser light scatter  BS-HAEM-SOP-75	A, B, C
Whole blood EDTA	Reticulocyte count	BS-HAEM-SOP-75	A
Whole blood EDTA	Erythrocyte Sedimentation Rate (ESR)	Ailfax ESR Test 1 analyser (photometric capillary stopped flow kinetic analysis) BS-HAEM-SOP-25	A, B,
Whole blood EDTA	Glandular Fever Screen	Clearview IM II test (lateral flow immunoassay) BS-HAEM-SOP-27	A
Whole blood EDTA	Sickle cell solubility	Sickledex Screening Test, HbS solubility test kit (quantitative tube test) using: BS-HGP-SOP-56	A,
Whole blood EDTA	<u>Sickle Cell Screening Test</u>	Lateral Flow chromatographic qualitative immunoassay test kit, Sickle SCAN (detection of HbA, HbS and HbC) using: BS-HAEM-SOP-69.	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:  Documented -in-house methods to meet the requirements of the Sick cell and Thalassaemia (SCT) screening programme screening programme(s) laboratory QA evidence requirements'	
Whole blood EDTA	Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: HbS HbC HbD HbE HbLepore HbOArab	TOSOH G8 analyser (HPLC):  BS-HGP-SOP-57	A
Whole blood EDTA	HbS estimation	BS-HGP-SOP-57	A
Whole blood EDTA	Hb Variant confirmation:  HbA, HbF, HbS, HbC	Haemoglobinopathy Acid Haemoglobin Electrophoresis BS-HGP-SOP-5 Haemoglobinopathy Alkaline Haemoglobin Electrophoresis BS-HGP-SOP-6	A
Whole blood EDTA	Qualitative G6PD screen	Binax NOW Test (enzyme chromatographic test) BS-HGP-SOP-51	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:  Documented -in-house methods to meet the requirements of the Sick cell and Thalassaemia (SCT) screening programme screening programme(s) laboratory QA evidence requirements'	
Plasma Citrate	Emicizumab	Modified FVIII performed on ACL TOP 50 series coagulation analysers BS-SCOAG-SOP-32	A
	Edoxaban	Modified Ant-Xa chromogenic assay performed on ACL TOP 50 series coagulation analysers BS-COAG-SOP-19	A
	Chromogenic VIII	Chromogenic VIII assay performed on ACL TOP 50 series coagulation analysers BS-SCOAG-SOP-31	A
Plasma Citrate	ADAMTS13 Activity	Automated ELISA on Acustar analyser BS-SCOAG-SOP-30	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Whole blood EDTA	Identification of normal and abnormal morphologies including WBC differential count	Automated smear and staining: Sysmex SP-50 BS-HAEM-SOP-76  Thiazin and Eosin Stain and manual microscopy  RAL Stainer Wrights stain and manual microscopy  BS HAEM-SOP-73	A  A, B, C
Bone marrow aspirate EDTA slides	Reporting of normal and abnormal morphologies	Aerospray Hematology ProSlide Stainer  Thiazin and Eosin Stain and manual microscopy  Perls Stain  BS-HAEM-SOP-10 HD-GEN-POL-1 BS-HODS-SOP-29	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Whole blood EDTA	Malaria screening for: <i>P. falciparum</i> <i>P. vivax</i> <i>P. ovale</i> <i>P. malariae</i> <i>P. knowlesi</i>	Automated smear and staining using: Sysmex SP-50 BS-HAEM-SOP-76  Thiasin and Eosin stain and manual microscopy.  Thin films: BS-HAEM-SOP-10 BS-HAEM-SOP-17  RAL Stainer BS HAEM-SOP-73 Wrights stain and manual microscopy  BS-HAEM-SOP-58	A        A,B,C
Whole blood EDTA	Malarial antigens of: <i>P. falciparum</i> <i>P. vivax</i> <i>P. ovale</i> <i>P. malariae</i> <i>P. knowlesi</i>	BinaxNow Malaria Screening Test (MST)  BS-HAEM-SOP-11	A
Whole blood EDTA Bone marrow aspirate EDTA Cerebrospinal fluid Pleural fluid Synovial fluid Ascitic fluid	Cytospin and staining preparations	Aerospray hematology Pro Slide Stainer  HD-IMP-SOP-14 BS-HAEM-SOP-10	A



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<p><b>HUMAN BODY FLUIDS (cont'd)</b></p> <p>Whole blood EDTA Bone marrow aspirate EDTA Cerebrospinal fluid Pleural fluid Synovial fluid Ascitic fluid FNA</p>	<p><u>Haematological examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Immunophenotyping of the following markers/antigens for the diagnosis and monitoring of Haematological malignancy including the following disorders:</p> <ul style="list-style-type: none"> <li>Acute leukaemia – AML, ALL (B and T)</li> <li>Chronic myeloid disorders – MDS, CML, CMML</li> <li>Mature lymphoid disorders – B and T lymphoproliferative disorders, Lymphoma, Myeloma</li> </ul> <p>CD1a CD2 CD3 CD4 CD5 CD7 CD8 CD10 CD11b CD11c CD13 CD14 CD15 CD16 CD19 CD20 CD22 CD23 CD25 CD26</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:</p> <p>BD FACSLytic analyser, flow cytometry (laser flow cytometry) using manufacturer supplied panels or in house documented methods. BD FACSLytic.</p> <p>BS-HODS-SOP-39 HD-IMP-INF-8 BS-HODS-SOP-46 BS-HODS-SOP-43 BS-HODS-SOP-21 BS-HODS-SOP-22 HD-IMP-SOP-20 BS-HODS-SOP-50 HD-IMP-SOP-10 HD-IMP-EXTD-15</p>	A



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<p><b>HUMAN BODY FLUIDS</b> (cont'd)</p> <p>Whole blood EDTA Bone marrow aspirate EDTA Cerebrospinal fluid Pleural fluid Synovial fluid Ascitic fluid FNA (cont'd)</p>	<p><u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Immunophenotyping of the following markers/antigens for the diagnosis and monitoring of Haematological malignancy (cont'd)</p> <p>CD27 CD30 CD33 CD34 CD38 CD43 CD45 CD56 CD64 CD79a CD79b CD81 CD103 CD117 CD123 CD138 CD200 CD235a B2 Microglobulin cLysozyme FMC-7 HLA-DR TSLPR</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:</p> <p>BD FACSLyric analyser, flow cytometry (laser flow cytometry) using manufacturer supplied panels or in house documented methods. BD FACSLyric.</p> <p>BS-HODS-SOP-39 HD-IMP-INF-8 BS-HODS-SOP-46 BS-HODS-SOP-43 BS-HODS-SOP-21 BS-HODS-SOP-22 HD-IMP-SOP-20 BS-HODS-SOP-50 HD-IMP-SOP-10 HD-IMP-EXTD-15</p>	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Whole blood EDTA	Kappa Lambda TCR-GD MPO TdT  PNH Screen  CD14 CD15 CD24 CD45 CD59 CD64 CD235a FLAER	BD FACSLyric analyser, flow cytometry (laser flow cytometry) BD FACSLyric.  HD-IMP-SOP-20 HD-IMP-SOP-10 HD-IMP-EXTD-15      HD-IMP-SOP-16	
Urine	Reporting of normal and abnormal morphologies  <u>Coagulation examination activities for the purpose of clinical diagnosis</u>	Perl's staining for Haemosiderin. BS-HODS-SOP-29 HD-IMP-SOP-6  Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	A
Plasma citrate		ACL 500 and ACL 750 (clot end point detection)	





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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Plasma citrate	Activated Partial thromboplastin time (APTT)	BS-COAG-SOP-4	A, B
	Activated Partial thromboplastin time Ration (APTR)	BS-COAG-SOP-3	
	Prothrombin time (PT)		
	International normalised ratio (INR)		
	Anti-Xa (Heparin) Assay	BS-COAG-SOP-10	A
	Clauss Fibrinogen	BS-COAG-SOP-5	A, B
	Mixing studies for investigation of prolonged PT and APTT	BS-COAG-SOP-12	A
Plasma citrate	D-Dimer	ACL TOP 500 and ACL TOP 750 (latex agglutination)	A
		BS_COAG-SOP-6	
Plasma citrate	Clotting factors: PT based: II V VII X	ACL TOP 500 and ACL TOP 750 (clot end point detection)	A
	APTT based: VIII IX,XI,XII	BS-SCOAG-SOP-7	



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Plasma citrate	LUPUS screening	ACL TOP 750 (clot end point detection, turbidimetric immunoassay and chromogenic) BS-SCOAG-SOP-11 BS-SCOAG-SOP-12 BS-SCOAG-SOP-13	A
	Factor XIII antigen	ACL TOP 750 (Latex enhanced immunoassay)  BS-COAG-SOP-29	A
	Clotting factor inhibitors: Factor VIII and IX inhibitors	ACL TOP 750 (clot end point detection)  BS-SCOAG-SOP-8	A
Plasma citrate	Thrombophilia screen: Antithrombin activity and antigen Protein C activity Free protein S NAPCR	ACL TOP 750 (clot end point detection, turbidimetric immunoassay and chromogenic) BS-SCOAG-SOP-9 BS-SCOAG-SOP-10	A
	Von Willebrands screen:	ACL TOP 750 (latex particle enhanced immunoturbidimetric assay)	A
	Von Willebrands antigen Von Willebrands activity	BS-COAG-SOP-15 BS-COAG-SOP-16	



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

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**Issue No: 005    Issue date: 08 February 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 (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:	
Plasma citrate	Heparin Induced thrombocytopenia (HIT) IgG	IL Coagulation Acustar bychemiluminescence (2 analysers) BS-SCOAG-SOP-22	A
	Anticardiolipin antibodies (IgG and IgM)	BS-SCOAG-SOP-21 BS-SCOAG-SOP-23	
	B-2-Glycoprotein IgM VW: RcO	BS-SCOAG-SOP-21 BS-SCOAG-SOP-23	
	Collagen binding antigen (CBA)B-2-Glycoprotein IgG	BS-SCOAG-SOP-21 BS-SCOAG-SOP-15	
		SpectraMax plate reader (ELISA) BS-SCOAG-SOP-34	A
	ADAMTS-13 Activity	BS-SCOAG-SOP-6	
	ADAMST-13 Inhibitor	BS-SCOAG-SOP-5	
	Thrombophilia screen: Protein C antigen Total protein S	BS-SCOAG-SOP-9 BS-SCOAG-SOP-10 BS-SCOAG-SOP-26 BS-SCOAG-SOP-27	A
Plasma citrate	Prothrombin Gene Mutation (PGM) – qualitative	GeneXpert Dx HemosIL assay	A
	Factor V Leiden (FVL)	BS-SCOAG-SOP-1	
END			