


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9785</p> <p>Accredited to ISO 15189:2012</p>	<h3>Liverpool University Hospitals NHS Foundation Trust</h3> <p>Issue No: 004 Issue date: 04 November 2021</p>	
	<p>Liverpool Clinical Laboratories Liverpool University Hospitals NHS Foundation Trust Prescot Street Liverpool L7 8XP</p>	<p>Contact: Ines Santos Tel: +44 (0)151 706 4374 E-Mail: Ines.Santos@liverpoolft.nhs.uk Website: www.liverpoolcl.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address Royal Liverpool University Hospital Prescot Street Liverpool L7 8XP</p> <p>Local contact Ines Santos As above</p>	<p>Haematology Blood Transfusion Clinical Biochemistry</p>	A
<p>Address Broadgreen Hospital / Liverpool Heart and Chest Hospital Thomas Drive Liverpool L7 3PE</p> <p>Local contacts Ines Santos As above</p>	<p>Haematology Blood Transfusion Transfusion Haematology Clinical Biochemistry</p>	B
<p>Address Liverpool Women's Hospital. Crown Street Liverpool L8 7SS</p> <p>Local contacts Ines Santos As above</p>	<p>Haematology Blood Transfusion Transfusion Haematology</p>	C



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Site activities performed away from the locations listed above:

Location details	Activity
Accident and Emergency Royal Liverpool University Hospital Prescot Street Liverpool L7 8XP	Blood storage & issue Fridge managed by Haematology
Main Theatres Royal Liverpool University Hospital Prescot Street Liverpool L7 8XP	Blood storage & issue Fridge managed by Haematology
Vascular Hybrid Theatres Royal Liverpool University Hospital Prescot Street Liverpool L7 8XP	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	
	Quantitative determination of:	Roche Cobas 8000 (colorimetric) using	
Serum	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
	AST	BS-CORE-SOP-51	A
	ALT	BS-CORE-SOP-112	A, B
	GGT	BS-CORE-SOP-61	A, B
Serum	Amylase	BS-CORE-SOP-100	A, B
Serum	CK	BS-CORE-SOP-64	A
	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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	Quantitative determination of: (cont'd)	Roche Cobas 8000 (colorimetric) using	
Serum	Lithium	BS-CORE-SOP-38	A
Serum	Urate	BS-CORE-SOP-18	A
Serum	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)	Roche Cobas 8000 (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:	Roche Cobas 8000 (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	
α1-antitrypsin	BS-CORE-SOP-52	A	
Urine/Serum	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:	Roche Cobas 8000 (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:	Roche Cobas 8000 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:	Roche Cobas 8000 c501 module (enzymatic) using:	
	Ethanol	BS-CORE-SOP-5	A
	Quantitative determination of:	Roche Cobas 8000 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:	Roche Cobas 8000 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</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
	Quantitative determination of: (cont'd)	Roche Cobas 8000 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)	Roche Cobas 8000 e602/601 module (electrochemiluminescence) using:	
	Anti-thyroglobulin Abs	BS-CORE-SOP-77	A
	Digoxin	BS-CORE-SOP-7	A
Cerebrospinal fluid	Detection of xanthochromia	Uvikon XS spectrophotometer using BS-CORE-SOP-68	A
Serum and urine	Osmolality	Advanced instruments Osmometer Model 3320 using: BS- CAUH-SOP-51	A
Serum	Blood gas analysis	Cobas b123 blood gas analyser using: 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



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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
Serum	Quantitative determination of: P3NP	Berthold gamma counter using: BS-NONA-SOP-41	A
Urine and serum	Quantitative determination of: Tyrosine	Agilent 6490 LC-MS/MS using: 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
Plasma	Quantitative determination of: Homocysteine	Gilson/Jasco HPLC system (reverse phase HPLC with pre-column derivatisation and fluorescence detection) using: 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)	Gilson/Jasco HPLC system (derivatisation HPLC with fluorescence detection) using: BS-NONA-SOP-54	A
Serum	Quantitative determination of: Vitamin A	Gilson/Jasco HPLC system (revers phase HPLC with UV detection using a Chromsystems kit) using: BS-NONA-SOP-23	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	25-Hydroxyvitamin D (D2, D3, Total)	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:	IDS Radioimmunoassay kit using:	
Serum	1,25-Dihydroxyvitamin D (D2, D3, Total)	BS-NONA-SOP-52	A
	Quantitative determination of:	Thermo ICP-MS Inductively Coupled Mass Spectrometry (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	
	Quantitative determination of:	Thermo ICP-MS Inductively Coupled Mass Spectrometry (ICPMS) using:	
Whole blood	Chromium	BS-NONA-SOP-55	A
Urine	Copper	BS-NONA-SOP-47	A
Serum	Peg prolactin (precipitation of macroprolactin)	BS-NONA-SOP-53	A
	Quantitative determination of:	Roche 9180 electrolyte analyser using:	
Serum/urine	Sodium	BS-CORE-SOP-12	A
Serum/urine	Potassium	BS-CORE-SOP-13	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	
	<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>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
	<u>Calculated tests (cont'd)</u>		
	Urine Phosphate/24hrs	BS-CORE-SOP-99	A
	Urine chromium/creatinine ratio	BS-CORE-SOP-99	A
	Urine copper/24 hrs	BS-CORE-SOP-99	
	Urine cobalt/creatinine ratio	BS-CORE-SOP-99	
	Urine nickel/24 hrs	BS-CORE-SOP-99	
	<u>Blood Transfusion examinations to assist in clinical investigations</u>	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 Vision(column agglutination) using: BS-TRAN-SOP-23	A, B
Blood Plasma	Automated Antibody Screen Rh: anti-C ^w , anti-C, anti-c, anti-D, anti-E, anti-e Kell: anti-K, anti-k, anti-Kp ^a Kidd: anti-Jk ^a , anti-Jk ^b Duffy: anti-Fy ^a , anti-Fy ^b Lutheran: anti-Lu ^a , anti-Lu ^b MNS: anti-M, anti-N, anti-S, anti-s Lewis: anti-Le ^a , anti-Le ^b P: anti-P ₁	Automated using Ortho Vision (column agglutination) using: BS-TRAN-SOP-23	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:	
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 ^w , anti-C, anti-c, anti-D, anti-E, anti-e Kell: anti-K, anti-k, anti-Kp ^a Kidd: anti-Jk ^a , anti-Jk ^b Duffy: anti-Fy ^a , anti-Fy ^b Lutheran: anti-Lu ^a , anti-Lu ^b MNS: anti-M, anti-N, anti-S, anti-s Lewis: anti-Le ^a , anti-Le ^b P: anti-P ₁	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-C ^w , anti-C, anti-c, anti-D, anti-E, anti-e Kell: anti-K, anti-k, anti-Kp ^a Kidd: anti-Jk ^a , anti-Jk ^b Duffy: anti-Fy ^a , anti-Fy ^b Lutheran: anti-Lu ^a , anti-Lu ^b MNS: anti-M, anti-N, anti-S, anti-s Lewis: anti-Le ^a , anti-Le ^b P: anti-P ₁	Manual method using column agglutination technology on BIO-RAD LISS/Coombs cards using: BS-TRAN-SOP-41	A, B, C



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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: Column agglutination technology using the Diamed system using:	
EDTA Whole Blood	Direct Antiglobulin Test	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	Antibody panels – Antigens of the following systems: Rh – C,D,E,c,e,C ^w Kell – K,k,Kp ^a Duffy – Fy ^a , Fy ^b MNSs – M,N,S,s Kidd – Jk ^a , Jk ^b Lutheran – Lu ^a , Lu ^b Lewis – Le ^a , Le ^b P –P ₁	Column agglutination technology on BIO-RAD LISS/Coombs cards using: BS-TRAN-SOP-41	A, B, C
EDTA plasma	Antenatal 3 cell antibody screen – Antigens of the following system: Rh – C,E,c,e, Kell – K,k,Kp ^a Duffy – Fy ^a , Fy ^b MNSs – M,N,S,s Kidd – Jk ^a , Jk ^b Lutheran – Lu ^a , Lu ^b Lewis – Le ^a , Le ^b P –P ₁	Ortho Vision utilising Column agglutination technology using: BS-TRAN-SOP-23	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	FACSLyric 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 Cyclers 480 PCR Gel electrophoresis BS-MOLB-SOP-14	A
EDTA whole blood	BCR-ABL quantitation	Real-time PCR using the Light Cyclers 480: BS-MOLB-SOP-12 BS-MOLB-SOP-13	A
EDTA Whole blood	Detection of NPM1 mutation	Real-time PCR using the Light Cyclers 480 BS-MOLB-SOP-21	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 blood, bone marrow aspirate EDTA	Detection of c-KIT Mutation	Manual PCR on thermocycler TECHNE and Sanger Sequencing Real-time PCR using the Light Cycler 480 BS-MOLB-SOP-23 BS-MOLB-SOP-24	A
EDTA Whole blood	Detection of SETBP1	Manual PCR on thermocycler TECHNE and Sanger Sequencing BS-MOLB-SOP-18	A
EDTA Whole blood	Detection of CSF3R	Manual PCR on thermocycler TECHNE and Sanger Sequencing BS-MOLB-SOP-19	A
EDTA Whole blood	Detection of BCR-ABL Kinase Domain Mutation	Manual nested RT-PCR on thermocycler TECHNE/ ThermoHybaid PxE 0.5 machine and Sanger Sequencing BS-MOLB-SOP-17	A
EDTA Whole blood	Immunoglobulin heavy chain variable gene	PCR machine – Eppendorf mastercycler BS-MOLB-SOP-31 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 BS-MOLB-SOP-16	A
EDTA Whole blood	Fusion transcripts -AML translocation screening	Manual RT-PCR using the ThermoHybaid PxE 0.5 machine PCR Gel electrophoresis BS-MOLB-SOP-15	A
EDTA Whole blood	FLT3-ITD	Manual PCR on thermocycler TECHNE/ThermoHybaid PxE 0.5 machine PCR Gel electrophoresis and Sanger sequencing BS-MOLB-SOP-22	A



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Bone Marrow (including fixed cells), peripheral blood</p>	<p><u>Molecular genetic analysis for genetic mutations and variants</u> (cont'd)</p> <p>Targeted detection of mutations and gene fusions associated with myeloid disorders</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:</p> <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>Quantification by Agilent 2100 Bioanalyser using microfluidics technology BS-MOLB-SOP-65</p>	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: Emulsion PCR, Enrichment of Patient Libraries and Loading ISPs onto Chips using Ion Chef system BS-MOLB-SOP 64 Sequencing using ion Torrent S5 Next Generation Sequencing platform BS-MOLB-SOP 64 Oncomine Myeloid NGS data analysis and reporting using Ion Reporter and Oncomine Variant Annotator BS-MOLB-SOP-68	A
DNA from bone marrow or peripheral blood	Detection of hotspot mutation in MYD88 (L265P)	Allele Specific PCR and agarose gel electrophoresis using: Qiagen Allprep DNA Mini Kit or QIAamp Mini kit for DNA extraction: BS-MOLB-SOP-53 BS-MOLB-SOP-34 NanoDrop 8000 using spectrophotometry technology BS-MOLB-SOP-25 Agarose Gel electrophoresis and GeneFlow MultiSUB Choice Horizontal Gel Unit 15 x 15cm BS-MOLB-SOP-62 BS-MOLB-FOR-20	



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>DNA from bone marrow (or fixed cells) or blood</p> <p>PCR amplified DNA from above</p> <p>Data from sanger sequencing supplied by Genewiz UK Ltd</p>	<p><u>Molecular genetic analysis for genetic mutations and variants</u> (cont'd)</p> <p>DNA amplification for the purposes of analysis for TP53 mutations</p> <p>Referral to Genewiz UK Ltd for the purposes of sanger sequencing for TP53 mutations</p> <p>Analysis and reporting of TP53 mutations</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>PCR Amplification, Gel Electrophoresis as supplied by Genewiz UK Ltd using:</p> <p>Qiagen Allprep DNA Mini Kit BS-MOLB-SOP-52</p> <p>NanoDrop 8000 using spectrophotometry technology BS-MOLB-SOP-25 Agarose Gel electrophoresis and GeneFlow MultiSUB Choice Horizontal Gel Unit 15 x 15cm BS-MOLB-SOP-52</p> <p>Analysis and reporting – Gel interpretation</p> <p>BS-MOLB-SOP-61</p> <p>Analysis and reporting</p> <p>BS-MOLB-SOP-70</p>	



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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:	Unicel DxH800 Coulter Cellular Analysis System (Coulter principle, Volume, Conductivity and scatter (VCS) principle and photometry)	A, B
	WBC RBC HGB HCT MCV MCH MCHC RDW PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count	BS-HAEM-SOP-26 Unicel DxH 520 Coulter Cellular Analysis System (LWH) BS-HLWH-SOP-5	C
Whole blood EDTA	Reticulocyte count	BS-HAEM-SOP-26	A
Whole blood EDTA	Erythrocyte Sedimentation Rate (ESR)	Aifax ESR Test 1 analyser (photometric capillary stopped flow kinetic analysis) BS-HAEM-SOP-25	A, B, C
Whole blood EDTA	Glandular Fever Screen	Clearview IM II test (lateral flow immunoassay) BS-HAEM-SOP-27	A, B
Whole blood EDTA	Sickle cell solubility	Sickle -Check HbS solubility test kit (quantitative tube test) BS-HGP-SOP-31	A, B



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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	Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: HbS HbC HbD HbE HbLepore HbOArab	TOSOH G8 analyser (HPLC): BS-HAEM-SOP-31	A
Whole blood EDTA	HbS estimation	BS-HAEM-SOP-31	A
Whole blood EDTA	Hb Variant confirmation: HbA, HbF, HbS, HbC	Acid and Alkaline electrophoresis BS-HGP-SOP-5 and 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 (cont'd)</u>	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	Aerospray Hematology Pro slide stainer. Thiazin and Eosin Stain and manual microscopy Hematek Stainer Wrights stain and manual microscopy	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 BS-HODS-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>	Aerospray Hematology ProSlide Stainer Thiasin and Eosin stain and manual microscopy. Thin films: BS-HAEM-SOP-10 BS-HAEM-SOP-17 Hematek slide stainer Wrights stain and manual microscopy BS-HAEM-SOP-58	A
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>	Humansis Pf/pan antigen test (chromatographic immunoassay) BS-HAEM-SOP-11	A
Whole blood EDTA Bone marrow aspirate EDTA Cerebrospinal fluid Pleural fluid Synovial fluid Ascitic fluid	Cytospin and staining preparations	ThermoShandon Cytospin 3 centrifuge. Aerospray hematology Pro Slide Stainer BS-HODS-SOP-34 BS-HAEM-SOP-12	A



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<p>HUMAN BODY FLUIDS (cont'd)</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"> Acute leukaemia – AML, ALL (B and T) Chronic myeloid disorders – MDS, CML, CMML Mature lymphoid disorders – B and T lymphoproliferative disorders, Lymphoma, Myeloma <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 FACSLyric analyser, flow cytometry (laser flow cytometry) using manufacturer supplied panels or in house documented methods. BD FACSLyric.</p> <p>BS-HODS-SOP-35 BS-HODS-SOP-39 BS-HODS-INFO-10 BS-HODS-SOP-46 BS-HODS-SOP-43 BS-HODS-SOP-21 BS-HODS-SOP-22 BS-HODS-SOP-2 BS-SOP-HODS-3 BS-HODS-SOP-45</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS (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 (cont'd)</u></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-35 BS-HODS-SOP-39 BS-HODS-INFO-10 BS-HODS-SOP-46 BS-HODS-SOP-43 BS-HODS-SOP-21 BS-HODS-SOP-22 BS-HODS-SOP-2 BS-SOP-HODS-3 BS-HODS-SOP-45</p>	<p>A</p>



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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 FACSLytic analyser, flow cytometry (laser flow cytometry) BD FACSLytic. BS-HODS-SOP-35 BS-HODS-SOP-2 BS-SOP-HODS-3 BS-HODS-SOP-45	
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 BS-HODS-SOP-42 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)		
	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 500 and ACL 750 (latex agglutination)	A
		BS_COAG-SOP-6	
Plasma citrate	Clotting factors: PT based: II V VII X	ACL 500 and ACL 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 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 750 (Latex enhanced immunoassay) BS-COAG-SOP-29	A
	Clotting factor inhibitors: Factor VIII and IX inhibitors	ACL 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 750 (clot end point detection, turbidimetric immunoassay and chromogenic) BS-SCOAG-SOP-9 BS-SCOAG-SOP-10	A
	Von Willebrands screen:	ACL 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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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)	A,
	Anticardiolipin antibodies (IgG and IgM)	BS-SCOAG-SOP-21	
	Collagen binding antigen (CBA)	BS-SCOAG-SOP-21	
	B-2-Glycoprotein IgG		
	B-2-Glycoprotein IgM		
	VW: RcO	SpectraMax plate reader (ELISA)	A
	ADAMTS-13 Activity	BS-SCOAG-SOP-6	
	ADAMST-13 Inhibitor	BS-SCOAG-SOP-5	
	Thrombophilia screen: Protein C antigen	BS-SCOAG-SOP-9	A
	Total protein S	BS-SCOAG-SOP-10	
		BS-SCOAG-SOP-26	
		BS-SCOAG-SOP-27	
Plasma citrate	Prothrombin Gene Mutation (PGM) – qualitative	GeneXpert Dx HemosIL assay	A
	Factor V Leiden (FVL)	BS-SCOAG-SOP-1	
END			