Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9785

Accredited to ISO 15189:2022

Liverpool University Hospitals NHS Foundation Trust

Issue No: 010 **Issue date**: 27 May 2025

Blood Sciences
Clinical support services building

Liverpool University Hospitals NHS

Foundation Trust

Mount Vernon Street

Liverpool

L7 8YE

Contact: Ines Santos Tel: +44 (0)151 706 4374

 $\hbox{E-Mail: } In es. Santos@liverpool ft.nhs.uk$

Website: www.liverpoolcl.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | | Activity | Location code |
|--|--|--|---------------|
| Address Liverpool University Hospitals NHS Foundation Trust Mount Vernon Street Liverpool L7 8YE | Local contact Ines Santos As above | Haematology Transfusion Clinical Biochemistry Antenatal & Newborn Screening | A |
| Address Broadgreen Hospital / Liverpool Heart and Chest Hospital Thomas Drive Liverpool L7 3PE | Local contacts Ines Santos As above | Haematology Transfusion Clinical Biochemistry | В |
| Address Liverpool Women's Hospital. Crown Street Liverpool L8 7SS | Local contacts Ines Santos As above | Haematology Transfusion | С |
| Address Aintree University Hospital Longmoor Lane Liverpool L9 7AI | Local contacts Dr Lisa Bailey Tel: +44(0)151 706 4374 E-Mail: lisa.bailey@liverpoolcl.nhs.uk | Haematology Transfusion Clinical Biochemistry | D |

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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 |
| Main theatre A Aintree University Hospital | Storage of blood only. Under management responsibility of laboratory but no testing occurs at this site. |
| Phoenix Day Unit Aintree University Hospital | Storage of blood only. Under management responsibility of laboratory but no testing occurs at this site. |
| The Walton Centre Lower Lane Liverpool L9 7LJ | Storage of blood only. Under management responsibility of laboratory but no testing occurs at this site. |

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| Location details | Activity |
|----------------------|--|
| AED Theatre recovery | Storage of blood only. Under management responsibility of laboratory but no testing occurs at this site. |

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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of | _ Standard_specifications/ | Location |
|----------------------------|---|---|----------|
| Waterlais/1 readets tosted | measurement | Equipment/Techniques used | Code |
| HUMAN BODY FLUIDS | Biochemistry examination activities for the purpose of clinical diagnosis | 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 | А, В |
| | 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 | А, В |
| | AST | BS-CORE-SOP-51 | А |
| | ALT | BS-CORE-SOP-112 | A, B |
| | GGT | BS-CORE-SOP-61 | A, B |
| Serum | Amylase | BS-CORE-SOP-100 | A, B |
| Serum | СК | BS-CORE-SOP-64 | А |
| | ALP | BS-CORE-SOP-16 | A, B |
| | LDH | BS-CORE-SOP-109 | А |
| | Total Bilirubin | BS-CORE-SOP-119 | A, B |
| Serum | Lithium | BS-CORE-SOP-38 | А |

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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) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: (cont'd) | Roche Cobas 8000 (colorimetric) using | |
| Serum | Urate | BS-CORE-SOP-18 | А |
| Serum | Iron | BS-CORE-SOP-57 | A, B |
| | Salicylate | BS-CORE-SOP-19 | А |
| | Paracetamol | BS-CORE-SOP-22 | А |
| | 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 | А |
| | Creatinine (Jaffe) | BS-CORE-SOP-41 | А |
| | Albumin | BS-CORE-SOP-125 | А |
| | Protein | BS-CORE-SOP-124 | А |
| | Magnesium | BS-CORE-SOP-29 | А |
| | Amylase | BS-CORE-SOP-100 | А |
| | Urate | BS-CORE-SOP-18 | А |
| | Calcium | BS-CORE-SOP-110 | A |
| | Phosphate | BS-CORE-SOP-122 | А |
| | 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) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: (cont'd) | Roche Cobas 8000 (colorimetric) using | |
| Serum | Direct bilirubin | BS-CORE-SOP-107 | А |
| | ACE | BS-CORE-SOP-31 | А |
| | Ammonia | BS-CORE-SOP-53 | А |
| | Lactate | BS-CORE-SOP-108 | А |
| | LDH | BS-CORE-SOP-109 | А |
| | Bile acid | BS-CORE-SOP-50 | А |
| | Quantitative determination of: | Roche Cobas 8000 (Immunoturbidimetry) using: | |
| | CRP | BS-CORE-SOP-39 | A, B |
| | Transferrin | BS-CORE-SOP-37 | В |
| | IgA | BS-CORE-SOP-44 | A |
| | IgG | BS-CORE-SOP-45 | A |
| | IgM | BS-CORE-SOP-46 | A |
| | С3 | BS-CORE-SOP-62 | A |
| | C4 | BS-CORE-SOP-54 | A |
| | B2 Microglobulin | BS-CORE-SOP-87 | А |
| | α1-antitrypsin | BS-CORE-SOP-52 | А |
| Urine/Serum | Caeruloplasmin | BS-CORE-SOP-55 | А |
| | Haptoglobin | BS-CORE-SOP-113 | А |
| | | | |
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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: | Roche Cobas 8000 (Ion selective electrode ISE) using: | |
| Urine/serum | Sodium | BS-CORE-SOP-12 | A, B, D |
| | Potassium | BS-CORE-SOP-30 | A, B, D |
| | Chloride | BS-CORE-SOP-121 | A, B, D |
| | Quantitative determination of: | Roche Cobas 8000 c701 module (Agglutination immunoassay) using: | |
| Serum | Phenytoin | BS-CORE-SOP-8 | А |
| | Theophylline | BS-CORE-SOP-11 | А |
| | Carbamazepine | BS-CORE-SOP-13 | A |
| | Qualitative determination of: | | |
| | Rheumatoid Factor (RF) | BS-CRLUH-SOP-5 | A |
| | Quantitative determination of: | Roche Cobas 8000 c701 module (enzymatic) using: | |
| | Ethanol | BS-CORE-SOP-5 | А |
| | Quantitative determination of: | Roche Cobas 8000 c701 module (enzyme immunoassay) using: | |
| | Gentamicin | BS-CORE-SOP-93 | A |
| | Tobramicin | BS-CORE-SOP-101 | А |
| | Vancomycin | BS-CORE-SOP-120 | А |
| | Teicoplanin | BS-CORE-SOP-36 | А |
| | Amikacin | BS-CORE-SOP-103 | А |
| | valproate | BS-CORE-SOP-20 | А |

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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) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: | Roche Cobas 8000/C702 Module (photometric) | |
| Serum/Plasma | Albumin | BS-CORE-SOP-25 | D |
| | Alkaline Phosphatase | BS-CORE-SOP-16 | D |
| | ALT | BS-CORE-SOP-112 | D |
| | AST | BS-CORE-SOP-51 | D |
| | Bicarbonate | BS-CORE-SOP-123 | D |
| | Carbamazepine | BS-CORE-SOP-13 | D |
| | Cholesterol | BS-CORE-SOP-9 | D |
| | Creatine Kinase (CK) | BS-CORE-SOP-64 | D |
| | C Reactive Protein | BS-CORE-SOP-39 | D |
| | Creatinine | BS-CORE-SOP-40 | D |
| | Direct bilirubin | BS-CORE-SOP-107 | D |
| | Gentamycin | BS-CAUH-SOP-18 | D |
| | Gamma GT | BS-CORE-SOP-61 | D |
| | HDL Cholesterol | BS-CORE-SOP-3 | D |
| | Iron | BS-CORE-SOP-57 | D |
| | LDH | BS-CORE-SOP-109 | D |
| | Lithium | BS-CORE-SOP-38 | D |
| | Paracetamol | BS-CORE-SOP-22 | D |
| | Phenytoin | BS-CORE-SOP-8 | D |
| | Salicylate | BS-CORE-SOP-19 | D |

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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: (cont'd) | Roche Cobas 8000/C702 Module (photometric) | |
| Serum/Plasma | Theophylline | BS-CORE-SOP-11 | D |
| | Total bilirubin | BS-CORE-SOP-119 | D |
| | Triglyceride | BS-CORE-SOP-4 | D |
| | Valproate | BS-CORE-SOP-20 | D |
| | Vancomycin | BS-CORE-SOP-120 | D |
| | Ammonia | BS-CORE-SOP-53 | D |
| | Ethanol | BS-CORE-SOP-5 | D |
| | Lactate | BS-CORE-SOP-108 | D |
| | Amylase | BS-CORE-SOP-100 | D |
| | Calcium | BS-CORE-SOP-110 | D |
| | Magnesium | BS-CORE-SOP-29 | D |
| | Phosphate | BS-CORE-SOP-122 | D |
| | Urate | BS-CORE-SOP-18 | D |
| | Urea | BS-CORE-SOP-10 | D |
| Serum/Plasma/CSF | Glucose | BS-CORE-SOP-65 | D |
| Serum/Plasma/urine/CSF | Total Protein | BS-CORE-SOP-102 | D |
| Urine | Creatinine | BS-CORE-SOP-41 | D |
| | Microalbumin | BS-CORE-SOP-18 | D |
| | | | |
| | | | |

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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) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: | Roche Cobas 8000 e801 module (electrochemiluminescence) using: | |
| Serum | Troponin T (HS) | BS-CORE-SOP-118 | A, B |
| | NTproBNP | BS-CORE-SOP-17 | А |
| | 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 | А |
| | Progesterone | BS-CORE-SOP-1 | А |
| | Estradiol | BS-CORE-SOP-14 | А |
| | Testosterone (male) | BS-CORE-SOP-24 | А |
| | DHEAS | BS-CORE-SOP-81 | А |
| | SHBG | BS-CORE-SOP-23 | А |
| | LH | BS-CORE-SOP-2 | А |
| | FSH | BS-CORE-SOP-106 | А |
| | TSH | BS-CORE-SOP-95 | A, B |
| | FT4 | BS-CORE-SOP-96 | A, B |
| | FT3 | BS-CORE-SOP-97 | А |
| | | | |
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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) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: (cont'd) | Roche Cobas 8000 e801 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 | А |
| | CA-125 | BS-CORE-SOP-67 | A |
| | CA-15-3 | BS-CORE-SOP-69 | А |
| | CA-19-9 | BS-CORE-SOP-70 | А |
| | AFP | BS-CORE-SOP-26 | А |
| | HCG | BS-CORE-SOP-63 | А |
| | CEA | BS-CORE-SOP-71 | A |
| | Thyroglobulin | BS-CORE-SOP-76 | А |
| | P1NP | BS-CORE-SOP-82 | А |
| | СТх | BS-CORE-SOP-116 | А |
| | Anti TSH receptor Abs | BS-CORE-SOP-79 | А |
| | Anti TPO Abs | BS-CORE-SOP-78 | Α |
| 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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| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|----------------------------|--|--|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: (cont'd) | Roche Cobas 8000 801 module (electrochemiluminescence) using: | |
| Serum | 25 OH Vitamin D | BS-NONA-SOP-43 | A |
| | Anti-thyroglobulin Abs | BS-CORE-SOP-77 | A |
| | Digoxin | BS-CORE-SOP-7 | A |
| | | | |
| Serum | SFLT | BS-CORE-SOP-141 | Α |
| | PLGF | BS-CORE-SOP-140 | Α |
| | | Roche Cobas 8000/e602 (chemiluminescent immunoassay with photometric detection) | |
| Serum | AFP | BS-CORE-SOP-26 | D |
| | CA125 | BS-CORE-SOP-67 | D |
| | CA19-9 | BS-CORE-SOP-70 | D |
| | CEA | BS-CORE-SOP-71 | D |
| | Cortisol | BS-CORE-SOP-89 | D |
| | Digoxin | BS-CORE-SOP-7 | D |
| | Ferritin | BS-CORE-SOP-117 | D |
| | FSH | BS-CORE-SOP-106 | D |
| | fT3 | BS-CORE-SOP-97 | D |
| | fT4 | BS-CORE-SOP-96 | D |
| | Folate | BS-CORE-SOP-114 | D |
| | GH | BS-CORE-SOP-111 | D |

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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) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: (cont'd) | Roche Cobas 8000/e602 (chemiluminescent immunoassay with photometric detection) | |
| | hCG | BS-CORE-SOP-63 | D |
| | hs-TnT | BS-CORE-SOP-118 | D |
| | LH | BS-CORE-SOP-2 | D |
| | NT-proBNP | BS-CORE-SOP-17 | D |
| | Oestradiol | BS-CORE-SOP-14 | D |
| | Progesterone | BS-CORE-SOP-1 | D |
| | Prolactin | BS-CORE-SOP-15 | D |
| | PTH | BS-CORE-SOP-88 | D |
| | PSA | BS-CORE-SOP-72 | D |
| | SHBG | BS-CORE-SOP-23 | D |
| | Testerone | BS-CORE-SOP-24 | D |
| | TSH | BS-CORE-SOP-95 | D |
| | Vitamin B12 | BS-CORE-SOP-66 | D |
| 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 | А |
| | | Advanced micro Osmometer (freezing point depression) BS-CAUH-SOP-51 | D |
| | | | |

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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) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| 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 |
| | | Biosign hCG pregnancy testing using DXpress reader, solid phase chromatographic immunoassay | D |
| Urine | pH measurement | Hannah ph meter using: BS- NONA-SOP-21 | А |
| | | Roche Cobas 8000 e801 (Immunoassay) using: | |
| Serum | АМН | BS-CORE-SOP-2 | A |
| | NSE | BS-CORE-SOP-157 | А |
| | Quantitative determination of: | IDS isys chemiluminescence using: | |
| Plasma | Aldosterone | BS-NONA-SOP-27 | А |
| Plasma | Renin | BS-NONA-SOP-1 | А |
| Faeces | Faecal Immunochemical Testing (FIT) | Pledia OC Sensor by latex agglutination using: BS-NON-SOP-69 | А |
| Whole blood | Measurement of β- hydroxybutyrate | Nova StarStrip ketone meter POCT-SOP-11 | D |
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|----------------------------|--|---|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: | IDS isys chemiluminescence using: | |
| Serum | GH | BS-NONA-SOP-27 | А |
| Serum | IGF-1 | BS-NONA-SOP-29 | А |
| Serum | 1-25 OH Vitamin D | IDS-iSYS BD-NONA-SOP-76 | A |
| | Quantitative determination of: | DS2 automated ELISA using: | |
| Faeces | Faecal calprotectin | Biohit extraction ELISA BS-NONA-SOP-40 | А |
| | Faecal Elastase | IDK Pancreatic Elastase ELISA BS-NONA-SOP-83 | A |
| | | | |
| | | | |
| | 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 | А |
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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: | Thermo Vanquish Core HPLC System using) using: | |
| Whole blood | Thiamine (Vitamin B1) | BS-NONA-SOP-54 | А |
| Serum | Vitamin A | BS-NONA-SOP-23 | A |
| | Vitamin E | BS-NONA-SOP-23 | A |
| | Quantitative determination of: | TOSOH HLC-723 G8 using: | |
| | Glycated haemoglobin (HbA1c) | BS-NONA-SOP-44 | |
| Plasma Whole Blood only | (FIDATO) | | A D |
| | Quantitative determination of: | Waters Xevo TQD LC-MS/MS using: | |
| Whole blood | Cyclosporin | BS-NONA-SOP-63 | А |
| Whole blood | Sirolimus | BS-NONA-SOP-64 | А |
| Whole blood | Tacrolimus | BS-NONA-SOP-63 | А |
| Urine | 5HIAA | BS-NONA-SOP-24 | А |
| | Quantitative determination of: | Waters Acquity UPLC-TQS LC-MS/MS using: | |
| Urine | Urine Metadrenalines (metadrenaline, normetadrenaline, and 3- methoxytyramine) | BS-NONA-SOP-9 | A |
| Urine | Urine free cortisol | BS-NONA-SOP-56 | A |
| Serum | 17-OHP | BS-NONA-SOP-8 | А |
| Serum | Female Testosterone | BS-NONA-SOP-42 | А |
| Serum | Androstenedione | BS-NONA-SOP-42 | А |

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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: | Thermo ICAP ICPMS using: | |
| Serum | Copper | BS-NONA-SOP-47 | А |
| Whole blood | Lead | BS-NONA-SOP-13 | А |
| Whole blood | Manganese | BS-NONA-SOP-14 | А |
| Serum | Selenium | BS-NONA-SOP-47 | А |
| Serum | Zinc | BS-NONA-SOP-47 | А |
| Whole blood | Cobalt | BS-NONA-SOP-55 | А |
| Whole blood | Chromium | BS-NONA-SOP-55 | А |
| Urine | Copper | BS-NONA-SOP-47 | А |
| | Quantitative determination of: | Thermo ICP-MS Inductively Coupled Mass Spectrometry (ICPMS) | |
| Serum | Peg prolactin (precipitation of macroprolactin) | BS-NONA-SOP-53 | А |
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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Quantitative determination of: | Roche 9180 electrolyte analyser using: | |
| Serum/urine | Sodium | BS-CORE-SOP-12 | A |
| Serum/urine | Potassium | BS-CORE-SOP-13 | A |
| Arterial Blood | Blood Gas: pCO2 | Siemens Rapidpoint 500e | D |
| | pO2 Na+ K+ Ca2+ Cl- Glu Lactate tHb FO2Hb COHb | SOP: POCT-SOP-59 | |
| | FMetHb Calculated tests | | |
| Serum | Anion Gap | BS-CORE-SOP-80, BS-CAUH- SOP-36 | A, B, D |
| Serum | eGFR | BS-CORE-SOP-86, BS-CAUH- SOP-36 | A, B, D |
| Serum | AKI alerts | BS-CORE-SOP-91, BS-CAUH- SOP-36 | A, B, D |
| Serum | Adjusted Calcium | BS-CORE-SOP-85, BS-CAUH- SOP-36 | A, B, D |
| Serum | Globulins | BS-CORE-SOP-84, BS-CAUH- SOP-36 | A, B, D |
| Serum | Non-HDL cholesterol | BS-CORE-SOP-92, BS-CAUH- SOP-36 | A, B, D |
| Serum | LDL cholesterol | BS-CORE-SOP-92, BS-CAUH- SOP-36 | A, B, D |

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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Calculated tests (cont'd) | | |
| Serum | Cholesterol/HDL ratio | BS-CORE-SOP-92, BS-CAUH- SOP-36 | A, B, D |
| Plasma | Total Iron Binding Capacity (TIBC) | BS-CORE-SOP-94, BS-CAUH- SOP-36 | A, B, D |
| Serum | Fe % saturation | BS-CORE-SOP-92, BS-CAUH- SOP-36 | A, B, D |
| Urine | urine calcium/creatinine ratio | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| Urine | Urine protein/creatinine ratio | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| Urine | urine albumin/creatinine ratio | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| 24 hour Urine and Serum | Creatinine clearance | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| Urine | Urine Sodium/24hrs | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A. D |
| Urine | Urine Potassium/24 hrs | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| Urine | Urine Chloride/24 hrs | BS-CORE-SOP-99 | A |
| Urine | Urine Urea/24 hrs | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| Urine | Urine Creatinine/24 hrs | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| Urine | Urine Albumin/24 hrs | BS-CORE-SOP-99 | A |
| Urine | Urine Protein/24hrs | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A,.D |
| Urine | Urine Magnesium/24hrs | BS-CORE-SOP-99 | Α |

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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Calculated tests (cont'd) | | |
| Urine | Urine Amylase/24hrs | BS-CORE-SOP-99 | А |
| Urine | Urine Urate/24hrs | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A. D |
| Urine | Urine Calcium/24hrs | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| Urine | Urine Phosphate/24hrs | BS-CORE-SOP-99, BS-CAUH- SOP-36 | A, D |
| Urine | Urine Sodium/24hrs | BS-CORE-SOP-99 | А |
| Urine | Urine Potassium/24 hrs | BS-CORE-SOP-99 | А |
| Urine | Urine Chloride/24 hrs | BS-CORE-SOP-99 | A |
| Urine | Urine Creatinine/24 hrs | BS-CORE-SOP-99 | A |
| Urine | Urine Albumin/24 hrs | BS-CORE-SOP-99 | A |
| Urine | Urine Protein/24hrs | BS-CORE-SOP-99 | A |
| Urine | Urine Magnesium/24hrs | BS-CORE-SOP-99 | А |
| Urine | Urine Amylase/24hrs | BS-CORE-SOP-99 | А |
| Urine | Urine Urate/24hrs | BS-CORE-SOP-99 | A |
| Urine | Urine Calcium/24hrs | BS-CORE-SOP-99 | А |
| 24 hour Urine and Serum | AST/Platelet Ratio | BS-CAUH-SOP-36 | D |
| 24 hour Urine and Serum | Calcium Clearance | BS-CAUH-SOP-36 | D |
| 24 hour Urine and Serum | Calcium Excretion Index | BS-CAUH-SOP-36 | D |
| 24 hour Urine and Serum | Calcium: Creatinine ratio | BS-CAUH-SOP-36 | D |
| Serum | Calculated Osmolarity (part of OGAP) | BS-CAUH-SOP-36 | D |

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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures based on equipment manuals as relevant | |
| | Calculated tests (cont'd) | | |
| Serum | Estimated Monomeric Prolactin | BS-CAUH-SOP-36 | D |
| Serum | Fractional Excretion Magnesium | BS-CAUH-SOP-36 | D |
| Serum | Free Androgen Index | BS-CAUH-SOP-36 | D |
| Serum | Macroprolactin | BS-CAUH-SOP-36 | D |
| Serum | Osmolar Gap | BS-CAUH-SOP-36 | D |
| Serum | Serum Ascites Albumin Gradient | BS-CAUH-SOP-36 | D |
| Serum | Free Testosterone | BS-CAUH-SOP-36 | D |
| Serum | Ethanol | BS-CAUH-SOP-36 | D |
| Whole blood only | Standard bicarbonate | BS-CAUH-SOP-30 | D |
| Urine | Urine Phosphate/24hrs | BS-CORE-SOP-99 | A |
| Urine | Urine chromium/creatinine ratio | BS-CORE-SOP-99 | A |
| Urine | Urine copper/24 hrs | BS-CORE-SOP-99 | A |
| Urine | Urine cobalt/creatinine ratio | BS-CORE-SOP-99 | A |
| Urine | Urine nickel/24 hrs | BS-CORE-SOP-99 | A |
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| HUMAN BODY FLUIDS (cont'd) | Blood Transfusion examinations to assist in clinical investigations | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| Blood Plasma | Blood Group/Phenotype by detection and identification of antigens: A B O Rh | Automated using Ortho Vision and Ortho BioVuecolumn agglutination using: BS-TRAN-SOP-23 And RhK cards;- BS-TRAN-SOP 117 BS-TAUH-SOP-1 Automated using Ortho AutoVue and Ortho BioVue column technology BS-TRAN-SOP-34 Manual using BioRad Diamed Gel cards BS-TRAN-SOP-44 | A, B, D |
| Blood Plasma | Antibody Screen 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 | Automated using Ortho Vision and Ortho BioVue column agglutination and Ortho 3 and 11 cell panelsBS-TRAN-SOP-23 BS-TRAN-SOP-42 (11 cell) BS-TAUH-SOP-1 Automated using Ortho AutoVue and Ortho BioVue column technology and Ortho 3 and 11 cell panels BS-TRAN-SOP-34 (3 cell) BS-TRAN-SOP-42 (11 cell) | A, B, D |
| | | Manual using BioRad Diamed Gel cards and either/or Ortho 3 and 11 cell panels or NHSBT 2 and 10 cell panels BS-TRAN-SOP-41 | A, B, C |

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| HUMAN BODY FLUIDS (cont'd) | Blood Transfusion examinations to assist in clinical investigations (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) | BioRad BS-TRAN-SOP-43, BS-TAUH- SOP-1 | A, B, C, D |
| | Direct Antiglobulin Test (Automated) (Phenotype) | Automated using Ortho Vision (Column Agglutination Technology) using: BS-TRAN-SOP-43 | А, В |
| EDTA Whole Blood | Electronic Issue | BS-TRAN-SOP-6 | A, B, C |
| EDTA plasma | Serological Crossmatch (Manual) | BioRad BS-TRAN-SOP-45, BS-TAUH- SOP-14 | A, B, C, D |
| EDTA Whole Blood | Electronic cross match | BS-TAUH-SOP-30 | D |
| EDTA plasma | Manual 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 |

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| HUMAN BODY FLUIDS (cont'd) | Blood Transfusion examinations to assist in clinical investigations (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 plasma | Automated 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 | Biovue IAT (Column agglutination technology) using: BS-TRAN-SOP-42 BS-TUAH-SOP-12 | A, B, D |
| EDTA plasma | Antibody screen manual Rhesus: 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 | BIOVUE IgG/Poly cards (column agglutination technology) BS-TAUH-SOP-32 | D |
| EDTA whole blood | Blood grouping A B O Rhesus D status | Manual methods using BIOVUE cassette (column agglutination technology) BS-TAUH-SOP-33 | D |

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| HUMAN BODY FLUIDS (cont'd) | Blood Transfusion examinations to assist in clinical investigations (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 ^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 |
| EDTA Whole Blood | Automated Rh/K typing | Ortho Vision utilising Column agglutination technology using: BS-TRAN-SOP-117 | A, B |
| EDTA plamsa | IgG Anti A & B titres for ABO incompatible renal transplants | ABO titres using BioRad system using: BS-TRAN-SOP-10 | A |
| HUMAN BODY FLUIDS (cont'd) | Provision of stem cell preparations and related products for the purpose of stem cell transplantation | 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: | A |
| | | RBS-BMT-SOP-70 | |
| EDTA whole blood | CD3 cell enumeration | FACS Canto flow cytometer: | А |
| | | RBS-BMT-SOP-71 | |
| | | | |

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| HUMAN BODY FLUIDS (cont'd) | Molecular genetic analysis for genetic mutations and variants | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| A. Fixed bone marrow cells | DNA extraction from Fixed cells | Genomic DNA extraction from fixed cell using QIAamp® DNA Mini Kit BS-MOLB-SOP-34 | A |
| B. FFPE tissue sample | DNA extraction from FFPE tissue sample | Extraction of gDNA from FFPE tissue samples using QIAamp DNA FFPE Tissue Kit HD-MBO-SOP-3 | |
| C. EDTA whole blood | DNA extraction from EDTA whole blood | HODS DNA/RNA extraction by AllPrep DNA/RNA Mini Kit HD-MBO-SOP-25 | |
| D. EDTA whole blood | RNA extraction from EDTA whole blood | Haematology Molecular Biology Myeloid Manual RNA extraction by RNeasy Mini Kit BS-MOLB-SOP-35 | |
| | | Haematology Molecular Biology Use of QIAcube BS-MOLB-SOP-10 | |
| E. EDTA bone marrow | DNA extraction from EDTA bone marrow | HODS DNA/RNA extraction by AllPrep DNA/RNA Mini Kit HD-MBO-SOP-25 | |
| F. EDTA bone marrow | RNA extraction from EDTA bone marrow | Haematology Molecular Biology Myeloid Manual RNA extraction by RNeasy Mini Kit BS-MOLB-SOP-35 | |
| | | Haematology Molecular Biology Use of QIAcube BS-MOLB-SOP-10 | |
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| HUMAN BODY FLUIDS (cont'd) | Molecular genetic analysis for genetic mutations and variants (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| RNA extracted from sample types D and F above | Screening for BCR-ABL (p190 gene) | Manual RT-PCR on thermocycler 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 |
| RNA extracted from sample types D above | BCR::ABL1 Quantification | BCR::ABL Ultra p190 kit BCR::ABL Ultra kit p210 kit. RT-PCR using Cepheid GeneXpert system HD-MBO-SOP-46 | A |
| DNA extracted from sample types A, B, C and E above | Detection of NPMI mutation | Real-time PCR using the Light Cycler 480 NPM1 mutation by QIAGEN Ipsogen NPM1 MutScreen kit (BS-MOLB-SOP-21) | A |
| DNA extracted from sample types A, B, C and E above | Detection of c-KIT Mutation | Real-time PCR using the Light Cycler 480 Haematology Molecular Biology c-KIT mutation by real-time quantitative PCR (BS-MOLB- SOP-24) | A |
| RNA extracted from sample types D and F above | 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) | Molecular genetic analysis for genetic mutations and variants (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| DNA extracted from sample types A, B, C and E above | 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- | A |
| DNA and RNA extracted from samples types A, B, C, D, E and F above | Targeted detection of mutations and gene fusions associated with myeloid disorders | Oncomine Myeloid NGS Panel sequencing on Ion Torrent using: | |
| | | Haematology molecular Biology genomic DNA and Vilo cDNA preparation (BS-MOLB-SOP-66) | |
| | | Quantification by Qubit 2.0 fluorometer (HD-MBO-SOP-26) | |
| | | Library preparation and Sequencing using Ion Torrent Genexus, Next Generation Sequencinf Platform. (HD-MBO- SOP-9) | |
| | | Oncomine Myeloid NGS data analysis and reporting using Ion Reporter and Oncomine Variant Annotator (HD-MBO-SOP-19) | |
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| HUMAN BODY FLUIDS (cont'd) | Molecular genetic analysis for genetic mutations and variants (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| DNA extracted from samples types A, B, C, E above | Targeted detection of SNVs and small indels | Oncomine Lymphoma Core Panel NGS sequencing using Ion Torrent S5 Prime. | А |
| | | Library preparation and analysis using Ion Chef HD-MBO-SOP-1 Sequencing using Ion Torrent S5 Prime HD-MBO-SOP-2 | |
| | | Analysis using Thermofisher Ion Reporter HD-MBO-SOP-4 | |
| DNA extracted from samples types C and E above | Targeted detection of SNVs and small indels | TP53 Panel - Genexus Oncomine Myeloid NGS | А |
| | | Genexus Integrated Sequencer Myeloid Panel HD-MBO-SOP-9 | |
| | | TP53 mutation data analysis and reporting HD-MBO-SOP-28 | |
| | | Genexus Integrated Sequencer Myeloid data analysis and reporting HD-MBO-SOP-19 | |
| DNA extracted from samples types C and E above | Targeted detection of SNVs and small indels | Myeloproliferative Panel (MPN) Genexus NGS | A |
| | | Genexus Integrated Sequencer MPN Panel HD-MBO-SOP-10 | |
| | | Genexus Integrated Sequencer MPN data analysis and reporting HD-MBO-SOP-17 | |
| | | | |

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| HUMAN BODY FLUIDS (cont'd) Molecular genetic analysis for genetic mutations and variants (cont'd) Procedures documen manufacturer's equipment and company manuals in conjunction documented in-house procedures by the following methods: | nent n with |
|--|--|
| DNA from bone marrow or peripheral blood Detection of hotspot mutation in MYD88 (L265P) Allele Specific PCR a gel electrophoresis us Qiagen Allprep DNA I QIAamp Mini kit for D extraction: HD-MBO-SOP-25 BS-MOLB-SOP-34 NanoDrop 8000 using spectrophotometry te HD-MBO-SOP-20 Agarose Gel electrop Geneflow MultiSUB O Horizontal Gel Unit 18 HD-MBO-SOP-27 BS-MOLB-FOR-20 HD-MBO-SOP-27 | ing: fini Kit or NA chnology noresis and hoice |

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| HUMAN BODY FLUIDS (cont'd) | Haematological examinations for the purpose of clinical diagnosis | 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: | Sysmex XN automated analysers; hydrodynamic focusing, fluorescent staining, differential laser light scatter | A, B, C, D |
| | WBC RBC HGB HCT MCV MCH MCHC RDW PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count | BS-HAEM-SOP-75 AH-GHAE-SOP-8 | |
| Whole blood EDTA | Reticulocyte count | BS-HAEM-SOP-75 | А |
| Whole blood EDTA | Erythrocyte Sedimentation Rate (ESR) | Ailfax ESR Test 1 analyser (photometric capillary stopped flow kinetic analysis) BS-HAEM-SOP-25 | А, В, |
| | | Automated Starrsed analyser, modified Westergren method BS-HAUH-SOP-2 | D |
| Whole blood EDTA | Glandular Fever Screen | Clearview IM II test (lateral flow immunoassay) BS-HAEM-SOP-27 | A |

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| HUMAN BODY FLUIDS (cont'd) | Haematological examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| Whole blood EDTA | Sickle cell solubility | Sickledex Screening Test, HbS solubility test kit (quantitative tube test) using: BS-HGP-SOP-56 | Α, |
| Whole blood EDTA Serum or EDTA plasma | Detection of infectious mononucleosis heterophile antibodies | Clearview® IM II test. Rapid chromatographic immunoassay kit AH-GHAE-SOP-1 | D |
| Whole blood EDTA | Sickle Cell Screening Test | Lateral Flow chromatographic qualitative immunoassay test kit, Sickle SCAN (detection of HbA, HbS and HbC) using: BS-HAEM-SOP-69. | A |
| | | Documented -in-house methods to meet the requirements of the Sickle cell and Thalassaemia (SCT) screening programme screening programme(s) laboratory QA evidence requirements' | |
| Whole blood EDTA | Adult Haemoglobinopathy | TOSOH G11 analyser (HPLC): | А |
| | analysis (including Antenatal) by detection of haemoglobin variants: HbS HbC HbD HbE HbLepore HbOArab | BS-HGP-SOP-57 | |
| Whole blood EDTA | HbS estimation | BS-HGP-SOP-57 | A |

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| HUMAN BODY FLUIDS (cont'd) | Haematological examinations for the purpose of clinical diagnosis (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 Sickle cell and Thalassaemia (SCT) screening programme screening programme(s) laboratory QA evidence requirements' | |
| 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 | А |
| Whole blood EDTA | Malarial antigens of: P. falciparum P. vivax P. ovale P. malariae P.knowlesi | BinaxNow Malaria Screening Test (MST) BS-HAEM-SOP-74 | A |

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| HUMAN BODY FLUIDS (cont'd) | Morphology examinations for the purpose of clinical diagnosis | 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 | A |
| | | RAL Stainer Wrights stain and manual microscopy BS HAEM-SOP-73 | A, B, C |
| Whole blood | Identification of normal and abnormal morphologies including WBC differential count | Automated staining using RAL Stainer: Kit RAL Stainer MCDh Giemsa and May Grunwald stains. SOP: BS-HEAM-SOP-73 | D |
| Bone marrow aspirate EDTA slides | Reporting of normal and abnormal morphologies | Aerospray Hematology ProSlide Stainer HD-IMP-SOP-24 Thiazin and Eosin Stain and manual microscopy Perls Stain BS-HODS-SOP-29 HD-GEN-POL-1 | A |

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| HUMAN BODY FLUIDS (cont'd) | Morphology examinations for the purpose of clinical diagnosis (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: P. falciparum P. vivax P. ovale P. malariae P.knowlesi | Automated smear and staining using: Sysmex SP-50 BS-HAEM-SOP-76 Thiasin and Eosin stain and manual microscopy. Thin films: BS-HAEM-SOP-70 BS-HAEM-SOP-17 RAL Stainer Wrights stain and manual | A A, B, C |
| | | microscopy BS HAEM-SOP-73 | |
| Whole blood EDTA | Blood film analysis | May-Grunwald and Giemsa stains and manual microscopy. Automated smear and staining using Sysmex SP-10 AH-GHAE-SOP-18 Manual light microscopy (Nikon) AH-GHAE-SOP-16 | D |
| 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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| HUMAN BODY FLUIDS (cont'd) | Immunophenotyping examinations for the purpose of clinical diagnosis | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| Whole blood EDTA Bone marrow aspirate EDTA Cerebrospinal fluid Pleural fluid Synovial fluid Ascitic fluid FNA | Immunophenotyping of the following markers/antigens for the diagnosis and monitoring of Haematological malignancy including the following disorders: • Acute leukaemia – AML, ALL (B and T) • Chronic myeloid disorders – MDS, CML, CMML • Mature lymphoid disorders – B and T lymphoproliferative disorders, Lymphoma, Myeloma CD1a CD2 CD3 CD4 CD5 CD7 CD8 CD10 CD11b CD11c CD13 CD14 CD15 CD16 CD19 CD20 CD22 CD23 CD25 CD26 | BD FACSLyric analyser, flow cytometry (laser flow cytometry) using manufacturer supplied panels or in house documented methods. BD FACSLyric. HD-IMP-SOP-26 HD-IMP-INF-8 BS-HODS-SOP-46 BS-HODS-SOP-43 BS-HODS-SOP-21 HD-IMP-SOP-27 HD-IMP-SOP-20 BS-HODS-SOP-50 HD-IMP-SOP-10 | A |

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| HUMAN BODY FLUIDS (cont'd) Whole blood EDTA Bone marrow aspirate EDTA | Haematological examinations for the purpose of clinical diagnosis Immunophenotyping of the following markers/antigens for | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: BD FACSLyric analyser, flow | A |
| Cerebrospinal fluid Pleural fluid Synovial fluid Ascitic fluid FNA (cont'd) | the diagnosis and monitoring of Haematological malignancy (cont'd) CD27 CD30 CD33 CD34 CD38 CD45 CD56 CD64 CD79a CD79b CD81 CD103 CD117 CD123 CD138 CD200 CD235a B2 Microglobulin cLysozyme FMC-7 HLA-DR TSLPR | cytometry (laser flow cytometry) using manufacturer supplied panels or in house documented methods. BD FACSLyric. HD-IMP-SOP-26 HD-IMP-INF-8 BS-HODS-SOP-46 BS-HODS-SOP-21 HD-IMP-SOP-27 HD-IMP-SOP-20 BS-HODS-SOP-50 HD-IMP-SOP-10 | |

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| HUMAN BODY FLUIDS (cont'd) | Haematological examinations for the purpose of clinical diagnosis (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-SOP-16 HD-IMP-SOP-10 | A |
| Urine | Reporting of normal and abnormal morphologies Coagulation examination activities for the purpose of clinical diagnosis | 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) Werfen TOPs 300 (clot end point detection) | В |

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| HUMAN BODY FLUIDS (cont'd) | Coagulation examination activities for the purpose of clinical diagnosis (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 | А, В |
| | Activated Partial thromboplastin time Ration (APTR) | | |
| | Prothrombin time (PT) | BS-COAG-SOP-3 | |
| | International normalised ratio (INR) | | |
| | Activated partial thromboplastin time (APTT) and ratio | Clotting point detection method ACL TOP 550 Automated Coagulation Analysers': AH- COAG-SOP-22 | D |
| Plasma citrate | Mixing Studies for investigation of prolonged PT and APTT | ACL TOP 550 Automated Clotting point detection method AH-COAG-SOP-12 | D |
| | Prothrombin time (PT) and International normalised ratio (INR) | ACL TOP 550 Automated Clotting point detection method AH-COAG-SOP-21 | D |
| | Anti-Xa (Heparin) Assay | BS-COAG-SOP-10 | A |
| | Clauss Fibrinogen | BS-COAG-SOP-5 | A, B |
| | | ACL TOP 550 Automated Clotting point detection method AH-COAG-SOP-5 | D |
| | Mixing studies for investigation of prolonged PT and APTT | BS-COAG-SOP-12 | А |
| | | | |

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| HUMAN BODY FLUIDS (cont'd) | Coagulation examination activities for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| Plasma citrate | D-Dimer | ACL TOP 750 (latex agglutination) BS_COAG-SOP-6 | А |
| | | ACL TOP 550 Automated Immunoassay AH-COAG-SOP-7 | D |
| Plasma citrate | Clotting factors: PT based: | ACL TOP 750 (clot end point detection) | A |
| | V VII X | BS-SCOAG-SOP-7 | |
| | APTT based: VIII IX,XI,XII | | |
| 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) | А |
| | | BS-COAG-SOP-29 | |
| | Clotting factor inhibitors: Factor VIII and IX inhibitors | ACL TOP 750 (clot end point detection) | A |
| | | BS-SCOAG-SOP-8 | |
| | | | |
| | | | |

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| HUMAN BODY FLUIDS (cont'd) | Coagulation examination activities for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| 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 | |
| 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 | |
| | B-2-Glycoprotein IgG | BS-SCOAG-SOP-15 | |
| | Collagen binding antigen (CBA) | BS-SCOAG-SOP-21 BS-SCOAG-SOP-15 | |
| | | | |
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| HUMAN BODY FLUIDS (cont'd) | Coagulation examination activities for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| Plasma citrate | | 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 | А |
| Plasma citrate | Prothrombin Gene Mutation (PGM) – qualitative | GeneXpert Dx HemosIL assay | A |
| | Factor V Leiden (FVL) | BS-SCOAG-SOP-1 | |
| 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 | А |
| | Chromogenic VIII | Chromogenic VIII assay performed on ACL TOP 50 series coagulation ananaysers BS-SCOAG-SOP-31 | А |
| Plasma Citrate | ADAMTS13 Activity | Automated ELISA on Acustar analyser BS-SCOAG-SOP-30 | A |
| END | | | |

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