# Schedule of Accreditation

**issued by**

# United Kingdom Accreditation Service

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

**9133**

**Accredited to ISO 15189:2022**

## Gateshead Health NHS Foundation Trust

**operating as**

## South of Tyne & Wear Clinical Pathology Services

**Issue No:** 012 **Issue date:** 10 September 2026


**Sheriff Hill**
**Gateshead**
**Tyne & Wear**
**NE9 6SX**

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**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**<br>Queen Elizabeth Hospital<br>Gateshead Health NHS Foundation Trust<br>Sheriff Hill<br>Gateshead<br>Tyne & Wear<br>NE9 6SX | **Local contact**<br><br><br>As above | Biochemistry<br>Haematology, Blood Transfusion<br>Blood/product storage/issue<br>Microbiology<br>Serology<br>Immunology<br>Histopathology<br>Cytopathology – Non Gynae & Gynae<br>Andrology<br>HPV Screening Service<br><br>Management of Point of Care Testing Provision –<br>Clinical Chemistry<br>Clinical Haematology<br>Clinical Microbiology | A |

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

| Location details | | Activity | Location code |
|---|---|---|---|
| City Hospitals Sunderland<br>Kayll Road<br>Sunderland<br>Tyne & Wear<br>SR4 7TP | Local contact<br><br><br>As above | Biochemistry<br>Haematology, Blood Transfusion<br>Blood/product storage/issue<br>Andrology<br>Point of Care Testing Clinical Chemistry, Haematology | B |
| South Tyneside General Hospital<br>Harton Lane<br>South Shields<br>Tyne & Wear<br>NE34 OPL | Local contact<br><br><br>As above | Biochemistry<br>Haematology, Blood Transfusion<br>Blood/product storage/issue<br>Body Store<br>Point of Care Testing Clinical Chemistry, Haematology | C |
| Queen Elizabeth Hospital<br>Bowel Screening Hub and Point of Care Centre<br>Sheriff Hill<br>Gateshead<br>Tyne & Wear<br>NE9 6SX | Local contact<br><br>As above | Bowel Screening Service | D |
| Sunderland Eye Infirmary<br>Queen Alexandra Road<br>Sunderland<br>SR2 9HP | Local contact<br><br>As above | Point of Care Testing Clinical Chemistry | E |
| Old Pathology<br>Queen Elizabeth Hospital<br>Gateshead Health NHS Foundation Trust<br>Sheriff Hill<br>Gateshead<br>Tyne & Wear<br>NE9 6SX | Local contact<br><br>As above | Immunology | F |
| Queen Elizabeth Hospital<br>Sheriff Hill<br>Gateshead<br>Tyne & Wear<br>NE9 6SX | Local contact<br><br>As above | Mortuary Services/Body Store | G |

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| Location details | | Activity | Location code |
|---|---|---|---|
| City Hospitals Sunderland<br>Kayll Road<br>Sunderland<br>Tyne & Wear<br>SR4 7TP | Local contact<br><br><br>As above | Mortuary Services/Body Store | H |
| South Tyneside General Hospital<br>Harton Lane<br>South Shields<br>Tyne & Wear<br>NE34 OPL | Local contact<br><br><br>As above | Mortuary Services/Body Store | I |
| Queen Elizabeth Hospital<br>Theatres<br>Gateshead Health NHS Foundation Trust<br>Sheriff Hill<br>Gateshead<br>Tyne & Wear<br>NE9 6SX | Local contact<br><br><br>As above | Blood storage/issue | J |

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES | Pathological examination activities for the purpose of clinical diagnosis | Documented in-house procedures with manufacturer's instructions | |
| | **Clinical Biochemistry** | | |
| | Routine Chemistries: | Roche Cobas c502 and c702 analysers, Roche Cobas Pro (site C)<br>Measurement Principle: Spectrophotometry (End-point, Rate and Immunoturbidimetric) and Ion Selective Electrodes<br><br>Main SOP reference(s):<br>BC-AUT-SOP-008.ST Roche Cobas Pro Series<br>BC-AUT-SOP-023.QE.SR Roche Cobas C8000 Series<br>BC-AUT-SOP-030.UN Roche Cobas & SWA Analyte SOPs<br>BC-AUT-SOP-020.QE.SR Cobas Link e-Library<br><br>Non-Roche methods:<br>Buprenorphine analysis on Cobas c702 BC-AUT-SOP-038.QE<br>Bile Acids on Cobas c702 BC-AUT-SOP-037.SR.QE<br>Direct Bilirubin (Waco) c502/c702 BC-AUT-SOP-009.ST<br>Gentamicin (CEDIA) c702 BC-AUT-SOP-006.UN<br>Serum ACE c702 BC-AUT-SOP-045 | |
| Blood, unless specified | A1AT | | A, B |
| | Albumin | | A, B, C |
| Urine only | Albumin | | A, B |
| | ACE | | A |
| | ALT | | A, B, C |
| | ALP | | A, B, C |
| | Amylase(pancreatic) | | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| | **Clinical Biochemistry** (cont'd) | | |
| | Routine Chemistries: (cont'd) | | |
| Blood, unless specified | Adreno Corticotrophin Hormone (ACTH) | | A |
| | Apo B | | A |
| | AST | | A, B, C |
| | B2M | | A |
| | Benzodiazepine | | A |
| | Bicarbonate | | A, B, C |
| | Bile Acids | | A, B |
| | Bilirubin | | A, B, C |
| | Buprenorphine | | A |
| | C3 | | A, B |
| | C4 | | A, B |
| | Caeruloplasmin | | A, B |
| | Calcium (inc urine) | | A, B, C |
| Urine | Cannabinoids (THC) (urine) | | A |
| | Carbamazepine | | A, B |
| and Urine | Chloride (inc urine A) | | A, B, C |
| | Cholesterol | | A, B, C |
| | CK | | A, B, C |
| | Conjugated Bilirubin | | A, B, C |
| and. Urine | Creatinine (inc urine) | | A, B, C |
| | CRP | | A, B, C |
| | Ethanol | | A, B, C |
| | Gentamicin | | A, B, C |
| | GGT | | A, B, C |
| CSF only | Glucose | | A, B, C |
| | Glucose | | A, B |
| | Haptoglobin | | C |
| | HDL Cholesterol | | A, B, C |
| | Human Growth Hormone | | A |
| | IgA | | A, B |
| | IgE | | A |
| | IgG | | A, B |
| | IgM | | A, B |
| | Insulin Like Growth Factor 1 (IGF-1) | | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| | **Clinical Biochemistry** (cont'd) | | |
| | Routine Chemistries: (cont'd) | | |
| Blood, unless specified | Iron | | A, B, C |
| | Lactate | | C |
| | LDH | | A, B, C |
| | Lipoprotein (a) | | A |
| | Lithium | | A, B, C |
| and Urine | Magnesium (inc urine) | | A, B, C |
| | Paracetamol | | A, B, C |
| | Placental Growth Factor (PlGF) | | A, B |
| | Phenobarbitone | | A, B |
| | Phenytoin | | A, B |
| and Urine | Phosphate (inc urine) | | A, B, C |
| and Urine | Potassium (inc urine) | | A, B, C |
| | Porphobilinogen (PBG) | | A |
| and urine, CSF | Protein (inc urine and CSF) | | A, B, C |
| | Procollagen 1 Intact N-Terminal Propeptide (P1NP) | | B |
| | Rheumatoid Factor | | A, B |
| | Salicylate | | A, B, C |
| | Serum Indices | | A, B, C |
| and Urine | Sodium (inc urine) | | A, B, C |
| | Soluble fms-Like Tyrosine Kinase-1 (sFlt1) | | A, B |
| | STFR | | A |
| | Theophylline | | A, B, C |
| | Transferrin | | A, B |
| | Triglyceride | | A, B, C |
| and urine | Urea (inc urine) | | A, B, C |
| and urine | Uric Acid (inc urine) | | A, B, C |
| | Valproate | | A, B |
| | Phenytoin | | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Clinical Biochemistry** (cont'd)<br><br>Immunoassay: | Documented in-house procedures with manufacturer's instructions<br><br>Equipment:<br>Roche Cobas e801 analysers<br><br>Measurement Principle:<br>Electrochemiluminescence<br><br>Main SOP reference(s):<br><br>Roche Cobas C8000 Series BC-AUT-023.QE.SR<br>Roche Cobas SOPs BC-AUT-SOP-030.UN<br><br>Cobas Link e-Library BC-AUT-SOP-020.QE.SR<br>Serology Analysis BC-AUT-SOP-031.QE | |
| Blood | Anti-Mullerian Hormone (AMH) | | A |
| | AFP | | A, B |
| | Anti-HBs | Reporting and reflex testing performed in Microbiology | A |
| | Anti-HBc | Reporting and reflex testing performed in Microbiology | A |
| | Anti-HCV | Reporting and reflex testing performed in Microbiology | A |
| | B12 | | A, B, C |
| | CA125 | | A, B |
| | CA153 | | A, B |
| | CA199 | | A, B |
| | CEA | | A, B |
| | Cortisol | | A, B, C |
| | C-peptide | | A |
| | Digoxin | | A, B, C |
| | Oestradiol | | A, B |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| | **Clinical Biochemistry** (cont'd) | | |
| | Immunoassay: (cont'd) | | |
| Blood | fT3 | | A, B |
| | fT4 | | A, B, C |
| | Ferritin | | A, B, C |
| | Folate | | A, B, C |
| | FSH | | A, B |
| | HBSAg | | A |
| | HCG | | A, B, C |
| | HIV | | A |
| | Insulin | | A |
| | LH | | A, B |
| | NT-Pro-BNP | | A, B |
| | Procalcitonin | | B |
| | Progesterone | | A, B, C |
| | Prolactin | | A, B |
| | PSA | | A, B |
| | PTH | | A, B, C |
| | Rubella | | A, B |
| | SHBG | | A |
| | TBII (TRAB) | | A |
| | Testosterone | | A, B, C |
| | TPO | | A, B |
| | Troponin-T | | A, B, C |
| | TSH | | A, B, C |
| | Vancomycin | | B |
| | Vitamin D | | A, B |
| | Treponema pallidium (syphilis) | | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Clinical Biochemistry** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Blood | HbA1c Analysis | Equipment<br>Roche Cobas c513 analyser<br><br>Measurement Principle:<br>Turbidimetric Inhibition Immunoassay and Spectrophotometry<br><br>Main SOP reference BC-AUT-017.QE | A |
| Blood and Fluids | Blood Gas Parameters: | Equipment:<br>ABL90 Flex Plus blood gas analyser<br>Measurement Principle:<br>Ion Selective Electrodes and Spectroscopy<br><br>Main SOP reference(s):<br>Blood Gas Measurement using the ABL90 Flex Plus blood gas analyser PC-GAS-SOP-006.UN | |
| | pH | | A,B,C |
| | pO2 | | A,B,C |
| | pCO2 | | A,B,C |
| | Bilirubin | | A,B,C |
| | Calcium | | A, C |
| | Lactate | | A,B |
| | Glucose | | A,B |
| | Potassium | | A,B |
| | Sodium | | A,B,C |
| | COHb | | A,B,C |
| | MetHb | | A,B,C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions. | |
| | **Clinical Biochemistry** (cont'd) | | |
| Urine | Drugs of Abuse, Adrenaline Metabolites and cortisol: | Equipment:<br>Waters UPLC-TQ detector<br><br>Measurement Principle:<br>High Performance Liquid Chromatography and Mass Spectrometry<br><br>Main SOP reference(s):<br>Drugs of Abuse Analysis by LCMS BC-ROU-SOP-021.QE & Reporting BC-ROU-SOP-008.QE<br>Urinary Metadrenalines by LCMS BC-ROU-SOP-023.QE & reporting BC-ROU-SOP-020.QE | |
| | Morphine | | A |
| | Acetyl-Morphine | | A |
| | Codeine | | A |
| | Dihydrocodeine | | A |
| | EDDP | | A |
| | Methadone | | A |
| | Amphetamine | | A |
| | MDA | | A |
| | MDMA | | A |
| | MDEA | | A |
| | Cocaine Metabolites | | A |
| | Metadrenalin | | A |
| | Normetadrenalin | | A |
| | 3-Methoxytyramine | | A |
| | Cortisol (urine) | Urine Cortisol BC-ROU-SOP-035.QE | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Clinical Biochemistry** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Blood | Androgen profile | Equipment<br>Waters UPLC-TQ detector<br><br>Measurement principle: High Performance Liquid Chromatography and Mass Spectrometry<br><br>Main SOP reference: BC-ROU-SOP-033.QE Reporting BC-ROU-SOP-034.QE | |
| | Testosterone | | A |
| | 17-hydroxy progesterone | | A |
| | Androstenedione | | A |
| | DHEAS | | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Clinical Biochemistry** (cont'd)<br><br>Spectroscopy: | Documented in-house procedures with manufacturer's instructions | |
| CSF and Urine | Xanthochromia | UVIKON XS spectrophotometer<br>Measurement principle: spectrometry<br>Main SOP reference BC-ROU-SOP-030.QE | A |
| Urine | Porphyrin screen | UVIKON XS spectrometer<br>Measurement principle; spectrophotometry<br>Main SOP reference: BC-ROU-SOP-022.QE | A |
| Urine | Porphobilinogen screen | UVIKON XS spectrophotometer<br><br>Measurement Principle:<br>Anion exchange chromatography (Biorad) & Spectroscopy<br><br>Main SOP reference(s):<br>Urine Porphobilinogen BC-ROU-SOP-003.QE | A |
| Calculi | Renal Calculi Analysis: | Equipment:<br>Nicolet Summit Pro FT-IR Analyser<br><br>Measurement Principle:<br>Infra-Red Spectroscopy<br><br>Main SOP reference(s)<br>Renal Calculus Analysis BC-ROU-SOP-001.QE | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Clinical Biochemistry** (cont'd)<br><br>Protein Section: | Documented in-house procedures with manufacturer's instructions | |
| Blood | Serum Protein Electrophoresis and Immunotyping | Helena V8 Nexus Capillary Zone Electrophoresis<br><br>Main SOP references<br>BC-ROU-SOP-043.QE Helena V8 Nexus Routine Operation<br>BC-ROU-SOP-046.QE Electrophoresis interpretation & Immunotyping- using Helena Platinum | A |
| Serum and Urine | Immunofixation Electrophoresis (IgG, IgA, IgM, IgD and IgE) | Helena V8, SAS3 and SAS4 analysers<br><br>Main SOP references<br>BC-ROU-SOP-0440.QE Immunofixation Electrophoresis Using Helena V8, SAS 3 & SAS 4<br>BC-ROU-SOP-045.QE Bence Jones Protein Using the Helena V8, SAS3 and SAS 4 Instruments | A |
| Blood and Urine | Osmolality: | Equipment:<br>OSMO 1<br>Measurement Principle:<br>Depression of Freezing Point<br><br>Main SOP reference(s)<br>Serum / Urine Osmolality BC-ROU-SOP-002.UN | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| | **Clinical Biochemistry** (cont'd) | | |
| | Miscellaneous: | | |
| Faeces | Calprotectin | Roche C8000 series – turbidimetry BC-AUT-SOP-030.UN | A |
| Faeces | Faecal Immunochemical Test (symptomatic) | MAST OC Sensor Pledia using latex turbidimetry PC-FIT-SOP-001.UN | A |
| Faeces cards | Faecal Immunochemical Test (screening) | MAST OC Sensor Pledia using latex turbidimetry BO-LAB-SOP-024.QE | D |
| | Calculated parameters | Calculated tests are calculated within the LIMS (MediTech) | |
| | Estimated GFR. | | A, B, C |
| | Acute kidney Injury stage. | | A, B, C |
| | LDL cholesterol. | | A, B, C |
| | Non-HDL cholesterol. | | A, B, C |
| | STFR ratio. | | A, B, C |
| | Calculated osmolality. | | A, B, C |
| | Creatinine clearance. | | A, B, C |
| | Adjusted calcium. | | A, B, C |
| | Urine Calcium: Creatinine ratio. | | A, B, C |
| | Transferrin saturation. | | A, B, C |
| | Free androgen Index. | | A, B, C |
| | FIB4 score | | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES(cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Haematology/ Transfusion**<br><br>Routine Haematology | Documented in-house procedures with manufacturer's instructions | |
| Blood | Full Blood Count<br>-RBC<br>-WBC<br>-HCT<br>-RDW<br>-MCV<br>-MCH<br>-MCHC<br>-PLATELET<br>-NEUTROPHIL<br>-LYMPHOCYTE<br>MONOCYTE<br>-EOSINOPHIL<br>-BASOPHIL<br>-NRBC<br>Reticulocytes | Manufacturers Analyser (Sysmex, XN10/20,) using fluorescent flow cytometry and hydrodynamic focusing technologies.<br>HA-ROU-SOP-001.QE, HA-ROU-SOP-025.SR.ST | A, B, C |
| Blood | Erythrocyte Sedimentation Rate | Vitech Scientific InteRRliner and Compact.<br>Westergren Method. SOP HA-ROU-SOP-008.QE/SR | A ,B, C |
| Blood | Haemoglobin | Manufacturers Analyser (Sysmex, XN10/20,) using<br>Sodium Lauryl Sulphate using a Photometric Methodology. SOP HA-ROU-SOP-001.QE, HA-ROU-SOP-025.SR.ST | A, B, C |
| Blood | Blood Film for detection of abnormal cells | Manufacturers Analyser (Sysmex SP10) and Manual method, using Sysmex Staining (May Grunwald Giemsa). SOP HA-ROU-SOP-002.UN | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Haematology/Transfusion** (cont'd)<br><br>Routine Haematology (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Marrow | Bone marrow staining for detection of abnormal cells | Manufacturers Analyser (Sysmex SP10) and Manual method, using Sysmex Staining (May Grunwald Giemsa). SOP HA-ROU-SOP-002.UN | A, B, C |
| Blood | Detection presence of Infectious Mononucleosis (Glandular Fever) heterophile antibodies. | Clearview IM for the qualitative detection of Infectious Mononucleosis using a glycoprotein from bovine erythrocytes. HA-ROU-SOP-020.UN | A, B, C |
| Blood | Detection of abnormal Haemoglobin variants and measurement of HbA2 and HbF | Sebia Automated Capillary 3 OCTA Electrophoresis system HA-ROU-SOP-103.QE | A |
| Blood | Malarial screening - Differentiation between Plasmodium falciparum and non-Plasmodium falciparum infections. | Immuno-chromatographic test using CareUS rapid monoclonal antibodies against 'parasite lactate dehydrogenase' and 'Histidine-Rich Protein 2' HA-ROU-SOP-024.UN | A, B, C |
| Blood | Qualitative Solubility test for Sickling Haemoglobins | (Streck-SICKLECHEK) using Sodium Hydrosulphite and Saponin HA-ROU-SOP-036.UN Haemoglobin S Solubility Test | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Haematology/Transfusion** (cont'd)<br><br>Coagulation | Documented in-house procedures with manufacturer's instructions | |
| Plasma | Prothrombin Time<br>APTT<br>Clauss Fibrinogen<br>Thrombin Time<br>D-Dimer<br>Lupus Anti-coagulant<br>Reptilase<br>Anti-Xa assay (site A)<br>INR<br>APPT ratio | STAGO STA Max analysers utilising a Viscosity Based (Mechanical) Detection System<br>Neoplastin R<br>Actin FS and SynthAsil<br>STA Liquid Fibrinogen<br>STA Thrombin<br>STA Liatest DD<br>STAClot DRVV<br>STA-Liquid anti Xa (chromogenic)<br>HA-COA-SOP-014.UN<br>HA-COA-SOP-017.UN<br>HA-COA-SOP-018.UN<br>HA-COA-SOP-019.UN<br>HA-COA-SOP-020.UN<br>HA-COA-SOP-013<br>HA-COA-SOP-022.UN<br>HA-COA-SOP-023.UN<br>HA-COA-SOP-025.UN<br>HA-COA-SOP-026.UN<br>HA-COA-SOP-028.UN<br>HA-COA-SOP-029.UN<br>HA-COA-SOP-034.UN | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Haematology/Transfusion** (cont'd)<br><br>Antenatal & Newborn Screening | Documented in-house procedures with manufacturer's instructions<br><br>Documented -in-house methods to meet the requirements of the Sickle Cell and thalassemia screening programme(s) as defined in the July 2018 'NHS Sickle Cell and thalassemia screening: laboratory QA evidence requirements" | |
| Serum | Thrombophilia Screen<br>Protein C, Protein S, Antithrombin III | Stago STA-R Max coagulation analyser | A |
| | Blood Transfusion | Grifols Erytra and Eflexis Blood Grouping System | |
| Blood | Blood Group by detection and identification of antigens:<br><br>A D Positive<br>AB D Positive<br>B D Positive<br>D Positive<br>A D Negative<br>AB D Negative<br>B D Negative<br>D Negative<br>O positive<br>O negative<br><br>Crossmatch | <br><br>HA-BTX-SOP-006.UN Manual Blood Grouping Techniques<br>HA-BTX-SOP-015.UN<br><br><br><br><br><br><br><br><br><br>HA-BTX-SOP-022.UN Serological Crossmatch (IAT)<br>HA-BTX-SOP-009.UN Antigen Typing | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Haematology/Transfusion** (cont'd)<br><br>Blood Transfusion (cont'd) | Documented in-house procedures with manufacturer's instructions<br><br>Grifols Erytra and Eflexis Blood Grouping System with suppliers methods; Manual Grifols gel cards | |
| Blood | Antibody Screen by detection of antibodies to:<br><br>Rh which includes anti-C, D, E, c, e, f, Cw<br>K, k, Kpa , Kpb ,<br>Fya , Fya ,<br>Jka, Jkb<br>Lea, Leb<br>S, s, M, N<br>P1<br>Lua , Lub | HA-BTX-SOP-007.UN Manual Antibody Screen<br>HA-BTX-SOP-008.UN Antibody identification | A, B, C |
| Blood | Diagnosis of Feto-Maternal Haemorrhage (FMH) | manual staining – acid elution – Shepard's stain kit for FMH<br>HA-BTX-SOP-019.UN | A, B, C |
| Blood | Direct Antiglobulin Test (DFAT)<br><br>AHG, IgG and Cd3 | Gel Cards<br><br>HA-BTX-SOP-024.UN<br>Differential DAT<br>HA-BTX-SOP-086.UN Using the NHSBT Rh Negative Screen | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunology** | Documented in-house procedures with manufacturer's instructions | |
| Serum | Detection of ELiA IgA<br>-tissue Transglutaminase Antibodies (Abs) | Phadia 250 using FEIA. IM-ICP-SOP-003 | A |
| Serum | Detection of ELiA IgG<br>-Citrullinated Cyclic Peptide Abs<br>-ENA Abs Screen<br>-Ro Abs<br>-La Abs<br>-RNP/Sm Abs<br>-Sm Abs<br>-Jo1 Abs<br>-Scl70 Abs<br>-CENP Abs<br>-dsDNA Abs<br>-MPOs Abs<br>-PR3s Abs<br>-GBM Abs<br>-Cardiolipin Abs<br>-Beta-2-Glycoprotein A Abs<br>-Tissue Transglutaminase Abs<br>-M2<br>-Intrinsic Factor Antibody | Phadia 250 using FEIA. IM-ICP-SOP-004 | A |
| Serum | ELiA IgM<br>-Cardiolipin Abs<br>-Beta-2-Glycoprotein Abs | Phadia 250 using FEIA. IM-ICP-SOP-005 | A |
| Serum | Detection of Mast Cell Tryptase | Phadia 250 using CAP technology. IM-ICP-SOP-007 | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**<u>Immunology</u>** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Serum | Detection of Specific IgE<br><br>Ara hA (peanut)<br>-Ara h2 (peanut)<br>-Ara h3 (peanut)<br>-Ara h8 PR-A0 (peanut)<br>-Ara h9 LTP (peanut)<br>-Cor aA PR-A0 (hazel nut)<br>-Cor a8 LTP (hazel nut)<br>-Omega-5-Gliadin (wheat)<br>-Ovomucoid (egg)<br>-Bet VA (birch)<br>-Budgerigar droppings<br>-Cat epithelium & dander<br>-Chicken feathers<br>-Cow dander<br>-Dog dander<br>-Duck feathers<br>-Gerbil epithelium<br>-Goat epithelium<br>-Guinea Pig epithelium<br>-Hamster epithelium<br>-Horse dander<br>-Mixed feathers A<br>-Mixed feathers 2<br>-Parrot feathers<br>-Pigeon feathers<br>-Rabbit epithelium<br>-Rat<br>Sheep epithelium<br>-Amoxicilloyl<br>-Penicilloyl G<br>-Penicilloyl V<br>-Almond | Phadia 250 using CAP technology. IM-ICP-SOP-006 | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunology** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Serum (cont'd) | Detection of Specific IgE (cont'd)<br>-Apple<br>-Avocado<br>-Banana<br>-Barley<br>-Blue mussel<br>-Blueberry<br>-Brazil nut<br>-Brussel sprout<br>-Buck wheat<br>-Cacao<br>-Carrot<br>-Cashew nut<br>-Celery<br>-Cheese (cheddar type)<br>-Cherry<br>-Chick pea<br>-Chicken<br>-Chilli pepper<br>-Coconut<br>-Crab<br>-Egg<br>-Egg white<br>-Egg yolk<br>-Fish (cod)<br>-Fish mix 1<br>-Garlic<br>-Gluten<br>Goats milk<br>-Grape<br>-Grapefruit<br>-Haddock<br>-Hazel nut<br>-Kiwi fruit<br>-Lemon | Phadia 250 using CAP technology. IM-ICP-SOP-006 | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunology** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Serum (cont'd)<br><br>Serum/Plasma | Detection of Specific IgE (cont'd)<br>-Lentil<br>-Lime<br>-Lobster<br>-Lupin seed<br>-Macadamia nut<br>-Maize,corn<br>-Malt<br>-Mandarin<br>-Mango<br>-Melon<br>-Milk<br>-Mushroom<br>-Mustard<br>-Mutton<br>-Nut mix 1<br>-Nut mix 2<br>-Oat<br>-Onion<br>-Orange<br>-Pea<br>-Peach<br>-Pear<br>-Peanut<br>-Pecan nut<br>-Pineapple<br>-Pistachio<br>-Plum<br>-Pork<br>Potato<br>-Rape seed<br>-Raspberry<br>-Rice<br>-Salmon<br>-Sesame seed<br>-Shrimp<br>-Soybean | Phadia 250 using CAP technology. IM-ICP-SOP-006 | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunology** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Serum (cont'd)<br><br>Serum/Plasma | Detection of Specific IgE (cont'd)<br>-Strawberry<br>-Sweet chestnut<br>-Tomato<br>-Tuna<br>-Walnut<br>-Wheat<br>-White bean<br>-Yeast<br>-Barley pollen<br>-Cultivated oat pollen<br>-Cultivated Rye pollen<br>-Cultivated wheat pollen<br>-Grass pollen mix<br>-Maize, corn pollen<br>-Rye pollen<br>-Timothy grass pollen<br>-Common House Dust Mite<br>-European House Dust Mite<br>-Honey bee venom<br>-Latex<br><br>-Alternaria alternate<br>-Aspergillus fumigatus<br>-Cladoporium herbarum<br>-Mould mix<br>-Silver birch pollen<br>-Tree pollen mix<br>-Mugwort pollen<br>-Rape pollen<br>-Sheep sorrel<br>-Weed pollen mix | Phadia 250 using CAP technology. IM-ICP-SOP-006 | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunology** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Serum | Detection of Specific IgG<br><br>Aspergillus fumigatus<br>-Budgerigar droppings<br>-Budgerigar feathers<br>-Pigeon serum<br>-Pigeon feathers | Phadia 250 using CAP technology. IM-ICP-SOP-008 | A |
| Serum | Autoimmune Hepatitis Profile<br><br>-SLA<br>-LKMA<br>-LCA | Enzyme Immunoblot using EuroBlotOne IM-EUR-SOP-008 | F |
| Serum | Autoimmune diagnostics:<br><br>- Liver profile<br>- Autoimmune inflammatory myopathy<br>- Neuronal antigens | Enzyme Immunoblot using EuroBlotOne IM-EUR-SOP-008.UN IM-EUR-SOP-009.UN | F |
| Serum | Paraneoplastic Antibody Profile<br><br>-Hu<br>-Yo<br>-Ri<br>-Amphiphysin<br>-CV2<br>-Ma2<br>-recoverin<br>-SOXA<br>-titin<br>-zic4<br>-GAD65<br>-Tr | Enzyme Immunoblot using EuroBlotOne IM-EUR-SOP-010 | F |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunology** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Serum | Autoimmune Inflammatory Myopathies<br>Myositis Antibody Profile<br><br>16 Ag (Mi-2α, Mi-2β, TIF1γ, MDA5, NXP2, SAE1, Ku, PM-Scl100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ and Ro-52) - Extended profile<br><br>Detection of Functional Antibodies: | EuroBlotOne using enzyme immunoblot<br>IM-EUR-SOP-006<br>IM-EUR-SOP-009.UN | A |
| Serum | -HIB | DS2 using ELISA. IM-DS2-SOP-004 | A |
| Serum | -PCP | DS2 using ELISA. IM-DS2-SOP-003 | A |
| Serum | -Tetanus | DS2 using ELISA. IM-DS2-SOP-005 | A |
| Serum | GAD Antibodies | DS2 using ELISA. IM-DS2-SOP-006 | A |
| Serum | Islet Cell Antigen Type 2 | DS2 using ELISA. IM-DS2-SOP-010 | A |
| Serum | Anti-Histone Antibody | DS2 using ELISA. IM-DS2-SOP-009 | A |
| Serum | Anti-ZnT8 Antibody | DS2 using ELISA. IM-DS2-SOP-011 | A |
| Serum | Serum Free Light Chains | Optilite (Binding Site) analyser using turbimetry. IM-OPT-SOP-003 | A |
| Serum | Immunoglobulin Subclasses (IgGA, IgG2, IgG3, IgG4) | Optilite (Binding Site) analyser using turbimetry. IM-OPT-SOP-004 | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Microbiology**<br><br>Microbiology examination activities for the purpose of clinical diagnosis | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant | |
| Urine | Urinalysis for the detection and quantification of bacteria and cellular presence:<br>White blood cells, Red blood cells, Squamous epithelial cells, Bacterial cells, Yeast cells & fungal hyphae, Granular, hyaline & cellular casts | Light Microscopy Roche u701 Urine Analyser MC-CUL-SOP-034.QE<br>MC-CUL-SOP-004.QE Manual Urine Culture for and Microscopy | A |
| Sputum, Pleural fluid, Bronchoalveolar lavage | | MC-CUL-SOP-014.QE Examination of Sputum for Routine Culture<br>MC-CUL-SOP-015.QE Bronchoalveolar Lavages | A |
| Faeces | | MC-CUL-SOP-020.QE Enteric Culture<br>MC-CUL-SOP-024.QE C. difficile carriage | A |
| Genital swabs | Including presence of bacterial vaginosis, presence of Trichomonas vaginalis | MC-CUL-SOP-006.QE Microscopy and Examination of Genital Tract Specimens | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant | |
| | **Microbiology** (cont'd) | | |
| Wound swabs, Pus | | MC-CUL-SOP-023.QE - examination of Swabs - Skin, Superficial and Non-surgical swabs | A |
| Body fluids (from blisters, burns, ascites, CAPD fluids) | | MC-CUL-SOP-032.UN Examination of Body Fluids | A |
| Tissue | | MC-CUL-SOP-029.QE Examination of corneal scrapes<br>MC-CUL-SOP-032.QE Examination of tissue samples | A |
| Line tips | | MC-CUL-SOP-033.QE Examination of line tips and associated samples | A |
| Skin, Nail and Hair | Detection, Isolation and identification of fungi of clinical significance | MC-CUL0SOP-061.QE<br>Mycology Culture | A |
| Screening swabs | Screening for MRSA/MSSA/VRE | MC-CUL-SOP-028.QE Screening swabs MRSA, MSSA (including renal screen),VRE | A |
| Joint fluids | Detection and identification of birefringent crystals | MC-CUL-SOP-039.QE Examination of Joint Fluid for crystals using Polarised Light Microscopy | A |
| Blood | Isolation and characterisation of microorganisms of clinical significance in blood | Biomerieux Virtuo automated continuous monitoring blood culture system<br>MC-CUL-SOP-019.QE Investigation of Blood Cultures | A |
| CSF | Presence of bacteria and differentiation of white cells and isolation/ characterisation of microorganisms of clinical significance | MC-CUL-SOP-013.UN<br>CSF investigations.<br>Direct microscopy using modified Fuchs Rosenthal counting chamber, differential WBC counts, gram stain and culture | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Microbiology** (cont'd) | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant | |
| Bacterial cultures | Identification/classification of microorganisms | Gram Staining<br>MC-IDS-SOP-007.QE | A |
| Bacterial cultures | Automated identification and classification of microorganisms of clinical significance | Biomerieux Vitek MS Prime<br>MC-IDS-SOP-029.QE MALDI-TOF Biotyper Identification using Matrix-assisted laser desorption ionization–time of flight mass spectrometry (MALDI-TOF) | A |
| Bacterial Cultures, Blood cultures, Urine | Antibiotic Susceptibility testing | MC-IDS-SOP-003.QE<br>Manual using Disc Susceptibility Testing and and E-Test (EUCAST)<br>MC-IDS-SOP-006.QE ETEST SOP | A |
| Bacterial & Fungal Cultures | Colistin MIC susceptibilities and Fungal Yeast susceptibilities | Merlin Micronaut Colistin MIC<br>MC-IDS-SOP-023<br>Merlin Micronaut Yeast MIC<br>MC-IDS-SOP-024 | A |
| Bacterial Cultures | Confirmation of Streptococcus pneumoniae | Wellcogen Strep pneumoniae Latex agglutination test<br>MC-IDS-SOP-025. | A |
| Urine | Rapid detection of Legionella pneumophilia serogroup A and Pneumococcal Antigen | Immunochromatographic method:<br>MC-IDS-SOP-022.QE Legionella urine antigen test (Sofia) and MC-CUL-SOP-046 (Pneumococcal urine Antigen (Sofia) | A |
| Faeces | Rapid detection of presence of Rota/adenovirus | Bioconnections Gastrovir<br>MC-CUL-SOP-021.QE Rota/Adenovirus testing | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs), incorporating manufacturers' instructions where relevant | |
| | **Microbiology** (cont'd) | | |
| Urine | Detection of b-HCG to assist in confirmation of pregnancy | Invitech<br>MC-SER-SOP-011.QE Pregnancy test | A |
| Faeces | Identification of enteric parasitic infection (Ova, Cysts, parasites) | Parasep system<br>Light Microscopy<br>MC-CUL-SOP-027.QE Parasite investigations | A |
| Serum | Detection of Syphilis rapid plasma reagin | MC-SER-SOP-013.QE RPR test for syphilis | A |
| | Serological examinations for investigation for immunity and markers of infectious disease | Documented in-house procedures with manufacturer's instructions | |
| | Quantitative & Qualitative detection of antibodies to following: - | | |
| Faeces | GDH antigen | Gemini Analyser – ELISA<br>MC-SER-SOP-006-QE Gemini, maintenance, decontamination and use | A |
| Faeces | Faecal calprotectin | MICSERPR028 Faecal Calprotectin (EIA) on Phadia 100 | |
| Faeces | Rotavirus/Adenovirus antigen | Immunochromatographic strips<br>MC-CUL-SOP-021.QE Rotavirus/Adenovirus test (Techlab) | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | <u>Serological examinations for investigation for immunity and markers of infectious disease</u> (cont'd)<br><br>Quantitative & Qualitative detection of antibodies to following: - (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Serum | Antibodies to<br>Treponema pallidum<br>Rubella IgG<br>Hepatitis B Surface Antigen<br>Hepatitis C antibody<br>HIV Ag/Ab combo<br>Hepatitis B core<br>Anti Hbs | Roche e801Electrochemiluminescence immunoassay<br>MC-SER-SOP-002.QE Serology testing on e801 Biochemistry analyser | A |
| Serum | Detection of interferon-gamma following stimulation of T cells in-vitro, as an indicator of Tuberculosis specific antigen-mediated cell response | TB QuantiFERON Gold Serological testing using the Liaison QuantiFERON TB Gold Plus/ Diasorin Liaison XL<br><br>MC-SER-SOP-021.QE | |
| Serum | Measles IgG<br>CMV IgM and IgG<br>EBV IgM, IgG and EBNA<br>Hepatitis A IgM<br>Toxoplasma | Biomerieux Vidas – using Enzyme linked fluorescent assay -ELFA<br>MC-SER-SOP-001.QE Vidas | |
| Serum | Hepatitis A total antibodies | Biomerieux Vidas – using Enzyme linked fluorescent assay<br>C8. MC-SER-SOP-001 | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Serological examinations for investigation for immunity and markers of infectious disease (cont'd)<br><br>Molecular testing for quantification of DNA/RNA for specific organisms, viruses | Documented in-house procedures with manufacturer's instructions | |
| Genital swabs/urines<br>Rectal swabs<br>Pharyngeal swabs<br>Faeces<br>Ophthalmic swabs | Detection of: -<br>Chlamydia trachomatis / Neisseria gonorrhoea DNA TV/MG | Cobas 6800 and 8800<br>MC-PCR-SOP-005.UN Chlamydia and GC PCR on the COBAS 4800 | A |
| Vaginal or self taken cervical swab | Chlamydia trichomonas Neisseriae gonorrhoeae confirmation | Cepheid GeneXpert – PCR<br>C2.0 MC-PCR-SOP-010 | A |
| Blood | Anti-HBs | Test performed in Biochemistry and reporting and reflex testing performed in Microbiology | A |
| | Anti-HBc | Test performed in Biochemistry and reporting and reflex testing performed in Microbiology | A |
| | Anti-HCV | Test performed in Biochemistry and reporting and reflex testing performed in Microbiology | A |
| Swabs/respiratory samples | Detection of Respiratory bacterial and viral pathogens of clinical significance | Biomerieux Biofire Film Array<br>MC-PCR-SOP-026.QE | A |
| Cerebrospinal fluid (CSF) | Detection of bacterial, viral and fungal pathogens using multiplex PCR | Biomerieux BioFire FilmArray.<br>MC-PCR-SOP-018.QE | A |
| Swabs, vesicle fluids | Extraction of DNA for use in identification of VzV, HSV and Syphilis | Syphilis PCR Extraction and SpeeDx PlexPCR VHS (Promega Maxwell)<br>MC-PCR-SOP-032.QE | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Serological examinations for investigation for immunity and markers of infectious disease (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| | Detection of nucleic acids to following: - | | |
| | HPV - DNA | MC-PCR-SOP-006.QE HPV PCR on the Cobas 6800/8800 | A |
| | Norovirus - RNA | MC-PCR-SOP-004.QE GeneXpert - Norovirus | A |
| | Antenatal and Newborn Screening | Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening Programme as defined in the July 2018 'IDPS laboratory QA requirements' | A |
| Nose and throat swabs in VTM | Detection and differentiation of lineage β-betacoronavirus (β-βCoV) and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. Specifically, E and Orf1a/b gene targets | Roche Cobas 6800 using cobas® SARS-CoV-2 RT-PCR | A |
| Faeces | C difficile - DNA | MC-PCR-SOP-003.QE GeneXpert – Cepheid C difficile gene toxin | A |
| Faeces | C difficile Toxin A&B | ELISA Gemini C7.0 MC-CUL-SOP-009 | A |
| Faeces | Carbapenemase DNA | MC-CUL-SOP-022.QE Carbapenemase-Producing Enterobacteriaceae (CPE) Screening – Cepheid PCR | A |
| Blood | Factor II & V - DNA | MC-PCR-SOP-002.QE GeneXpert – FII & FV Testing | A |
| Faeces | Diagnosis of enteric bacterial and protozoal pathogens of clinical significance | Multiplex PCR using Serosep MC-PCR-SOP-014.QE | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Serological examinations for investigation for immunity and markers of infectious disease (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Faeces | Diagnosis of Helicobacter pylori | Diasorin Liaison XL with Liaison Meridian H pylori SA Assay MC-SER-SOP-023-QE | A |
| | **Cellular Pathology** | | |
| | Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | | |
| Human Tissue | Specimen dissection | | A |
| Formalin Fixed Tissue | Specimen embedding/histology processing | Production of paraffin wax blocks using a Sakura Vacuum Impregnation Processing machine (VIP) and section cutting using Leica Microtomes.<br><br>CP-HIS-SOP-012.UN Operation and Troubleshooting of Tissue Tek VIP Processors<br><br>CP-HIS-SOP-013.UN Maintenance and Changing of Tissue-Tek VIP Processor<br><br>CP-HIS-SOP-004.UN Histology Paraffin Block Embedding<br><br>CP-STQ-SOP-005.UN Decalcification and Processing of Histology Samples | |
| Formalin fixed paraffin embedded tissue blocks | Section cutting | CP-HIS-SOP-005.UN Histology Section Cutting | A |
| Fresh frozen tissue | Frozen section in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Frozen section CP-STQ-SOP-002 UN Frozen section receipt, handling and processing<br>Rapid stain with Haematoxylin/Eosin CP-STQ-INS-001.UN | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis<br><br>**Cellular Pathology** (cont'd)<br><br>Examinations in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| 4 µm Formalin fixed paraffin embedded tissue sections | Staining for the identification of clinically significant abnormal and normal cells and tissue components<br><br>**Immunohistochemistry** | The haematoxylin and eosin stain (H&E) • CP-HIS-SOP-006.UN - The Maintenance and Use of The Tissue Tek®Prisma and Film Cover Slipper | A |
| 4 µm Formalin fixed paraffin embedded tissue sections | Immunohistochemistry for the identification of cells/diseases below: - | In house documented procedures & manufacturer's instructions using Ventana Benchmark Ultra system automated ICC<br>CP-ICC-SOP-001.UN – Immunohistochemistry Procedure | A |
| | Smooth Muscle.<br>Germ cell tumours and hepatocellular carcinoma.<br>Prostate carcinoma.<br><br>Desmoid-type fibromatosis, synovial sarcoma, endometrial stromal sarcoma.<br><br>Mesothelioma.<br>Follicular lymphoma.<br><br>Pan—T cell marker.<br>Pan B cell marker<br>Reed Sternberg cells. | ACTIN<br>ALPHA FETO PROTEIN<br><br>AMACR (alpha methylacyl coenzyme A racemase)<br>Beta Catenin<br><br>CALRETININ<br>CD10 MARKER<br><br>CD 3 (T CELL MARKER)<br>CD 20 (B CELL MARKER)<br>CD30 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunohistochemistry** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| 4 µm Formalin fixed paraffin embedded tissue sections (cont'd) | Immunohistochemistry for the identification of cells/diseases below: - (cont'd) | In house documented procedures & manufacturer's instructions using Ventana Benchmark Ultra system automated ICC<br>CP-ICC-SOP-001.UN – Immunohistochemistry Procedure | A |
| | Endothelial cells.<br>Neuroendocrine tumour.<br>Histiocytes.<br>Pan B cell marker.<br>Neuroectodermal tumour cells.<br>GIST tumours.<br>Intestinal epithelium.<br>Colorectal cancers. | CD34<br>CD56<br>CD68<br>CD79A MARKER<br>CD99<br>CD117<br>CDX2<br>CARCINOEMBRYONIC ANTIGEN |
| | Neuroendocrine cells.<br>Broad spectrum epithelial marker.<br>Epithelial marker.<br>Epithelial neoplasms.<br>Breast, lung, endometrial adeno Ca.<br>Basal epithelial cells.<br>GI tract epithelia.<br>Small bowel / stomach epithelia. | CHROMOGRANIN<br>CYTOKERATIN (MNF)<br>CYTOKERATIN AE1/AE3<br>CYTOKERATIN 5/6<br>CYTOKERATIN 7<br><br>CYTOKERATIN 14<br>CYTOKERATIN 19<br>CYTOKERATIN 20 |
| | CMV infection.<br>Mantle cell lymphoma.<br>Lymphatic endothelium.<br>Desmin filaments in muscle.<br>.<br>Non-Small Cell lung cancer.<br>Non-Small Cell lung cancer.<br>Non-Small Cell lung cancer.<br><br>Non-Small Cell lung cancer. | CYTOMEGALOVIRUS (CMV)<br>Cyclin D1<br>D2-40 ICC<br>DESMIN<br>.<br>DUAL STAINING: CK5/6/TTF-1<br>DUAL STAINING: CK7/P63<br>DUAL STAINING OF D2-40 AND CK AE1/AE3 /PCK26 ANTIBODIES<br>DUAL STAINING OF CD34 AND CK AE1/AE3/PCK26 ANTIBODIES |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunohistochemistry** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| 4 µm Formalin fixed paraffin embedded tissue sections (cont'd) | Immunohistochemistry for the identification of cells/diseases below: - (cont'd) | In house documented procedures & manufacturer's instructions using Ventana Benchmark Ultra system automated ICC<br>CP-ICC-SOP-001.UN – Immunohistochemistry Procedure | A |
| | Basal cell carcinoma | BASAL CELL COCKTAIL (BCC, 34BE12+P63) AND AMACR (ALPHAMETHYLACYL COENZYME A RACEMASE) ANTIBODIES |
| | Epithelial marker. | E-CADHERIN |
| | Epithelial cells. | EPITHELIAL MEMBRANE ANTIGEN |
| | Endothelial cells | FACTOR VIII |
| | Endothelial cells. | FACTOR VIIIa |
| | Breast epithelium. | GATA-3 |
| | Smooth muscle – leiomyomas. | H-CALDESMON |
| | Germ cell tumour marker. | HCG |
| | Differentiates adenocarcinoma from mesothelioma. | HEA (BerEP4) |
| | Indicates suitability for Herceptin therapy. | HER2 |
| | Hepatocyte Specific Antigen. | OCH1E5 mouse monoclonal antibody (HSA) |
| | Melanocytic cells. | HMB45 |
| | Differentiates adrenocortical tumours from sex cord tumours. | INHIBIN A |
| | Proliferation marker. | KI-67 MARKER |
| | Hodgkin's lymphoma. | LEUCOCYTE COMMON ANTIGEN |
| | Melanocytes/melanomas. | MELAN A |
| | Melanoma. | MELAN A Red |
| | Germinal centre B cells, plasma cells and activated t cells. | MUM 1 |
| | Lung adenocarcinoma. | NAPSIN A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Immunohistochemistry** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| 4 µm Formalin fixed paraffin embedded tissue sections (cont'd) | Immunohistochemistry for the identification of cells/diseases below: - (cont'd) | In house documented procedures & manufacturer's instructions using Ventana Benchmark Ultra system automated ICC<br>CP-ICC-SOP-001.UN – Immunohistochemistry Procedure | A |
| | Breast carcinoma.<br>Seminoma, germinoma, dysgerminoma, embryonal carcinoma, gonadoblastoma.<br>Gynae tumours.<br>HPV marker.<br>Tumour suppressor gene.<br>Beckwith-Wiedemannsyndrome/hydatidiform mole<br>Basal epithelium.<br>Germ cell tumours.<br><br>Breast tumours.<br>Prostate carcinoma marker<br>Prostate carcinoma marker<br>Renal cell carcinomas<br>Nerves, glial cells, melanoma marker<br>Smooth muscle tumours<br>Sry-related HMG-BOX gene 10<br>Synaptic and neuroendocrine<br>Thyroid tumours<br>Thyroid/ thyroid tumours/lung tumours<br>Vascular smooth muscle/fibroblasts/endothelial cells/Langerhan's cells<br>Tumour suppressor gene | OESTROGEN RECEPTOR<br>OCT4<br><br>PAX-8<br>p16<br>p53<br>P57<br><br>p63<br>PLACENTAL ALKALINE PHOSPHATASE<br>PROGESTERONE RECEPTOR<br>PROSTATE SPECIFIC ANTIGEN<br>PROSTEIN<br>RENAL CELL CARCINOMA MARKER<br>S100<br><br>SMOOTH MUSCLE MYOSIN<br>SOX 10 DAB and SOX 10 Red<br>SYNAPTOPHYSIN<br>THYROGLOBULIN<br>THYROID TRANSCRIPTION FACTOR 1<br><br>VIMENTIN<br><br>WILMS TUMOUR SUPPRESSOR GENE MARKER (WT1) | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| 4 µm Formalin fixed paraffin embedded tissue sections | Staining to identify suspected pathogens or demonstrate specific cellular components that aid in the evaluation of disease states | Tinctorial staining techniques performed on Roche Benchmark Special Staining machine following the Roche protocol for the use "Benchmark Special Staining System Operator guide" and CP-SST-SOP-001.UN – Special Stain Procedures (and can also be performed manually) using the following SOP's: | A |
| | Mixed Mucins | CP-SST-INS-001 Alcian Blue PAS/DPA | |
| | Acid Mucins | CP-SST-INS-003.UN Special Stain: Alcian Blue | |
| | Amyloid | CP-SST-INS-005.UN Special Stain: Congo Red | |
| | Acid & Neutral mucins | CP-SST-INS-015.UN Special Stain: Periodic Acid Schiff | |
| | Fungi | CP-SST-INS-007.UN Special Stain: Grocotts Hexamine Silver stain for Fungi | |
| | Reticulin | CP-SST-INS-019.UN Special Stain: Reticulin | |
| | Glomerular Basement Membrane | CP-SST-INS-010.UN Special Stain: Methenamine Silver | |
| | Iron | CP-SST-INS-016.UN Special Stain: Perls Prussian Blue | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| 4 µm Formalin fixed paraffin embedded tissue sections (cont'd) | Staining to identify suspected pathogens or demonstrate specific cellular components that aid in the evaluation of disease states (cont'd) | Tinctorial staining techniques performed on Roche Benchmark Special Staining machine following the Roche protocol for the use "Benchmark Special Staining System Operator guide" and CP-SST-SOP-001.UN – Special Stain Procedures and(and can also be performed manually) using the following SOP's: | A |
| | Mycobacteria: Modified bacilli and atypical bacilli | CP-SST-INS-023.UN Special Stain: Ziehl Neelsen | |
| 4 µm Formalin fixed paraffin embedded tissue sections | Staining to identify suspected pathogens or demonstrate specific cellular components that aid in the evaluation of disease states | Manual staining using the following SOPs- | A |
| | Calcium Apatite Crystal Demonstration. | CP-NGY-SOP-016.UN Alizarin Red Procedure for | |
| | Elastic/Muscle/Connective tissue | CP-SST-INS-011.UN Special Stain: Millers Elastic Van Gieson | |
| | Helicobacter | CP-SST-INS-012.UN Special Stain: Modified Giemsa for Helicobacter Pylori | |
| | Bacterial Cells | CP-SST-INS-006.UN Special Stain: Gram | |
| | Connective Tissue | CP-SST-INS-013.UN Special Stain: Martius Scarlet Blue (MSB) | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| 4 µm Formalin fixed paraffin embedded tissue sections (cont'd) | Staining to identify suspected pathogens or demonstrate specific cellular components that aid in the evaluation of disease states (cont'd) | Manual staining using the following SOPs:- | A |
| | Muscle and fibrin & Glial cells | CP-SST-INS-017.UN Special Stain: Picro-Mallory | |
| | Collagen Fibres | CP-SST-INS-018.UN Special Stain: Picro Sirius Red | |
| | Mast Cells | CP-SST-INS-021.UN Special Stain: Toluidine Blue | |
| | Collagen | CP-SST-INS-022.UN Special Stain: Van Gieson | |
| | Calcium | CP-SST-INS-025.UN Special Stain: Von Kossa | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Slides prepared in house as above | Morphological assessment and interpretation/diagnosis | Light microscopy with reference to CP-GYN-SOP-021.UN and use of Leica DM2500. DMLB, Nikon Eclipse 50I, E400, E600and OlympusBX50F-3 microscopes. | A |
| | **Andrology** | | |
| HUMAN BODY FLUIDS | Andrological examination activities for the purposes of clinical diagnosis | | A |
| Semen | Post vasectomy<br>Detection of sperm | Based on 2016 Laboratory guidelines for post vasectomy semen analysis, manual method using CellVision fixed depth glass slides and phase contrast microscopy, and documented in-house procedure CP-FER-SOP-001.UN Post Vasectomy Semen | |
| Semen | Fertility testing | Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method using documented in-house procedure CP-FER-SOP-003.UN Semen Analysis (Infertility) | |
| | Volume | Volume/weight | |
| | pH | Colorimetric strips | |
| | Sperm morphology including TZI scoring | Stained slides (Papanicolau) microscopy (Bright field) | |
| | Sperm concentration | Improved Neubauer Haemocytometer and microscopy (Phase contrast) | |
| | Sperm motility | Microscopy (Phase contrast) | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Cytopathology**<br><br>Gynaecological cytopathology | Documented in-house procedures with manufacturer's instructions | |
| Liquid Based Cervical Cytology sample (cervical cells) in Hologic Thinprep vial | Qualitative detection of Human Papilloma Virus | Detection of HPV mRNA from 14 high risk types of HPV in cervical cell samples using target amplification nucleic acid probe test on the Cobas 8800 and Cobas 6800, production of liquid based cytology (LBC) slides using the Hologic T5000 Autoloader and staining of LBC slides using the Tissue Tek Prisma staining machine<br>CS-GYN-SOP-004.QE Preparation Procedure for LBC specimens ThinPrep.pdf<br>CS-GYN-SOP-006.QE ThinPrep Maintenance Routines.pdf<br>CS-GYN-SOP-007 QE Checking off LBC Samples after Processing.pdf<br>CS-GYN-SOP-008.QE Screening Cervical Cytology LBC Preparations.pdf<br>CS-GYN-SOP-009.QE Double Screening and Checking Procedure.pdf | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Cytopathology** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| | Non-Gynaecological Cytopathology for the purposes of identification of abnormal cells. | Preparation of Non-gynaecological Cytology specimens to allow differentiation of cells with the standard light microscope:<br>CP-NGY-SOP-001.UN Cytology Specimen Numbering<br>CP-NGY-SOP-002.UN Centrifuge Preparation<br>CP-NGY-SOP-003.UN Cytocentrifuge Preparation<br><br>CP-NGY-SOP-029.UN Use of the Aerospray slide stainer<br><br>CP-NGY-SOP-033.UN Use and Maintenance of the Hologic ThinPrep Genesis Processor<br><br>Specific procedures for the following sample types: - | A |
| Fine Needle Aspiration samples | | CP-NGY-SOP-004.UN Preparation of Fine Needle Aspiration (FNAs) | A |
| Bronchial Brush and EBUS samples in Cytolyt, Bronchial wash samples in Cytolyt, Sputum | | CP-NGY-SOP-006.UN Preparation of EBUS FNA Samples<br>CP-NGY-SOP-005.UN Preparation of Bronchial Brushings, Washings and Sputum Samples | A |
| Oesophageal Brush samples in Cytolyt<br>Oesophageal wash samples in cytolyt<br>Gastric Brush samples in Cytolyt<br>Gastric wash samples in cytolyt | | CP-NGY-SOP-007.UN Preparation of Oesophageal, biliary and Gastric Brushings, Washings Samples | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| | **Cytopathology** (cont'd) | | |
| Urine | | CP-NGY-SOP-008.UN Preparation of Urine Samples | A |
| Breast cyst fluid<br>Peritoneal fluid<br>Ascitic fluid<br>Pleural Fluid<br>Ovarian cyst fluid<br>Hydrocele fluid | | CP-NGY-SOP-009.UN Preparation of Fluid Samples | A |
| Cerebrospinal fluid | | CP-NGY-SOP-010.UN Preparation of Cerebrospinal Fluid (C.S.F) Samples | A |
| Prepared cytology slides | Staining of prepared slides to assist in identification of abnormal cells. | CP-GYN-SOP-032.UN Use and Maintenance of the Prisma Stainer Coverslipper<br><br>CP-GYN-SOP-009.UN Screening Cervical Cytology LBC Preparations Staining using Papanicolaou<br><br>CP-NGY-SOP-016.UN Alizarin Red Procedure for Demonstration of Calcium Apatite Crystals<br><br>CP-NGY-SOP-017.UN Assisting with FNA Procedures in other Hospital Location<br><br>CP-NGY-SOP-019.UN Preparation of Thrombin for Use in Cytology Clot Formation<br><br>CP-NGY-SOP-029.UN Use of the Aerospray slide stainer<br><br>CP-NGY-SOP-033.UN Use and Maintenance of the Hologic ThinPrep Genesis Processor | A |
| Slides prepared in house as above | Morphological assessment and interpretation/diagnosis | Light microscopy with reference to CP-GYN-SOP-021.UN and use of Leica DM2500. DMLB, Nikon Eclipse 50I, E400, E600and OlympusBX50F-3 microscopes. | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Provision of Point of Care testing:** | Documented in-house procedures with manufacturer's instructions | |
| Whole Blood | PoCT Full Blood Count<br>*-RBC*<br>*-WBC*<br>*-HCT*<br>*-PLATELET*<br>*-NEUTROPHIL*<br>*-LYMPHOCYTE*<br>*-MONOCYTE*<br>*-EOSINOPHIL*<br>BASOPHIL<br>-HB | Sysmex XS-1000i<br><br>Measurement via flow cytometry and Hydro Dynamic Focusing<br><br>PC-FBC-SOP-001.UN<br><br>Sysmex XS-5500 | A, B, C<br><br>A |
| Whole blood | PoCT Blood Gas<br>-pH<br>-pCO2<br>-pO2<br>-ctHb<br>-sO2<br>-cK<br>-cNa<br>-cCa<br>-cGlu<br>-cLac<br>-ctBil<br>-COHb<br>-02Hb<br>-MetHb | Radiometer ABL800 series<br>Radiometer ABL 90 Flexplus<br><br>Potentiometry and Amperometry<br><br>PC-GAS-SOP-001.UN<br>PC-GAS-SOP-005.UN<br>PC-GAS-SOP-006.QE.ST | A, B, C |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Provision of Point of Care testing:** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Whole Blood | PoCT INR | Roche CoaguChek Pro II<br><br>Electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin<br><br>PC-INR-SOP-001.QE.ST | A |
| Whole Blood | PoCT Haemoglobin | Radiometer HemoCue Hb 201 DM<br><br>Potentiometry measuring principles which yield an azidemethaemoglobin reaction.<br><br>PC-HBN-SOP-001-QE.ST | A |
| Whole Blood | PoCT Glucose | Roche Accu-Chek Inform II<br><br>Electrical detection of enzyme reaction on test strip, mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH), from Acinetobacter calcoaceticus, recombinant in E. coli, converts the glucose in the blood sample to gluconolactone<br><br>PC-GLU-SOP-001.UN | A, B, C, E |
| Whole blood | HbA1C | Siemens DCA Vantage<br><br>Latex immunoagglutination inhibition methodology.<br>PC-HBC-SOP-001-QE.ST | A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN FLUIDS & TISSUES (cont'd) | Pathological examination activities for the purpose of clinical diagnosis (cont'd)<br><br>**Provision of Point of Care testing:** (cont'd) | Documented in-house procedures with manufacturer's instructions | |
| Urine | Screen: blood, glucose, ketone, protein, SG, pH, urobilinogen, bilirubin, ascorbic acid, nitrites and leucocytes | Siemens CLINITEK 50, Status and Status + models.<br><br>Reflectance photometry<br><br>Main SOP Reference(s): PC-URI-SOP-002-QE and PC-UI-SOP-003-QE.ST | A |
| Venous and Capillary Whole Blood | PoCT Blood Ketones | ApexBio KETOSURE POC analyser Electrochemical Strip Technology PC-KET-SOP-004.UN and PC-KET-SOP-005.UN | A, B, C |

**(See Appendix A below for detailed locations of accredited POCT examinations)**

END

## Appendix A

| Queen Elizabeth Hospital Delivery Points (A) | Glucose Roche AccuChek Inform II |
|---|---|
| Ward 1 Mt 1 | X |
| Ward 1 Mt 2 | X |
| EAU (New ECC) Mt 1 | X |
| EAU (New ECC) Mt 2 | X |
| Short Stay Unit Mt 1 (SSU) | X |
| Short Stay Unit Mt 2 (SSU) | X |
| A&E Triage T.04 | X |
| A&E Resus | X |
| A&E Minors Mt 1 | X |
| A&E Minors Mt 2 | X |
| A&E Majors Mt 1 | X |
| A&E Majors Mt 2 | X |
| Paed A&E | X |
| Ward 9 | X |
| Ward 11 | X |
| Ward 12 / PIU | X |
| Ward 14 Mt 1 | X |
| Ward 14 Mt 2 | X |
| Emergency Surgical Assessment Unit (Located on Ward 9) | X |
| X-ray | X |
| ENT | X |
| Ward 4 | X |
| Biochemistry | X |
| Colposcopy | X |
| Winter Bed (Old Ward 14a) | X |
| Endoscopy Mt1 | X |
| Endoscopy Mt2 | X |
| OPD | X |
| Windy Nook (new OPD) | X |
| CCD (HDU) | X |
| CCD (ITU) | X |
| Theatre Holding Bay | X |
| Theatre Recovery | X |
| Surgical Admission Suite (QE POD) | X |
| Ward 8 Cardiology Mt 1 | X |

| Queen Elizabeth Hospital Delivery Points (A) | Glucose Roche AccuChek Inform II |
|---|---|
| Ward 8 Cardiology Mt 2 | X |
| Ward 9 | X |
| Ward 11 | X |
| Ward 12 / PIU | X |
| Ward 14 Mt 1 | X |
| Ward 14 Mt 2 | X |
| Emergency Surgical Assessment Unit (Located on Ward 9) | X |
| Jubilee Day Unit | X |
| Ward 21 | X |
| Ward 22 | X |
| Ward 23 Male | X |
| Ward 23 Female | X |
| Ward 24 Mt1 | X |
| Ward 24 Mt2 | X |
| Ward 25 (Contact: Denise West) | X |
| SC Recovery | X |
| SC POD | X |
| SC Level 1 | X |
| SC Level 2 | X |
| Pre Op Assesment Level 3 | X |
| ECT | X |
| Lamesley Ward | X |
| Fellside Ward | X |
| Sunniside Ward (Located Lyndhurst, Tranwell) | X |
| Craigside Court (Female) | X |
| Antenatal/Postnatal Ward | X |
| Labour Ward | X |
| Pregnancy Assessment Unit | X |
| Chemo Day Unit | X |
| Ward 20 | X |
| St Bedes (Elmwood) (QEH) | X |
| Diabetes Unit | X |
| Ellison Unit | x |

| **Queen Elizabeth Hospital Delivery Points (A)** | **INR Roche CoaguChek Pro II** |
|---|---|
| QEH - Unstable INR Clinic | X |
| Endoscopy | X |
| SCPods | X |
| Same day Emergency Care (SDEC) | X |
| **Queen Elizabeth Hospital Delivery Points (A)** | **Haemoglobin Radiometer HemoCue** |
| Labour ward | X |
| Theatre Recovery | X |
| Theatre Reception | X |
| **Queen Elizabeth Hospital Delivery Points (A)** | **Full Blood Count Sysmex XS-1000i** |
| Chemotherapy Day Unit | X |
| Medical Outpatients | X |
| **Queen Elizabeth Hospital Delivery Points (A)** | **Full Blood Count Sysmex XN - 5500** |
| Accident & emergency Department | X |
| **City Hospital Sunderland (B)** | **Full Blood Count Sysmex XS-1000i** |
| Phoenix Unit | X |
| **South Tyneside General Hospital Delivery Points (C)** | **Full Blood Count Sysmex XS-1000i** |
| Oncology/Haematology Day Unit | X |

| **Queen Elizabeth Hospital Delivery Points (A)** | **HbA1C Siemens DCA Advantage** |
|---|---|
| Ward 20 COPD | X |
| Trinity Square diabetic clinic | X |
| **Queen Elizabeth Hospital Delivery Points (A)** | **Blood Gases Radiometer ABL800 Series and ABL90 Flexplus** |
| Critical care | X |
| A&E | X (ABL90) |
| Biochemistry | X |
| SCBU | X |
| Labour Ward | X |
| Emergency Admission Unit | X (ABL90) |
| **City Hospital Sunderland (B)** | **Blood Gases Radiometer ABL800** |
| Biochemistry | X |
| **South Tyneside General Hospital Delivery Points (C)** | **Blood Gases Radiometer ABL90Flexplus and ABL800** |
| Labour Ward | X (ABL90) |
| Biochemistry | X (ABL800) |

| Queen Elizabeth Hospital Delivery Points (A) | Urinalysis Siemens Clinitek 50, Status, Status + |
|---|---|
| Short Stay Unit | X |
| 22 | X |
| Surgical Admissions Unit (QE POD) | X |
| Surgical Centre POD | X |
| Surgical Pre Assessment Level 3 | X |
| Ellison Unit BGH | X |
| QEH Outpatients Nurses Rm 13/14/15/16 Blaydon Primary Care Centre | X |
| Riverside | X |
| Woodside Unit/St Bede's Day Unit DHH | X |
| 14a Winter Beds - closed in summer | X |
| Ward 1 | X |
| Ward 4 | X |
| Ward 8 (Cardiology) | X |
| Ward 9 | X |
| Ward 11 | X |
| Ward 14 | X |
| Ward 20 | X |
| Ward 23 | X |
| Ward 24 | X |
| Ward 25 | X |
| Ward 12/PIU | X |
| Ward 21 | X |
| A&E Minors 1 and 2 | X |
| A&E Majors | X |
| Chemo Day Unit | X |
| COPD (Paeds OP) | X |
| Jubilee Day Hosp | X |
| Labour Ward/Delivery Suite | X |
| EAU (Emergency Assessment Unit) 1 and 2 | X |
| Paeds A+E | X |
| Post Natal/Ante Natal | X |
| Pregnancy Assessment Unit | X |

| Queen Elizabeth Hospital Delivery Points (A) | Urinalysis Siemens Clinitek 50, Status, Status + |
|---|---|
| St Bedes (Elmwood), QEH | X |
| Surgery Centre Level 1 | X |
| Surgery Centre Level 2 | X |
| Urology | X |
| QE Outpatients | X |
| Sunniside Unit (Tramwell Unit) | X |
| Cragside Court (Females) | X |
| Cragside Court (Males) | X |
| Diabetes Centre, Trinity Square Health Centre | X |
| Womens Health | X |

| Queen Elizabeth Hospital Delivery Points (A) | ApexBio KETOSURE POC |
|---|---|
| Ward 14 | X |
| Surgery Centre | X |
| SDEC | X |
| Children's Day Unit | X |
| EAU ward 1 | X |
| Biochem MT2 | X |
| A&E Paeds | X |
| EAU ward 2 | X |
| CCD red | X |
| Spare 1 | X |
| Biochem MT1 | X |
| CCD yellow | X |
| A&E Resus | X |

| City Hospital Sunderland (B) | ApexBio KETOSURE POC |
|---|---|
| Paediatric A&E | X |
| SDEC | X |
| POCT | X |
| Endocrine & Metabolic Medicine | X |
| EAU | X |
| EAU | X |
| Biochemistry | X |
| A&E | X |
| D40 | X |

| | |
|---|---|
| F63 | X |
| Delivery Suite | X |
| C36 | X |
| E54 Annex | X |
| A&E | X |
| C31 | X |
| Biochemistry | X |
| B22 | X |
| ICCU | X |
| B28 | X |
| F64 | X |
| **South Tyneside General Hospital Delivery Points (C)** | **ApexBio KETOSURE POC** |
| ITU | X |
| Biochemistry | X |
| Paediatric A&E | X |
| Ward 3 | X |
| Ward 6 | X |
| A&E Resus | X |
| EAU | X |
| SDEC | X |
| Point of Care | X |
| Biochemistry | X |
| Ward 7 | X |
| **South Tyneside General Hospital Delivery Points (C)** | **Glucose Roche AccuChek Inform II** |
| A&E Majors M1 | X |
| A&E Majors M2 | X |
| A&E Majors M 3 | X |
| A&E Triage | X |
| A&E Ambulatory Care | X |
| A&E RESUS | X |
| Adult Physiotherapy Cardiac Rehab (PALMER'S) | X |
| Bede 1 | X |
| Bede 2 | X |
| Bede 3 | X |
| Cardiac Rehab (STDH) | X |
| DC (Diagnostic Clinic -OPD) | X |
| Endoscopy Day Ward | X |
| General Theatres Recovery M1 | X |
| General Theatres Recovery M2 | X |
| ITU / HDU M1 | X |

| | |
|---|---|
| ITU / HDU M2 | X |
| ITU / HDU M3 (NURSES STATION) | X |
| ITU / HDU M4 | X |
| **South Tyneside General Hospital Delivery Points (C)** | **Glucose Roche AccuChek Inform II** |
| ITU / HDU M5 (SIDE ROOM 2) | X |
| ITU / HDU M6 (SIDE ROOM 1) | X |
| Jane Palmer Day Ward (PALMER'S HOSPITAL) | X |
| Moorlands Day Unit M1 | X |
| Moorlands Day Unit ENDO | X |
| OPD (Palmer's Out Patient) M1 | X |
| OPD (Palmer's Out Patient) M2 | X |
| Primrose Unit on Wd 20 | X |
| Special Care Baby Unit | X |
| St Clares (At primrose Hill Hospital) | X |
| Ward 1- M1 | X |
| Ward 1- M2 | X |
| Ward 10-M1 | X |
| Ward 10 M2 | X |
| Ward 12 | X |
| ECC M2 | X |
| Ward 18 | X |
| Ward 19 MT 1 | X |
| Ward 19 MT 2 | X |
| Ward 2 Mt 1 | X |
| Ward 2 Mt 2 | X |
| Ward 22 | X |
| Ward 25 (Delivery) - G33 | X |
| Ward 3 MT 1 | X |
| Ward 3 MT 2 | X |
| Ward 4 MT 2 | X |
| Ward 4 MT 3 PA1306 | X |
| Ward 4 PA1339 (MT 1) | X |
| Ward 4 PA1340 Sister Franklin | X |
| Ward 5 - M1 | X |
| Ward 5 - M2 | X |
| EAU A | X |
| EAU M1 | X |

| | |
|---|---|
| Ward 6 (Card) M2 | X |
| Ward 6 (Card) M3 | X |
| Ward 6 (CCU) | X |
| Ward 8 (Stroke Unit) | X |
| Ward 9 M1 | X |
| **South Tyneside General Hospital Delivery Points (C)** | **Glucose Roche AccuChek Inform II** |
| Ward 9 M2 | X |
| Paediatric Emergency Care Centre (ECC) | X |
| Ward 11 OHDU | X |
| Ward 7 Winter Pressures | X |
| X-RAY MT 1 | X |
| X-RAY MT 2 | X |
| **City Hospital Sunderland (B) and Eye Infirmary (E) Delivery Points** | **Glucose Roche AccuChek Inform II** |
| A & E ANNEXE | X |
| A & E SEE & MANAGE ROOMS/TRIAGE | X |
| A & E Paediatrics | X |
| A & E RESUS | X |
| A & E WALK IN | X |
| A&E Triage | X |
| A&E SPARE | X |
| A/E Pallion Centre | X |
| Ward C33 | X |
| AMU Ward C34 M2 (ON D44) | X |
| AMU Ward C34 M1 (ON E55) | X |
| AMU Ward C35 (RATU) M3 | X |
| Antenatal Clinic | X |
| Antenatal Day care | X |
| Anatenatal/Postnatal Ward | X |
| Catheter lab B22 | X |
| Delivery Suite | X |
| DIAB/ENDO/METB MED | X |
| Endscopy Unit | X |
| Fracture Clinic | X |

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|---|---|
| GUM Clinic | X |
| Phoenix Unit Chemo Day Unit | X |
| **City Hospital Sunderland (B) and Eye Infirmary (E) Delivery Points** | **Glucose Roche AccuChek Inform II** |
| ICCU Ward 38 RM 01 | X |
| ICCU Ward 38 RM 02 | X |
| ICCU Ward 38 RM 03 | X |
| ICCU Ward 38 RM 04 | X |
| ICCU Ward 38 RM 05 | X |
| ICCU Ward 38 RM 06 | X |
| ICCU Ward 38 RM 07 | X |
| ICCU Ward 38 RM 08 | X |
| ICCU Ward 38 RM 09 | X |
| ICCU Ward 38 RM 10 | X |
| ICCU Ward 38 RM 11 | X |
| ICCU Ward 38 RM 12A | X |
| ICCU Ward 38 RM 12B | X |
| ICCU Ward 38 RM 14 | X |
| ICCU Ward 38 RM 15 | X |
| ICCU Ward 38 RM 16 | X |
| ICCU Ward 38 RM 18 | X |
| MEDICAL DAY CARE UNIT | X |
| NIALL QUINN CHILDRENS | X |
| OPD ORAL AND FACIAL | X |
| PODIATRY DEPT | X |
| RENAL UNIT | X |
| RENAL Ambulatory Care | X |
| SURGICAL DAY CASE LEVEL D MT1 | X |
| SURGICAL DAY CASE LEVEL D MT2 | X |
| SURGICAL DAY CASE LEVEL D MT3 | X |
| Theatres F65 | X |
| Theatres LEVEL C M1 | X |
| Theatres LEVEL C M2 | X |
| Theatres LEVEL C M3 | X |
| Theatres LEVEL C M4 | X |

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|---|---|
| Theatres LEVEL D RECOVERY 1 (10/11) MT1 | X |
| **City Hospital Sunderland (B) and Eye Infirmary (E) Delivery Points** | **Glucose Roche AccuChek Inform II** |
| Theatres LEVEL D RECOVERY 2 (D1 TO D9) MT3 | X |
| Theatres LEVEL D RECOVERY 2 (D1 TO D9) MT4 | X |
| Urology Theatres LEVEL D MT1 | X |
| Urology Theatres LEVEL D MT2 | X |
| Urology OPD | X |
| Ward B20 | X |
| Ward B21 | X |
| Ward B22 (Cardiology) | X |
| Ward B22 (CCU) | X |
| Ward B22 (Chest Pain) | X |
| Ward B26 (Renal Ward) | X |
| Ward B28 M1 | X |
| Ward B28 M2 | X |
| Ward B28 M3 | X |
| Ward B28 M4 | X |
| Ward C30 | X |
| Ward C31 | X |
| Ward C36 | X |
| Surgical Day Case Unit C LEVEL MT2 | X |
| Ward C37 Surgical Day Case MT3 | X |
| Ward D40 (re-opened 17/11/14) | X |
| Ward D41 | X |
| Ward D42 | X |
| Ward D43 | X |
| Ward D44 (Integrated Admissions Unit) Mt1 | X |
| Ward D44 (Integrated Admissions Unit) Mt2 | X |

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|---|---|
| Ward D46 | X |
| Dosa Unit (Urology) D Floor | X |
| Ward D47 (GYNAE) | X |
| **City Hospital Sunderland (B) and Eye Infirmary (E) Delivery Points** | **Glucose Roche AccuChek Inform II** |
| Ward D48 M1 | X |
| Ward D48 M2 | X |
| Ward E50 | X |
| Ward E51 | X |
| Ward E52 | X |
| Ward E53 MT1 | X |
| Ward E53 MT2 | X |
| Ward E54 | X |
| Ward E55 | X |
| Ward E56 | X |
| Ward E58 M1 | X |
| Ward E58 M2 | X |
| Ward F61 M1 | X |
| Ward F61 M2 | X |
| Ward F62 | X |
| Ward F63 | X |
| Ward F64 | X |
| Ward F65 | X |
| C LEVEL X-RAY | X |
| Sunderland Eye Iinfirmary A & E | X |
| Cataract Theatre 1 | X |
| Cataract Theatre 2 | X |
| HAYGARTH clinic | X |
| HAYGARTH Ward | X |
| Macular Unit | X |
| Mayling Clinic | X |
| OPD A | X |
| OPD B | X |
| Theatre 1 DAY | X |
| Theatre 2 DAY | X |
| Theatre RECOVERY | X |
| Central Clinic Childrens Centre | X |