Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8646

Accredited to ISO 15189:2012

Integrated Pathology Solutions LLP

Issue No: 015 Issue date: 27 August 2024

Pathology Department Contact: Rebecca Parish

Fewston Wing Tel: +44 (0) 1423 555 842

Harrogate District Hospital E-Mail: rebecca.parish2@nhs.net

Lancaster Park Road Website: www.hdft.nhs.uk/our-services/department-

Harrogate service-g-z/pathology/

North Yorkshire HG2 7SX

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Testing locations:

| Location details | | Activity | Location code |
|---|---|---|---------------|
| Pathology Laboratory Fewston Wing Harrogate District Hospital Lancaster Park Road Harrogate North Yorkshire HG2 7SX | Local contact Rebecca Parish | Biochemistry Haematology Blood Transfusion Histopathology & non-gynae cytology Microbiology | A |
| Hospital Wards Address Harrogate District Hospital Lancaster Park Road Harrogate North Yorkshire HG2 7SX | Local contact Dr Sarah Glover | Point of Care Testing Clinical Chemistry | В |
| Hospital Wards Address Ripon Community Hospital Firby Lane Ripon HG4 2PR | Local contact Dr Sarah Glover | Point of Care Testing Clinical Chemistry | С |
| Off site Clinics: Address Gastro Follow-up Clinic Wharfedale Hospital Newall Carr Road Otley Leeds LS21 2LY | Local contact Dr Sarah Glover | Point of Care Testing Clinical Chemistry | D |

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| Location details | | Activity | Location code |
|--|---|--|---------------|
| Off site Clinics (cont'd): Address Surgical OP Wetherby Health Centre Hallfield Lane Wetherby Leeds LS22 6JS | Local contact Dr Sarah Glover | Point of Care Testing Clinical Chemistry | D |
| Address Surgical OP Alwoodly Medical Centre Saxon Mount Leeds LS17 5DT | Local contact Dr Sarah Glover | Point of Care Testing Clinical Chemistry | D |
| Address Surgical OP Yeadon Health Centre 17 South View Road Yeadon Leeds LS9 7PS | Local contact Dr Sarah Glover | Point of Care Testing Clinical Chemistry | D |
| Hospital Clinics Address Harrogate District Hospital Lancaster Park Road Harrogate North Yorkshire HG2 7SX | Local contact Dr Sarah Glover | Point of Care Testing Clinical Chemistry | E |
| Domicillary Address Patients homes | Local contact Dr Sarah Glover | Point of Care Testing Clinical Chemistry | F |

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Additional site activities performed at main location listed above:

| Location details | | Activity |
|---|---|---|
| Harrogate District Hospital Lancaster Park Road Harrogate North Yorkshire HG2 7SX | | Phlebotomy |
| On-site Mortuary and Body Store | | Storage of bodies Record keeping (body identification and audit trail) |
| Maternity Blood Fridge Harrogate District Hospital | Local contact Laura Baglow Transfusion Laboratory Manager | Blood storage only |

Site activities performed away from the main laboratory location listed above:

| Location details | | Activity |
|--|---|--------------------|
| BMI The Duchy Hospital Queens Road Harrogate Yorkshire HG2 0HF | Local contact Laura Baglow Transfusion Laboratory Manager | Blood storage only |
| Sir Robert Ogden Macmillan centre 1 Willaston Crescent Harrogate North Yorkshire HG2 7BF | Local contact Laura Baglow Transfusion Laboratory Manager | Blood storage only |

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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---------------------------|--|--|---------------|
| HUMAN BODY FLUIDS | Examination activities for the purpose of clinical diagnosis | In house documented methods incorporating manufacturers' instructions where relevant | A |
| | <u>Biochemistry</u> | Beckman AU 5800 by Spectrophotometry and Ion selective electrodes and SOP BS- CP-LP- AU5800 | |
| Serum (SST) | ALT – Alanine transaminase Albumin ALP -Alkaline Phosphatase Amylase AST- aspartate transaminase Bicarbonate Beta2-microglobulins Bile Acids Bilirubin Total Bilirubin Conjugated Calcium Chloride Cholesterol Complement 3 Complement 4 C-Reactive Protein Creatine Kinase Creatinine Digoxin Gamma GT Gentamicin Haptoglobin H.D.L. Cholesterol IgA IgM IgG Iron LDH – lactate dehydrogenase Lithium Magnesium Paracetamol Phosphate Potassium Rheumatoid Factor Salicylate Sodium Theophyline | CP-LP- AU3800 | |

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ISO 15189:2012

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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) | Examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions where relevant | А |
| | Biochemistry (cont'd) | BeckmanAU 5800 by Spectrophotometry and Ion selective electrodes and SOP BS- CP-LP- AU5800 | |
| Serum (SST) (cont'd) | Total Protein Transferrin Triglycerides Urea Uric Acid Vancomycin | CF-LF- A03000 | |
| Fluoride Oxalate | Alcohol | | |
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|----------------------------|---|--|---------------|
| HUMAN BODY FLUIDS (cont'd) | Examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions where relevant | A |
| | Biochemistry (cont'd) | Beckman DXi 800 by Chemiluminescence and SOP BS- LP-DxI800-OP | |
| Serum | Alpha feto protein (AFP) Beta -hCG Cancer antigen 125 Cancer antigen 153 Cancer antigen 199 Carcinoembryonic antigen Cortisol Digoxin Ferritin Folate Freethryoxine Free triiodothyronine Follicle stimulating hormone HCG Leuteinising hormone | | |
| Plasma Serum | Oestradiol Parathyroid hormone Prolactin Procalcitonin PSA SHBG TPO Troponin I Thyroid stimulating hormone Testosterone Vitamin B12 Vitamin D SARS CoV-2 antibodies | | |
| | | | |

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|-------------------------------|--|---|---------------|
| HUMAN BODY FLUIDS (cont'd) | Examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions where relevant | А |
| | Biochemistry (cont'd) | Beckman au 5800by spectrophotometry and ion selcective electrodes and SOP SOP BS-CP-LP- AU5800 | |
| Plasma | Glucose Lactate Ammonia | | |
| Urine | Amylase Calcium Creatinine Magnesium Sodium Potassium Chloride Phosphate Protein Urea Uric acid Microalbumin | | |
| CSF | Glucose Protein Lactate | | |
| Serum Urine | Osmolality | Vitech 3200 suppliers method and measurement by freezing point depression CP-LP-MT-OSM | |
| CSF | Xanthochromia | Varian Cary 50B, suppliers method and measurement by spectrophotometry CP-LP-MT-CSFS | |
| Sweat | Sweat test | Sweatcheck 3120 supplier method measurement by conductivity and sherwood 926s, suppliers method measurement by colorimetry CP-LP-MT-STEST | |

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|----------------------------|--|--|---------------|
| HUMAN BODY FLUIDS (cont'd) | Examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions where relevant | А |
| | Biochemistry (cont'd) | | |
| Serum SST | Serum Protein Electrophoresis: Monoclonal protein band detection, identification and quantitation | Sebia Minicap, supplier method measurement by capillary electrophoresis /immunophenotyping CP-LP-MT-EPS | |
| Serum | Free light chains – free kappa and Lambda assays | Binding site Optilite measurement by turbidmetry and SOP BS-CP-LP-OPTILITE | |
| Serum SST | Monoclonal protein band identification and quantitation | Sebia Hydrasys, supplier method measurement by gel electrophoresis/Immunofixation CP-LP-MT-SFIX | |
| Serum SST | Alkaline Phosphatase Isoenzymes: Placental Bone Liver Intestinal | Sebia Hydrasys, supplier method measurement by gel electrophoresis/I Lectin binding CP-LP-MT-APIS | |
| Urine | Bence Jones Protein: Monoclonal protein band identification | Sebia Hydrasys, supplier method measurement by gel electrophoresis/Immunofixation CP-LP-MT-UFIX CP-LP-MT-UHR | |
| Whole blood EDTA | Glycated Haemoglobin | TOSOH G8 supplier method measurement by HPLC CP-LP-MT-G8 | |
| Faeces | Quantitative measurement of Calprotectin | DiaSorin Liaison XL using chemiluminesence and SOP MB-LP-VSOPLIAISON | |
| | | | |

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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) | Examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions where relevant | A |
| | <u>Haematology</u> | | |
| Whole blood EDTA | White Blood Cell Count (total) Neutrophil Count Lymphocyte Count Monocyte Count Eosinophil Count Basophil Count Haemoglobin Red Cell Count Platelet Count Mean Cell Volume Reticulocyte Count Nucleated Red Cell Count | Sysmex 2100xn supplier methods and measurement by; fluorescent flow cytometry, calorimetry, light scatter, direct current and impedance HM-LP USE OF SYSMEX XN-2100 | |
| Whole blood EDTA | Sickle Screen | Strek Sickledex suppliers method and measurement by optical reading of opacity BS-HM-LP-038 | |
| Whole blood EDTA | Blood Films: Morphology Intra-erythrocytic Parasites | Light microscopy BS-HM-LP-035 BS-HM-LP-037 | |
| Bone Marrow EDTA | Bone Marrow Films | BS-HM-LP-051 | |
| EDTA plasma | Epstein-Barr Virus (EBV) antibodies (Infectious Mononucleosis screen) | Clearview IM screen suppliers method and measurement by membrane diffusion antibody reaction BS-HM-LP-036 | |

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|----------------------------|--|---|---------------|
| HUMAN BODY FLUIDS (cont'd) | Examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions where relevant | А |
| | Haematology (cont'd) | | |
| EDTA Blood | Differential detection of Plasmodum falciparum and pan-detection of other Plasmodium species: Plasmodium malariae, Plasmodium falciparum, Plasmodium ovale & Plasmodium vivax | Apacor CareStart Malaria kit using combined HRP2/pLDH (Pan) technology BS-HM-LP-037 | |
| EDTA whole blood | Erythrocyte Sedimentation Rate | Automated using Elitech Mixrate X20 and SOP BS-HM-LP-ESR | |
| | Blood Transfusion | Automated – Grifols Erytra Eflexis analysers BS-BT-LP-051 Manual – DG ther, DG spin and interfaced DG card reader BS-BT- LP-025 | |
| Whole blood EDTA | Blood group ABO Rh D | Automated & Manual BS-BT-LP-016 | |
| | KIID | Full Group: DG Gel ABO/Rh ("D) + K cards, Serigrup Diana A1 B cells BS-BT-LP-016 | |
| | | Confirmation Group: DG Gel Confirm P cards BS-BT-LP-016 | |
| | | Cord & Neonatal: DG Gel Newborns cards BS-BT-LP-013 | |
| | Red cell antibody screen: C, E, c, e, K | Automated & Manual DG Gel Coombs AHG cards, Serascan Diana 3 screening cells BS-BT-LP-016 | |

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|----------------------------|--|--|---------------|
| HUMAN BODY FLUIDS (cont'd) | Examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions where relevant | А |
| | Blood Transfusion (cont'd) | Automated – Grifols Erytra Eflexis analysers BS-BT-LP-051 Manual - Erytra card incubator, card centrifuge and interfaced DG card reader BS-BT-LP-025 | A |
| | Extended Rh phenotyping: C, c, E, e | Automated & Manual DG Gel Rh Pheno cards BS-BT-LP-016 | |
| | Red cell antibody identification C, E, c, e, K | Automated & Manual DG Gel Coombes AHG cards, DG Gel Neutral, Identisera Diana panel cells & Identisera Diana P enzyme panel cells BS-BT-LP-025 BS-BT-LP-030 | |
| | Crossmatch | Automated & Manual DG Gel Coombs AHG cards BS-BT-LP-011 | |
| | Direct Antiglobulin test | Automated & Manual DG Gel Coombs AHG cards BS-BT-LP-009 | |
| | Monospecific Direct Antiglobulin test; | Manual DG Gel Scan mono DAT cards BS-BT-LP-009 | |
| Whole blood EDTA | Kleihauer estimation of Foetal/Maternal haemorrhage (FMH) via count of foetal cells in maternal blood film/calculation of total bleed (ml) Screen only performed | Guest Medical FMH kit suppliers method and detection by microscopy following alkali denaturation to detect foetal cells and calculation of bleed. Screen only BS-BT-LP-035 | |
| | | | |

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|----------------------------|--|--|---------------|
| HUMAN BODY FLUIDS (cont'd) | Examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions where relevant | А |
| | Coagulation examination activities for the purpose of clinical diagnosis | | |
| | Blood coagulation | Werfen ACL TOPS 550 | |
| Citrated Plasma | Prothrombin time INR Activated | BS-HM-LP-ACL01 | |
| Citrated Plasma | Clauss Fibrinogen Thrombin Time Anti-Xa assays (Low molecular weight heparin, Apixaban, Rivaroxaban) D-Dimer | BS-HM-LP-ACL01 | |
| | | | |
| | | | |

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|---|---|---|---------------|
| HUMAN BODY FLUIDS AND TISSUES | Microbiology examination activities for the purpose of clinical diagnosis | In house documented methods following related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | A |
| Swabs (nasal, wound, neonatal, throat, mouth, genital, eye, ear, superficial wounds & skin), corneal scrapings, sputum, pleural fluid, bronchoalveolar samples, urine, tissues and biopsies, CSF, synovial fluids, fluids from normally sterile sites, intravascular cannulae | General isolation and characterisation of microorganisms of clinical significance | Manual culture, Nasal swabs MB-LP-BSOP5 Pus and exudate MB-LP-BSOP14 Throat swabs MB-LP-BSOP9 Mouth swabs MB-LP-BSOP4 Pernasal swabs MB-LP-BSOP6 Bile MB-LP_SOP15 Bacterial Eye infections MB- MB-LP-BSOP2 Ear swabs MB-LP-BSOP1 Superficial wounds and skin MB-LP-BSOP11 Using manual culture, Investigation of sputum, pleural | |
| | | fluid, BAL & associated specimens MB-LP-BSOP57 Investigation of Urine MB-LP-BSOP41 Investigation of tissues and biopsies MB-LP-BSOP17 MB-LP-BSOP42 Investigation of bone & soft tissue associated with osteomyelitis; Investigation of orthopadeic implant associated infections MB-LP-BSOP44; Investigation of CSF MB-LP-BSOP27; Investigation of Fluids from Normally Sterile Sites MB-LP-BSOP 26; Investigation of Intravascular cannulae | |
| Genital swabs | General isolation and characterisation of microorganisms of clinical significance | MB-LP-BSOP122 Investigation of Genital swabs and associated speciments MB-LP-BSOP28 | |

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|---|---|---|---------------|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods following related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | A |
| | Diagnosis of Bacterial vaginosis | Using HAYS criteria by Gram staining microscopy MB-LP-BSOP28 | |
| Faeces | Isolation and characterisation bacterial pathogens: Salmonella sp. Shigella spp. Campylobacter spp. Escherichia coli O157 Vibrio spp. Yersinia spp. | Manual culture Investigation of faeces for pathogens MB-LP-BSOP30 | |
| Whole blood | Detection of microbial growth and general isolation and characterisation of micro- organisms of clinical significance | Liquid culture using Bactec Fx Investigation of blood cultures MB-LP-BSOP37; Operation of the Bactec Fx instrument MB-LP-BSOP147 | |
| Bacterial culture isolates produced by the laboratory | Antibiotic susceptibility testing (including screening for ESBL and other multi resistant organisms) | EUCAST (manual disc diffusion) MB-LP-BSOP45, Antimicrobial susceptibility testing MB-LI-BGESBL Laboratory detection of multiclass resistance, ESBL and AmpC beta lactamases | |

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|--|--|--|---------------|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods following related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | A |
| Bacterial and fungal culture isolates produced by the laboratory | Identification of micro- organisms of clinical significance | API kits (including API 20E, NE, NH, CORNE, 20 Strep, rapid 32, Strep, rapid 32A Anaerobe MB-LP-BSOPTP62 Catalase test MB-LP-BSOPTP8 coagulase test (including Prolex staph latex) MB-LP-BSOPTP10 DNase test MB-LP-BSOPTP12 oxidase tests MB-LP-BSOPTP26 staining/microscopy MB-LP-BSOPTP96 Staining/microscopy MB-LP-BSOPTP97 Prolex Streptococcal Grouping kit MB-LP-BSOPTP97 Urease test MB-LP-BSOPTP97 Urease test MB-LP-BSOPTP97 (Optochin / Bile solubility test MB-LP-BSOPTP98; ID of Moraxella catarrhalis by butyrate discs MB-LP-BSOPTP97; Detection of Beta-Lactamase by Nitrocefin MB-LP-BSOPTP98 (ID of Moraxella catarrhalis by butyrate discs MB-LP-BSOPTP97 (ID of Moraxella catarrhalis by Detection of Beta-Lactamase by Nitrocefin MB-LP-BSOPTP98 (ID of Moraxella catarrhalis identification SOPs: | |

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|--|---|---|---------------|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods following related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | A |
| Nose swabs | Isolation of MRSA | Manual chromogenic culture MRSA screening swabs MB-LP-BSOP29 | |
| Urine | Detection and quantification of red cells, white cells, epithelial cells, bacteria and yeasts | UF5000 by flow cytometry Investigation of urine MB-LP-BSOP41 MB-LP-BSOP148 | |
| | | Manual using Kova slides MB-LP-BSOP41 MB-LI-BGurine MB-LI-BSOP41 MB-LI-BGUF5000 | |
| CSF | Detection, identification and quantification (inc. differential) of: White blood cells Red blood cells Bacterial and fungal cells | Microscopy (stained and unstained, inc. Gram and differential) MB-LP-BSOP27 | |
| Synovial fluid | Presence of crystals | Microscopy MB-LP-BSOP26 | |
| Sputum, Pleural fluid, bronchoalveolar samples (urgent samples only) | Screening for acid-alcohol fast bacilli | Microscopy (urgent only) using auramine stains Investigation of Specimens for Mycobacterium sp MB-LP-BSOP40 Staining Procedures MB-LP-BSOP109 | |
| | | Manual immunochromatographic membrane assays: | |
| Urine | Detection of Legionella pneumophila serotype 1 antigen | Binax Now kit by Alere MB-LP-VSOP 5 | |

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|---|--|---|---------------|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods following related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | A |
| Urine & CSF | Detection of pneumococcal soluble Antigen | Binax Now kit by Alere MB-LP-VSOP 6 | |
| Faeces | Detection of Clostridium difficile GDH antigen | Techlab C Diff Chek kit by Alere MB-LP-BSOPTP66 | |
| Faeces | Rota/Adenovirus antigen detection | GastroVir strip by Coris MB-LI-BSOP30A | |
| Urines and genital swabs | Detection of <i>Chlamydia</i> trachomatis and <i>Neisseria</i> gonorrhoea rRNA | Hologic Panther Aptima Combo 2 assay Molecular: transcription – mediated amplification of the RNA target detected by hybridisation and real time fluorescence MB-LP-MSOP3 | |
| nasopharyngeal, nose/throat swabs in viral transport media (VTM | Detectection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences ORF1ab gene | Hologic Panther and transcription mediated amplification (TMA) and dual kinetic assay using Aptima SARS-CoV-2 assay MB-LP-MSOP4 | A |
| Faeces | Detection of organisms carrying Carbapenase enzyme (CPE) C. difficile toxin B gene | Cepheid GeneXpert using real time PCR MB-LP-BSOP67 | |
| nasopharyngeal, nose/throat swabs in viral transport media (VTM | Detectection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences e, N2 | Cepheid Gene Xpert and realtime PCR Xpert Xpress SARS-CoV-2 assay MB-LP-BSOP67 | A |
| Nasal, throat and nasopharyngeal and mid-turbinate swab, nasal wash and aspirates | Qualitative detection and differentiation of: Qualitative detection and differentiation of: SARS-CoV-2 Influenza A Influenza B RSV | MB-LP-BSOP149 | |

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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods following related PHE Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | A |
| Nasopharyngeal swab | Qualitative detection and differentiation of: | BioFire Film Array Torch multiplex PCR technology analyser | |
| | SARS-CoV-2 | MB-LP-BSOP149 | |
| | Influenza A | | |
| | Influenza B | | |
| | RSV | | |
| | Serological examination activities for the purpose of clinical diagnosis | Documented -in-house methods to meet the requirements of the Infectious diseases in pregnancy (IDPS) screening programme(s) as defined in the July 2018 Infectious diseases in pregnancy screening: laboratory QA evidence requirements (tests marked *) | A |
| Serum | Hep A IgM Hep B antibody Hep B surface antigen* Hep C antibody HIV-1 antibodies, HIV-1 p24 antigen and HIV-2 antibodies* Rubella IgG Treponema pallidum antibodies* VZV IgG Measles IgG Toxoplasma IgG & IgM Borrelia IgG & IgM EMV IgM EBV IgM Hepatitis B core antibody Parvovirus IgG & IgM | DiaSorin Liaison XL using chemiluminesence MB-LP-VSOPLIAISON | |
| Faeces | Qualitative determination of Clostridium difficile toxins A & B | MB-LP-VSOPLIAISON | |

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|---|--|--|---------------|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | Parasitology examination activities for the purpose of clinical diagnosis | In house documented methods incorporating manufacturers' instructions where relevant | A |
| Faeces | Isolation and identification of faecal ova, cysts and parasites. | Concentration method and microscopy MB-LP-BSOP31 | |
| | Mycology examination activities for the purpose of clinical diagnosis | In house documented methods incorporating manufacturers' instructions where relevant | A |
| Hair, skin and nails | Examination for superficial mycoses | Manual culture MB-LP-BSOP39 Potassium hydroxide test & microscopy | |
| | Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: | А |
| Fine Needle Aspirations, Sputa, Bronchial Washings, Bronchial Brushings, Urines, Joint, Cyst And Serous Fluids, Serous Effusions | Cytopathology | Centrifugation: Thermo Scientific Sorvall ST8 centrifuge Thermo Fisher cytospin 4 HP-LP-013 | |
| Serous Enusions | Staining for the purposes of: | Automated staining using Leica Histocore Spectra ST autostainer Papanicalou Stain H&E | |
| | Acid mucins | Alcian blue | |
| | Mucins | AB/PAS for mucins | |
| | Glycogen | Pas Technique (+/- diastase digestion) | |
| | Cell differentiation Morphology | Manual staining: Giemsa Rapid Diff method | |
| | Microorganisms | HP-LP-013 | |

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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 AND TISSUES (cont'd) | Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) Cytopathology (cont'd) | Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: | A |
| Slides prepared in house as above | Morphological assessment and interpretation/diagnosis | Microscopy HP-LP-021 | |
| Tissue samples | Histopathology | Specimen dissection HP-LP-004 HP-LP-027 | |
| | | Decalcification Of Calcified Specimens HP-LP-006 | |
| | | Tissue processing Leica Histocore Peloris 3 HP-LP-007 | |
| | | Embedding Leica Histocore Arcadia H&C | |
| | | HP-LP-008 Microtomy Leica AS microtomes HP-LP-009 | |
| | | Frozen section and intra operative procedures Leica CM1860 UV cryostat HP-LP-012 | |
| | | Leica Cerebro sample tracking system | |
| | Routine staining for identification of basophilic and eosinophilic structures | Haematoxylin and Eosin stain Automated: Leica Histocore Spectra ST automated stainer HP-LP-010 | |
| | | Leica Histocore Spectra CV automated coverslipper | |

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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) Histopathology (cont'd) | Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: | A |
| Tissue samples (cont'd) | Special staining to identify the following: | Special stains Manual: HP-LP-042 | |
| | Amyloid | Congo Red | |
| | Elastic fibres | Elastic Van Gieson/H&E | |
| | Reticulin fibres | Reticulin Stain | |
| | Bacteria | Gram Stain | |
| | Fungi | Grocott Methanamine Silver | |
| | Fibrin | Martius Scarlet Blue technique | |
| | Melanin | Masson Fontana | |
| | Connective tissue | Masson Trichrome | |
| | Ferric iron | Perl's Prussian Blue reaction | |
| | Mast cells | Toluidine Blue method | |
| | Special staining to identify the following: | Special stains Manual: HP-LP-042 | |
| | Connective tissue | Haematoxylin Van Gieson technique | |
| | Acid fast bacilli | Ziehl-Neelsen stain | |
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|--|--|--|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) Histopathology (cont'd) | Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: | A |
| Tissue samples and cell blocks | Immunochemistry for the identification of: | Immunohisto/cytochemical staining Automated Ventana Benchmark Ultra HP-LP-011 & HP-LP-035 | |
| | Normal & Abnormal epithelial cells | AE1/3 | |
| | Epithelial cell types | BER-EP4 | |
| | Maligant ovarian epithelial cells, seminal vesical carcinoma & anaplastic lymphoma | CA125 | |
| | Leucocyte differentiation | CD56 | |
| | GI Tract tumours | CDX2 | |
| | Normal & Abnormal epithelial lineage | CEA | |
| | Tissues of neuroendocrine origin | CHROMOGRANIN A | |
| | Mesothelioma, prostate carcinoma | CK5/6 | |
| | Normal and neoplastic epithelia | CK7 | |
| | Squamous cell carcinomas, metaplastic carcinomas of the breast | CK14 | |
| | Gastric and intestinal epithelium, urothelium and Merkel Cells | CK20 | |
| | Normal duct epithelial cells, ductal carcinoma | E-CADHERIN | |

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| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|--|--|--|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) Histopathology (cont'd) | Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: | A |
| Tissue samples and cell blocks (cont'd) | Immunochemistry for the identification of: (cont'd) | Immunohisto/cytochemical staining Automated Ventana Benchmark Ultra HP-LP-011& HP-LP-035 | |
| | Luminal epithelial cells of breast and urothelial carcinoma | GATA-3 | |
| | P53 mutations in neoplastic cells neoplastic cells in epithelium | P53 | |
| | Tumour types including thyroid, renal cell and ovarian serous carcinomas | PAX-8 | |
| | Nuclei of cells showing expression of progesterone | PR antibodies | |
| | Many carcinomas – normal and neoplastic cells from various tissues | ЕМА | |
| | Estrogen Receptor antigen | ESTROGEN RECEPTOR | |
| | Breast Carcinoma | GCDFP-15 | |
| | Classification of melanomas | HMB45 | |
| | Leucocytes | CD45 (LCA) | |
| | Primary and metastatic malignant melanoma | MELAN A | |
| | HPV infection in dysplastic squamous epithelium | P16 | |
| | | | |

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|--|--|--|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) Histopathology (cont'd) | Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: | A |
| Tissue samples and cell blocks (cont'd) | Immunochemistry for the identification of: (cont'd) | Immunohisto/cytochemical staining Automated Ventana Benchmark Ultra HP-LP-011& HP-LP-035 | |
| | Benign and malignant prostatic or breast lesions, differentiation of lung squamous cell carcinoma and lung adenocarcinoma | P63 | |
| | Prostate secretory and ductal epithelium | PSA | |
| | Melanomas, neural cells | S100 | |
| | Smooth Muscle Cells | SMA | |
| | Visceral and vascular smooth muscle cells, myoepithelial cells | SMM | |
| | Melanoma subtypes | so | |
| | Neoplasms of lung and thyroid, mesothelioma | TTF1 | |
| | Wilm's Tumour | WT1 | |
| | Detection of H.pylori | H.pylori | |
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| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|--|---|--|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Provision of Point of Care testing in accordance with ISO 22870: 2016 related to the following: | In house documented methods incorporating manufacturers' instructions where relevant | |
| Whole blood | Blood Gas and associated tests: Blood Gases (pH, pCO2 and pO2) Electrolytes (Na+, K+, Ca2+) Co-oximetry (O2Hb, COHb, MetHb) Glucose, lactate, haematocrit (Hct), total Hb (tHb) bilirubin | Werfen Gem 5000 Blood Gas analyser BS-PC-LP-023 | В |
| Whole blood | Glucose/Ketones (inclusive of sampling) | Abbott Freestyle Precision Pro BS-PC-LP-005 | B, C, D |
| Whole blood | HbA1C (inclusive of sampling) | Abbott Afinion 2 BS-PC-LP-009 | E |
| Urine | Screen: blood, glucose, ketone, protein, SG, pH, urobiligen, bilirubin, ascorbic acid, nitrites and leucocytes (inclusive of sampling) | Sterilab BS-Urilyzer 100 Pro/Urine dipstick PC-LP-013 | B, C, D |
| Whole blood | Blood Gas and associated tests: Blood Gases (pH, pCO2 and pO2), glucose, lactate | EPOC PC-LP-012 | F |
| Capillary and venous blood sample | Haemoglobin | Radiometer Hemacue (modified azide-methemoglobin reaction measurement) BS-PC-LP-024 | В |

(See Appendix 1 for details of accredited examinations at location types B - G)

END

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Accredited to

ISO 15189:2012

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Testing performed by the Organisation at the locations specified

Appendix 1

| B Harrogate Hospital Wards | Glucose / Ketones | Urine Dipstick | Blood Gas | Haemoglobin |
|---|----------------------|-------------------|--|-------------|
| A&E | Х | Х | Х | |
| Fountains Ward -medical Short Stay MSS | Х | Х | | |
| ANC | X | Х | | |
| Byland Ward | X | | | |
| CAT Clinic (SDEC) | Х | х | | |
| Cardiac Rehab Nurses (above Farndale) | Х | | | |
| Medical Assessment Unit MAU Farndale Ward | Х | Х | x (Gas, electrolytes, co-oximetry, glucose, lactate, Hct, tHb) | |
| Clinical Investigations | | X | | |
| Day Surgery /DS Recovery /Eye pre Assessment / Ophthalmology | Х | Х | | |
| Diabetes centre | Х | | | |
| Elmwood | Х | Х | | |
| Endoscopy | Х | | | |
| Farndale | Х | Х | | |
| Granby | Х | Х | | |
| Harlow Ward | Х | Х | | |
| Heart Centre | Х | | | |
| ITU | х | Х | x (Gas, electrolytes, glucose, lactate, tHb, Hct) | |
| Jervaulx | Х | | | |
| Labour Ward | Х | Х | x (Gas, tHb, Hct) | |
| Lascelles Neuro rehabilitation Unit | Х | х | | |
| Littondale Ward | Х | Х | | |
| MDU / Dermatology | Х | Х | | |
| Nidderdale Ward | Х | Х | | |
| Oakdale Ward | Х | Х | | |
| OPD inc. Eye Clinic | Х | | | |
| OPD1 | | х | | |
| OPD2 | | х | | |
| Pannal Ward | Х | Х | | |
| Phoenix Unit | Х | | | |
| Podiatry | Х | | | |
| Pre-Assessment Unit | Х | Х | | |
| Radiology | Х | | | |
| Recovery (theatres) | Х | | | Х |

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| B Harrogate Hospital Wards | Glucose / Ketones | Urine Dipstick | Blood Gas | Haemoglobin |
|----------------------------|----------------------|-------------------|--|-------------|
| Resus | | | x (Gas, electrolytes, co-oximetry, glucose, lactate, Hct, tHb) | |
| Resusitation Training | Х | | | |
| SCBU | Х | | x (Gas, electrolytes, glucose, lactate, tHb, Hct) | |
| SROMC Unit | Х | Х | | |
| Elective Admissions | Х | | | |
| Wensleydale ward | Х | Х | | |
| Woodlands | Х | Х | | |

| C Ripon Hospital Wards | Glucose / Ketones | Urine Dipstick |
|------------------------|----------------------|-------------------|
| Minor Injuries Unit | Х | X |
| Ripon OPD | | Х |
| Trinity Ward | Х | |

| D Off Site Clinics | Glucose/ Ketones | Urine Dipstick |
|---|---------------------|-------------------|
| | Х | |
| Outpatient clinic, Wetherby Health Centre | | Х |
| Outpatient clinic, Alwoodley Medical Centre | | Х |
| Outpatient clinic, Yeadon Health Centre | | Х |

| E Harrogate Hospital Clinics | HbA1c |
|------------------------------|-------|
| Diabetes centre | Х |
| Paediatric OP | x |

| F Domicillary | EPOC |
|---------------|------|
| Patient homes | Х |

| G Harrogate Hospital | Haemoglobin |
|----------------------|-------------|
| Emergency department | Х |

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