


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|---|---|---|
|  <p>UKAS MEDICAL 7880</p> <p>Accredited to ISO 15189:2022</p> | <p>Pathology First LLP</p> <p>Issue No: 023 Issue date: 09 July 2025</p> | |
| | <p>Pathology Department Pathology First Bentalls Basildon SS14 3BY</p> | <p>Contact: Kim Aston Tel: +44 (0) 7393232402 E-Mail: kim.aston@synlab.co.uk</p> |

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 |
|---|--|---------------|
| <p>Address Pathology First Hub Laboratory Bentalls Basildon Essex SS14 3BY</p> <p>Local contact Emma Parker (Microbiology) Email: emma.parker@synlab.co.uk Teresa Green (Blood Sciences) Email: Teresa.Green@synlab.co.uk Tel: 01268 968227</p> | <p>Microbiology Blood Sciences Immunology</p> | HUB |
| <p>Pathology Department Basildon University Hospital Nethermayne Basildon Essex SS16 5NL</p> <p>Emma Parker(Microbiology) Email: emma.parker@synlab.co.uk Teresa Green (Blood Sciences) Email Teresa.Green@synlab.co.uk Tomos Saunders (Cellular Pathology) E-mail: tomos.saunders@synlab.co.uk Tel: 01268 524900 (ext. 8888)</p> | <p>Microbiology (BD BACTEC FX automated primary culture only) Blood Sciences including Blood Transfusion Histopathology Non gynae Cytology Frozen Section for intraoperative diagnosis. Storage and issue of blood and FFP</p> | BUH |
| <p>Pathology Department Southend Hospital 2nd Floor Prittlewell Wing. Southend University Hospital Prittlewell Chase Westcliff on Sea SS0 0RY</p> <p>Emma Parker(Microbiology) Email: emma.parker@synlab.co.uk Teresa Green (Blood Sciences) Email: Teresa.green@synlab.co.uk Tomos Saunders (Cellular Pathology) E-mail: tomos.saunders@synlab.co.uk Tel: 01702 435555 (ext. 6630)</p> | <p>Microbiology (BD BACTEC FX automated primary culture only) Blood Sciences including Blood Transfusion Histopathology Frozen Section for intraoperative diagnosis. Andrology Storage and issue of blood and FFP</p> | SUH |



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Issue No: 023 Issue date: 09 July 2025

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Site activities performed away from the locations listed above:

| Location details | | Activity |
|---|---|---|
| Address: Cardio Thoracic Centre (CTC) Basildon Hospital (BUH) Nethermayne Basildon SS16 5NL | Local Contact Louise Meaney Tel: +44(0)1268 524900 (ext:5076} Email: Louise.Meaney@synlab.co.uk | Satellite Blood Issue Fridge for storage of blood and thawed FFP only |
| Maternity Unit Basildon Hospital Nethermayne Basildon SS16 5NL | Louise Meaney Tel: +44(0)1268 524900 (ext:5076} Email: Louise.Meaney@synlab.co.uk | Satellite Blood Issue Fridge for storage of blood and thawed FFP only |
| Main Theatres Basildon Hospital Nethermayne Basildon SS16 5NL | Louise Meaney Tel: +44(0)1268 524900 (ext:5076} Email: Louise.Meaney@synlab.co.uk | Satellite Blood Issue Fridge for storage of blood and thawed FFP only |
| Surgical Day Unit Basildon Hospital Nethermayne Basildon SS16 5NL | Louise Meaney Tel: +44(0)1268 524900 (ext:5076} Email: Louise.Meaney@synlab.co.uk | Satellite Blood Issue Fridge for storage of blood and thawed FFP only |
| Haematology Day Unit Orsett HospitalRowley RoadOrsettEssex RM16 3EU | Louise Meaney Tel:+44(0)1268 524900 (ext:5076} Email: Louise.Meaney@synlab.co.uk | Satellite Blood Issue Fridge for storage of blood and thawed FFP only |
| Main Theatres Spire Wellesley Southend on Sea Essex | Louise Meaney Tel:+44(0)1268 524900 (ext:5076} Email: Louise.Meaney@synlab.co.uk | Satellite Blood Issue Fridge for storage of blood and thawed FFP only |



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Issue No: 023 Issue date: 09 July 2025

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| Location details | | Activity |
|---|--|---|
| Basildon Hospital Nethermaine Basildon Essex SS16 5NL | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Corringham Integrated Medical and Wellbeing Centre 105 The Sorrells Standford-le-hope SS17 7ES | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Brockfield House Kemble Way Wickford SS11 7FE | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Canvey PCC (Paddocks) Long Road Canvey Island SS8 0JA | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Clifton Lodge Care Home Balmoral Road Westcliff-on-Sea SS0 7DB | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Hadleigh Clinic 49 London Road Benfleet SS7 2QL | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |



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| Leigh Primary Care Centre (Pall Mall Surgery) 918 London Road Leigh on Sea SS9 3NG | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Orsett Hospital Rowley Road Orsett Grays RM16 3EU | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Rayleigh Clinic Eastwood Road Rayleigh SS6 7JP | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Riverside Medical Centre 175 Ferry Road Hullbridge SS5 6JH | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| South Ockenson Health Centre Southn Ockendon Essex RM15 5LP | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| St Andrews Stock Road Billericay CM12 0BH | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |



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| St Mary's Church Hall Church End Lane Wickford SS11 7JQ | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Tyrells 39 Seamore Avenue Benfleet SS7 4EX | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Valkyrie PCC 50 Valkyrie Road Westcliffe on Sea SS0 8BU | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Brentwood Community Hospital Crescent Drive Shenfield Brentwood CM15 8DR | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |
| Unit 26-27, Southend Victoria Shopping Centre 362 Chartwell Square Southend-on-Sea SS2 5SP | Pathology First Phlebotomy Clinic - Local Contact Claire Thomas Tel: +44 (0) 1268 968235 E-Mail: Claire.thomas@synlab.co.uk | Phlebotomy – venous collection of blood |



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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 AND TISSUES | <u>Microbiology examination activities for the purpose of clinical diagnosis</u> | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | |
| Blood Non-Blood Fluids | Microbial growth | Cultures followed by manual subculture of positive growth, identification and susceptibility testing at the HUB using methods stated in schedule below PF-MIC-LP-12 Blood cultures using BD BACTEC FX analyser PHE SMI B37 i8.1 | FXsited at BUH SUH Culture, ID & AST at Hub |
| CSF | Detection/Quantification of cells and differentiation polymorphs and lymphocytes. Isolation and identification of clinically significant micro organisms | PF-MIC-LP-52 CSF processing. Using light microscopy and culture.PHE SMI B27 i6.1 | HUB |
| CAPD | Detection/Quantification of cells and differentiation polymorphs and lymphocytes. Isolation and identification of clinically significant micro organisms | PF-MIC-LP-53 CAPD Using light microscopy and culture PHE SMI B25 i6 | HUB |
| Naso-pharyngeal aspirate | RSV antigen | Binax Now RSV PF-MIC-LP-42 | HUB |
| Faeces, Swabs, Tissues, Urine and other body fluids | Isolation and identification of bacteria of clinical significance | Culture and microscopy with biochemical identification PHE SMI ID 1 i1.6 | HUB |
| Bacterial/yeast in-house isolates | General bacterial identification | Using Bruker MALDI-TOF (Matrix Assisted Laser Desorption Ionisation Time-Of-Flight) alongside IdentifA on Kiestra for target plates PF-MIC-LP-9 PHE SMI: TP40 Issue no: 1 10.10.16 | HUB |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | |
| Bacterial isolates (in-house) | Antibiotic sensitivity testing | Disc diffusion using EUCAST guidelines PF-MIC-LP-57 | HUB |
| Urine | Detection and enumeration of WBC, RBC, epithelial cells, yeast cells, bacteria, casts | Automated microscopy flow cytometry using IQ Sprint 200 PF-MIC-LP-17 PHE SMI B41 i8.7 | HUB |
| Blood, Sputum, Pus, Tissue, Urine, Bronchial washings, Swabs | Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.) | Liquid culture using BD MGIT with microscopical examination of auramine and/or Zn stained smears PF-MIC-LP-1 PF-MIC-LP-5 PHE SMI B40i7.2 | HUB |
| Blood, Sputum, Pus, Tissue, Urine, Bronchial washings | Detection of Acid Fast Bacilli | Microscopy of auramine stained smears PF-MIC-LP-5 PHE SMI B40i7.2 | HUB |
| Urine | <i>Legionella pneumophila</i> serogroup 1 antigen | Using Binax Now kit PF-MIC-LP-80 PHE SMI ID18 i3 | HUB |
| Urine | <i>Streptococcus pneumoniae</i> antigen | Detection of antigen using Binax Now kit PF-MIC-LP-96 | HUB |
| Urine | <i>Schistosoma haematobium</i> ova | Detection of ova using light microscopy – SOP PF-MIC-LP-104 PHE SMI B31 i5.1 | HUB |
| Faeces | Detection of <i>C.difficile</i> toxin (Combined GDH/toxin A+B) | Using Quikchek Complete card assay – SOP PF-MIC-LP-105 PHE SMI B10 i1.7 | HUB |
| Faeces | Rotavirus and Adenovirus antigens | Antigen detection using Certest Rota-Adeno assay – SOP PF-MIC-LP-108 PHE SMI B30 i8.1 | HUB |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | |
| Faeces | Detection of ova, cysts and parasites | Using Apacor Midi Parasep parasite concentrators and microscopic examination for parasites – SOP PF-MIC-LP-76 PHE SMI B31 i5.1 | HUB |
| Clear Adhesive Tape | Detection of <i>Enterobius vermicularis</i> ova | Detection of ova using light microscopy – SOP PF-MIC-LP-106 PHE SMI B31 i5.1 | HUB |
| Faeces | Detection of <i>Cryptosporidium</i> oocysts | Detection of oocysts using Phenol auramine stain with fluorescent microscopy – SOP PF-MIC-LP-76 PHE SMI B31 i5.1 | HUB |
| Skin, hair, nails, diverse specimens | Isolation of clinically significant fungi and yeasts | Manual inoculation and interpretation PF-MIC-LP-71 PHE SMI B39 i3.1 | HUB |
| | <u>Molecular activities for the purpose of clinical diagnosis</u> | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | |
| Urine, genital swabs, | Detection of RNA profiles for Chlamydia trachomatis (CT) and or Neisseria gonorrhoea (NG) | Aptima CT/GC using Hologic Panther NAAT (TMA) PF-MIC-LP-19 | HUB |
| Combined nose and throat swab Throat swabs Nasal swabs In viral transport media (VTM) | Detection of: SARS-CoV-2 RNA (COVID-19) specific gene sequences: E, N2 and RdRP Influenza A Influenza B RSV | Cepheid GeneXpert RT-PCR Xpert Xpress SARS-CoV-2/Flu/RSV <i>plus</i> PF-MIC-LP-151 | HUB |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Miscellaneous examination activities for the purpose of clinical diagnosis</u> | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | |
| Urine | Pregnancy testing (β HCG) detection | Documented procedures based on manufactures instructions Surestep kit PF-MIC-LP-62 | HUB |
| Serum | <u>Serology examination activities for the purpose of clinical diagnosis</u> | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | |
| | Detection of: | Documented-in-house methods to meet the requirements of the IDPS screening programme as defined in the July 2018 IDPS screening: laboratory QA evidence requirements | HUB |
| | Hepatitis C antibody | Automated chemi-luminescence using Beckman Coulter DXi PF-BIO-LP-2 PF-MIC-LP-85 (PHE SMI V5 i7) | |
| | HIV 1 and 2 antibody/p24 antigen screen | PF-MIC-LP-89 (PHE SMI V11 i4.1) | |
| | Hepatitis B core Total antibody | PF-MIC-LP-84 (PHE SMI V4 i6) | |
| | Cytomegalovirus IgG & IgM antibody | PF-MIC-LP-88 (PHE SMI V28 i4) | |
| | Toxoplasma IgG & IgM antibody | PF-MIC-LP-87 (PHE SMI V30 i5) | |
| | Hepatitis A IgM antibody | PF-MIC-LP-86 (PHE SMI V27 i4) | |
| | Hepatitis A Total antibody | PF-MIC-LP-86 (PHE SMI V27 i4) | |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | |
| Serum | Hepatitis B surface antigen | PF-MIC-LP-84 (PHE SMI V4 i6) | HUB |
| | Quantification of: | Automated chemi-luminescence using Beckman Coulter DXi PF-BIO-LP-2 | |
| | Hepatitis B surface antibody | PF-MIC-LP-84 (PHE SMI V4 i5.3) | |
| | Rubella IgG antibody | PF-MIC-LP-83 (PHE SMI V30 i5) | |
| Serum | Detection of: | PF-MIC-LP-29 by ELISA-based technique using Biomerieux VIDAS PF-MIC-LP-115 | HUB |
| | Varicella Zoster Virus IgG (VZV) | PF-MIC-LP-86(PHE SMI V27 i4) PF-MIC-LP-84(PHE SMI V4 i6) | |
| | Hepatitis B surface antigen | | |
| | Hepatitis B core IgM antibody | | |
| | Hepatitis B e-antigen | | |
| | Hepatitis B e-antibody | | |
| | HIV 1 and 2 antibody/p24 antigen screen | | |
| | Mumps IgG antibody | PF-MIC-LP-126 | |
| | Measles IgG antibody | PF-MIC-LP-127 | |
| Serum | Detection of Streptococcal antibody AntiStreptolysin O (ASO) | Using Biokit Rhemajet ASO kit PF-MIC-LP-110 | HUB |



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| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Serology examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented methods based on related UK Standards for Microbiology Investigations (SMIs) and incorporating manufacturers' instructions where relevant | |
| Faeces | Helicobacter pylori Stool Antigen | Dynex DS2 and Dynex Agility Amplified IDEIA Hp StAR PF-MIC-LP-91 | HUB |
| Serum | Syphilis total antibody | Dynex DS2 and Dynex Agility Enzyme Immunoassay PF-MIC-LP-90 | HUB |
| | <u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> | In house documented methods and incorporating manufacturers' instructions where relevant | |
| Venous whole blood, EDTA | ABO group (forward and reverse) RhD type | Manual Method, column agglutination, manual tube technique SOP PF-BTR-LP-9 | BUH SUH |
| Venous whole blood, EDTA | ABO group and RhD type (forward and reverse) | Automated method; Ortho Vision card/column agglutination. (SOP PF-BTR-LP-2) | BUH SUH |
| | Red cell antibody screen | Manual Method, column agglutination, SOP PF-BTR-LP-9 | BUH SUH |
| | Red cell antibody screen | Automated method; Ortho Vision card/column agglutination. (SOP PF-BTR-LP-2) | BUH SUH |
| Venous whole blood, EDTA | Direct Antiglobulin Test (DAGT) | Manual Tube Method, SOP PF-BTR-LP-9 | SUH |
| | Direct Antiglobulin Test (DAGT) as below: | Automated method; Ortho Vision card/column agglutination. (SOP PF-BTR-LP-2) | BUH SUH |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)</u> | In house documented methods and incorporating manufacturers' instructions where relevant | |
| | Rhesus blood group antibodies: anti-C, anti-c, anti-D, anti-E, anti-e | Manual Method, column agglutination (SOP PF-BTR-LP-9) | SUH BUH |
| | Rh/K Red Blood Cell phenotype antigens: D, C, c, E, e, K | | |
| Venous whole blood, EDTA | Serological cross match - serological compatibility testing between donor red cell antigens and patient plasma antibody. | Manual method; Ortho BioVue card/column agglutination SOP BT-BTR-LP-32 | BUH SUH |
| Venous whole blood, EDTA | Detection and Estimation of Foetal Maternal Haemorrhage through quantification of foetal Hb in maternal blood | Kleihauer test using Guest medical foetal detection kit SOP PF-BTR-LP-10 | BUH SUH |
| | <u>Haematology examination activities for the purpose of clinical diagnosis</u> | In house documented methods and incorporating manufacturers' instructions where relevant | |
| Venous whole blood, EDTA | Haemoglobin Red cell count Platelet count Haematocrit White blood cell count (total) Differential white blood cell count (Neutrophil, Lymphocyte, Monocyte, Eosinophil, Basophil) Reticulocyte count MCV MCH RDW | Beckman Coulter: Unicel DxH900 analysers using AIM technology incorporating : fluorescence flow cytometry, electrical impedance, RBC pulse height detection method, sheath flow direct current (DC) detection method and calculated red cell parameters. (SOP PF-HAE-LP-2) | BUH SUH HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods and incorporating manufacturers' instructions where relevant | |
| Venous whole blood, EDTA | Reporting of normal and abnormal morphologies | Staining of peripheral blood smear with Romanowsky stains using Aerospray analyser (automated) ¹ and manual methods ² Examination by light microscopy ² . (SOP PF-HAE-LP-15, PF-HAE-LP-19, PF-HAE-LP-20, PF-HAE-LP-21, PF-HAE-LP-23) | BUH ^{1,2} SUH ^{1,2} HUB ¹ |
| Bone marrow | Reporting of normal and abnormal morphologies | Staining of bone marrow using Romanowsky stain using Aerospray (automated) method (PF-HAE-LP-15, PF-HAE-LP-18) | BUH SUH |
| Venous whole blood, EDTA Bone marrow Urine | Detection of iron and ferritin | Perl's Prussian Blue iron stain using a manual technique with examination by light microscopy. (SOP PF-HAE-LP-17) | BUH SUH |
| Venous whole blood, EDTA | Erythrocyte sedimentation rate | Sedimentation rate of red cells by automated analyser Alifax Test 1 ¹ and Alifax Roller 20 ² (SOP PF-HAE-LP-11) | BUH ² SUH ² HUB ¹ |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented methods and incorporating manufacturers' instructions where relevant | |
| Venous whole blood, EDTA | Detection and speciation of malaria parasites; Plasmodium vivax Plasmodium falciparum Plasmodium ovale Plasmodium malariae Plasmodium knowlesi | Microscopic detection by: Thin Film by Giemsa stain. Thick film by Fields Stain. All with examination by light microscopy and using SOP (PF-HAE-LP-22) | BUH SUH HUB |
| | Histidine Rich protein II Plasmodium Falciparum | Immunodiagnostic testing by CareStart Malaria RAPYDTEST cards (SOP PF-HAE-LP-22) | BUH SUH HUB |
| | Non falciparum common antigens: Plasmodium vivax, malaria and ovale | | |
| Venous whole blood, EDTA | Infectious Mononucleosis Screening / Glandular fever – heterophile antibody testing | Infectious mononucleosis screen using the Clearview IM II Kit. (SOP PF-HAE-LP-10) | HUB |
| Venous whole blood, EDTA | Detection of Haemoglobin S | Manual sickle solubility assay using the Sickledex Test kit. (SOP PF-HAE-LP-6) | BUH SUH HUB |
| Venous whole blood, EDTA | G6PD qualitative screen | Fluorescence under UV light using Trinity Biotech screening reagents and manual technique (SOP PF-HAE-LP-3) | HUB |
| Venous whole blood, EDTA | Determination of Haemoglobin variants. | Documented-in-house methods to meet the requirements of the SCT screening programme as defined in the July 2018 NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements Separation of haemoglobin variants by HPLC using Biorad Variant II analyser (SOP PF-HAE-LP-5, PF-HAE-LP-4) | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented methods and incorporating manufacturers' instructions where relevant | |
| Venous whole blood, EDTA | Haemoglobin HbA1c | Biorad D-100 analyser using HPLC. (SOP PF-HAE-LP-1) | HUB |
| | <u>Haematology (Coagulation) examination activities for the purpose of clinical diagnosis</u> | In house documented methods and incorporating manufacturers' instructions where relevant | |
| Venous whole blood, citrated | Coagulation Clotting Screen, (PT, INR, APTT, APTT-ratio, Derived and Clauss Fibrinogen, D-Dimer, Thrombin Time (TT) | Automated using Werfen ACL TOP 350s by immunoassay and coagulometric assays. (SOP's PF-HAE-LP-8 , PF-HAE-LP-30, PF-HAE-LP-32) | BUH SUH |
| Venous whole blood, citrated | Coagulation Clotting Screen, (PT, INR, APTT, APTT-ratio, Derived and Clauss Fibrinogen, D-Dimer, Thrombin Time (TT) | Automated using Werfen ACL TOP 550 by immunoassay and coagulometric assays. (SOP's PF-HAE-LP-8 , PF-HAE-LP-30, PF-HAE-LP-32) | BUH |
| Venous whole blood, citrated | Coagulation Factor assays for II, V, VII, VIII, IX, X, XI and XII | Werfen ACL TOP 750s by coagulmetric assays. (SOP's PF-HAE-LP8 + PF-HAE-LP-29) | HUB |
| | Coagulation Factor anti Xa assay | Werfen ACL TOP 350s by coagulmetric assays. (SOP's PF-HAE-LP8 + PF-HAE-LP-29) | SUH BUH |
| Venous whole blood, citrated | Von Willebrands Factor assays for antigen and Ristocetin Cofactor activity | Werfen ACL TOP 750s by immunoassay. (SOP's PF-HAE-LP8 + PF-HAE-LP-33) | HUB |
| Venous whole blood, citrated | Thrombophilia screen, consisting of: • Protein C activity, • Antithrombin activity, Free Protein S assay, Lupus anticoagulant screen | Werfen ACL TOP 750s by chromogenic, immunoassay and coagulmetric assays. (SOP's PF-HAE-LP-8, PF-HAE-LP-28, + PF-HAE-LP-40) | HUB |



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Pathology First LLP
Issue No: 023 Issue date: 09 July 2025

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| <p>HUMAN TISSUES AND FLUIDS</p> <p>Body Fluids: Cerebrospinal Fluid (CSF) Urine (General body fluids including serous fluids and respiratory samples)</p> | <p><u>Diagnostic Cytology examination activities for the purposes of clinical diagnosis</u></p> <p>Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Preparation/centrifugation Documented in house methods in conjunction with manufacturer's instructions for: Hologic T2000 Centra-CL3 centrifuge Shandon Cytospin 4 centrifuge PF-CYT-LP-24 PF-CYT-LP-25 PF-CYT-LP-26 PF-CYT-LP-27 PF-CYT-LP-28 PF-CYT-LP-30 PF-CYT-LP-31 PF-CYT-LP-29 PF-CYT-LP-25 PF-CYT-LP-12 PF-CYT-LP-47 PF-CYT-LP-50 PF-CYT-LP-41 PF-CYT-LP-21 PF-CYT-LP-32</p> | <p>BUH</p> |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Diagnostic Cytology examination activities for the purposes of clinical diagnosis (cont'd)</u> | In house documented methods incorporating manufacturers' instructions as required | |
| Synovial Fluids | Detection and identification of birefringent crystals: Urate and Pyrophosphate crystals | Documented in house methods in conjunction with manufacturer's instructions for the operation of polarising microscope (2 planes) PF-CYT-LP-29 | BUH |
| Slides prepared in-house from sample types specified | | Papanicolaou staining Documented in house methods in conjunction with manufacturer's instructions for the operation of Prisma Autostainer and Coverslipper PF-HIS-LP-66 (Automated PAP) PF-HIS-EXT-200 | BUH |
| | | May Grunwald Giemsa staining Documented in house manual staining process PF-CYT-LP-54 | BUH |
| | Morphological assessment and interpretation/ diagnosis | Microscopy (qualitative analysis) Documented in house methods – SOP's: PF-CYT-LP-17 Using Microscopes as follows: Olympus BX45 Olympus BX50 Nikon Eclipse 50I Nikon Eclipse E400 | BUH SUH |



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| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin fixed, fresh and frozen tissue</p> | <p><u>Histopathology examination activities for the purposes of clinical diagnosis</u></p> <p>Preparation and examination to identify or exclude morphological & cytological abnormalities</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>In House documented methods for specimen dissection (consultant) staining and interpretation supported by SOPs and, where relevant, manufacturer's instructions for cutting up, processing, embedding dehydration, clearing and mounting PF-HIS-LP-40 PF-HIS-LP-64</p> <p>Using: Tissue Processeors</p> <ul style="list-style-type: none"> • Sakura VIP6 • Leica Histocore Peloris 3 <p>Sakura Tec V embedder x 2</p> <p>Leica Histocore Biocut microtomes</p> <p>PF-HIS-LP-60</p> <p>Using: Tissue processors:</p> <ul style="list-style-type: none"> • Leica Histocore Peloris 3 <p>Leica Histocore Arcadia embedding centre</p> <p>Leica Histocore Biocut microtomes</p> | <p>BUH SUH</p> <p>BUH</p> <p>SUH</p> |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purposes of clinical diagnosis (cont'd)</u> | In house documented methods incorporating manufacturers' instructions as required | |
| Frozen Tissue | Intraoperative examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | PF-HIS-LP-62 Frozen Section in conjunction with manufacturer's instructions for Leica Cryostat CM1950UV | BUH SUH |
| Fixed, fresh and frozen tissue | | Routine Haematoxylin & Eosin (H&E) staining and coverslipping PF-HIS-LP-66 in conjunction with manufacturer's instructions for Sakura Prisma Autostainer and Coverslipper using Haematoxylin and Eosin stains (H and E) | BUH SUH |
| Fixed, fresh and frozen tissue | Detection of the following: | Documented methods (reference in parentheses) using manual special stains as indicated | |
| | Acid Mucins | Alcian Blue PF-HIS-LP-17 | BUH |
| | Acid and neutral mucins | ABPAS PF-HIS-LP-90 | BUH |
| | Amyloid | Congo Red PF-HIS-LP-18 | BUH |
| | Elastic fibres & connective tissue | EVG PF-HIS-LP-12 | BUH |
| | Haematopoietic cells | Long Giemsa PF-HIS-LP-27 | BUH |
| | Gram positive and negative bacteria | Gram PF-HIS-LP-13 | BUH |
| | Nuclei and connective tissue | HVG PF-HIS-LP-20 | BUH |
| | Melanin | Masson Fontana PF-HIS-LP-92 | BUH |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u> | | |
| Fixed, fresh and frozen tissue (cont'd) | Detection of the following: (cont'd) | Documented methods (reference in parentheses) using stains as indicated | |
| | H. pylori | Modified Giemsa (PF-HIS-LP-25) | BUH |
| | Fibrin connective tissue | Martius Scarlet Blue (MSB) (PF-HIS-LP-22) | BUH |
| | Polysaccharides including glycogen | PAS (PF-HIS-LP-90) | BUH |
| | Hemosiderin | Perls Prussian Blue (PF-HIS-LP-14) | BUH |
| | Reticulin fibres | Reticulin (PF-HIS-LP-15) | BUH |
| | Mast Cells | Toluidine Blue (PF-HIS-LP-26) | BUH |
| | Mycobacterium spp including tuberculosis | Ziehl Neelsen (PF-HIS-LP-16) | BUH |
| FFPE tissue | Detection of the following: | Documented in-house methods (PF-HIS-LP-37 & PF-HIS-LP-34) used in accordance with Leica's operating instructions for the use of Bond III (SUH, BUH) & Ventana Ultra automated immunostainers (SUH). | |
| | Foetal Liver Cells | AFP (PF-HIS-EXT-222) | BUH SUH |
| | Epithelial Cells | BerEp4 (PF-HIS-EXT-122) | BUH SUH |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purposes of clinical diagnosis (cont'd)</u> | | |
| FFPE tissue (cont'd) | Detection of the following: (cont'd) | Immunohistochemistry Leica Bond III (SUH, BUH) & Ventana Ultra immunostainers (SUH) (cont'd) | |
| | T-cells, B-cells in the mantle zone | Bcl-2 oncoprotein (PF-HIS-EXT-163) | BUH SUH |
| | Follicular centre B-cells | Bcl-6 (PF-HIS-EXT-13) | BUH SUH |
| | Luminal cells of the fallopian tube | Ca125 (PF-HIS-EXT-15) | BUH SUH |
| | Sialyl Lewis | Ca19.9 (PF-HIS-EXT-108) | BUH |
| | Mesothelial cell lining | Calretinin (PF-HIS-EXT-97) | BUH SUH |
| | Low molecular weight marker | Cam 5.2 (PF-HIS-EXT-136) | BUH SUH |
| | Dendritic cells and thymocytes | CD1a (PF-HIS-EXT-92) | BUH |
| | T-cell marker | CD3 (PF-HIS-EXT-22) | BUH SUH |
| | T-helper cells | CD4(PF-HIS-EXT-25) | BUH SUH |
| | T-cells, B-cells in the mantle zone | CD5 (PF-HIS-EXT-28) | BUH SUH |
| | T-Cell, NK cells | CD7 (PF-HIS-EXT-96) | BUH |
| | Cytotoxic T-cells | CD8 (PF-HIS-EXT-127) | BUH |
| | Immature B Lymphocytes | CD15 (PF-HIS-EXT-135) | BUH SUH |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purposes of clinical diagnosis (cont'd)</u> | | |
| FFPE tissue (cont'd) | Detection of the following: (cont'd) | Immunohistochemistry Leica Bond III (SUH, BUH) & Ventana Ultra immunostainers (SUH) (cont'd) | |
| | B-cell marker | CD20 (L26) (PF-HIS-EXT-19) | BUH SUH |
| | Mature B-cells and FDC | CD21 (PF-HIS-EXT-20) | BUH SUH |
| | FDC and EBV transformed blasts | CD23 (PF-HIS-EXT-21) | BUH SUH |
| | RS Cells | CD30 (Ber-H2) (PF-HIS-EXT-54) | BUH SUH |
| | Endothelial | CD31 (PF-HIS-EXT-199) | BUH SUH |
| | Endothelial Marker | CD34 (PF-HIS-EXT-24) | BUH SUH |
| | Plasma cells and activated T-Cell | CD38 (PF-HIS-EXT-117) | BUH SUH |
| | T-cell and myeloid cells | CD43 (PF-HIS-EXT-26) | BUH SUH |
| | Leukocyte common antigen | CD45 (LCA) (PF-HIS-EXT-27) | BUH SUH |
| | Neural cell adhesion molecule | CD56 (PF-HIS-EXT-29) | BUH SUH |
| | Macrophages | CD68 (PF-HIS-EXT-30) | BUH SUH |
| | B-Cell marker | CD79a (PF-HIS-EXT-31) | BUH SUH |
| | Mic2 gene products | CD99 (MIC2) (PF-HIS-EXT-194) | BUH SUH |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purposes of clinical diagnosis (cont'd)</u> | | |
| FFPE tissue (cont'd) | Detection of the following: (cont'd) | Immunohistochemistry Leica Bond III (SUH, BUH) & Ventana Ultra immunostainers (SUH) (cont'd) | |
| | Mast cells and GIST | CD117 (c-kit) (PF-HIS-EXT-40) | BUH SUH |
| | Plasma cells | CD138 (PF-HIS-EXT-55) | BUH SUH |
| | Carcinoembryonic antigen | CEA (Mono) (PF-HIS-EXT-34) | BUH SUH |
| | Intestinal epithelial | CDX2 (PF-HIS-EXT-33) | BUH SUH |
| | Neuroendocrine | ChromograninA (PF-HIS-EXT-35) | BUH SUH |
| | Mantle cell lymphoma | CyclinD1 (PF-HIS-EXT-41) | BUH SUH |
| | Squamous and myoepithelial | Cytokeratin 5/6 (PF-HIS-EXT-124) | BUH SUH |
| | Glandular, transitional epithelia | Cytokeratin 7 (PF-HIS-EXT-39) | BUH SUH |
| | Squamous, basal epithelia | Cytokeratin 14 (PF-HIS-EXT-36) | BUH SUH |
| | Epithelial cells | Cytokeratin 19 (PF-HIS-EXT-37) | BUH SUH |
| | Gastrointestinal epithelia | Cytokeratin 20 (PF-HIS-EXT-38) | BUH SUH |
| | Broad-range cytokeratin | Cytokeratin AE1/AE3 (PF-HIS-EXT-11) | BUH SUH |
| | Lymphatic endothelium | D2-40 (PF-HIS-EXT-210) | SUH |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purposes of clinical diagnosis</u> (cont'd) | | |
| FFPE tissue (cont'd) | Detection of the following: (cont'd) | Immunohistochemistry Leica Bond III (SUH, BUH) & Ventana Ultra immunostainers (SUH) (cont'd) | |
| | Intermediate filament | Desmin (PF-HIS-EXT-42) | BUH SUH |
| | GIST | DOG-1 (PF-HIS-EXT-43) | BUH SUH |
| | Cell adhesion molecule | E-Cadherin (PF-HIS-EXT-45) | BUH SUH |
| | Epithelial membrane antigen | EMA (PF-HIS-EXT-44) | BUH SUH |
| | Fibrohistocytic Tumour | Factor XIIIa (PF-HIS-EXT-130) | BUH SUH |
| | Gross Cystic Disease Fluid Protein | GCDFP-15 (PF-HIS-EXT-47) | BUH SUH |
| | Trophoblasts | HCG (PF-HIS-EXT-211) | BUH SUH |
| | CK's 1,5,10 and 14 | High Molecular Weight Cytokeratin 34 β E12 (PF-HIS-EXT-9) | BUH SUH |
| | Melanosomes | HMB45 (PF-HIS-EXT-48) | BUH SUH |
| | Leydig, Sertoli cells | Inhibin (PF-HIS-EXT-12) | BUH SUH |
| | Immunoglobulin Kappa light chains | Kappa light chains (PF-HIS-EXT-212) | BUH |
| | Proliferation marker | Ki67 (PF-HIS-EXT-49) | BUH SUH |
| | Immunoglobulin Lambda light chains | Lambda light chains (PF-HIS-EXT-213) | BUH |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purposes of clinical diagnosis (cont'd)</u> | | |
| FFPE tissue (cont'd) | Detection of the following: (cont'd) | Immunohistochemistry Leica Bond III (SUH, BUH) & Ventana Ultra immunostainers (SUH) (cont'd) | |
| | Melanocytes | Melan A (PF-HIS-EXT-50) | BUH |
| | Mesothelial cells/Colorectal | Mesothelin (PF-HIS-EXT-97) | BUH |
| | Broad range cytokeratin | MNF116 (PF-HIS-EXT-132) | BUH SUH |
| | B-cells | MUM-1 (PF-HIS-EXT-131) | BUH SUH |
| | Lung adenocarcinoma | Napsin (PF-HIS-EXT-118) | BUH SUH |
| | Seminoma | Oct 3/4 (PF-HIS-EXT-52) | BUH SUH |
| | mRNA/ p16 HPV biomarkers | P16 INK4 (PF-HIS-EXT-195) | BUH SUH |
| | Tumour suppressor gene | P53 (PF-HIS-EXT-53) | BUH SUH |
| | Basal cell marker | P63 (PF-HIS-EXT-91) | BUH SUH |
| | Neuroendocrine marker | PGP9.5 (PF-HIS-EXT-214) | SUH |
| | Placental Alkaline Phosphatase | PLAP (PF-HIS-EXT-190) | BUH SUH |
| | Prostate specific antigen | PSA (PF-HIS-EXT-90) | BUH SUH |
| | Neoplastic prostate glands | Racemase (P504S) (PF-HIS-EXT-10) | BUH SUH |
| | Proximal tubules | RCC (PF-HIS-EXT-215) | BUH SUH |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purposes of clinical diagnosis (cont'd)</u> | | |
| FFPE tissue (cont'd) | Detection of the following: (cont'd) | Immunohistochemistry Leica Bond III (SUH, BUH) & Ventana Ultra immunostainers (SUH) (cont'd) | |
| | Melanoma, neuroendocrine | S100 (PF-HIS-EXT-58) | BUH SUH |
| | Mesenchymal marker | SMA (PF-HIS-EXT-59) | BUH SUH |
| | Neuroendocrine marker | Synaptophysin (PF-HIS-EXT-61) | BUH SUH |
| | Early B-Cell, thymocytes marker | Tdt (PF-HIS-EXT-62) | BUH SUH |
| | Lymphatic endothelial | Thrombomodulin (CD141) (PF-HIS-EXT-250) | BUH |
| | Thyroid Transcription factor-1 | TTF-1 (PF-HIS-EXT-63) | BUH SUH |
| | Mesenchymal Marker | Vimentin (PF-HIS-EXT-64) | BUH SUH |
| | Plasma cell marker | VS38c (plasma cell) (PF-HIS-EXT-117) | SUH |
| | Wilms tumour gene product | WT-1 (PF-HIS-EXT-197) | BUH SUH |
| | B cell marker (found in reactive populations) | BOB-1 (PF-HIS-EXT-14) | SUH |
| | B cell marker (wide variety of normal and neoplastic cells) | CD10 (PF-HIS-EXT-17) | SUH |
| | Normal T cells and related neoplasms(e.g T lymphoblastic Leukaemia) | CD2 (PF-HIS-EXT-18) | SUH |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology examination activities for the purposes of clinical diagnosis (cont'd)</u> | | |
| FFPE tissue (cont'd) | Detection of the following: (cont'd) | Immunohistochemistry Leica Bond III (SUH, BUH) & Ventana Ultra immunostainers (SUH) (cont'd) | |
| | B cell marker, lymphoblastic leukaemia | Pax5 (PF-HIS-EXT-18) | SUH |
| | For identification of myoepithelial cells in the breast and for identification of Smooth muscle neoplasm | Smooth Muscle Myosin (PF-HIS-EXT-60) Roche Ventana Immuno stainer | SUH |
| FFPE tissue | Anti Oestrogen Receptor antibody | ER (PF-HIS-EXT-46) | SUH |
| FFPE tissue | Anti Progesterone Receptor Antibody | PR (PF-HIS-EXT-94) | SUH |
| FFPE tissue | Anti HER-2 (Herceptin Antibody) 4B5 clone | HER2 (PF-HIS-EXT-178) | SUH |
| | Morphological assessment and interpretation/diagnosis | Microscopy (qualitative analysis) In-house procedures using light microscopy PF-CYT-LP-17 | BUH SUH |



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| HUMAN BODY FLUIDS | <u>Andrological examination activities for the purposes of clinical diagnosis</u> | | |
| Semen | <u>Post vasectomy:</u> Detection of sperm | Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy and documented in-house procedure SOP PF-HIS-LP-10 | SUH |
| Semen | <u>Fertility testing:</u> | Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) Manual method and documented in-house procedure SOP PF-HIS-LP-9 PF-HIS-LP-76 PF-HIS-LP-110 | SUH |
| | Volume | Volume/weight | |
| | pH | Colorimetric strips | |
| | Sperm morphology including TZI scoring | Stained slides (Papanicolau) microscopy (Bright field) PF-HIS-LF-132 | |
| | Sperm concentration | Improved Neubauer counting chambers and Microscopy (Phase contrast) | |
| | Sperm motility | Microscopy (Phase contrast) | |
| | Sperm vitality | Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field) | |



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| HUMAN BODY FLUIDS (cont'd) | <u>Andrological examination activities for the purposes of clinical diagnosis</u> (cont'd) | | |
| Semen (cont'd) | <u>Fertility testing:</u> (cont'd) Sperm motility Sperm concentration | Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and documented in-house procedure Semen Analysis in conjunction with manufacturer's instructions for analysis using SCA CASA (Microm) SOP PF-HIS-LP-96 | SUH |
| | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: Beckman Coulter AU680 analysers with random access colorimetry or turbidimetry technology. Therapeutic drug monitoring PF-BIO-LP-6 PF-BIO-LP-3 | |
| Serum/Plasma | Amikacin | | BUH SUH |
| | Carbamazepine | | BUH |
| | Gentamicin | | BUH SUH |
| | Paracetamol | | BUH SUH |
| | Salicylate | | BUH SUH |
| | Theophylline | | BUH SUH |
| | Vancomycin | | BUH SUH |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: Beckman Coulter AU5800 (HUB) and AU680 (BUH, SUH) analysers with random access colorimetry or turbidimetry technology. Therapeutic drug monitoring PF-BIO-LP-6 PF-BIO-LP-3 | |
| Serum/Plasma (cont'd) | Digoxin | | BUH SUH HUB |
| | Phenytoin | | BUH SUH |
| | Lithium | | BUH SUH HUB |
| Serum / Plasma | Alpha 1 Anti-trypsin Haptoglobin Transferrin | Beckman Coulter AU5800 analysers with random access colorimetry or turbidimetry technology. Biochemical marker analysis: PF-BIO-LP-3 | HUB |
| Serum / Plasma | Bicarbonate Iron | Beckman Coulter AU5800 (HUB) and AU680 (SUH, BUH) analysers with random access colorimetry or turbidimetry technology. Biochemical marker analysis: PF-BIO-LP-3 PF-BIO-LP-6 | HUB BUH SUH |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum / Plasma | Conjugated Bilirubin Ammonia Bile Acids Ethanol | Beckman Coulter AU680 analysers with random access colorimetry or turbidimetry technology. Biochemical marker analysis: PF-BIO-LP-6 | BUH SUH |
| Serum/Plasma/Urine | Sodium Potassium Chloride | Beckman Coulter AU5800 (HUB) and AU680 (SUH, BUH) analysers with ion selective electrode technology. Electrolyte analysis: PF-BIO-LP-3 PF-BIO-LP-6 | HUB BUH SUH |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: Beckman Coulter AU5800 (HUB) and AU680 (SUH, BUH) analysers with random access colorimetry or turbidimetry technology. Routine biochemistry tests PF-BIO-LP-3 PF-BIO-LP-6 | |
| Serum/Plasma | Albumin ALP ALT Amylase AST Total Bilirubin Calcium Cholesterol CK Creatinine(Enzymatic) GGT Glucose HDL cholesterol LDH Magnesium Phosphate Total Protein Triglycerides Urate Urea | | HUB BUH SUH |
| Serum/Plasma | Vitamin D | Beckman Coulter Dxl 800 routine biochemistry testing: PF-BIO-LP-2 | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Urine | Creatinine Total protein Urea Urate | Beckman AU5800 (HUB) and AU680 (BUH, SUH) analysers with random access colorimetry, turbidimetry technology. Routine Biochemistry Testing: PF-BIO-LP-3 PF-BIO-LP-6 | HUB BUH SUH |
| Urine | Phosphate Albumin Calcium | Beckman AU5800 analysers with random access colorimetry, turbidimetry technology. Routine Biochemistry Testing: PF-BIO-LP-3 PF-BIO-LP-6 | HUB |
| Cerebral Spinal Fluid | Glucose Total Protein Lactate | Beckman AU680 analysers with random access colorimetry, turbidimetry technology. Routine Biochemistry Testing: PF-BIO-LP-3 | BUH SUH |
| Plasma | Lactate | Beckman AU680 analyser with random access technology. Routine Biochemistry Testing: PF-BIO-LP-3 Enzymatic | BUH SUH |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum / Plasma | CRP | Beckman AU5800 (HUB) and AU680 (BUH, SUH) analysers with random access colorimetry, turbidimetry technology. Biochemistry Immunological testing: PF-BIO-LP-3 PF-BIO-LP-6 | HUB BUH SUH |
| Serum / Plasma | C3 C4 IgA IgG IgM Rheumatoid factor II Immunoglobulin E | Beckman AU5800 analysers with random access colorimetry, turbidimetry technology. Biochemistry Immunological testing: PF-BIO-LP-3 | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum / Plasma | B12 Folate FSH FT3 LH Oestradiol Prolactin Macroprolactin PSA PTH SHBG Testosterone Thyroid peroxidase antibodies (TPO) | Beckman Coulter Dxl 800 for chemiluminescence immunoassay: PF-BIO-LP-2 | HUB SUH BUH |
| Serum / Plasma | Cortisol Ferritin FT4 bHCG Progesterone TSH | Beckman Coulter Dxl 800/Access 2 for chemiluminescence immunoassay: PF-BIO-LP-1 | BUH SUH HUB |
| Serum | Serum Kappa Free light chains Serum Lambda Free Light Chains | Binding site Optilite analyser using PF-BIO-LP-115 | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum / Plasma | AFP Ca-125 Ca-199 Ca-153 CEA | Roche Cobas E411 random access colorimetry or turbidimetry or chemiluminescence technology for tumour markers: PF-BIO-LP-7 | HUB |
| Serum / Plasma | NT-Pro-BNP | Roche Cobas E411 random access colorimetry or turbidimetry or chemiluminescence technology for cardiac markers: PF-BIO-LP-7 | HUB BUH SUH |
| Serum / Plasma | Troponin T | Roche Cobas E411 random access colorimetry or turbidimetry or chemiluminescence technology for cardiac markers: PF-BIO-LP-7 | HUB BUH SUH |
| Serum/Plasma | Procalcitonin | Roche Cobas E411, chemiluminescence. PF-BIO-LP-7 | SUH BUH |
| Serum | Serum protein Electrophoresis and serum Monoclonal Protein Quantitation | Sebia Capillarys 2 Flex Capillary Zonaelectrophoresis (CZE) PF-BIO-LP-47 | HUB |
| Serum | Serum Monoclonal Protein Typing | Sebia Capillarys 2 Flex Immunotyping/subtraction | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum | Serum Monoclonal Protein Typing | Sebia Hydrasys 2 Scan using serum immunofixation PF-BIO-LP-30 | HUB |
| Urine | Urine Protein Electrophoresis Urine Monoclonal Protein Typing | Sebia Hydrasys 2 Scan using immunofixation and Gel Zonal electrophoresis. PF-BIO-LP-30 PF-BIO-LP-33 | HUB |
| Serum/Urine | Osmolality | Advanced Instruments OSMO 1 Freezing Point Depression | BUH SUH |
| Sweat | Chloride | Sherwood Meter using titrimetric method PF-POC-LP-68 | SUH |
| Cerebral Spinal Fluid | Xanthochromia | Spectrophotometric method using Northstar BIO-UVSpectrophotometry: With Bio-c program PF-BIO-LP-41 | SUH BUH |
| Faeces | Faecal Calprotectin | Beckman Coulter AU5800 analysers with random access particle enhanced turbidimetry technology. PF-BIO-LP-3 PF-BIO-LP-44 | HUB |
| Faeces | Faecal Pancreatic Elastase | Beckman Coulter AU5800 analysers using particle enhanced turbidimetry technology. PF-BIO-LP-44 | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont)</u> | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum / Plasma | Growth Hormone Erythropoietin B2 Microglobulin IGF1 | Immolute 2000 :Electro chemiluminescence immunoassay PF-BSM-LP-8 | HUB |
| | <u>Immunology examination activities for the purpose of clinical diagnosis</u> | | |
| Serum / Plasma | Almond Alternaria Apple Apricot Ara h2 peanut ARA H8 Specific IgE Aspergillus fumigatus Aspergillus fumigatus specific IgG Aspergillus niger Avocado Banana Barley Basil Beef Black pepper Blackberry Blue Mussel Blueberry Brazil nut Broccoli Buckwheat Budgerigar feathers Budgerigar specific IgG Cabbage | Phadia 250 analysers with fluorescence enzyme immunoassay technology PF-IMM-LP-14 PF-BSM-CP-1 | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd) | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: Phadia 250 analysers with fluorescence enzyme immunoassay technology PF-IMM-LP-14 PF-BSM-CP-1 | HUB |
| Serum/Plasma (cont'd) | Cacao Candida albicans Carrot Casein Cashew Cat dander Celery Cheddar cheese Cherry Chick pea Chicken Chilli pepper Cladosporium herbarum Clam Clove Coconut Coffee Common ragweed Common wasp COR A8 specific IgE Coriander Cotton, crude fibres Cows milk Crab Cranberry Crayfish Cucumber Date Dog dander Duck feathers Egg white Egg yolk Fish (cod) Fish mix Food mix Fruit mix specific IgE Garlic Ginger | | |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd) | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum/Plasma (cont'd) | Gluten Goat milk Goat epithelium Grain mix Grape Grapefruit Grass mix Green bean Green pepper Guinea pig Haddock Hamster Lemon Lentil Lettuce Lime Lobster Lupine seed Macadamia nut Mackerel Maize/corn Mango Melon Micropolyspora faeni specific Mint Mosquito Rat mix Red Kidney bean Rice Rye Sage Salmon Scallop Sesame seed Sheep epithelium Shrimp Silver Birch Soybean | Phadia 250 analysers with fluorescence enzyme immunoassay technology PF-IMM-LP-14 PF-BSM-CP-1 | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd) | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum/Plasma (cont'd) | Squid Strawberry Sunflower seed Sweet Potato Tea Timothy grass Tomato Tree pollen mix UK Tryptase Tuna Walnut Wheat White bean Yeast | Phadia 250 analysers with fluorescence enzyme immunoassay technology PF-IMM-LP-14 PF-BSM-CP-1 | HUB |
| Serum / Plasma | Detection of autoantibodies Anti-MPO Anti-PR3 Anti-TTG IgA Anti-cardiolipins (IgG and IgM) ENA CTD antibodies Ds DNA (EIA) Anti-TTG IgG Anti-GBM CPP (IgG) | Phadia 250 analysers with fluorescence enzyme immunoassay technology. PF-IMM-LP-14 PF-IMM-LP-10 PF-IMM-LP-11 PF-IMM-LP-15 PF-IMM-LP-17 PF-IMM-LP-18 PF-IMM-LP-19 PF-IMM-LP-20 PF-IMM-LP-21 PF-IMM-LP-22 | HUB |
| Serum | Detection of autoantibodies: EMA IgG EMA IgA | NovaLite monkey oesophagus slides using Indirect Immunofluorescence method PF-IMM-LP-8 PF-IMM-LP-9 | HUB |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd) | Documented in-house procedures in conjunction with manufacturer's instructions for analysis using: | |
| Serum | ANCA abs | NovaLite ANCA slides using Indirect Immunofluorescence method PF-IMM-LP-2 | HUB |
| Serum | Anti-dsDNA (crithida) antibodies | NovaLite Crithidia luciliae slides using Indirect Immunofluorescence method PF-IMM-LP-3 | HUB |
| Serum | Anti-nuclear antibodies | Biosystems HEp-2 slides using Indirect Immunofluorescence method PF-IMM-LP-1 | HUB |
| Serum / Plasma | Liver and pernicious anaemia | Detection of autoantibodies using ImmuGlo mouse liver/kidney/stomach slides using Indirect Immunofluorescence method PF-IMM-LP-7 | HUB |
| Serum / Plasma | Intrinsic Factor as part of pernicious anaemia screen | QuantLite Intrinsic Factor Werfren Agility ELISA | HUB |
| END | | | |