


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|--|---|
|  <p>UKAS MEDICAL</p> <p>9844</p> <p>Accredited to ISO 15189:2012</p> | <p>York and Scarborough Teaching Hospitals NHS Foundation Trust</p> <p>Issue No: 013 Issue date: 23 March 2022</p> | |
| | <p>Pathology Department Pathology Building Hull Royal Infirmary Anlaby Road Hull HU3 2JZ</p> | <p>Contact: Dave Oglesby Tel: +44 (0)148 260 7722 E-Mail: david.oglesby@nhs.net Website: www.hey.nhs.uk</p> |
| <p>Testing performed by the Organisation at the locations specified below</p> | | |

Locations covered by the organisation and their relevant activities

| Location details | Activity | Location code |
|---|--|---------------|
| <p>Address Pathology Laboratory Hull Royal Infirmary Anlaby Road Hull HU3 2JZ</p> <p>Local contact Jennifer Williams Jennifer.williams69@nhs.net</p> <p>Ngozi Loades Ngozi.loades@hey.nhs.uk</p> <p>Dr Ree Nee Tiam reenee.tiam@nhs.net</p> <p><u>Mark Hajjawi</u> mark.hajjawi@hey.nhs.uk</p> <p>Lisa Mead: Lisa.Mead@YORK.NHS.UK</p> | <p>Haematology and Blood Transfusion</p> <p>Biochemistry</p> <p>Cellular Pathology</p> <p>Immunology</p> <p>Microbiology</p> | <p>HRI</p> |
| <p>Address Pathology Laboratory Castle Hill Laboratory Castle Hill Hospital Castle Road Cottingham HU16 5JQ</p> <p>Local contact Jannene Sanders Jannene.sanders@hey.nhs.uk</p> <p>Katie Tweddle Katie.tweddle@hey.nhs.uk</p> | <p>Haematology</p> <p>Biochemistry</p> | <p>CHH</p> |



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Site activities performed away from the locations listed above:

| Location details | Activity | |
|---|---|---|
| Address Women's and Children's Hospital Hull Royal Infirmary Anlaby Road Hull HU3 2JZ | Local contact Bob Elshaw robert.elshaw@hey.nhs.uk Tel: 01482 607791 | Blood storage & issue only Management of Women's and Children's theatre fridge |
| Address Hull Royal Infirmary Anlaby Road Hull HU3 2JZ | Local contact Bob Elshaw robert.elshaw@hey.nhs.uk Tel: 01482 607791 | Blood storage & issue only Management of Tower Block blood fridge |
| Address Queen's Centre Castle Hill Hospital Castle Road Cottingham HU16 5JQ | Local contact Bob Elshaw robert.elshaw@hey.nhs.uk Tel: 01482 607791 | Blood storage & issue only Management of Day unit blood fridge Management of Cardiology Unit blood fridge |



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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|--|---------------|
| HUMAN BODY FLUIDS | <u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> | Manufacturer's instructions and documented In-house methods using: | HRI |
| Whole Blood: EDTA samples Red cells and plasma | Blood Grouping <ul style="list-style-type: none"> • A B O • Rhesus D status | Glass microbead column technology using Ortho Vision analysers SOP BT/GR/001 Glass microbead column technology using manual Ortho BioVue methods SOP BT/GR/004 | |
| Plasma | Red cell Antibody Screening Antibodies of the following systems: <ul style="list-style-type: none"> • Rhesus • Kell • Duffy • Kidd • MNSs • P • Lutheran • Lewis | Glass microbead column technology using Ortho Vision analysers SOPBT/GR/001 & BT/SP/001 Glass microbead column technology using manual Ortho BioVue methods SOP BT/SP/001 & BT/GR/004 | |
| | Compatibility Testing <ul style="list-style-type: none"> • Manual testing of patient plasma and donor red blood cells. | Glass microbead column technology using manual OrthoBioVue. SOP BT/XM/001 | |



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| HUMAN BODY FLUIDS | <u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> | <u>Manufacturer's instructions and documented In-house methods using:</u> | HRI |
| Red cells | Direct anti-globulin test | Glass microbead column technology using Ortho Vision analysers SOP BT/SP/002 & BT/GR/001 Glass microbead column technology using manual Ortho BioVue methods SOP BT/SP/002 | |
| Red cells | Rhesus phenotype and Kell type to include the specific antigens: D, C, c, E, e, K | Glass microbead column technology using: Ortho Vision analysers SOP BT/SP/004 | |
| Red cells | Kleihauer test for estimation of foeto-maternal haemorrhage | Manual modified Kleihauer-Betke method. SOP BT/SP/005 & BT/SP/006 | |
| Plasma (tri-sodium citrate) | <u>Coagulation examination activities for the purpose of clinical diagnosis</u> Blood Coagulation Prothrombin time Activated partial Clauss Fibrinogen Thromboplastin time Fibrinogen Thrombin time INR for warfarin therapy APTT/APTR for Heparin monitoring Reptilase time Mixing tests | <u>Manufacturer's instructions and documented In-house methods using:</u> Sysmex CS-series (CS-5100/CS-2500) Auto Analyser Optical clot detection SOP HA/G/501 Routine coagulation SOP HA/G/501 Routine coagulation | |



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| HUMAN BODY FLUIDS Plasma (tri-sodium citrate) | <p><u>Coagulation examination activities for the purpose of clinical diagnosis</u></p> <p>Activated partial Thromboplastin time using actin FS</p> <p>D-Dimer</p> <p>Anti-Xa levels</p> <p>Factor's: VII IX XI XII V X II VIII</p> <p>Lupus anticoagulant</p> <p>Von Willebrands factor antigen Von Willebrands factor activity</p> <p>Inhibitor Screen and Bethesda Assay</p> <p>Von Willebrands factor antigen Von Willebrands factor activity</p> | <p>Manufacturer's instructions and documented In-house methods using:</p> <p>Sysmex CS-series (CS-5100/CS-2500) Auto Analyser</p> <p>SOP HA/G/501 Routine coagulation</p> <p>Optical clot detection</p> <p>HA/G/501</p> <p>Optical clot detection SOP HA/G/501 Routine coagulation</p> <p>Clot based optical assay SOP HA/G/503 Coagulation laboratory specialist</p> <p>Clot based optical assay SOP HA/G/503 Coagulation laboratory specialist</p> <p>Latex base turbidometric assay SOP HA/G/503 Coagulation laboratory specialist</p> <p>Immunoassay SOP HA/G/503 Coagulation laboratory specialist</p> | HRI |



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| HUMAN BODY FLUIDS | <u>Coagulation examination activities for the purpose of clinical diagnosis</u> | Manufacturer's instructions and documented In-house methods using: | HRI |
| | Heparin Induced Thrombocytopenia | SOP HA/G/503 Coagulation laboratory specialist | |
| | Chromogenic Factor VIII | Chromogenic Assay SOP HA/G/503 Coagulation laboratory specialist | |
| Plasma (tri-sodium citrate) | Collagen Binding for Von Willebrands Activity | Enzyme linked Immunosorbent assay (ELISA) using Triturus plate reader SOP HA/G/503 Coagulation laboratory specialist | |



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| Whole blood in EDTA | <p><u>Haematology examination activities for the purpose of clinical diagnosis</u></p> <p>Full Blood count:</p> <ul style="list-style-type: none"> • Haemoglobin • Red Blood Cells • Platelet count • Haematocrit • Mean cell volume • Mean cell haemoglobin • Red cell distribution width • White cell count • White Cell Differential • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils <p>Reticulocyte count (including immature reticulocyte fraction and haemoglobin content)</p> | <p>Sysmex XN series (XN-9000 HRI and XN-3100 CHH)</p> <p>SOP HA/G/500 Routine Haematology</p> <p>HA/H/401 Sysmex XN Series – Operation Procedures.</p> | HRI, CHH |



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| HUMAN BODY FLUIDS | <u>Haematology examination activities for the purpose of clinical diagnosis</u> | Manufacturer's instructions and documented In-house methods using: | |
| Whole blood in EDTA | Detection of Nucleated red cell count | Sysmex SP-50 automated slide preparation and manual microscopy May-grunwald Giemsa stain | HRI |
| | | Manual slide preparation and manual microscopy – May-grunwald Giemsa stain | HRI, CHH |
| | Identification of normal and abnormal morphologies including WBC differential count | SOP HA/G/500 Routine Haematology | HRI |
| | | Manual slide preparation and manual microscopy – May-grunwald Giemsa stain | HRI, CHH |
| Bone marrow aspirate slides | Malaria screening for: <i>P. falciparum</i> <i>P. vivax</i> <i>P. ovale</i> <i>P. malariae</i> <i>P. knowlesi</i> | Thick and thin films | HRI |
| | | Giemsa stain and manual microscopy | |
| | Reporting of normal and abnormal morphologies | OptiMal IT rapid immunochromatographic dipstick Monoclonal Antibody test against parasite LDH | |
| | | SOP HA/G/500 Routine Haematology | |
| | | MGG stain using Mirastainer II | |



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| HUMAN BODY FLUIDS | <u>Haematology examination activities for the purpose of clinical diagnosis</u> | Manufacturer's instructions and documented In-house methods using: | HRI |
| Whole blood in EDTA | Screening test for Glucose 6 phosphate dehydrogenase deficiency | Visual qualitative fluorescence via an ICSH modification of the Beutler and Mitchell method SOP HA/G/500 Routine Haematology | |
| Whole blood in EDTA, serum, plasma | Detection of infectious mononucleosis heterophile antibodies | Clearview IM II test chromatographic immunoassay kit SOP HA/G/500 Routine Haematology Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia (SCT) screening programme as defined in the July 2018 'NHS Sickle Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements.' | |
| Whole blood in EDTA | Antenatal Haemoglobinopathy screening: Detection of haemoglobin variants: HbA2 HbF HbS. | Automated HPLC using Menarini Arkray HA 8160 SOP BT/SP/005 HA/G/502/Haemoglobinopathy | |
| Whole blood in EDTA | Determine the presence of variant haemoglobins – HbA, HbF, HbS, HbC Detection of haemoglobin S (Hb-S) | Citrate agar acid electrophoresis and cellulose acetate alkaline electrophoresis using Helena SAS1, SAS2, SAS3 & SAS4 instruments. HA/S/050 Alkaline electrophoresis HA/S/056 Acid electrophoresis Microgen S-test HA/S/004 | |



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| HUMAN BODY FLUIDS | <u>Biochemistry examination activities for the purposes of clinical diagnosis</u> | Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH) | |
| Serum/plasma | Quantitative determination of: ALT(IFCC) Alanine Aminotransferase ALP(IFCC) AST Aspartate Aminotransferase AST CK NAC Creatinine Kinase Ethanol Ethyl Alcohol Glucose hexokinase LDH (L-P) IFCC Urea STAT | Kinetic UV Colorimetric BI/AU/001 BI/A12/012 | HRI & CHH |
| Serum/plasma/urine | | Immunoturbidimetric | |
| Serum | Alpha-1-antitrypsin | BI/AU/001 | HRI |
| CSF/Urine | UALB Albumin in CSF and Urine | | |
| Serum/plasma | B2 Microglobulin C3/C4 Complement C-Reactive Protein Haptoglobin IgA IgG IgM Rheumatoid Factor Transferrin Vancomycin | | HRI & CHH HRI |



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| HUMAN BODY FLUIDS | <u>Biochemistry examination activates for the purposes of clinical diagnosis</u> | Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH) | |
| Serum/Plasma | Quantitative determination of: Albumin BCP | BCP Dye-Binding Colorimetric BI/AU/001, BI/A12/012 | HRI & CHH |
| Serum/plasma | Alkaline Phosphatase | Kinetic Colorimetric BI/AU/Chemifus | HRI & CHH |
| Serum/plasma/urine/ Serum/plasma | Alpha-amylase Gamma- Glutamyltransferase Total Bile Acids | Direct enzymatic | HRI |
| Plasma | Ammonia (GLDH) | Enzyme immunoassay BI/AU/001, BI/A12/012 | |
| Urine | Amphetamine/Ecstasy | BI/AU/001, BI/A12/012 | |
| Serum/plasma | Benzodiazepines | | |
| Urine | Carbamazepine | | |
| Urine | Cocaine | | |
| | Methadone metabolite | | |
| | Gentamicin | | |
| | Methotrexate | | |
| | Morphine/codeine/ heroin | | |
| Serum/plasma | Phenobarbital | | |
| | Phenytoin | | |
| Urine | THC Cannabis | | |
| Serum/plasma | Theophylline | | |
| | Valproic Acid | | |



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| HUMAN BODY FLUIDS | <u>Biochemistry examination activates for the purposes of clinical diagnosis</u> | Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH) | |
| Serum/plasma | Angiotensin Converting Enzyme (ACE) | Enzymatic | HRI |
| Serum/plasma | Bicarbonate Cholesterol (CHOD-PAP) | BI/AU/001, BI/A12/012 | HRI & CHH |
| Serum/plasma/urine Serum/plasma | Creatinine enzymatic Fructosamine HDL -Cholesterol Lactate Salicylate Acid | | HRI |
| Serum/plasma Serum/plasma/urine | Triglyceride Uric Acid | Photometric /colorimetric | HRI & CHH |
| Serum/plasma/urine Serum/plasma | Calcium (Arsenazo) Direct Bilirubin Inorganic phosphate Iron (TPTZ) Lithium Magnesium Total Protein Protein | BI/AU/001, BI/A12/012 | HRI |
| Serum/plasma Urine/CSF | | Indirect ISE | HRI & CHH |
| Serum/plasma/urine | Chloride Potassium Sodium | BI/AU/001, BI/A12/012 | |



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| HUMAN BODY FLUIDS | <u>Biochemistry examination activates for the purposes of clinical diagnosis</u> | Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH) | |
| Serum/plasma | Digoxin | Immuno-inhibition BI/AU/001, BI/A12/012 | HRI |
| Serum/plasma | Total Bilirubin | Colorimetric BI/AU/001, BI/A12/012 | HRI & CHH |
| Serum | Paracetamol | Enzyme immunoassay BI/AU/001 | HRI |
| | Tobramycin | Beckman UniCel DXi 800 (Magnetic particle based Chemiluminescence) | |
| | TSH | BI/S/700 | |
| | FT4 | | |
| | FT3 | | |
| | Anti TPO | | |
| | Cortisol | | |
| | FSH/LH | | |
| | Prolactin | | |
| | Progesterone | | |
| | Oestradiol | | |
| | Testosterone | | |
| | DHEA | | |
| | AFP | | |
| | CA125 | | |
| | CA153 | | |
| | CA199 | | |
| | CEA | | |
| | PSA | | |
| | HCG | | |
| | B12 | | |
| | Folate | | |
| | Ferritin | | |



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| HUMAN BODY FLUIDS | <u>Biochemistry examination activates for the purposes of clinical diagnosis</u> | Documented in house methods and manufacturer's instructions for analysis using: | |
| Serum/plasma | ACTH Trop T (high sensitivity) Pro BNP P1NP | Roche Cobas e411(Magnetic particle based Chemiluminescence) BI/S/414 | HRI |
| Serum | sFit-1/PIGF pre-eclampsia ratio Human growth hormone (Hgh) IGFBP-3 IGF-1 | Roche Cobas e411 (Electrochemiluminescence immunoassay ECLIA) BI/S/414 IDS-isys (Magnetic particle based Chemiluminescence) BI/S202 | |
| Faeces | Calprotectin | Phadia Unicap 250 (Antibody/Antigen onto solid phase) B1/G6 | |
| Urine | Urine Catecholamines 5HIAA | Waters 2795 HPLC BI/M17 BI/M18 | |
| Serum/plasma | Vitamin A Vitamin E | BI/M19 | |



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| HUMAN BODY FLUIDS | <u>Biochemistry examination activates for the purposes of clinical diagnosis</u> | Documented in house methods and manufacturer's instructions for analysis using: Waters Acquity Tandem Quadruple TQD (Tandem Mass Spectrophotometry) | HUMAN BODY FLUIDS |
| Urine | Toxicology Confirmation of the following: Morphine 6-Monoacetylmorphine Morphine Glucuronide Codeine Dihydrocodeine Acetyl codeine Amphetamine Methamphetamine Methylenedioxyamfetamine (MDMA) Methylenedioxyamfetamine (MDA) Cocaine metabolite (benzoylecgonine) Pholcodine Oxycodone Tramadol Meconin Methadone Methadone metabolite (EDDP) | BI/M/60 | HRI |
| | Buprenorphine/ Norbuprenorphine Cortisol Drug Screening (Chromalynx) | BI/M/TOX/131 BI/M/60 BI/G3 | |



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| HUMAN BODY FLUIDS | <u>Biochemistry examination activates for the purposes of clinical diagnosis</u> | Documented in house methods and manufacturer's instructions for analysis using: Waters Acquity Tandem Quadruple Micromass Quattro XE Mass (Tandem Mass Spectrophotometry) | HRI |
| Serum/plasma | Tacrolimus/FK506 Ciclosporin | BI/M/043 | |
| | Testosterone and Androstenedione Vitamin D | BI/M/42 BI/M/52 | |
| Serum/plasma | Trace Metals: Copper Zinc Selenium | Agilent 220FZ/220Z (Atomic Absorption spectrophotometry) BI/M/AA/007 BI/M/AA/007 BI/M/AA/011 | |
| Whole blood | Lead | Lead BI/M/AA/008 Menarini 9210 (Borate affinity) | |
| Whole blood EDTA | Glycated Haemoglobin | BI/M/060 Helena SAS-3 | |
| Serum/plasma | ALP Iso-enzymes | BI/M/004 | |
| CSF | Xanthochromia | Uvikon XL (Spectrophotometry) BI/M/022 | |
| Serum/plasma/urine | Osmolality | Advanced Instrument Osmometer 3320 (freezing point osmometry) BI/M/002 | |
| Sweat | Chloride | Sherwood 926 Chloride meter BI/M/016 | |



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| HUMAN BODY FLUIDS | <u>Biochemistry examination activates for the purposes of clinical diagnosis</u> | Documented in house methods and manufacturer's instructions for analysis using: | HRI |
| Faeces | FIT - Faecal immunochemical testing - Haemoglobin | HM-KACKarc BI/S613 Manual test: Colorimetric | |
| Urine | Urine oxalate | BI/M/006 | |
| Serum | Cholinesterase | BI/M/005 | |
| Faeces | Paraquat | BI/M/TOX/013 ELISA Schebo Pancreatic Elastase kit | |
| Urine | Calculated Tests (data from primary tests, primary test sample requirements listed under that test) | BSI/167 | |
| Urine | 24hr Urine Calcium | | |
| Urine | 24hr Urine Creatinine | | |
| Urine | 24hr Urine Phosphate | | |
| Urine | 24hr Urine Potassium | | |
| Urine | 24hr Urine Sodium | | |
| Urine | 24hr Urine Uric Acid | | |
| Urine | Albumin: Creatinine Ratio | | |
| Urine | Protein: Creatinine Ratio | | |
| Serum | Calcium, adjusted | | |
| Urine | Calcium: Creatinine Excretion Ratio | | |
| Urine | Calcium: Creatinine Ratio | | |
| Serum and urine | Creatinine Clearance (L/24hr) | | |
| Serum and urine | Creatinine Clearance (mL/min) | | |
| Serum | eGFR (CKD-EPI) | | |
| Serum | Non-HDL Cholesterol | | |



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| <p>HUMAN BODY FLUIDS</p> <p>Serum Urine Serum Serum Serum Serum and urine</p> <p>Urine</p> | <p><u>Biochemistry examination activates for the purposes of clinical diagnosis</u></p> <p>Calculated Tests (data from primary tests, primary test sample requirements listed under that test)</p> <p>LDL-Cholesterol Protein:Creatinine Ratio Free androgen index AKI Globulins Renal tubular absorption of phosphate (TmP/GFR)</p> <p>24hr Urine Uric Acid</p> | <p>Documented in house methods and manufacturer's instructions for analysis using:</p> | <p>HRI</p> |



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| <p>HUMAN BODY TISSUE SAMPLES</p> <p>Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens</p> | <p><u>Histopathology & Neuropathology</u></p> <p>Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis</p> | <p>Documented in house methods and manufacturer's instructions for analysis using:</p> <p>Macroscopic and Microscopic examination:</p> <p>SOP HP/PROC/0102 and as appropriate to specimen type:</p> <p>General specimens Cardiothoracic GIT and Liver Gynaecological Head and Neck Skin Soft Tissue and Bone Urology Breast Central and peripheral nervous system Ophthalmic</p> <p><u>Specimen dissection & tissue processing</u></p> <p>Documented in-house procedure SOP HP/PROC/0200 in conjunction with manufacturer's instructions for Peloris II & Leica ASP 300 tissue processors</p> <p><u>Tissue Embedding</u></p> <p>Documented in-house procedure SOP HP/PROC/0300 in conjunction with manufacturer's instructions for Leica EG1160, Leica Histocore Arcadia and Medite tissue embedding centres</p> | HRI |



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Issue No: 013 Issue date: 23 March 2022

Testing performed by the Organisation at the locations specified

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| <p>HUMAN BODY TISSUE SAMPLES</p> <p>Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens</p> <p>DIF: Skin, renal and buccal mucosa biopsy</p> <p>Frozen sections</p> <p>Intra-operatives: Central and peripheral nervous system.</p> | <p><u>Histopathology & Neuropathology</u></p> <p>Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis</p> <p>Diagnostic Frozen sections and Intra-operatives – frozen / smears</p> | <p>Documented in house methods and manufacturer's instructions for analysis using:</p> <p><u>Tissue Sectioning</u></p> <p>Documented in-house procedure SOP HP/PROC/0400. Sections are produced on microtomes; Leica RM2235, Leica RM2135 and Leica Histocore Biocut.</p> <p>Direct immunofluorescence</p> <p>HP/PROC/0802 Direct Immunofluorescence Technique (DIF)</p> <p>HP/PROC/0803 DIF Antibody Dilutions</p> <p>HP/PROC/0819 Preparation of Intra-Operative Smears</p> <p>HP/PROC/0815 Frozen Section Procedure</p> <p>Documented in-house procedure SOP HP/PROC/0800 (special techniques) in conjunction with manufacturer's instructions for the Leica cryostat CM1900 and CM1850</p> <p><u>Staining</u></p> <p>Automated Routine Stains</p> | HRI |



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Schedule of Accreditation

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Issue No: 013 Issue date: 23 March 2022

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| HUMAN BODY TISSUE SAMPLES Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens | Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in-house procedure SOP HP/PROC/0500 in conjunction with manufacturer's instructions for & Leica Autostainer XL and Dako Coverstainer | HRI |
| | Nuclei and other cellular components | Haematoxylin & Eosin HP/PROC/0804 & HP/PROC/0612 manual and HP/PROC/0500 automated | |
| | Mast cells | Manual Special Stains: Documented in-house procedure SOP HP/PROC/0600. | |
| | Acid mucins, elastic fibres & connective tissue | Acidified Toluidine Blue (HP/PROC/0601) | |
| | Acid and neutral mucins | Alcian Blue EVG (Millers) (HP/PROC/0637) | |
| | Acid mucopolysaccharides | Alcian Blue PAS & Diastase (HP/PROC/0603) | |
| | Amyloid | Alcian Blue pH 2.5 (HP/PROC/0604) | |
| | Elastic fibres | Congo Red (HP/PROC/0606) | |
| | Protozoans | Elastic van Gieson (Millers) (HP/PROC/0608) | |
| | Gram +/- organisms | Giemsa (HP/PROC/0609) | |
| | Fungi | Gram (HP/PROC/0610) | |
| | Haemosiderin | Grocott Gomori (HP/PROC/0611) | |
| | Basement membrane | Iron (Perls Prussian Blue) (HP/PROC/0613) | |
| | Jones Methenamine Silver (HP/PROC/0614) | | |



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Schedule of Accreditation

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York and Scarborough Teaching Hospitals NHS Foundation Trust

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| HUMAN BODY TISSUE SAMPLES Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens | Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in house methods and manufacturer's instructions for analysis using: | HRI |
| | Myelin | Luxol Fast Blue/Cresyl fast violet (HP/PROC/0640) | |
| | Melanin | Masson-Hamperl (HP/PROC/0617) | |
| | Connective tissue | Masson's Trichrome (HP/PROC/0618) | |
| | Melanin | Melanin Bleach (HP/PROC/0619) | |
| | Helicobacter pylori | Modified Giemsa (HP/PROC/0620) | |
| | Fibrin | MSB (HP/PROC/0621) | |
| | Hepatitis B and copper – associated protein | Orcein (Shikata's) (HP/PROC/0623) | |
| | PAS +ve substances e.g.: glycogen (and cells of pituitary) and fungi | Periodic Acid Schiff, (HP/PROC/0624) | |
| | Reticulin fibres | Reticulin (Gordon and Sweet) (HP/PROC/0626) | |
| | Amyloid | Sirius Red (HP/PROC/0627) | |
| | Metachromatic substances | Toluidine blue (HP/PROC/0630) | |
| | Connective tissue | Van Gieson (HP/PROC/0632) | |
| | Calcium | Von Kossa (HP/PROC/0633) | |
| | Spirochetes | Warthin Starry (HP/PROC/0634) | |
| Tubercle bacilli (TB) | Ziehl – Neelsen (HP/PROC/0635) | | |
| Mycobacterium leprae bacilli | Wade fite modified ZN (HP/PROC/0639) | | |



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

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Issue No: 013 Issue date: 23 March 2022

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| HUMAN BODY TISSUE SAMPLES Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens | Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in house methods and manufacturer's instructions for analysis using: | HRI |
| FFPE slides (formalin fixed paraffin embedded) and frozen sections | | Interpretive/diagnostic microscopy (HP/CONS/001) | |
| HUMAN BODY TISSUE SAMPLES & cell blocks | <u>Immunocytochemistry:</u> Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies: | HRI |
| | Germinal centre macrophages - tonsil | A-1-AT | |
| | ACTH secreting cells - pituitary | ACTH | |
| | Smooth muscle actin | ACTIN | |
| | Epithelial cells | AE1/3 | |
| | Foetal liver cells | AFP | |
| | Astrocytoma identification | ATRX | |
| | Scattered T cells in germinal centres and mantle zone B cells | BCL-2 | |
| | Epithelial cells of the colon | BEP4 | |
| | Luminal cells of fallopian tube | CA125 | |
| | Parafollicular C cells of the thyroid | CALCITONIN | |



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| HUMAN BODY TISSUE SAMPLES & cell blocks | <u>Immunocytochemistry:</u> Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies: | HRI |
| | Smooth muscle of blood vessels and of bowel wall | CALD | |
| | Peripheral nerve ganglion | CALRETININ | |
| | Epithelial cells of the colon | CAM5.2 | |
| | All germinal centre cells of tonsil | CD10 | |
| | Neutrophils, eosinophils, macrophages, R-S cell in Hodgkins lymphoma | CD15 | |
| | Langerhans Cell in skin | CD1A | |
| | Germinal mantle zone B lymphocytes | CD20 | |
| | Activated lymphocytes and plasma cells. RS cells in Hodgkins lymphoma | CD30 | |
| | Endothelial cells cells, activated B & T lymphocytes | CD31 | |
| | Endothelial cells | CD34 | |
| | T lymphocytes | CD3 | |
| | All leucocytes | CD45 | |
| | Peripheral nerves | CD56 | |
| Macrophages | CD68 | | |
| Mantle zone B cells, germinal centre B cells, plasma cells | CD79A | | |



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| HUMAN BODY TISSUE SAMPLES & cell blocks | <u>Immunocytochemistry:</u> Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies: | HRI |
| | T cells, cytotoxic suppressor cells | CD8 | |
| | Endothelial cells | CD99 | |
| | Islets of Langerhan cells of the pancreas | CHROMAGRANIN | |
| | Squamous epithelium | CK 14 | |
| | Umbrella cells of ureter | CK20 | |
| | Squamous epithelium | CK34BE12 | |
| | Squamous epithelium | CK5/6 | |
| | Transitional epithelium of ureter | CK7 | |
| | Mast cells, GIST | CKIT | |
| | Epithelial cells | CKPAN | |
| | Cytomegalovirus infected cells | CMV | |
| | Collagen IV in basement membranes | COLLAGEN IV | |
| | Smooth & striated muscle cells | DESM | |
| | Gastrointestinal stromal tumours | DOG1 | |
| Epstein Barr virus infected cells | EBV | | |
| Epithelial cell membranes | E-CAD | | |



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Schedule of Accreditation

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

York and Scarborough Teaching Hospitals NHS Foundation Trust

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| HUMAN BODY TISSUE SAMPLES & cell blocks | <p><u>Immunocytochemistry:</u></p> <p>Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis</p> <p>Epithelial cells of the kidney</p> <p>FSH secreting cells of the pituitary</p> <p>G - cells of stomach</p> <p>Epithelial cells of sweat glands</p> <p>Astrocytes</p> <p>GH secreting cells of pituitary</p> <p>Glucagon secreting cells of the pancreas</p> <p>hepatocytes</p> <p>Trophoblasts of placenta, secreting HCG</p> <p>Melanoma cells</p> <p>H-pylori bacterium</p> <p>Herpes simplex virus infected cells</p> <p>Oligo dentroglioma</p> <p>Leydig and Steroli cells in testis</p> <p>Insulin secreting cells in pancreas</p> | <p>Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies:</p> <p>EMA</p> <p>FSH</p> <p>GASTRIN</p> <p>GCDF</p> <p>GFAP</p> <p>GH</p> <p>GLUCOGON</p> <p>HSA</p> <p>HCG</p> <p>HMB45</p> <p>HPYL</p> <p>HSV</p> <p>IDH-1</p> <p>INHIBIN</p> <p>INSULIN</p> | HRI |



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

York and Scarborough Teaching Hospitals NHS Foundation Trust

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| HUMAN BODY TISSUE SAMPLES & cell blocks | Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies: | HRI |
| | Proliferating cells in germinal centre B cells | Ki67 | |
| | LH secreting cells in pituitary | LH | |
| | Dendrites and perikarya of neurons | Map-2 | |
| | Melanocytes | MELAN A | |
| | Mesothelial cells, some epithelial cells of tonsil | MESOTHELIN | |
| | Striated muscle cells | MYOGLOBULIN | |
| | Small muscle myosin | MYOSIN | |
| | Neurons | NFP | |
| | Neuroendocrine & neuronal cells | NSE | |
| | Squamous cell carcinoma | P40 | |
| | Colon adenoca | P53 | |
| | Trophoblasts in placenta | P57 | |
| | Autophagosome marker | P62 | |
| | Squamous epithelium | P63 | |
| PD-L1 protein expression | PDL1 | | |



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

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| HUMAN BODY TISSUE SAMPLES & cell blocks | Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies: | HRI |
| | Prostate glands | PIN | |
| | Pituitary marker somatotroph cell adenoma | PIT-1 | |
| | Tropoblasts of placenta | PLAP | |
| | Polyoma virus | POLV | |
| | PRL secreting cells of pituitary | PrI | |
| | Prostate glands | PSA | |
| | Epithelial cells of proximal tubules of kidney | RCC | |
| | Schwann cell, adipocytes, cartilage | S100 | |
| | Pituitary marker gonadotroph cell adenoma | SF-1 | |
| | Islets of Langerhans cells of pancreas | SYNAPTOPHYSIN | |
| Follicular epithelial cells of thyroid | THROG | | |
| TSH secreting cells of the pituitary | TSH | | |



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| HUMAN BODY TISSUE SAMPLES & cell blocks | Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis | Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies: | HRI |
| | Pituitary marker corticotroph cell adenoma | T-PIT | |
| | Follicular epithelial cells of thyroid, Type II pneumocytes i.e.; smooth muscle, endothelium, lymphocytes | TTF1 | |
| | Mesenchymal cells | WT1 | |
| | Amyloid | Amyloid A | |
| | Breast carcinoma | HER 2 | |
| | Breast cancer and normal gland | OEST | |
| | Breast cancer | PROG | |
| | ALK positive non-small cell lung carcinomas | ALK | |
| | | Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Ventana Ultra immunocytochemistry stainers and using antibodies: | |



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| <p>HUMAN BODY TISSUE SAMPLES, fine needle aspirates & brushings Including Urine, nipple discharge, cyst fluid, skin scrapings, synovial fluid, CSF, sputum, bronchial washings / brushings, pleural fluid, peritoneal ascites, pericardial fluid, FNA solid organ, Endoscopic USScan guided FNA and USScan guided transbronchial FNA</p> | <p><u>Non-gynaecological cytology examination activities:</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis</p> <p>Basic cellular components on fixed preparations and air-dried preparations (HG)</p> | <p><u>Sample preparation, processing & routine staining</u></p> <p>Documented in-house procedure SOP CY-PROC/100 in conjunction with manufacturer's instructions for Shandon Varistain 24-4 and Hologic T2000 using:</p> <p>Papanicolaou stain CY/PROC/111</p> <p>Hema- Gurr (HG) rapid stain CY/PROC/111</p> <p>Dako Coverstainer - automated H&E (HP/PROC/0500)</p> <p><u>Interpretive Microscopy</u></p> <p><u>Leica Microscope</u> <u>Nikon Microscope</u> <u>Olympus Microscope</u></p> <p>SOP HP/PROC/0102 and as appropriate to specimen type</p> | |



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| HUMAN BODY FLUIDS | <u>Immunological examinations for the purpose of clinical diagnosis</u> | | HRI |
| | <u>Autoimmune Disease Testing</u> | | |
| Serum | Liver, kidney, stomach & nuclear/cytoplasmic specific antibodies (IgG). Anti-Neutrophil cytoplasmic antibodies (IgG) Endomysial antibodies (IgA & IgG) Skin (IgG) Antibodies | Manual slide preparation or Automated slide preparation in conjunction with manufacturer's instructions using: Zenit pro followed by Indirect immunofluorescence microscopy using the following SOP's : IM/A/034 | |
| Serum | Crithidia (IgG) Antibodies | Manual slide preparation followed by indirect immunofluorescence microscopy using the following SOP: IM/A/009 | |
| Serum | IgG Cyclic Citrullinated Peptide antibodies | Luminex Bead Assay in conjunction with manufacturer's instructions using Bioplex 2200 using in-house procedures: IM/A/028 | |
| Serum | Coeliac Screen: IgA Tissue transglutaminase Ab IgG Tissue transglutaminase Ab IgA Deamidated gliadin peptide Ab IgG Deamidated gliadin peptide Ab | Luminex Bead Assay in conjunction with manufacturer's instructions using Bioplex 2200 using in-house procedures: IM/A/028 | |



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| HUMAN BODY FLUIDS | <u>Immunological examinations for the purpose of clinical diagnosis</u> | | HRI |
| | <u>Autoimmune Disease Testing</u> | | |
| Serum | Vasculitis Screen (IgG): Glomerular basement protein Ab Proteinase 3 Ab Myeloperoxidase Ab | Luminex Bead Assay in conjunction with manufacturer's instructions using Bioplex 2200 using in-house procedures: IM/A/028 | |
| Serum | Antiphospholipid screen (IgG): Cardiolipin Ab Beta-2-glycoprotein I Ab | Luminex Bead Assay in conjunction with manufacturer's instructions using Bioplex 2200 using in-house procedures: IM/A/028 | |
| Serum | Antinuclear antibodies (IgG): Double stranded DNA Ro52 Ro60 La SmRNP Sm RNP-68 RNP-A Chromatin Ribosomal P Scl-70 Centromere B Jo-1 | Luminex Bead Assay in conjunction with manufacturer's instructions using Bioplex 2200 using in-house procedures: IM/A/028 | |
| Serum | Intrinsic factor antibodies | Competitive inhibition immunoenzymatic assay in conjunction with manufacturer's instructions using Beckman DXi and using in-house procedures: BI/S/7001 BI/S/700 | |



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| HUMAN BODY FLUIDS | <u>Immunological examinations for the purpose of clinical diagnosis</u> | | HRI |
| | <u>Autoimmune Disease Testing</u> | | |
| Serum | Thyroid peroxidase antibodies | Immunoenzymatic sandwich assay BI/S/700 in conjunction with manufacturer's instruction using DXi and in-house procedures | |
| Serum | Extractable Nuclear Antigens (IgG): Ro La Sm SmRNP Jo-1 Scl-70 | Immunoblot using Immunoblot One in conjunction with manufacturer's instructions and in-house procedures: IM/A/032 | |
| Serum | Liver antibodies (IgG): Anti-M2 M2-3E LKM 1 SLA/LP LC-1 | Immunoblot using Immunoblot One in conjunction with manufacturer's instructions and in-house procedures: IM/A/032 | |
| Serum | Specific Mitochondrial Antibodies (IgG/IgM): Anti-M2/M4/M9 | Manual line blots in conjunction with manufacturer's instructions and in-house procedures: IA/A/030 | |
| Serum | Specific vaccine related antibodies: Pneumococcal Haemophilus influenzae B Tetanus toxoid | ELISA using Triturus automated processor in conjunction with manufacturer's instructions and in house procedures: IM/A/022 | |



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| HUMAN BODY FLUIDS | <u>Immunological examinations for the purpose of clinical diagnosis</u> | | HRI |
| Serum | <u>Immunochemistry</u> Detection and immunotyping of monoclonal paraproteins | Capillary zone electrophoresis and Immunosubtraction on Helena V8 Nexus and Gel Immunofixation on SAS3/SAS4 in conjunction with manufacturer's instructions and in-house procedures: IM/M/035, IM/M/034 | Serum |
| Urine | Detection and immunotyping of monoclonal paraproteins | Gel electrophoresis and Immunofixation using Helena SAS3,SAS4 in conjunction with manufacturer's instructions and in-house procedures IM/M/034 | |
| Serum | Cryoglobulins | Visual inspection and by gel and capillary zone electrophoresis using in-house procedures. Helena V8, SAS3, SAS4. IM/M/007 | Serum |
| Serum | Specific proteins: Immunoglobulin G Immunoglobulin M Immunoglobulin A Complement C3 Complement C4 Rheumatoid factor Beta-2-Microglobulin Haptoglobin | Turbidimetry using in-house procedures BI/AU/001 and in conjunction with manufacturer's instructions using: AU 5800 | Serum |
| Serum | Serum free light chains: Free lambda Free kappa C1 Inhibitor antigenic assay | Turbidimetry using in-house procedures IM/M/031, IM/M/037 and in conjunction with manufacturer's instructions using: Optilite SOP IM/M/040 | Serum |



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| HUMAN BODY FLUIDS | <u>Immunological examinations for the purpose of clinical diagnosis</u> | | HRI |
| EDTA Plasma | <u>Immunochemistry</u> C1 inhibitor functional assay | ELISA using Quidel Functional C1e Inhibitor assay kit and in-house procedure IM/M/033 in conjunction with manufacturer's instructions using Triturus plate reader | EDTA Plasma |
| Whole blood EDTA | <u>Immunodeficiency</u> Lymphocyte subsets: <ul style="list-style-type: none"> • CD45/CD3 • CD45/CD3/CD4 • CD45/CD3/CD8 • CD45/CD19 • CD45/CD56/16 • CD45/CD3/CD56/16 • CD45/CD3/TCRalpha-beta • CD45/CD3/TCRgamma-a-delta • CD45/CD3/HLA-DR T cell subsets for HIV monitoring <ul style="list-style-type: none"> • CD45/CD3 • CD45/CD3/CD4 • CD45/CD3/CD8 B Cell subsets <ul style="list-style-type: none"> • CD45/CD19/CD27-/IgD+ • CD45/CD19/CD27+/IgD+ • CD45/CD19/CD27+/IgD- • CD21_{lo} B-cells HLA B27 CD34 | Flow cytometry using in-house procedures IM/C/004, IM/C/006, IM/C/007 in conjunction with manufacturer's instructions using: FC500 flow cytometer | |



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Schedule of Accreditation

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York and Scarborough Teaching Hospitals NHS Foundation Trust

Issue No: 013 Issue date: 23 March 2022

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| HUMAN BODY FLUIDS | <u>Immunological examinations for the purpose of clinical diagnosis</u> | | HRI |
| Heparinised whole blood | <u>Immunodeficiency</u> T-SPOT for TB | Flow cytometry and ELISPOT count using in-house procedures IM/C/031 in conjunction with manufacturer's instructions using: Beckman Coulter FC500 flow cytometer, Microgalaxy CO ₂ Incubator and Zoom XTL-101 stereo microscope. | |
| Heparinised whole blood | Neutrophil function tests: Neutrophil burst test Neutrophil MPO test Reporting proportion of neutrophils positive for DHR activity and MPO staining | Flow cytometry using in-house procedures IM/C/016,IM/C/017 in conjunction with manufacturer's instructions: measured on Beckman Coulter FC500 flow cytometer | |
| EDTA whole blood | Neutrophil function test: Nitroblue tetrazolium test | In-house methodology: Proportion of neutrophils with NBT dye precipitation in slide preparation by light microscopy. Shandon Cytospin 3 and Nikon Eclipse E400 light microscopes | |
| Serum | Total ImmunoglobulinE (IgE): Sp. IgE Tryptase PR3/MPO/GBM antibodies (IgG) | Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 | |
| Serum | Detection and quantification of specific IgE to the following allergens: Timothy grass Bermuda grass Ragweed Mugwort Wall pellitory Plantain | | |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Saltwort Birch Cypress Olive Saltwort Birch <i>Alternaria alternata</i> <i>Aspergillus fumigatus</i> <i>Aspergillus oryzae</i> Dog Cow Cat Horse House dust mite Honeybee venom Common wasp venom Paper wasp venom Latex Pineapple Papaya Egg Maxatase Savinase Pig pepsin Kiwi Cashew nut Celery Peanut Brazil nut Milk Hazel nut Carp</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <u>Immunological examinations for the purpose of clinical diagnosis</u> Detection and quantification of specific IgE to the following allergens: Cod Soy Glycinin Walnut Apple Shrimp Peach Wheat Bovin thyroglobulin Bahia grass Barley Brome grass Canary grass Cocksfoot Common reed Cultivated oat Cultivated rye Cultivated wheat False oat grass Johnson grass Maize corn Meadow fescue Meadow grass Rye grass Salt grass Velvet grass Sweet vernal grass Wild rye grass Alfafa Camomile Careless weed Cocklebur Common ragweed Dandelion Dog fennel | Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens:</p> <p>False ragweed Firebush Giant ragweed Goldenrod Goosefoot Japanese hop Lupin Marguerite Mugwort Nettle Plantain Rape Rough marshelder Saltwort Scale Sheep sorrel Sugar beet Sunflower wall pellitory Western ragweed Wormwood Yellow dock Acacia American beech Australin pine Blad cypress Bayberry Box elder Cedar Cedar elm Chestnut</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Common silver birch Cotton wood Cypress Date Douglas fir Elder Elm Eucalyptus European ash Grey alder Hackberry Hazel Horn beam Horse chestnut Italian/Mediterranean/Funeral cypress Japanese cedar Linden Maple leaf sycamore, Melaleuca Mesquite Mountain juniper Mulberry Oak Oil Palm Paloverde Pecan, Peppertree Pine Privet Queen palm</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Red cedar Red mulberry Russian olive Scotch broom Spruce Sweet gum Walnut White ash White hickory White pine Willow Virginia live oak Acremonium kiliense Alternaria alternata Aspergillus flavus Aspergillus fumigatus Aspergillus niger Aspergillus terreus Aureobasidium pullulans Botrytis cinerea Candida albicans Chaetomium globosum Cladosporium herbarum Curvularia lunata Epicoccum purpurascens Fusarium proliferatum Setomelanomma rostrata Malassezia spp. Mucor racemosus Penicillium chrysogenum Penicillium glabrum</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Phoma betae Pityrosporum orbiculare Rhizopus nigricans Staphylococcal enterotoxin A Staphylococcal enterotoxin B Staphylococcal enterotoxin C Staphylococcal enterotoxin TSST Stemphylium herbarum Tilletia tritici Trichoderma viride Trichophyton mentagrophytes var. goetzii Trichophyton mentagrophytes var. interdigitale Trichophyton rubrum Trichosporon pullulans Ulocladium chartarum Budgerigar droppings Budgerigar feathers Canary bird droppings Canary bird feathers Cat dander Chicken droppings Chicken feathers Chicken, serum proteins Chinchilla epithelium Cow dander Deer epithelium Dog dander Duck feathers Ferret epithelium</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens:</p> <ul style="list-style-type: none"> Ferret epithelium Finch feathers Fox epithelium Gerbil epithelium Goat epithelium Goose feathers Guinea pig epithelium Hamster epithelium Horse dander Horse, serum proteins Mink epithelium Mouse epithelium Mouse epithelium, serum proteins and urine proteins Mouse serum proteins Mouse urine proteins Parakeet droppings Parakeet feathers Parakeet serum Parrot feathers Pigeon droppings Pigeon feathers Rabbit epithelium Rabbit, serum proteins Rabbit, urine proteins Rat epithelium Rat epithelium, serum proteins and urine proteins Rat serum proteins Rat urine proteins Reindeer epithelium | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens:</p> <p>Rat epithelium, serum proteins and urine proteins Rat serum proteins Sheep epithelium Swine epithelium Turkey feathers Storage mite House dust mite Berlin beetle Blood worm Cockroach Fire ant Grain weevil Green nimitti Horse fly Mediterranean flour moth moth Bumble bee venom European paper wasp White faced hornet Amoxicilloyl Ampicilloyl Cefaclor Chlorhexidine Chymopapain Gelatin bovine Insulin bovine Insulin human Insulin porcine Penicilloyl G Penicilloyl V</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Pholcodine Morphine Suxamethonium (succinylcholine) Abachi wood dust Bougainvillea Castor bean Chloramin T Cotton seed Ethylene oxide Ficus Formaldehyde/Formalin Green coffee bean Hexahydrophthalic anhydrid Isocyanate HDI Isocyanate MDI Isocyanate TDI Ispaghula Methyltetrahydrophthalic anhydrid Phthalic anhydride Silk Silk waste Sunflower seed Trimellitic anhydride fish feed Cotton Daphni Seminal fluid Streptavidin Tobacco leaf</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Anisakis Ascaris Apple Apricot Asparagus Aubergine Avocado Persea americana Bamboo shoot Banana Beetroot Blackberry Blueberry Broccoli Brussel sprouts Cabbage Carambola Carrott Cauliflower Cherry Cucumber Fennel Fig Garlic Grape Grapefruit Guava Jack fruit Jujube Kiwi Lemon Lettuce</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Lime Litchi Mandarin (tangerine, clementine, satsumas) Mango Melon Olive (black, fresh) Onion Orange Papaya Passion fruit Pear Persimon Pineapple Plum Potato Pumpkin Raspberry Red currant Rose hip Spinach Strawberry Sweet potato Tomato Watermelon Almond Barley Blue vetch Cashew nut Chickpea Coconut</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <u>Immunological examinations for the purpose of clinical diagnosis</u> Detection and quantification of specific IgE to the following allergens: Common millet Fenugreek Foxtail millet Gluten Green bean Japanese millet Lentil Lima bean Linseed Lupin seed Macadamia Pea Peanut Pecan nut Pine nut Pistachio Poppy seed Pumpkin seed Quinoa Rape seed Red kidney bean Rice Rye Sesame seed Soybean Spelt wheat Sugar-beet seed Sweet chestnut White bean Allspice | Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens:</p> <ul style="list-style-type: none"> Anise Basil Bay leaf Black pepper Caraway Cardamon Chilipepper Clove Coriander Curry Dill Fennel seed Ginger Green pepper Lovage Mace Marjoram Mint Mustard Oregano Paprika Parsley Saffron Sage Tarragon Thyme Vanilla Abalone Anchovy Blue mussel | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Catfish Chub mackerel Clam Crab Crayfish Eel Grouper Gulf flounder Haddock Hake Halibut Herring Jack mackerel Langust Lobster Mackerel Megrin Octopus Orange roughy Oyster Pacific squid Plaice Pollock Red snapper Salmon Sardine Japanese Pilchard Sardinops melanosticta Scallop Shrimp Snail</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Sole Squid Swordfish Tilapia Trout Tuna Walleye pike Whitefish Chicken Gallus spp. Egg white Egg yolk Turkey meat Chicken Cheese, cheddar type Cheese, mold type Cow's whey Goat milk Mare's milk Milk Milk, boiled Sheep milk Sheep whey Carob (E410) Guar, guar gum (E412) Gum arabic (E414) Tragacanth (E413) Cochineal extract (Carmine red) (E120) Cacao Coffee</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Honey Hop Malt Mushroom Tea Yeast</p> <p><u>Food mixes of:</u></p> <p>Peanut, Hazel nut, Brazil nut, Almond, Coconut</p> <p>Fish, Shrimp, Blue mussel, Tuna, Salmon</p> <p>Wheat, Oat, Maize, Sesame seed, Buckwheat</p> <p>Egg white, Milk, Fish, Wheat, Peanut, Soybean</p> <p>Tomato, Yeast, Garlic, Onion, Celery</p> <p>Hazel nut, Brazil nut, Orange, Apple, Cacao</p> <p>Almond, Kiwi, Melon, Banana, Grape</p> <p>Pork, Beef, Egg yolk, Chicken, Turkey</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <p><u>Immunological examinations for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens: Maize, Pea, White bean, Carrot, Broccoli</p> <p>Rye, Rice, Potato, Mushroom, Pumpkin</p> <p>Pea, White bean, Carrot, Potato</p> <p>Tomato, Spinach, Cabbage, Paprika</p> <p>Orange, Apple, Banana, Peach</p> <p>Strawberry, Pear, Lemon, Pineapple</p> <p>Apple, Banana, Pear, Peach</p> <p>Pea, Peanut, Soybean</p> <p>Carrot, Potato, Spinach, Cucumber</p> <p>Wheat, Rye, Barley, Rice</p> <p>Kiwi, Melon, Banana, Peach, Pineapple</p> <p>Pecan nut, Cashew nut, Pistachio, Walnut</p> | <p>Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> | HRI |



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| HUMAN BODY FLUIDS Serum | <u>Immunological examinations for the purpose of clinical diagnosis</u> Detection and quantification of specific IgE to the following allergens: Pork, Beef, Chicken meat, Turkey meat Hazel nut, Shrimp, Kiwi, Banana Sesame seed, Yeast, Garlic, Celery | Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 | HRI |
| HUMAN BODY FLUIDS AND TISSUES Aspirates Cellular and fluid material contained on swabs and cannulae Faeces Fluids (incl. contact lenses fluid) | <u>Microbiology examination for the purposes of clinical diagnosis</u> General isolation of microorganisms of clinical significance. | In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs): Manual inoculation followed by culture using: Ears examination MI/655 Eye examination MI/368 General bench SOP MI/012 Enteric processing MI/380 Campylobacter MI/382 E.coli O157 MI/654 Yersinia MI/657 Vibrio/Pleisiomonas/Aeromonas MI/659 Salmonella MI/660 Shigella MI/665 MI/039 CAPD MI/010 CSF MI/012 ascitic fluids | HRI |



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| HUMAN BODY FLUIDS AND TISSUES | <u>Microbiology examination for the purposes of clinical diagnosis</u> | In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs): | HRI |
| Genital samples | | Genital bench specimen processing MI/662 | |
| Samples from sterile sites | | Prosthetic joint associated tissue samples MI/363 | |
| Tissues | | Clinical and hot bench specimen processing MI/662 | |
| Urine | | General urine methods MI/008 Urine sample processing MI /378 | |
| | Detection, identification and quantification of: | Staining (inc Gram) and microscopic examination using: MI/02 | |
| Aspirates Cellular and fluid material contained on swabs and cannulae Fluids Tissues Cultures isolated in house from the above | White blood cells Red blood cells Bacterial cells Yeast cell and fungal hyphae | | |
| Whole blood | General isolation of microorganisms of clinical significance. | Automated culture using BD BACTEC FX continuous monitoring system MI/009 | |
| Urine | Quantification of white and red blood cells, bacteria and epithelial cells | Automated urine analysis using Sedimax image urine analyser. Sedimax automated image urine analyser MI/1030 | |
| Urine | Quantification of white and red blood cells, bacteria and epithelial cells | Manual Inverted Microscopy/enumeration and manual inoculation using MI/008 general urine methods MI/378 urine sample processing | |



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| HUMAN BODY FLUIDS AND TISSUES | <u>Microbiology examination for the purposes of clinical diagnosis</u> | In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs): | HRI |
| Cerebral fluid samples | Quantification of white and red blood cells and bacteria | Microscopy (inc. Gram Stain) using MI/010 CSF MI/012 Gram stain | |
| Female genital tract swabs | Microscopic diagnosis of bacterial vaginosis | Microscopy examination (Hay's criteria) using: MI/011 MI/662 Genital bench specimen processing | |
| Swabs | Screening for Methicillin resistant <i>Staphylococcus aureus</i> (MRSA) | Manual inoculation and culture using MI/014 Resistance screening MI/667 MRSA/MSSA screening | |
| Sputum | General isolation of microorganisms of clinical significance | Manual inoculation and culture using: Culture media, growth SOP MI/1025 | |
| Bronchial lavage | | Respiratory investigations MI/1026 Manual inoculation and culture using MI/661 resistance screening and: MI/672 | |
| Rectal swabs | Screening for Vancomycin resistant enterococci (VRE) | MI/706 | |
| Faeces | Screening for Extended-spectrum betalactamases (ESBL) | MI/014 | |
| Rectal swabs | Screening for Extended-spectrum betalactamases (ESBL) | MI/705 | |
| Faeces and rectal swabs | Screening for Carbapenamase producing Enterobacteriaceae (CPE) | | |



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| HUMAN BODY FLUIDS AND TISSUES | <u>Microbiology examination for the purposes of clinical diagnosis</u> | In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs): | HRI |
| Faeces and rectal swabs | Trans-rectal screening for Carbapenamase producing Enterobacteriaceae (CPE) and Ciprofloxacin and Gentamicin resistance | MI/705 | |
| Respiratory samples Urine Tissue Swabs (including endoscopy) Body fluids | Presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium spp</i>) | Fluorescent microscopy using Auramine stain. Mycobacterial investigations MI/016 | |
| Respiratory samples Urine Tissue Swabs (including endoscopy) Body fluids | Isolation and presumptive identification of Acid-alcohol fast bacilli (inc <i>Mycobacterium spp</i>) | Automated culture using BD MGIT continuous monitoring system. MI/009 Fluorescent microscopy as above. | |
| Whole Blood | Isolation and presumptive identification of Acid-alcohol fast bacilli (inc <i>Mycobacterium spp</i>) | Automated culture using BD BacTec 40 continuous monitoring system. MI/009 Fluorescent microscopy as above. | |
| Hair, skin, nail | General isolation and characterisation of clinically significant fungi. | Manual culture and Calcofluor white fluorescent microscopy using MI/013 | |
| Cultures isolated in house from the above | Identification of clinically significant bacteria. | Biochemical profile determination using automated Matrix-assisted laser desorption/ionisation (MALDITOF) MI/674 Maldi Biotyper MI/095 VITEK MI/1011 API | |



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Schedule of Accreditation

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Testing performed by the Organisation at the locations specified

| 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 for the purposes of clinical diagnosis</u> | In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs): | HRI |
| Whole blood – positive blood culture specimens | Direct identification of clinically significant bacteria. | Bruker Sepsityper kit using Matrix-assisted laser desorption/ionisation (MALDITOF) MI/674 MaldiBiotyper | |
| Cultures isolated in house from the above | Antimicrobial susceptibility testing of clinically significant bacteria. | Manual disc diffusion and/or automated methods using EUCAST methodology using MI/670 EUCAST method of disc diffusion Gradient MIC determination by E-test using MI/1010 Minimum inhibitory concentration (MIC) method | |
| Fungal cultures isolated in house from the above | Antifungal Susceptibility Testing of Yeasts of clinical significance. | Sensititre YeastOne (Trek Diagnostic Systems) by colourimetric microdilution MIM068 | |
| Culture isolated in house from the above | Identification of Staphylococcal isolates | Prolab Staphylococcal Latex Agglutination kit MI/003 | |
| Culture isolated in house from the above | Serological identification of groups A,B,C,D,F and G of the Lancefield groups of Streptococci grown in agar plates. | Prolex Streptococcal Grouping latex Kit MI/696 | |
| Urine | Detection of Legionella antigen | Binax NOW Legionella Urinary Antigen Test kit by Alere MI/677 | |
| END | | | |