


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>Accredited to ISO 15189:2012</b>	<b>Whittington Health NHS Trust</b> <b>Issue No: 003    Issue date: 18 June 2020</b>	
	<b>Pathology Department</b> <b>5th Floor, K Block</b> <b>Whittington Hospital</b> <b>Magdala Avenue</b> <b>London</b> <b>N19 5NF</b> <b>United Kingdom</b>	<b>Contact: Jayne Fowler</b> <b>Tel: +44 (0)20 72883158</b> <b>E-Mail: Jayne.fowler@nhs.net</b> <b>Website: www.whittington.nhs.uk</b>

**Testing performed at the above address only**

### Site activities performed away from the location listed above

Location details	Site Activity
Whittington Hospital Magdala Avenue London N19 5NF United Kingdom	Mortuary
As above - Thalassemia Unit	Blood storage/issue
As above - Main Theatre	Blood storage/issue
As above - Labour Ward	Blood storage/issue



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#### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS: Serum/ Plasma unless otherwise specified	<u>Biochemistry examination activities for the purpose of clinical diagnosis:</u>	Documented procedures & manufacturer's instructions for Roche Cobas 8000 analyser using manufacturers reagents unless otherwise specified with specific reference to: TP BS 300 004 - Roche Cobas 8000 Operating Procedure
& fluids	Albumin Alcohol ALP ALT Ammonia AST B12 Bile acids Bilirubin C3 C4 Calcium Carbamazepine Chloride Cholesterol CK Conjugated Bilirubin Creatinine CRP Digoxin estimated glomerular filtration rate (eGFR) Ferritin Folate Fructosamine gamma GT Gentamicin Glucose HDL Cholesterol IgG IgM Ionised Calcium Iron	photometric photometric photometric photometric photometric photometric photometric Photometric (Dialab 903120) photometric photometric photometric photometric photometric Ion Selective Electrode photometric photometric photometric photometric photometric calculation  photometric photometric photometric photometric photometric photometric photometric photometric photometric photometric
& fluids		
& fluids		
& fluids		
& fluids/CSF		



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HUMAN BODY FLUIDS (cont'd):  Serum/ Plasma unless otherwise specified  & CSF & fluids  Urine  & Fluids/ Urine  & Fluids/CSF & Urine  Whole Blood (EDTA ) unless otherwise stated	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd).</u>  Lactate LDH LDH Cholesterol Lithium Magnesium Microalbumin Paracetamol Phenytoin Potassium Salicylate Sodium Theophylline Total Iron Binding Capacity (TIBC) Total Bicarbonate Total Protein Uric Acid Valproic Acid Vancomycin Hepatitis B surface antibodies (HbsAb) Hepatitis B surface antigen (HbsAg) Hepatitis C antibody HIV Ab/AG screen Syphilis Total antibody  AFP CA125 CEA Cortisol beta HCG Free T3 Free T4 FAI NT pro BNP Oestradiol Progesterone	Documented procedures & manufacturer's instructions for Roche Cobas 8000 analyser with specific reference to: TP BS 300 004  photometric photometric photometric photometric photometric photometric photometric Ion Selective Electrode photometric Ion Selective Electrode photometric photometric photometric photometric photometric photometric photometric photometric electrohemiluminiscence  electrochemiluminescence electrochemiluminescence electrochemiluminescence chemiluminescence  Documented procedures & manufacturer's instructions for Roche Cobas e602 analyser with TP BS 300 004  electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence



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HUMAN BODY FLUIDS (cont'd): Whole Blood (EDTA ) unless otherwise stated (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's instructions for Roche Cobas e602 analyser with TP BS 300 004
Serum	Prolactin PSA parathyroid Hormone (PTH) SHBG Testosterone Troponin T (high sensitivity)TSH Vitamin D  Detection and identification of serum proteins	electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence electrochemiluminescence  Serum Immunofixation Electrophoresis Documented procedures & manufacturer's instructions for SEBIA HYDRASYS (gel electrophoresis and immunofixation) with specific reference to: TP BS 300 036 – Serum Protein Electrophoresis and TP BS 300 038 – Serum Immunofixation
Urine	Detection of urine monoclonal proteins	Urine Immunofixation Electrophoresis (IFE) Documented procedures & manufacturer's instructions for SEBIA HYDRASYS (gel electrophoresis and immunofixation) with specific reference to: TP BS 300 037 – Urine Protein Electrophoresis and TP BS 300 039 – Urine Immunofixation
Whole Blood (EDTA)	HBA1c	Documented procedures & manufacturer's instructions for Menarini Hb9210 HPLC with specific reference to: TP BS 300 013 - Menarini Hb9210 Operating Procedure



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HUMAN BODY FLUIDS (cont'd):	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures & manufacturer's instructions
Urine/serum	Osmolality	Documented procedures & manufacturer's instructions for Advanced Micro-Osmometer M3320 analyser with specific reference to: TP BS 300 025- Use of Advanced Osmometer M3320
Faeces	Faecal Occult Blood	Documented procedures & manufacturer's instructions for Beckmann Coulter Hemocult oxidation of guaiac acid by H <sub>2</sub> O <sub>2</sub> with specific reference to: TP BS 300 040 - Faecal Occult Blood
Whole Blood (EDTA) unless otherwise stated	<u>Haematology investigation activities for the purpose of clinical diagnosis</u>  Full Blood Count using the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, HCT, MPV, NEUT, LYMPH, MONO, EOS, BASO, NRBC	Documented procedures & manufacturer's instructions for Sysmex XN 2000 analyser with specific reference to: TP BS 300 016
Bone Marrow Aspirate slides and Whole blood EDTA	Microscopic examination for evidence of haematological disease.  Blood films and Bone Marrow films	Documented procedures & manufacturer's instructions for Elitech Aerospray stainer with specific reference to: TP BS 300 001 – Blood Films and Staining Procedures TP BS 300 021 - FBC, Blood Film , Malaria and Bone Marrow Reporting Procedures
	Microscopic examination of thick and thin blood films for detection of malariaparasites	Giemsa staining Leishman Staining using SOP TP BS 300 030 – Malaria Parasite Detection



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Whole Blood (EDTA ) unless otherwise stated</p> <p>Whole Blood (EDTA)</p>	<p><u>Haematology investigation activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Erythrocyte Sedimentation Rate (ESR)</p> <p>Detection of P falciparum HRP2 and pan specific plasmodium LDH</p> <p>Detection of igm heterophile antibodies</p>	<p>Documented procedures &amp; manufacturer's instructions for Vitech StaRRsed Auto Compact ESR analyser (Westergren method) with specific reference to: TP BS 300 050 – Procedure for the Use of the StaRRsed Auto Compact ESR Analyser</p> <p>Documented procedures &amp; manufacturer's instructions for CareStart Malaria Rapydtest with specific reference to: TP BS 300 030 – Malaria Parasite Detection</p> <p>Documented procedures &amp; manufacturer's instructions for Clearview IM Immunochromatographic method with specific reference to: TP BS 300 053 – Glandular Fever Screen</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology investigation activities for the purpose of clinical diagnosis (cont'd)</u>  <u>Antenatal &amp; Newborn Screening</u>  Detection of HbA2, HbF, HbA and other variants such as Hb S,C,D,G,E and other less common variants.	Documented -in-house methods to meet the requirements of the Sickle Cell and thalassemia screening programme(s) as defined in the July 2018 'NHS Sickle Cell and thalassemia screening: laboratory QA evidence requirements'  Documented procedures & manufacturer's instructions for Biorad Variant II HPLC with specific reference to: TP BS 300 048 – Procedure for the Use of the Bio-Rad Variant II Analyser Documented procedures & manufacturer's instructions for Helena Biosciences SAS MX (Agarose Gel electrophoresis) with specific reference to: TI BS 300 057 – Agarose Gel Hb Electrophoresis as confirmatory test detected by BioRad HPLC.
Whole Blood (EDTA ) unless otherwise stated	Sickle solubility test	Documented procedures & manufacturer's instructions for Microgen Bioproducts S test kit Immunochromatographic method with specific reference to: TP BS 300 035 – Sickle Solubility Test



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HUMAN BODY FLUIDS (cont'd)  Plasma (citrated)	<u>Haematology investigation activities for the purpose of clinical diagnosis</u> (cont'd)  Coagulation  Prothrombin Time (PT) INR Activated partial thromboplastin time (APPT) Fibrinogen Partial Thromboplastin Time (PTT) Lupus anticoagulant D-Dimer	Documented procedures & manufacturer's instructions for Sysmex CS-2100i using scattered light detection method with specific reference to: TP BS 300 012 – Procedure for the use of CS-2100i Analyser
HUMAN BODY FLUIDS (cont'd)  Whole Blood (EDTA ) unless otherwise stated	<u>Transfusion investigation activities for the purpose of clinical diagnosis:</u>  Group and antibody screen <ul style="list-style-type: none"> <li>- Automated Blood Groups</li> <li>- ABO and RhD systems:</li> <li>- RhD positive</li> <li>- A RhD positive</li> <li>- B RhD positive</li> <li>- AB RhD positive</li> <li>- RhD negative</li> <li>- A RhD negative</li> <li>- B RhD negative</li> </ul> AB RhD negative	Documented procedures & manufacturer's instructions for IBG Immucor ECHO Lumena analyser, NHSBT Reagents and Lorne Reagents. Solid and liquid phase and haemagglutination assays and manual analyses with specific reference to: TP BT 400 001 – Procedure for the use of the Echo Lumena  TP BT 400 001 – Procedure for the use of the Echo Lumena (Automated) TP BT 400 011 – Blood Grouping (Automated) TP BT 400 002 – Blood Grouping (Manual) using NHSBT reagents TP BT 400 004 – Antibody Investigations (Manual tube method using NHSBT 3-cell screen and Lorne reagent)





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<p>HUMAN BODY FLUIDS (cont'd)</p>	<p><u>Transfusion investigation activities for the purpose of clinical diagnosis: (cont'd)</u></p> <p>Antibody identification (C, c, D, E, e, K, k, Fya, Fyb, Jka, Jkb, S, s, M, N, P1, Lea, Leb, Lu(a), Kp(a))</p> <p>Red cell phenotyping - Blood Groups (phenotyping) (C, c, E, e, K, k, Fya, Fyb, Jka, Jkb, S, s, M, N, P1, Lea, Leb, Lu(a), , Kp(a))</p> <p>Cross match-manual</p> <p>Direct antiglobulin test (DAT) (C3d, IgG)</p>	<p>TP BT 400 004 – Antibody Investigations (Manual tube method using Lorne reagents) TP BT 400 001 – Procedure for the use of the Echo Lumena (Automated)</p> <p>TP BT 400 014 – Red Blood Cell Phenotyping by manual tube method using Lorne and NBS reagents</p> <p>TP BT 400 025 – Cross Matching Serology and TI BT 400 293 – Cross Matching and Red Cell Antibodies</p> <p>TP BT 400 001 – Procedure for the use of the Echo Lumena (Automated) TP BT 400 012 – Direct Antiglobulin Test (Automated) TP BT 400 003 – Direct Antiglobulin Test (Manual)</p>
<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Whole Blood (EDTA ) unless otherwise stated</p>	<p><u>Transfusion investigation activities for the purpose of clinical diagnosis: (cont'd)</u></p> <p>Determination of fetomaternal haemorrhage (Kleihauer)</p>	<p>Clin-Tech Kit manual haemagglutination assay TP BT 400 028 – Kleihauer Test</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum/ Plasma unless otherwise specified</p>	<p><u>Immunology investigation activities for the purpose of clinical diagnosis:</u></p> <p>ANA autoantibody screen Anti CCP Aspergillus igg ab screen Tissue transglutaminase (ttg) Total IgE Specific IgE - Allergens as below Walnut Almond Aspergillus ige Birch pollen Brazil nut Cashew nut Cat dander Cladosporium Coconut Dog dander Egg white Fish (cod) Hazelnut House dust mite Milk Mixed feathers Mixed food Mixed grass Mixed mould Mixed nuts Mixed seafood Mixed tree Mixed weed Peanuts Pecan nut Pistachio Soya bean Wheat</p> <p>ANCA screen</p> <p>anti-Glomerular Basement membrane (GBM)</p>	<p>Documented procedures &amp; manufacturer's instructions for Phadia Immunocap analyser (EIA) with specific reference to: INS 04 - Phadia 250</p> <p>TI MIC 702 206 TI MIC 702 202 TI MIC 702 203 TI MIC 702 201 TI MIC 702 205 TI MIC 702 204</p> <p>Soya bean Walnut Wheat</p> <p>SOP TI MIC 702 211 TI MIC 702 209</p> <p>TI MIC 702 226</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum/ Plasma unless otherwise specified</p>	<p><u>Immunology investigation activities for the purpose of clinical diagnosis: (cont'd)</u></p> <p>Anti-neutrophil cytoplasmic antibody (ANCA) confirmation Antimitochondrial antibodies (M2)</p> <p>anti-Intrinsic Factor (IF)</p> <p>ANA confirmation</p> <p>Autoantibody screen (rat tissue) ENA profile</p>	<p>Documented procedures &amp; manufacturer's instructions for Launch Alegria analyser (EIA) with specific reference to: TP MIC 702 220</p> <p>TI MIC 702 224 Anti-MPO and TI MIC 702 225 anti-PR3</p> <p>TI MIC 702 223</p> <p>Documented procedures &amp; manufacturer's instructions for ASP 1200 automated slide processor and manual fluorescence microscopy with specific reference to: TP MIC 702 210 -ASP 1200</p> <p>New SOP TI MIC 702 212</p> <p>TI MIC 702 213 RAT IIF TP MIC 702 230 – ENA Profile Determination Manual Immunoblot</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Fixed, paraffin-wax processed tissue (diagnostic / biopsy, excision and resection specimens from a variety of anatomical sites throughout the human body)</p> <p>Fixed, paraffin-wax processed tissue (diagnostic / biopsy, excision and resection specimens from a variety of anatomical sites throughout the human body)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house manual methods and manufacturer's instructions documented in the following procedures:</p> <p>Specimen Dissection and decalcification Manual method using documented procedures : TP HIST 600 002 - Dissection Cut Up Procedure TI HIST 600 381 - Protocol For Cut Up of Skin Specimens, TI HIST 600 382 - Protocol for Cut Up of Urological Specimens, TI HIST 600 383 - Protocol for Cut Up of Gastrointestinal Specimens, TI HIST 600 384 - Protocol for Cut Up of Gynaecological Specimens, TI HIST 600 385 - Protocol for Cut Up of Breast Specimens, TI HIST 600 386 - Protocol for Cut Up of Miscellaneous Specimens</p> <p>Supported by Documented procedure &amp; manufacturer's instructions using Tissue Tek VIP6 and Tissue tec VIP 2000 processors TP HIST 600 005 – Tissue Processing VIP2000 and VIP6 Procedures</p> <p>Documented procedure &amp; manufacturer's instructions using THERMO Shandon Histocentre and Tissue Tec embedding centre TP HIST 600 008 - Embedding Procedure</p> <p>Documented procedure &amp; manufacturer's instructions using Leica RM2235, RM2125 and Leiz Microtomes for tissue sectioning TP HIST 600 009 - Microtomy Procedure</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Routine Histopathology examinations to assist in clinical investigations:</u>	In-house manual methods and manufacturer's instructions documented in the following procedures:
FFPE slides (Formalin fixed paraffin embedded)	Routine staining for identification of basophilic and eosinophilic structures	Documented procedure & manufacturer's instructions using Tissue Tec autostainer TP HIST 600 010 - Automated staining
Fresh (unfixed and unprocessed) tissue /Frozen sections	Frozen Section Histology examinations to assist in clinical investigations to detect abnormal cells	Documented procedure & manufacturer's instructions using Leica cryostat CM1850 Cryotomy TP HIST 600 007 - Frozen Sections HIST 600 574 – (rapid) H&E staining TP-HIST 600 048 Oil-Red-O
Fixed, paraffin-wax processed tissue	Special tinctorial staining of Histopathology examinations to assist in detection of clinical abnormalities	In House manual methods manual technique (dye chemistry / dye tissue interaction) and light microscopy (reporting).
	Detection of weakly sulphated and acidic mucins	Alcian Blue (AB) technique TI HIST 600 574 Acian Blue (with PAS +/- amylase)
	Detection of amyloid	Congo Red technique TI HIST 600 576 Congo Red
Fixed, paraffin-wax processed tissue	Detection of elastic connective tissue fibres	Elastic van-Gieson (EVG) (Miller's) technique – TI HIST 600 578-Elastic Van Gieson
	Detection of reticulin connective tissue fibres	Gordon and Sweets silver technique TI HIST 600 590-Retic
	Detection of organisms	Gram technique TP HIST 600 580



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HUMAN BODY FLUIDS (cont'd)	<u>Routine Histopathology examinations to assist in clinical investigations: (cont'd)</u>	In House manual methods manual technique (dye chemistry / dye tissue interaction) and light microscopy (reporting).
Fixed, paraffin-wax processed tissue	Detection of fungi	Grocott Hexamine Silver technique DLPATH53 TP HIST 600 581-Grocott
	Detection of iron / haemosiderin	Perls Prussian Blue technique TP HIST 600 589 Perls
	Detection of melanin and argetaffin granules	Masson Fontana silver technique TI HIST 600 583 Masson Fontana
	Detection of carbohydrate	PAS and DPAS TI HIST 600 588 PAS (+/- diastase)
	Detection of glycogen, mucopolysaccharide components, fungi and basement membranes	Periodic Acid-Schiff (PAS) technique TP HIST 600 026
	Detection of glycogen	Diastase Periodic Acid-Schiff (D PAS) technique TI HIST 600 588 PAS (+/- diastase)
	Detection of iron	Perls Prussian Blue TI HIST 600 589-Perls
	Detection of Hepatitis B surface antigen, copper associated protein	Shitata's Orcein TI HIST 600 586- Orcein
	Detection of mast cells / metachromatic tissue components	Toluidine Blue technique TI HIST 600 592-Toluidine Blue
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	Microscopy TP-HIST-040-Reporting procedures TP CYTO 600 103- Reporting Responsibility and Quality Control



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HUMAN BODY FLUIDS (cont'd)	<u>Cytology(Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	Processing of cellular preparations using manufacturer's instructions for Thermo Cytospin, automated stainer Tissue Tek Prisma TP CYTO 600 118 – Rapid Papanicolaou Stain on the Rack
Bronchial washings/bronchial lavage	Detection of cell populations and/or abnormal cells and/or infection	TP CYTO 600 109 – Preparation of Bronchial Washings
Bronchial Brushings	Detection of abnormal cells	TP CYTO 600 110 – Preparation of Brush Specimens
Sputum	Detection of abnormal cells and/or infection	TP CYTO 600 108 – Preparation of Sputum
Cerebrospinal Fluid (CSF)	Detection of cell populations and/or abnormal cells and/or infection	TP CYTO 600 113 – Preparation of CSF
Fine Needle Aspirates from solid organs- Gastro-Intestinal (GI) brushings, Urine, Cyst fluid, Serous effusion/Peritoneal washings	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	TP CYTO 600 114 – Preparation of FNA TP CYTO 600 110 - Gastro-Intestinal (GI) brushings TP CYTO 600 112- Urine TP CYTO 600 112 - Cyst fluid TP CYTO 600 111 - Serous effusion/Peritoneal washings TP CYTO 600 103- Reporting Responsibility and Quality Control TP CYTO 600 121 Preparation of Cell Block Using the Shandon Cell Block System
Synovial Fluids	Detection and identification of Crystals of Monosodium urate Calcium pyrophosphate Basic Calcium Phosphate Cholesterol	TP CYTO 600 116 -Preparation and microscopy of Synovial fluids Using Polarising crystallography Microscopes
Inter-operative sentinel Lymph node	Detection of cell populations and/or abnormal cells and/or infection	Processing of lymphnodes using commercial Kit and DISF-Quick Stain TP CYTO 600 123 -Interoperative Sentinel node
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	Microscopy TP CYTO 600 103- Reporting Responsibility and Quality Control



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<p><b>HUMAN BODY FLUIDS (cont'd)</b></p> <p>Swabs from various body sites, and various body specimens: Wound swabs including swabs from other body sites, sterile ascitic and joint fluids, small fragments of bone and tissue taken at operation, IV Cannula tips</p> <p>Respiratory samples (Sputum, bronchial alveolar lavage, pleural fluid)</p> <p>Swabs from human tissue and body fluids</p> <p>Swabs from genital samples</p> <p>CSF</p> <p>Urine</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis</u></p> <p>General isolation and characterisation of micro-organisms of clinical significance</p> <p>Presence of white blood cells, organisms and epithelial cells</p> <p>Detection of white blood cells, yeast cells and Trichomonas vaginalis</p> <p>Quantification of white and red blood cells and culture</p> <p>Semi quantitative assessment of white and red blood cells, bacteria and epithelial cells</p>	<p>Documented in house method using culture and microscopy in conjunction with PHE guidelines TP MIC 701 501 Skin and Wound infections, Pus and exudates and Genital tract samples TP MIC 701 502 Sterile tissue and fluids, bone, orthopaedic samples and catheter tips TP MIC 701 503 Ear, nose throat, eye and oral samples TP MIC 701 403 – – Respiratory Samples</p> <p>Gram stain and manual microscopy 501 Skin and Wound infections, Pus and exudates and Genital tract samples TP MIC 701 502 Sterile tissue and fluids, bone, orthopaedic samples and catheter tips TP MIC 701 503 Ear, nose throat, eye and oral samples</p> <p>TP MIC 701 100 Staining methods</p> <p>Wet prep and Gram stain. Manual microscopy. MG 064 Genital samples using Hays criteria TP MIC 701 501 Skin and wound infections, Pus and exudates and Genital tract samples, TP MIC 701 100 Staining Methods</p> <p>Documented in house method using Neubauer counting chamber and manual culture SOP TP MIC 701 500</p> <p>Documented in house method in conjunction with PHE guidelines using manual inverted microscopy TP MIC 701 300</p>





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HUMAN TISSUE and BODY FLUIDS as specified	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
Urine	General isolation of micro-organisms of clinical significance	Documented in house method in conjunction with PHE guidelines TP MIC 701 300
Faeces	General isolation and characterisation of Salmonella, Shigella, Campylobacter & E. coli O157	Documented in house method in conjunction with PHE guidelines Manual culture TP MIC 701 303 Culture of Faeces samples
Faeces	Detection of enteric pathogens using PCR	TP MIC 700 611 Operation of BD MAX Enteric PCR TI MIC 701 307
Faeces	Detection of <i>Clostridium difficile</i> GDH antigen and toxin A/B detection	Documented in house method in conjunction with manufacturer's instructions using KIT (ELISA) on Launch DS2 analyser and single test device EIA. TP MIC 700 615 – DS2 Procedures. TI MIC 701 702 TP MIC 700 706 GDH testing by Immunocard TI MIC 701 704 C.difficile toxin testing
Faeces	Detection of Helicobacter pylori antigen	Documented in house method in conjunction with manufacturer's instructions using KIT(ELISA) on Launch DS2 analyser TP MIC 700 615 – DS2 Procedures SOP TI MIC 701 703 Helicobacter antigen testing
Faeces	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Documented in house method Formol ether concentration using Parasep system and manual microscopy TP MIC 701 309 Examination for Parasites



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**Whittington Health NHS Trust**  
Issue No: 003 Issue date: 18 June 2020

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and BODY FLUIDS as specified (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
Culture of isolates	Identification of clinically relevant isolates  Streptococci Staphylococci Enteric pathogens  Actinomyces  Pseudomonas Neisseria HACEK organisms C.diphtheria B.pertussis	Documented in house identification methods (biochemical, serological, growth requirement, inhibition) in conjunction with manufacturer's instructions using MALDI ToF. TP MIC 700 605 MALDI-TOF TP MIC 701 100 Staining Methods TP MIC 701 103 Streptococcal ID TP MIC 701 104 TP MIC 701 303 MB 040 API protocols MB 098 Actinomyces MB 102 Miscellaneous tests MB 104 Pseudomonas MG 031 Neisseria MR 087 HACEK organisms MW 028 C diphtheriae MW 049 Bordetella
Swabs from nose and perineum	Isolation of MRSA	Documented in house method chromogenic agar culture TP MIC 701 700 Cross-infection screening (MRSA)
Respiratory samples sputum, bronchoalveolar lavage, tissue	Detection of microbial growth and isolation of Mycobacteria sp.	Becton Dickinson Bactec MGIT Fluorimetric growth detection. TP MIC 701 406 operation of MGIT And Culture of mycobacterium species including auramine phenol staining AAFB microscopy
Respiratory samples sputum, bronchoalveolar lavage, tissue	General isolation of micro-organisms of clinical significance	Documented in house method using culture and microscopy in conjunction with PHE guidelines TP MIC 701 403 Culture of Respiratory Samples
Positive vials and Mycobacterial cultures isolated in-house	Detection of Mycobacterium tuberculosis complex and Rifampicin Resistance	Documented in house method in conjunction with manufacturer's instructions for Cepheid GeneXpert INS 10 – GeneXpert and MT 07 MTB/rif PCR



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and BODY FLUIDS as specified (cont'd)	<u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
Nasopharyngeal aspirate and Nose/throat swabs	detection of Flu A/B and RSV (RNA)	Documented in house method in conjunction with manufacturer's instructions for Focus Simplexa intergrated cyler SOP TI MIC 701 705 Simplexa Flu A/B & RSV
Skin scrapings and nail clippings	General isolation and characterisation of fungi of clinical significance	Documented in house methods using manual culture and microscopy TP MIC 701 413 Mycology Methods
Clinical isolates from human tissue and body fluids	antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	Documented in house methods using EUCAST method and Etests MIC 701 203- Sensitivity Testing MB 051 - E-tests
Urine / Endocervical swabs/ eye swabs/rectal swabs	Detection of Chlamydia trachomatis /Neisseria gonorrhoeae	Documented in house method in conjunction with manufacturer's instructions for BD Viper (strand displacement amplification) TP MIC 701 630- Operation of the BD Viper MT 01
Anogenital lesion swabs	Detection of Herpes simplex 1 & 2	Documented in house method in conjunction with manufacturer's instructions for BD Viper (strand displacement amplification) TP MIC 701 630- Operation of the BD Viper and MT 02



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HUMAN BODY FLUIDS	<u>Serology examination activities for the purposes of clinical diagnosis</u>	Documented procedures & manufacturer's instructions for BioMerieux Vidas analyser (EIA) with specific reference to: TP MIC 702 320 Vidas Operation
Serum unless otherwise stated	Hepatitis C antibody confirmation Toxoplasma IgG VZV IgG	TI MIC 702 327 TI MIC 702 323 TI MIC 702 322
	<u>Antenatal &amp; Newborn Screening</u>	Documented -in-house methods to meet the requirements of the Sickle Cell and thalassaemia screening programme(s) as defined in the July 2018 'NHS Infectious diseases in pregnancy screening: laboratory QA evidence requirements'
	HIV Ab/AG confirmation Hepatitis B core total antibody	TI MIC 702 326 TI MIC 702 329 Hep B Markers on VIDAS
	Hepatitis B e antigen Hepatitis B e antibody Hepatitis B core IgM Hepatitis surface antigen (HBsAg)	
	Syphilis IgM	Documented procedures & manufacturer's instructions for Launch DS2 analyser (EIA) with specific reference to: TP MIC 700 615 Operation of DS2 TP MIC 702 335 Syphilis IgM
	TPPA Syphilis confirmation test	Documented procedures & manufacturer's instructions for manual agglutination. – TP MIC 702 333 TPPA
	Semi-quantitative detection of RPR	Documented procedures & manufacturer's instructions for manual agglutination Randox SYP RPR – MS 017



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HUMAN BODY FLUIDS (cont'd)  Semen	<p><u>Andrology examination activities for the purposes of clinical diagnosis</u></p> <p>Post vasectomy semen analysis Detection of the presence or absence of spermatazoa</p> <p>Sperm concentration, volume and count</p> <p>Sperm motility</p> <p>Assessment of sperm morphology</p>	<p>Documented in house methods SOP TP MIC 701 600 –Semen Analysis in conjunction with British Andrology Society guidelines for the assessment of post vasectomy semen samples (2002)</p> <p>WHO 5<sup>th</sup> Ed Examination and processing of human semen (2010) Documented in house method SOP TP MIC 701 600 –Semen Analysis using Improved Neubauer counting chamber</p> <p>Documented in house method, SOP TP MIC 701 600 –Semen Analysis, using phase contrast Microscope with heated stage.</p> <p>Manufacturer's instructions for Tissue Tek Prisma stainer and documented in house methods Papanicolaou stain TP CYTO 600 118 and TP CYTO 600 115 - Preparation and Morphology of Semen Specimens</p>
END		