


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8118 Accredited to ISO 15189:2022	Kettering General Hospital NHS Foundation Trust	
	Issue No: 018 Issue date: 20 November 2025	
	Pathology Kettering General Hospital Rothwell Road Kettering NN16 8UZ	Contact: Caroline Parkes Tel: +44 (0) 1536 492825 Fax: +44 (0) 1536 492704 E-Mail: caroline.parkes@nhs.net Website: www.kgh.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Site activities performed away from the locations listed above:

Location details	Activity	
North Northamptonshire Council, Kettering Area Offices Bowling Green Road Kettering NN15 7QX	Local contact Simon Hewson	Phlebotomy
Nene Park Outpatient Services Nene Park Attley Way Irthlingborough NN9 5GF	Local contact Simon Hewson	Phlebotomy
Isebrook Hospital Irthlingborough Road Wellingborough NN8 1LP	Local contact Simon Hewson	Phlebotomy
Nuffield Diagnostic Centre Cottingham Road Corby NN17 2UW	Local contact Simon Hewson	Phlebotomy



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Testing performed at the above address only

Additional site activity performed away from the laboratory:

Location details	Activity
Kettering General Hospital	Phlebotomy
Maternity Unit	Blood Issue Fridge

Site activities performed away from the locations listed ab

Location details	Activity	
Address Histology Archives Kettering General Hospital Rothwell Road Kettering NN16 8UZ	Local contact Fiona Yalvac Tel: +44 (0) 1536 491518 f.yalvac@nhs.net	Histology Archives Storage of records only



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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	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for
Serum/Plasma/Urine	Quantitative determination of: Sodium Potassium Chloride	Roche Cobas 8000: ISE Module (ion selective electrodes) LP-BIO-702 Assays
Serum/Plasma	Albumin Alkaline Phosphatase ALT Amylase AST Bicarbonate Bilirubin Cholesterol Creatine Kinase (CK) C Reactive Protein Enzymatic Creatinine Gamma GT Gentamicin HDL Cholesterol LDH Paracetamol Salicylate Theophylline Total Protein Triglyceride	Roche Cobas 8000: 702 Module (multi assay photometry) LP-BIO-702 Assays
Serum/Plasma/Urine	Calcium Magnesium Phosphate	
Urine Serum/Plasma/Urine	Creatinine Ethanol	
Serum/Plasma/CSF	Glucose	
Serum/Plasma/Urine	Urea Uric acid	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for
Urine/ CSF	Albumin Total Protein	Roche Cobas 8000: 702 Module (multi assay photometry) LP-BIO-702 Assays
Serum/Plasma	Iron UIBC Vancomycin	
Serum	Bile acids Lithium Teicoplanin	
Serum/Plasma	Direct bilirubin	
Plasma	Ammonia	
Serum, plasma	Specific Proteins: IgG IgA IgM C3 C4	and LP-IMM-IgG/A/M LP-IMM-C3/C4
Serum, plasma	Specific Proteins: Alpha-1-Antitrypsin Haptoglobin Transferrin	
Plasma	Lactate	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturer's instructions for
Serum/Plasma	Quantitative determination of: (cont'd)	Roche Cobas 8000: 801 Module (sandwich and competitive chemiluminescent immunoassay) LP-BIO-801 Assays (cont'd)
	FT4 FT3 hCG LH Procalcitonin Progesterone Prolactin PSA SHBG Testosterone TSH Vitamin B12 Vitamin D	
Serum	PTH Troponin	
Serum	sFLT:PLGF Ratio	LP-BIO-sFLT PLGF
Whole Blood	HbA1c	TOSOH G11 (ion exchange chromatography) LP-BIO-HbA1c
Serum/Plasma/Urine	Osmolality	Vitech OSMO1 Osmometer (freezing point depression) LP-BIO-OSMO
Sweat	Sweat Test Chloride	Wescor Chlorochek Model 3400 LP-BIO-Sweat Chloride Analysis
Urine	5HIAA	Agilent 1260 using reverse phase HPLC with electrochemical detection LP-BIO-5HIAA
Urine	Metanephrines	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u>	Documented in house methods and manufacturer's instructions for
		<i>Documented in-house methods to meet the requirements of the Fetal Anomaly Screening Programme as defined in laboratory QA evidence requirements (tests marked *)</i>
Serum only	<i>First Trimester Downs Screening:</i> PAPP-A* Free bhCG*	Revvity DelfiaXpress (fluorometric immunoassay) LP-BIO-First Trimester Analysis
Serum	<i>Second Trimester Downs Screening-:</i> UE3 and Inhibin-A*	Beckman Coulter Access 2 (chemiluminescent immunoassay) LP-BIO-Inhibin A and UE3 analysis LP-BIO-Second Trimester Analysis
Serum	AFP*	Roche Cobas 8000: 801 Module (sandwich and competitive chemiluminescent immunoassay)
Serum	hCG*	LP-BIO-Second Trimester Analysis
Faeces	Calprotectin	Thermo ImmunoCAP 250 EliA Calpro2 (fluorometric immunoassay) LP-BIO-Faecal Calprotectin LP-IMM-FCAL
CSF	Xanthochromia	Northstar Scientific BIO-UV Spectrophotometer (spectrophotometry) LP-BIO-CSF Xanthochromia
Whole blood	pH pCO2 pO2 tHb and derivatives Sodium Potassium Chloride Lactate Glucose Ionised calcium	Radiometer ABL90 Blood Gas Analyser (ion selective electrodes and co-oximetry) LP-POCT-ABL90 Blood Gas Analyser



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum/Plasma</p> <p>Whole Blood</p> <p>Urine</p>	<p><u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Calculated Tests for the purposes of clinical diagnosis:</p> <p>eGFR (MDRD) eGFR (Cockcroft & Gault) AKI Score TIBC Transferrin Saturation Adjusted Calcium LDL Cholesterol:HDL Ratio Non-HDL Cholesterol Free Androgen Index</p> <p>Standard Bicarbonate Actual Bicarbonate Base Excess</p> <p>ACR PCR</p> <p>24hr Urine Excretions: Total Protein Urea Creatinine Sodium Potassium Calcium Chloride Phosphate Magnesium Urate</p> <p>5-Hydroxyindoleacetic acid</p>	<p>Documented in house methods and manufacturer's instructions for</p> <p>LP-BIO-Calculated Tests</p> <p>By calculation</p> <p>By calculation</p> <p>By calculation</p>
<p>Serum/Plasma & Urine</p>	<p>Calcium/Creatinine Clearance Ratio Creatinine Clearance</p>	<p>By calculation</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood Plasma	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative	Automated using BioRad IH-1000 and manual column agglutination using BioRad cards SOP: IH SOP LP-BTR-IH1000, LP-BTR-ManualGel, LP-BTR-GrpScreenProbs
Blood Plasma	Antibody Screen by detection of antibodies to: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	Automated using BioRad IH-1000 SOP: IH SOP LP-BTR-IH1000 LP-BTR-GrpScreenProbs
Blood Plasma	Antibody Screen by detection of antibodies to: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	Manual column agglutination using BioRad cards LP-BTR-ManualGSGel,



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood Plasma	Compatibility testing of patient's plasma with donor cells	Automated using BioRad IH-1000 analyser SOP:LP-BTR-Compatibility, LP-BTR-MassTrans, LP-BTR-TxNeoInf, LP-BTR-EmergBlood, LP-BTR-SeroIXM
Blood Plasma	Compatibility of testing patient's plasma with donor cells	Manual column agglutination using BioRad cards SOP:LP-BTR-Compatibility, LP-BTR-TxNeoIn, LP-BTR-EmergBlood
	Compatibility of testing patient's plasma with donor cells	Electronic issue SOP LP BTR Compatibility
Blood	Direct Antiglobulin Test (DAT)	IH-1000 BioRad LP-BTR- <u>PaedSamples</u>
Blood	Direct Antiglobulin Test (DAT)	Manual Column agglutination using BioRad cards LP-BTR-DAT
Blood Plasma	Antibody identification Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	IH-1000 BioRad SOP: LP-BTR-AnttiInvestGel
Blood	Detection of foetal cells in maternal circulation	Manual method using Source Guest Medical acid elution kit SOP: LP-BTR-Kleihauer



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Erythrocyte Sedimentation Rate (ESR)	Starssted Interrliner SOP: LP-HAE-ESR, LP-HAE-ManESR
Plasma Serum	Glandular Fever Screen – detection of infectious mononucleosis antibodies	Biokit Monogen commercial kit, latex micro particle immunoassay SOP: LP-HAE-IMScreen
Blood	G6PD	Commercial (Trinity Biotech) kit, functional enzyme colourimetric assay LP-HAE-G6PD
Blood	Full Blood Count (FBC) analysis of the following parameters: WBC RBC HGB HCT MCV MCH MCHC RDW-CV PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count	Sysmex XN automated analysers, differential laser light scatter SOP: XN-9000



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood</p> <p>Bone Marrow</p> <p>Blood</p> <p>EDTA Blood</p>	<p><u>Morphology and immunophenotyping examinations for the purpose of clinical diagnosis</u></p> <p>Blood film and staining</p> <p>Bone marrow film staining</p> <p>Detection & speciation (thin films) of malaria parasites:</p> <p><i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> <i>Plasmodium ovale</i> <i>Plasmodium vivax</i> <i>Plasmodium knowlesi</i></p> <p>Differential detection: P. falciparum</p> <p>Pan detection for: Plasmodium malariae, Plasmodium ovale and Plasmodium vivax.</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Romanowski Staining Manual RAL stainer SOP-HAE-ManStain LP-HAE-RALStainer</p> <p>or automated using Sysmex SP1000i (SP-10) LP-HAE-SP10</p> <p>May Grunwald-Giemsa staining Manual LP-HAE-BMarrow RAL stainer LP-HAE-RALStainer</p> <p>Preparation of thick and thin films, manual Romanowski staining and light microscopy LP-HAE-FilmExam</p> <p>CareUs Malaria Rapydtest using combined HRP2/PLDH technology LP-HAE-Malaria</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haemoglobinopathy examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: Documented in-house methods to meet the requirements of the SCT Screening Programme as defined in the July 2018 version of 'Sickle Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements'
Blood	Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: Hb A2 Hb F Hb S Hb C Hb D Punjab Hb E	TOSOH G8, HPLC LP-HAE-HPLC LP-HAE-ANHBEP
Blood	Sickle cell solubility	Sickle Check Commercial Kit (HD Supplies, Buckingham) SOP: LP-HAE-Sickle



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<p>HUMAN BODY FLUIDS/TISSUE</p> <p>Urine</p> <p>Cerebro spinal fluid</p> <p>Faeces</p> <p>Urine</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis</u></p> <p>Detection, identification & quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts</p> <p>Isolation of clinically significant bacteria and fungi</p> <p>Detection, identification and quantification of: White blood cells Red blood cells, Bacterial cells</p> <p>Detection & identification of ova, cysts and parasites</p> <p><i>Schistosoma haematobium</i> ova</p>	<p>In house documented methods based on UK Standards for Microbiology Investigations (UK SMIs) and incorporating manufacturers' instructions where relevant</p> <p>Automated urinalysis for presence and enumeration of cells using IQ 200 LP-MIC-BSOP 41 Urines and LP-MIC-SOP 102 Use of Sprint Urine Analyser</p> <p>Manual culture using LP-MIC-BSOP 41 Urines</p> <p>Microscopic examination using counting chamber. LP-MIC-SOP- 43 CSF</p> <p>Parasep concentration (faeces only) followed by microscopic analysis Using LP-MIC-SOP- 016 Parasitology</p>



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>Swab, fluid, pus, respiratory samples faeces, tissue, bone, contact lenses, IUCD, seminal samples.</p> <p>Skin, hair, nails</p> <p>Swabs, urine, sputum</p> <p>Blood</p>	<p><u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Isolation of clinically significant bacteria</p> <p>Isolation of clinically significant fungi</p> <p>MRSA screening Staph screening</p> <p>Isolation of clinically significant bacteria</p>	<p>In house documented methods based on UK Standards for Microbiology Investigations (UK SMIs) and incorporating manufacturers' instructions where relevant</p> <p>Manual culture and microscopy using: LP-MIC-BSOP 54 Inoculation of culture media LP-MIC-SOP 12 Micro methods LP-MIC-BSOP 1 ear</p> <p>LP-MIC-BSOP 26 Fluids from sterile sites LP-MIC-BSOP 14 Pus and exudates LP-MIC-BSOP 2 eye LP-MIC-BSOP 4 Mouth LP-MIC-BSOP 5 nose LP-MIC-SOP 26 Catheter Tips LP-MIC-BSOP 11 Skin and Superficial Wounds LP-MIC-BSOP 2 BAL LP-MIC-BSOP 17 Tissue, Biopsy and Bone LP-MIC-BSOP 9 Throat LP-MIC-BSOP 8 sputum LP-MIC-SOP-065 Faeces culture.</p> <p>LP-MIC-BSOP 28 Genital tract specimens.</p> <p>Manual culture and microscopy using: LP-MIC-BSOP 42-Mycology</p> <p>LP-MIC-BSOP 29 MRSA and MSSA Screening</p> <p>Automated culture using Biomerieux BacT/Alert VirtuO. LP-MIC-SOP VirtuO</p>



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Microbiological examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on UK Standards for Microbiology Investigations (UK SMIs) and incorporating manufacturers' instructions where relevant
Sputum, pus, urine, sterile fluids, bronchial aspirates/lavage	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	Automated culture using Biomerieux BacT/Alert 3D followed by staining of slides by either auramine-phenol, or Gram stain and microscopy. LP-MIC-BSOP 40 Mycobacteria
Organism isolates	Determination of bacterial susceptibility to a range of antibiotics.	Sensitivity testing following EUCAST guidelines LP-MIC-SOP Sens testing EUCAST
Pathogenic isolates	Determination of bacterial and <i>Candida</i> spp. susceptibility to a range of antimicrobial agents	Biomerieux Vitek 2 LP-MIC-SOP 92 VITEK 2
Pathogenic isolates: bacteria and yeasts	Identification of bacteria and yeasts	Automated: BioMerieux Vitek 2 LP-MIC-SOP 92 VITEK 2 Manual: LP-MIC-SOP 010 Ident Method
		BioMerieux Vitek MS analyser using mass spectrophotometry LP-MIC-SOP Vitek MS



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Serological examination activities for the purpose of clinical diagnosis</u>	In house documented methods based on UK Standards for Microbiology Investigations (UKSMIs) and incorporating manufacturers' instructions where relevant
Faeces	Detection of antigens of pathogenic micro-organisms: Rotavirus	Membrane immunochromatographic assay using: Meridian Immunocard STAT Rotavirus SOP LP-MIC-SOP 60 Rotavirus
Faeces	C difficile toxins A & B	Immunocard Toxins A&B SOP LP-MIC-SOP 141. C.dif Immunocard Toxins AB
Faeces	Cryptosporidium/giardia lamblia	RIDA Quick Cryptosporidium/giardia Combi Kit LP-MIC-SOP 111 CGF Confirmation
Faeces	Detection of: Clostridioides (formerly Clostridium) difficile GDH antigen	Gemini ELISA platform LP-MIC-SOP Gemini ELISA using: Meridian Premier C. difficile GDH assay SOP: GDH LP-MIC-SOP 132 C.difficile GDH
Faeces	Helicobacter pylori antigen	Premier H. pylori Stool Antigen EIA assay SOP: LP-MIC-SOP 78 HpSA
Serum	Varicella zoster virus IgG	Serion ELISA classic Varicella-Zoster Virus IgG assay SOP: LP-MIC-SOP 147 VZV IgG EIA
Serum	Measles IgG	Virion/Serion Measles IgG assay SOP: LP-MIC-SOP 107 Measles IgG Serion ELISA
Heparinised whole blood	Interferon gamma release	QuantiFERON-TB Gold Plus (QFT-Plus) assay SOP: LP-MIC-SOP 79 Quantiferon TB Gold
Faeces	Giardia lamblia Cryptosporidium	IVD Giardia/Cryptosporidium Combo Antigen kit SOP: LP-MIC-SOP 112 CGF ELISA



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	In house documented methods based on UK Standards for Microbiology Investigations (UK SMIs) and incorporating manufacturers' instructions where relevant
GU swabs, urine	Detection of ribosomal RNA from pathological samples: Chlamydia trachomatis, Neisseria gonorrhoeae	Nucleic acid amplification technique (NAAT) using Hologic Panther system and Cepheid GeneXpert (PCR) LP-MIC-SOP-CT GC-Panther LP-MIC-SOP-CT NG PCR LP-MIC-SOP 116 Panther Operation
Faeces samples	Detection of bacterial DNA sequence in stool <i>C difficile</i>	Realtime PCR Cepheid Genexpert. LP-MIC-SOP C.dif PCR
Faeces	Detection of Norovirus Genogroup I and II	PCR using Xpert Norovirus assay and the Cepheid Genexpert LP-MIC-SOP Norovirus PCR
Urine/Endocervical or vaginal swab	Detection of Trichomonas vaginalis	PCR using Xpert TV assay and the Cepheid Genexpert LP-MIC-SOP TV PCR
Nose swabs, nasopharyngeal swabs, Sputum, BAL	Detection of SARS-CoV-2 RNA, specific gene sequences: N2 and E genes	PCR using Cepheid GeneXpert and Xpert Xpress SARS CoV2 assay LP-MIC-SOP Xpress SARS CoV2
Nose swabs, nasopharyngeal swabs	Detection of: SARS-CoV-2 RNA, specific gene sequences: N2 and E genes, FluA FluB RSV	PCR using Cepheid GeneXpert and Xpert Xpress SARS CoV2/Flu/RSV assay SOP-LP-MIC-SOP Xpress SARS CoV2/Flu/RSV Flu/RSV assay SOP-LP-MIC-SOP Xpress Flu RSV PCR
Nose swabs	Detection of MRSA	PCR using Cepheid GeneXpert and Xpert MRSA NxG LIP-MIC-SOP Xpert MRSA



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>Nose and nasopharyngeal swabs</p> <p>Urine</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of Respiratory Pathogens: Adenovirus Influenza A (and subtypes H1, H1-2009 and H3) Influenza B Coronavirus 229E Coronavirus OC43 Coronavirus NL63 Coronavirus HKU1 MERS Coronavirus Rhinovirus Parainfluenza virus types 1, 2, 3 and 4 Respiratory Syncytial Virus Bordetella pertussis Bordetella parapertussis Chlamydia pneumoniae Mycoplasma pneumoniae Human metapneumovirus 8 SARS-CoV-2 RNA, specific gene sequences: S and M</p> <p>Detection of the following antigens:</p> <p>Streptococcus pneumoniae</p> <p>Legionella pneumophila (serogroups 1, 3, 4 and 6)</p>	<p>In house documented methods based on UK Standards for Microbiology Investigations (UK SMIs) and incorporating manufacturers' instructions where relevant</p> <p>Biofire Filmarray using multiplex nucleic acid test (FilmArray RP2.1+ (Respiratory) Panel) LP-MIC-SOP FilmArray Respiratory</p> <p>Quidel Sofia using fluorescence immunoassay</p> <p>MP-MIC-SOP Sofia Pneumococcal FIA MP-MIC-SOP Sofia Legionella FIA</p>



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<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, resection</p> <p>Tissue: biopsy, excision, resection specimens</p> <p>Formalin fixed paraffin wax blocks of processed tissue.</p> <p>Tissue for frozen sections</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>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Specimen dissection – LP-HIS-SOP-General cut up Cassette writer (Thermo Scientific Print Mate AS) – LP-HIS-SOP- Labelling Cassettes</p> <p>Tissue processing Leica HistoCore PELORIS 3 Tissue processors</p> <p>LP-HIS--GEN-Leica Peloris Use</p> <p>Decalcification: LP-HIS-Decals</p> <p>Tissue Embedding Using Thermo Histostar embedding centre LP-HIS-SOP-Embedding procedure</p> <p>Tissue Sectioning Using Leica HistoCore & RM2235 microtomes -LP-HIS-SOP-Sectioning</p> <p>Cryotomy Intra-operative frozen sections Using Leica Cryostat CM1950 section staining – Rapid H&E LP-HIS-SOP-Frozen sections</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Routine morphological staining For the detection of: Basophilic and eosinophilic structures	Routine morphological staining Using Leica SPECTRA autostainer and Leica SPECTRA Coverslipper LP-HIS-SOP Histology Staining Machine Use and Maintenance LP-HIS-SOP-Leica SPECTRA Coverslipper LP-HIS-Histology Staining machine use and maintenance LP-HIS-SOP-checking out H&E sections Frozen Section Staining (Rapid H&E) LP-HIS-SOP-Frozen sections
FFPE slides	Special stains for the detection of: Acid Mucopolysaccharides Acid and Neutral Mucopolysaccharides Neutral Mucopolysaccharides Amyloid Reticulin fibres Gram positive and negative microorganisms	Documented in-house procedures for manual special stains Alcian Blue -LP-HIS-SOP-Alcian blue Alcian Blue/PAS -LP-HIS-SOP-Alcian blue PAS Diastase PAS -LP-HIS-SOP-DPAS Congo Red - -LP-HIS-SOP-Congo Red Gordon & Sweets Reticulin - LP-HIS-SOP- Reticulin -LP-HIS-SOP-Gram



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
	Special stains for the detection of: (cont'd)	Documented in-house procedures for manual special stains
FFPE slides (cont'd)	Fungi and Pneumocystis nos	Grocott -LP-HIS-SOP-Grocott
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana - LP-HIS-SOP-Masson Fontana
	Elastic fibres	Millers Elastic - 10981-LP-HIS-SOP-Millers Elastic
	Neutral Mucopolysaccharides, glycogen and fungus	Periodic Acid Schiff (PAS) - LP-HIS-SOP-PAS
	Haemosiderin and ferric iron	Perl's Prussian Blue - LP-HIS-SOP-Perls Prussian blue
	Collagen	Van Gieson - LP-HIS-SOP-Van Gieson
	Tubercle bacilli	Ziehl Neelsen - LP-HIS-SOP-ZN
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	LP-PATH-SOP-Use of DXC LIMs for CellPath Reporting



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following:</p> <p>Cytokeratin cocktail for CK1-8, 10, 14-16 and 19</p> <p>Embryonic cell in normal tissues and germ tumours</p> <p>Carcinoma of breast and carcinoma of prostate</p> <p>Liver disease marker (congenital disease)</p> <p>Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.</p> <p>Prognostic marker in some B-cell Non-Hodgkin's lymphomas</p> <p>Differentiates between . differentiate lobular and ductal carcinomas of the breast, and E-cadherin positive lobular carcinoma</p> <p>Trophoblastic cells of the placenta</p> <p>Epithelial marker</p> <p>Ovarian cancer</p> <p>Differentiation between invasive and in-situ breast cancer, and benign sclerosing adenosis of the breast from infiltrating ductal carcinoma.</p> <p>Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunocytochemistry Equipment Roche Ventana BenchMark ULTRA LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA LP-HIS-SOP-IHC EQA BenchMark ULTRA</p> <p>Incorporating the following antibodies:</p> <p>AE1/AE3</p> <p>Alpha Fetoprotein</p> <p>Androgen</p> <p>A-1AT</p> <p>BCL2</p> <p>BCL6</p> <p>Beta-catenin</p> <p>Beta HCG</p> <p>BEREP4</p> <p>CA 125</p> <p>Calponin</p> <p>Calretinin</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunocytochemistry Equipment Roche Ventana BenchMark ULTRA LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA LP-HIS-SOP-IHC EQA BenchMark ULTRA Incorporating the following antibodies:
	T cells	CD3
	T Helper Cells	CD4
	Mature T cells, T cell lymphomas	CD5
	Mature B cells, follicular dendritic cells, CALLA	CD8
	Granulocytes Reed-Sternberg cells	CD10
	Reed-Sternberg and lymphomas	CD15
	Mature B cells, Follicular dendritic cells	CD20
	B Cells, Reed-Sternberg cells	CD23
	Reed-Sternberg cells and ALCL	CD30
	Haematopoietic cells, vascular endothelium	CD31
	T cells and some soft tissue	CD34
	Leukocyte common antigen	CD45



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Tissues of neuroendocrine origin</p> <p>Stratified squamous epithelium, basal cells, mesotheliomas</p> <p>Normal and neoplastic epithelia</p> <p>Squamous cell carcinoma</p> <p>Identification of tumours of epithelial origin</p> <p>Identification of epithelial tumours, and may be useful in identifying cholangiocellular carcinomas</p> <p>Adenocarcinomas, columnar epithelial cells</p> <p>Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunocytochemistry Equipment Roche Ventana BenchMark ULTRA LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA LP-HIS-SOP-IHC EQA BenchMark ULTRA Incorporating the following antibodies:</p> <p>Chromogranin</p> <p>CK5/6</p> <p>CK7</p> <p>CK14</p> <p>CK8/18</p> <p>CK19</p> <p>Cytokeratin 20</p> <p>CK HMW (34βE12)</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunocytochemistry Equipment Roche Ventana BenchMark ULTRA LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA LP-HIS-SOP-IHC EQA BenchMark ULTRA Incorporating the following antibodies:
	Expressed in variety tumours E.g., Mantle cell lymphoma	Cyclin D1
	Lymphatic endothelium, lymphangioma and Kaposi sarcoma, also expressed in epithelioid mesotheliomas and seminomas.	D2-40
	Striated and smooth muscle cells	Desmin
	DOG-1 protein	Dog 1
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin
	Normal and neoplastic epithelium	EMA
	For differentiation between dermatofibroma, dermatofibrosarcoma protuberans and desmoplastic malignant melanoma	Factor 13a



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunocytochemistry Equipment Roche Ventana BenchMark ULTRA LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA LP-HIS-SOP-IHC EQA BenchMark ULTRA Incorporating the following antibodies:
	Urothelial and breast carcinoma	GATA 3
	Breast carcinoma marker	GCDFP-15
	Benign and malignant liver-derived tissues, and adult and foetal liver tissue	Heppar
	HER2 antigen in normal and neoplastic breast and gastric tissue	Her 2
	Melanoma, melanocyte differentiation	HMB45
	Proliferating Cells	Ki 67
	Melanoma marker	Melan-A
	Mismatch repair deficiency	Mis Match Repair



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Lung adenocarcinoma</p> <p>Squamous epithelium</p> <p>Germ cells/Seminoma</p> <p>Nuclei of cells containing a high level of oestrogen</p> <p>Thyroid</p> <p>SCC Lung</p> <p>Neoplastic cells in epithelium</p> <p>Squamous epithelium</p> <p>HPV driven tumour e.g., Squamous cell carcinoma</p> <p>Germ cell tumours</p> <p>Nuclei of cells showing expression of Progesterone</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunocytochemistry Equipment Roche Ventana BenchMark ULTRA LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA</p> <p>LP-HIS-SOP-IHC EQA BenchMark ULTRA</p> <p>Incorporating the following antibodies</p> <p>Napsin A</p> <p>Multicytokeratin</p> <p>Oct 4</p> <p>Oestrogen Receptors</p> <p>PAX8</p> <p>P40</p> <p>P53</p> <p>P63</p> <p>P16</p> <p>PLAP</p> <p>Progesterone Receptors</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunocytochemistry Equipment Roche Ventana BenchMark ULTRA LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA
	Identification of prostate adenocarcinoma	LP-HIS-SOP-IHC EQA BenchMark ULTRA Incorporating the following antibodies P504S
	Prostate secretory and ductal epithelium	PSA
	Schwann cells, nerve processes, S100 +ve neoplasms e.g., Melanoma	S100
	Smooth muscle cells, myoepithelial cells	Smooth Muscle Actin (SMA)
	Smooth muscle cells, myoepithelial cells	Smooth Muscle Myosin (SMM)
	Melanocytes and myoepithelial cells	Sox-10
	Neuroendocrine cells	Synaptophysin
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF
	Cells of mesenchymal origin	Vimentin
	Lung	Wilms's tumour
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	Microscopy and reporting SOP – Path-SOP- Immunohistochemistry reporting LP-CYT-SOP- SFA Reporting and Authorisation



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<p>HUMAN BODY FLUIDS</p> <p>Fine needle aspirate cytology including breast and ENT/head&neck. GI specimens - washing/brushing specimens from oesophagus and/or common bile duct Respiratory specimens including broncho-alveolar lavage, bronchial washings and brushings, EBUS-TBNA and lung FNA. Serous fluid specimens, urine and ureteric washings</p> <p>Slides prepared in house as above</p> <p>Slides prepared in house as above</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Tinctorial stains for the demonstration of : Cells (nuclei and cytoplasm) and micro organisms</p> <p>Morphological assessment and interpretation/diagnosis</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Diagnostic cytology (non-gynae) in-house documented automated and manual procedures for preparation Screening and Reporting Rotana 460 Centrifuge LP-CYT-SOP Centrifuge use LP-CYT-SOP_CytoSpin Use ThinPrep T2000 (T2) LP-CYT-SOP T2000 Maintenance LP-CYT-SOP ThinPrep Processor T2000 LP-CYT-SOP Set up Microscope LP-CYT-SOP Microscope use.</p> <p>Papanicolaou stain for Non-Gynae Specimens LP-CYT-SOP-Cytology Pap Staining May-Grunwald & Giemsa stain for air dried slides LP-CYT-SOP-MGG Staining</p> <p>Microscopy and reporting SOP Path-SOP-Non-Gynae-Reporting</p> <p>Home reporting of Cellular Slides using microscope and computer with DXC LIMS Software</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood/serum</p>	<p><u>Immunology examination activities for the purposes of clinical diagnosis:</u></p> <p>Detection of Auto antibodies</p> <p>ANA-Hep2, Mitochondrial, LKM, smooth muscle, gastric parietal cell ANCA Pemphigus, pemphigoid Endomysial</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Indirect Immunofluorescence on Hep2 cells, rat liver, kidney, stomach, monkey oesophagus and ethanol fixed neutrophils. Preparation of slides on ASP supplied by Werfen Read by eye using UV microscopy. Reagents produced by Innova</p> <p>LP-IMM-Asp LP-IMM-Hep2 LP-IMM- AutoAb LP-IMM-ANCA LP-IMM-Pemp LP-IMM-Endo</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturer's instructions for:
Blood/serum	Autoimmunity antibodies to	Fluorescent enzyme immunoassay Phadia (Thermo Fisher) Immunocap 250. Reagents produced by Phadia
Blood	Anti-intrinsic Factor antibodies	LP-IMM-EliA INF (35489)
Blood	Rheumatoid factor	LP-IMM-EliA RF IgM
Blood	Thyroid peroxidase antibodies	LP-IMM-EliA TPO
	Cardiolipin IgG and IgM, MPO, PR3 ENA, SSA,SSB,SCL70, Jo1, U1 RNP, RNP 70, centromere and Smith antigens	LP-IMM-ELIA ACLA LP-IMM-ELIA MPO/PR3 LP-IMM-ENA
	DNA GBM CCP tTG IgG tTG IgA β2 glycoprotein Ab IgG and IgM	LP-IMM-DNA LP-IMM-ELIA GBM LP-IMM-ELiA CCP LP-IMM-GTTG LP-IMM-ELIA IgA TTG LP-IMM-ELiA B2GP
	ALLERGY	
	Total IgE Specific IgE allergens Amoxicilloyl Ampicilloyl Aspergillus fumigatus Cat epithelium & dander Common silver birch Common wasp venom (yellow jacket) Dog dander Duck feathers Guinea pig epithelium Hamster epithelium M6 Alternaria alternata	LP-IMM-Total IgE LP-IMM-SplgE
Serum	TSH receptor antibodies	Phadia 250 analyser EliA method LP-IMM-EliA TSH-R



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood/serum</p>	<p><u>Immunology examination activities for the purposes of clinical diagnosis: (cont'd)</u></p> <p>Total IgE Specific IgE allergens HDM Honey bee venom Horse dander Latex Penicilloyl G Penicilloyl V Rabbit epithelium Timothy grass pollen</p> <p>Allergens tested at KGH cont. Mixed moulds Mixed tree pollen Mixed weed pollen</p> <p>Mixed moulds = Penicillium notatum, Cladosporium herbarum, Aspergillus fumigatus, Alternaria alternata Mixed tree pollen = box elder, common silver birch, hazel, oak, sycamore Mixed weed pollen = ragweed, mugwort, plantain, goosefoot, saltwort</p> <p>Almond Apple Brazil nut Cashew nut Cheese (cheddar type) Cocoa Coconut Egg white Egg yolk Fish (cod) Hazel nut</p>	<p>Documented in house methods and manufacturer's instructions for:</p> <p>Fluorescent enzyme immunoassay Phadia (Thermo Fisher) Immunocap 250 (cont'd)</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis: (cont'd)</u>	Documented in house methods and manufacturer's instructions for:
Blood/serum	Protein electrophoresis, Paraprotein levels Immunotyping	Sebia Capillarys analyser using Capillary zone electrophoresis. Reagents produced by Sebia. LP-IMM-CZE LP-IMM-Serum Ep LP-IMM-Immuno Type LP-IMM-GelFix
Urine	Electrophoresis, FLC (BJP) quantification Immunofixation	Sebia Hydrasys analyser using gel electrophoresis. Reagents produced by Sebia. LP-IMM-Phoresis LP-IMM-BJP LP-IMM-GelFix
Blood/serum	α 1antitrypsin phenotyping	Sebia Hydrasys analyser using isofocusing on gel electrophoresis. Reagents produced by Sebia. LP-IMM-CZE LP-IMM-PAAT
Urine	Detection of β HCG.(Pregnancy test)	Double antibody sandwich immunoassay- cartridge. Reagents from Invitech. Read by eye. LP-IMM-Invitech
Whole blood	Detection of cryoglobulins	Visual comparison for precipitate of samples at 4 °C which becomes soluble when re-warmed to 37°C. LP-IMM-Cryo
Serum	Crithidia luciliae dsDNA antibodies	ASP 1200 analyser using indirect immunofluorescence LP-IMM- Crithidia
END		