


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>8118</b> Accredited to ISO 15189:2012	<b>Kettering General Hospital NHS Foundation Trust</b>	
	Issue No: 007 Issue date: 03 March 2022	
	<b>Pathology</b> Kettering General Hospital Rothwell Road Kettering NN16 8UZ	<b>Contact: Caroline Parkes</b> 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	Location code
North Northamptonshire Council, Kettering Area Offices Bowling Green Road Kettering NN15 7QX <b>Local contact</b> Mike Silverstone	Phlebotomy	
Nene Park Outpatient Services Nene Park Attley Way Irthlingborough NN9 5GF <b>Local contact</b> Mike Silverstone	Phlebotomy	
Isebrook Hospital Irthlingborough Road Wellingborough NN8 1LP <b>Local contact</b> Mike Silverstone	Phlebotomy	
Nuffield Diagnostic Centre Cottingham Road Corby NN17 2UW <b>Local contact</b> Mike Silverstone	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
Kettering General Hospital	Mortuary Services

**Site activities performed away from the locations listed above:**

Location details	Activity
<b>Address</b> Histology Archives Kettering General Hospital Rothwell Road Kettering NN16 8UZ	<b>Local contact</b> Judy Langham Tel: +44 (0) 1536 491518 Judy.langham@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>  Quantitative determination of:	Documented in house methods and manufacturer's instructions for
Serum/Plasma/ /Urine	Sodium Potassium Chloride	<b>Roche Cobas 8000: ISE Module (ion selective electrodes)</b> LP-BIO-ISEs
Serum/Plasma	Albumin Alkaline Phosphatase  ALT  Amylase Bilirubin Cholesterol Creatine Kinase (CK) C Reactive Protein Gamma GT HDL Cholesterol Paracetamol Salicylate Total Protein Triglyceride	<b>Roche Cobas8000: 702 Module (multi assay photometry)</b> LB-BIO-ALB LP-BIO-Alkaline Phosphatase (ALP) LP-BIO-Alanine Transaminase (ALT) LP-BIO-Amylase LP-BIO-Total Bilirubin LP-BIO-Cholesterol LP-BIO-Creatine Kinase (CK) LP-BIO-C-Reactive Protein (CRP) LP-BIO-Gamma GT (GGT) LP-BIO-HDL LP-BIO-Paracetamol LP-BIO-Salicylate LP-BIO-Total Protein LP-BIO-Triglycerides
Serum/Plasma/Urine	Calcium Magnesium Phosphate	LP-BIO-Calcium LP-BIO-Magnesium LP-BIO-Phosphate
Serum/Plasma/Urine	Creatinine Ethanol	LP-BIO-Creatinine LP-BIO-Ethanol
Serum/Plasma/CSF	Glucose	LP-BIO-Glucose
Serum/Plasma/Urine	Urea	LP-BIO-Urea
Urine/ CSF	Albumin Total Protein	LP-BIO-Urine Albumin LP-BIO-Urine Total Protein



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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)  AST  Bicarbonate Direct Bilirubin  Gentamicin Iron LDH  Theophylline UIBC Vancomycin	<b>Roche Cobas 502 Module (multi assay photometry)</b> LP-BIO-Aspartate Aminotransferase (AST) LP-BIO-Bicarbonate LP-BIO-Direct Bilirubin  LP-BIO-CEDIA GENT LP-BIO-Iron LP-BIO-Lactate Dehydrogenase (LDH)  LP-BIO-Theophylline LP-BIO-UIBC LP-BIO-Vancomycin
Serum/Plasma/Urine Plasma only	Uric Acid Lactate	LP-BIO-Uric Acid LP-BIO-Lactate
Plasma	Ammonia	LP-BIO-Ammonia
Serum	Lithium	LP-BIO-Lithium
Serum/Plasma	AFP– Second Trimester Downs Screening	<b>Roche Cobas 8000: 801 Module (sandwich and competitive chemiluminescent immunoassay)</b> LP-BIO-Second Trimester Analysis
Serum/Plasma	AFP- Tumour marker Pro-BNP CA125 Ca199 CA153 CEA Cortisol Digoxin Oestradiol Ferritin Folate FSH	LP-BIO-801 Assays



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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)	<b>Roche Cobas 8000: 801 Module</b> (sandwich and competitive chemiluminescent immunoassay) LP-BIO-801 Assays (cont'd)
	FT4 FT3 hCG LH Progesterone Prolactin PSA SHBG Testosterone TSH Vitamin B12 Vitamin D	
Serum	PTH Troponin	<b>Roche Cobas 8000 : 602 Module</b> (sandwich and competitive chemiluminescent immunoassay) LP-BIO-Procalcitonin LP-BIO-Second Trimester Analysis
Serum/Plasma Serum	Procalcitonin HCG	
Whole Blood	Blood Gas Analysis pH pCO2 pO2 tHb & derivatives Sodium Potassium	<b>Roche Cobas b221 Blood Gas Analyser</b> (ion selective electrodes and co-oximetry) LP-BIO-Blood Gas Analysis



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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
Urine	Quantitative determination of: (cont'd)	<b>Thermo Ultima 3000 HPLC (reverse phase HPLC with electrochemical detection)</b> LP-BIO-CATECHOL LP-BIO-5HIAA
Urine	Catecholamines	
Urine	5-Hydroxyindoleacetic acid	
Whole Blood	HbA1c	<b>TOSOH G11 (ion exchange chromatography)</b> LP-BIO-HbA1c
Serum/Plasma/Urine	Osmolality	<b>Vitech OSMO1 Osmometer (freezing point depression)</b> LP-BIO-OSMO
CSF	Detection of xanthochromia through quantification of bilirubin and oxyhaemoglobin	<b>Perkin Elmer Lambda 25 Spectrophotometer (spectrophotometry)</b> LP-BIO-CSF Xanthochromia
Sweat	Sweat Test Chloride	<b>Wescor Chlorochek Model 3400</b> LP-BIO-Sweat Chloride Analysis
		Documented in-house methods to meet the requirements of the Fetal Anomaly Screening Programme as defined in the July 2018 version of "Fetal Anomaly Screening Programme: laboratory QA evidence requirements"



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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 only	First Trimester Downs Screening PAPP-A Free bhCG	Perkin Elmer DelfiaXpress (fluorometric immunoassay)  LP-BIO-First Trimester Analysis
Serum only	Second Trimester Downs Screening Total hCG  AFP	Perkin Elmer DelfiaXpress (fluorometric immunoassay)  LP-BIO-Second Trimester Analysis
Serum only Serum	Inhibin-A Second Trimester Downs Screening- UE3	<b>Beckman Coulter Access 2 (chemiluminescent immunoassay)</b> LP-BIO-Inhibin A Analysis  LP-BIO-Inhibin A and UE3 analysis LP-BIO-Second Trimester Analysis
Faeces	Calprotectin	<b>Thermo ImmunoCAP 250 EliA Calpro2 (fluorometric immunoassay)</b> LP-BIO-Faecal Calprotectin LP-IMM-FCAL



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum/Plasma</p> <p>Whole Blood</p> <p>Urine</p> <p>Serum/Plasma &amp; 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 &amp; 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 5-Hydroxyindoleacetic acid</p> <p>24hr Urine Excretions: Total Protein Urea Creatinine Sodium Potassium Calcium Chloride Phosphate Magnesium Urate Adrenaline Noradrenaline Dopamine</p> <p>Calcium/Creatinine Clearance Ratio Creatinine Clearance</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>By calculation</p>





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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood Plasma</p> <p>Blood Plasma</p> <p>Blood Plasma</p>	<p><u>Blood Transfusion examinations to assist in clinical investigations</u></p> <p>Blood Group by detection and identification of antigens:</p> <p>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 Including the presence of A2 antigens</p> <p>Antibody Screen by detection of antibodies to:</p> <p>Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb</p> <p>Antibody Screen by detection of antibodies to:</p> <p>Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Automated using Biorad IH-1000 and manual column agglutination using DiaMed cards SOP: IH SOP LP-BTR-IH1000, LP-BTR-ManualGel, LP-BTR-GrpScreenProbs</p> <p>Automated using Biorad IH-1000 SOP: IH SOP LP-BTR-IH1000 LP-BTR-GrpScreenProbs</p> <p>Manual column agglutination using DiaMed cards LP-BTR-ManualGSGel, LP-BTR-Rapid abo testing gel and tube</p>



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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 Diamed IH-1000 Gel Station SOP: LP-BTR-Compatibility, LP-BTR-BldSelAdult, LP-BTR-BldSelBpi, LP-BTR-EmergOneg, LP-BTR-Issue un-X matched blood, LP-BTR-GelStation
Blood Plasma	Compatibility of testing patient's plasma with donor cells	Manual column agglutination using DiaMed cards SOP: LP-BTR-Compatibility, LP-BTR-TxNeoln, LP-BTR-Emerg,
	Compatibility of testing patient's plasma with donor cells	Electronic issue SOP LP BTR Compatibility
Blood	Direct Antiglobulin Test (DAT)	IH-1000 Diamed LP-BTR-BabyGrpDctPaedSamples
Blood	Direct Antiglobulin Test (DAT)	Manual Column agglutination using DiaMed cards LP-BTR-DatGel
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 Diamed SOP: LP-AnttiInvestGel  Guest Foetal Cell Detection Kit Kleihauer Acid Elution Kit SOPLP-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)	Sysmex Interrliner and Autocompact 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	Malarial antigens of: <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	Commercial Binax NOW Malaria Kit LP-HAE-Malaria
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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Haemostasis and thrombosis 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:
Plasma	Routine Coagulation testing for: Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Fibrinogen (Clauss) Thrombin Time (TT)	Sysmex CS5100 automated analysers, optical end-point detection and in-house procedures: SOP:CS5100, PT, APTT, TT SOP: CS5100 Fibrinogen
Plasma	D-Dimer	SOP: CS5100 D-Dimer
Plasma	Factor Assay analysis: FII FV FVII FVIII FIX FX FXI FXII	Sysmex CS5100 automated analysers, optical end-point detection and in-house procedures: SOP: CS5100 Intrinsic assay SOP: CS5100 Extrinsic assay
Plasma	Acquired Thrombophilia (Lupus) Screen (DRVVT screen / confirm, Actin FSL)	SOP: CS5100 Lupus
Plasma	Direct Thrombin inhibitors	SOP: CS5100 Danaparoid, DTI Sysmex CS5100 automated analysers, chromogenic assay and in-house procedures:
Plasma	Inherited Thrombophilia Screen: Antithrombin Protein C Protein S	SOP: CS5100 Prot C, Prot S
Plasma	Low Molecular Weight Heparin Screen - Anti-Xa	SOP: CS5100 anti Xa



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood</p> <p>Bone Marrow</p> <p>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 &amp; speciation (thin films) of malaria parasites:</p> <p><i>Plasmodium falciparum</i> <i>Plasmodium malariae</i> <i>Plasmodium ovale</i> <i>Plasmodium vivax</i></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 SOP-HAE-ManStain</p> <p>or automated using Sysmex SP1000i (SP-10) LP-HAE-SP10</p> <p>May Grunwald-Giemsa staining Manual LP-HAE-BMarrow</p> <p>Preparation of thick and thin films, manual Romanowski staining and light microscopy LP-HAE-FilmExam</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 Thassaemia 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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HUMAN BODY FLUIDS/TISSUE	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>	In house documented methods based on UK Standards for Microbiology Investigations (PHE SMIs) and incorporating manufacturers' instructions where relevant
Sputum, tissue, sterile fluid, swabs	Detection of acid fast bacilli	Microscopy using laboratory microscope with specialist stain. LP-MIC-SOP 12 Micro Methods
Urine	Detection, identification & quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells Casts	Automated urinalysis for presence and enumeration of cells using Beckman IQ 200 LP-MIC-BSOP 41 Urines and LP-MIC-SOP 102 Use of Sprint Urine Analyser
Cerebro spinal fluid	Isolation of clinically significant bacteria and fungi	Manual culture using LP-MIC-BSOP 41 Urines
	Detection, identification and quantification of: White blood cells Red blood cells, Bacterial cells	Microscopic examination using counting chamber. LP-MIC-SOP- 43 CSF
Faeces	Detection & identification of ova, cysts and parasites	Parasep concentration (faeces only) followed by microscopic analysis Using LP-MIC-SOP- 016
Urine	<i>Schistosoma haematobium</i> ova	Parasitology



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>Swab, fluid, pus from a variety of anatomical sites. Eye swab, nose swab, throat swab, ear swab, wound swab, faeces, sputum, bronchial aspirates/lavage, tissue, bone, prosthetic devices contact lenses, blood products. HVS, CX, Ur, IUCD, genital site swabs, 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 (PHE SMIs) and incorporating manufacturers' instructions where relevant</p> <p>Manual culture and microscopy using: LP-MIC-BSOP 54 Inoculation... 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-SOP 117 Transfusion Reaction LP-MIC-BSOP 9 Throat LP-MIC-BSOP 8 sputum LP-MIC-SOP-065 Faeces culture. LP-MIC-SOP 042 Mycology 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 (PHE SMIs) and incorporating manufacturers' instructions where relevant
Sputum, pus, urine, lymph nodes, tissue samples from a variety of anatomical sites, 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, ZN or Gram stain LP-MIC-BSOP 40 Mycobacteria
Faeces	<i>C difficile</i> toxins A & B	Membrane immunochromatographic assay using: Immunocard Toxins A&B LP-MIC-SOP 141 C.dif Immunocard Toxins AB
Organism isolates	Determination of bacterial susceptibility to a range of antibiotics.	Sensitivity testing following EUCAST guidelines LP-MIC-SOP Sens testing EUCAST Using E-tests, MICE, Liofilchem where appropriate
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	Identification of bacterial and fungal pathogens	Automated: Biomerieux Vitek 2 LP-MIC-SOP 92 VITEK 2 Manual: LP-MIC-SOP 010 Ident Method
Cultures of <i>Candida</i> sp isolated in house	Identification of <i>Candida</i> sp	Selected from morphological, biochemical, antigenic characterisation tests LP-MIC-SOP 010 Ident Methods





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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 GDH	Gemini ELISA platform LP-MIC-SOP Gemini ELISA and  Premier C. difficile GDH LP-MIC-SOP 132 C. difficile GDH
Faeces	Cryptosporidium/ Giardia	IVD Research Crypto/Giardia Combi EIA LP-MIC-SOP 112 CGF ELISA
Serum	Varicella zoster virus IgG	SERION ELISA Varicella IgG LP-MIC-VZV IgG EIA
Serum	Measles IgG	SERION ELISA classic Measles IgG LP-MIC-SOP 107 Measles IgG Serion ELISA
Faeces	H. pylori stool antigen	Premier Platinum HPSA Plus LP-MIC-SOP 78 Helicobacter Stool Antigen
Serum	Quantiferon	Qiagen QFT Plus 2 LP-MIC-SOP 79 Quantiferon TB Gold



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Issue No: 007    Issue date: 03 March 2022

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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 (PHE SMIs) and incorporating manufacturers' instructions where relevant
Faeces	Cryptosporidium/giardia	RIDA Quick Cryptosporidium/giardia Combi Kit LP-MIC-SOP 111 CGF Confirmation
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 LP-MIC-SOP-CT GC-Panther LP-MIC-SOP-CT NG PCR LP-MIC-SOP 116 Panther Operation
Nasopharyngeal swabs/nose swabs	Detection of FluA, Flu B and RSV	Xpert Xpress Flu/RSV assay using the Cepheid Genexpert LP-MIC-SOP FLU RSV PCR
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



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on UK Standards for Microbiology Investigations (PHE SMIs) and incorporating manufacturers' instructions where relevant
CSF	Detection of Bacteria: Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis (encapsulated) Streptococcus agalactiae Streptococcus pneumoniae Detection of Viruses: Cytomegalovirus Enterovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpesvirus 6 Human parechovirus Varicella zoster virus Detection of Yeast: Cryptococcus neoformans/gattii	Biofire Filmarray multiplex nucleic acid test LP-MIC-SOP Filmarray ME Panel



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<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, resection</p> <p>Tissue: biopsy, excision, resection specimens</p> <p>Formalinfixed 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 1045-LP-HIS-SOP-Embedding procedure</p> <p>Tissue Sectioning Using Leica HistoCore &amp; RM2235 microtomes 1106-LP-HIS-SOP-Sectioning</p> <p>Cryotomy Intra-operative Frozen sections Using Thermo Cryotome FSE cryostat 1050-LP-HIS-SOP-Frozen sections 1036-LP-HIS-SOP-Cryostat maintenance and decontamination</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 Autostainer XL and Leica SPECTRA Coverslipper 1072-LP-HIS-SOP Histology Staining Machine Use and Maintenance LP-HIS-SOP-Leica SPECTRA Coverslipper 1033-LP-HIS-SOP-Automated coverslipping 1029-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 -1023-LP-HIS-SOP-Alcian blue  Alcian Blue/PAS - 1022-LP-HIS-SOP-Alcian blue PAS  Diastase PAS – 9764-LP-HIS-SOP-DPAS  Congo Red - 12732-LP-HIS-SOP-Congo Red  Gordon & Sweets Reticulin - 1053-LP-HIS-SOP- Reticulin  Gram - 1062-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 -1056-LP-HIS-SOP-Grocott
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana - 1137-LP-HIS-SOP-Masson Fontana
	Elastic fibres	Millers Elastic - 10981-LP-HIS-SOP-Millers Elastic
	Copper-associated protein and Hepatitis B-affected cells	Orcein - 1089-LP-His-SOP-Orcein(Shikata)
	Neutral Mucopolysaccharides, glycogen and fungus	Periodic Acid Schiff (PAS) - 1097-LP-HIS-SOP-PAS
	Haemosiderin and ferric iron	Perl's Prussian Blue - 1098-LP-HIS-SOP-Perls Prussian blue
	Collagen	Van Gieson - 1128-LP-HIS-SOP-Van Gieson
	Tubercle bacilli	Ziehl Neelsen - 1136-LP-HIS-SOP-ZN Classic and cold techniques
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>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>Trophoblastic cells of the placenta</p> <p>Epithelial marker</p> <p>Ovarian cancer</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 25647-LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA 25652 - LP-HIS-SOP-IHC EQA BenchMark ULTRA Incorporating the following antibodies:</p> <p>AE1/AE3</p> <p>Alpha Fetoprotein</p> <p>A-1AT</p> <p>BCL2</p> <p>BCL6</p> <p>Beta HCG</p> <p>BEREP4</p> <p>CA 125</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 25647-LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA 25652 - 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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Issue No: 007 Issue date: 03 March 2022

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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 25647-LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA 25652 - LP-HIS-SOP-IHC EQA BenchMark ULTRA Incorporating the following antibodies:
	Neuroendocrine cells	CD56
	Macrophages	CD68
	B lymphocytes	CD79alpha
	GIST marker	CD117 (C-kit)
	Plasma cells	CD138
	Adenocarcinoma and carcinoid (intestinal epithelium)	CDX2
	CEA glycoproteins in adenocarcinoma	CEA



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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 25647-LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA 25652 - 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 25647-LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA 25652 - LP-HIS-SOP-IHC EQA BenchMark ULTRA Incorporating the following antibodies:
	Expressed in variety tumours E.g., Mantle cell lymphoma	Cyclin D1
	Striated and smooth muscle cells	Desmin
	DOG-1 protein	Dog 1
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin
	Normal and neoplastic epithelium	EMA
	Urothelial and breast carcinoma	GATA 3
	Breast carcinoma marker	GCDFP-15
	Melanoma, melanocyte differentiation	HMB45
	B cells and plasma cells	Kappa
	Proliferating Cells	Ki 67
	B cells and plasma cells	Lambda
	Melanoma marker	Melan-A
	Mismatch repair deficiency	Mis Match Repair



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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 25647-LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA  25652 - LP-HIS-SOP-IHC EQA BenchMark ULTRA  Incorporating the following antibodies
	Lung adenocarcinoma	Napsin A
	Squamous epithelium	Multicytokeratin
	Germ cells/Seminoma	Oct 4
	Nuclei of cells containing a high level of oestrogen	Oestrogen Receptors
	Lymphoma	PAX5
	Thyroid	PAX8
	SCC Lung	P40
	Neoplastic cells in epithelium	P53
	Squamous epithelium	P63
	HPV driven tumour e.g., Squamous cell carcinoma	P16
	Germ cell tumours	PLAP
	Nuclei of cells showing expression of Progesterone	Progesterone Receptors



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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 25647-LP-HIS-SOP-Automated IHC Ventana BenchMark ULTRA
	Identification of prostate adenocarcinoma	25652 - LP-HIS-SOP-IHC EQA BenchMark ULTRA
	Prostate secretory and ductal epithelium	Incorporating the following antibodies P504S
	Schwann cells, nerve processes, S100 +ve neoplasms e.g., Melanoma	PSA
	Smooth muscle cells, myoepithelial cells	S100
	Smooth muscle cells, myoepithelial cells	Smooth Muscle Actin (SMA)
	Neuroendocrine cells	Smooth Muscle Myosin (SMM)
	TTF-1 found in lung and thyroid (thyroid follicular cells)	Synaptophysin
	Cells of mesenchymal origin	TTF
	Lung	Vimentin
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	Wilms's tumour
		Microscopy and reporting SOP – Path-SOP-Immunohistochemistryreporting



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HUMAN BODY TISSUE (cont'd)	<u>Andrology examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Semen (Post Vasectomy)	Detection of non-motile spermatozoa	Documented in house manual method for examination of direct wet preparation and centrifuged pellet based on WHO Manual 2010 (5th Edition) LP-CYT-SOP-Post Vasectomy Seminal Analysis 949-LP-CYT-SOP Set up Microscope
Semen	Fertility Testing:	Documented in house manual method for examination of direct wet preparation and centrifuged pellet based on WHO Manual 2010 (5th Edition) 995LP-CYT-SOP-SFA technical procedure LP-CYT-SOP SFA Reporting and Authorisation based on WHO Laboratory Manual for Examination and Processing of Human Semen 5th Edition 2010
	Volume	Volume/weight
	Sperm motility	Manual microscopy
	pH	pH meter
	Sperm concentration	Manual microscopy
	Sperm morphology	Stained slide assessment using Papanicolaou stain for Non-Gynae Specimens LP-CYT-SOP-Cytology Pap Staining
	Sperm vitality	Stained slide assessment using 5% Eosin as per 995-LP-CYT-SOP-SFA technical procedure
	Appearance	Visual observation
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	LP-CYT-SOP- SFA Reporting and Authorisation





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<p><b>HUMAN BODY FLUIDS</b></p> <p>Fine needle aspirate cytology including breast and ENT/head&amp;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><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>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 &amp; Giemsa stain for air dried slides LP-CYT-SOP-MGG Staining</p>
<p>Slides prepared in house as above</p>	<p>Morphological assessment and interpretation/diagnosis</p>	<p>Microscopy and reporting SOP Path-SOP-Non-Gynae-Reporting</p>
<p>Slides prepared in house as above</p>	<p>Morphological assessment and interpretation/diagnosis</p>	<p>Home reporting of Cellular Slides using microscope and computer with DXC LIMS Software</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for:
Blood/serum	Detection of Auto antibodies	Indirect Immunofluorescence on Hep2 cells, rat liver, kidney, stomach, monkey oesophagus and ethanol fixed neutrophils. Preparation of slides on ASP supplied by Instrumentation Laboratories. Read by eye using UV microscopy. Reagents produced by Innova
	ANA-Hep2, Mitochondrial, LKM, smooth muscle, gastric parietal cell ANCA Pemphigus, pemphigoid Endomysial	LP-IMM-Asp LP-IMM-Hep2 LP-IMM- AutoAb LP-IMM-ANCA LP-IMM-Pemp LP-IMM-Endo
Blood/serum	Identification of specific proteins	Nephelometry using Beckman Coulter Immage 800. Reagents produced by Beckman
	IgG, IgA & IgM C3 & C4 Transferrin $\alpha$ 1antitrypsin Haptoglobin ASOT	LP-IMM-Immage LP-IMM-IgG/A/M LP-IMM-C3/C4 LP-IMM-TRF LP-IMM-AAT LP-IMM-HPT LP-IMM-ASOT



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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	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 Aspergillus & avian precipitins, pigeon, parrot & budgie,	LP-IMM-Specific IgG
	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



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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><b>Mixed moulds</b> = Penicillium notatum, Cladosporium herbarum, Aspergillus fumigatus, Alternaria alternata  <b>Mixed tree pollen</b> = box elder, common silver birch, hazel, oak, sycamore  <b>Mixed weed pollen</b> = 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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**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Kettering General Hospital NHS Foundation Trust**

Issue No: 007    Issue date: 03 March 2022

**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
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	Allergens tested at KGH cont.  Kiwi Milk Orange Peanut Shrimp (prawn) Soya bean Strawberry Tomato Walnut Wheat Mixed fish Mixed nuts Food mix  <b>Mixed nuts</b> = peanut, brazil, hazel, almond & coconut  Dairy Product screen = F1, F2, F14, F75  <b>Mixed fish</b> = cod, shrimp, blue mussel, tuna & salmon <b>Mixed food</b> = egg white, milk, cod, wheat, peanut & soya bean	Fluorescent enzyme immunoassay Phadia (Thermo Fisher) Immunocap 250 (cont'd)
Blood/serum	Intrinsic factor Haemophilus antibodies, Tetanus antibodies	Manual Enzyme Immunoassay read on Bio-Tek ELX800 plate reader at 450nm. Reagents from; Innova LP-IMM-MicroPlate LP-IMM-IF LP-IMM-HIB LP-IMM-Tet



8118  
Accredited to  
ISO 15189:2012

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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	$\alpha$ 1antitrypsin phenotyping	Sebia Hydrasys analyser using isofocusing on gel electrophoresis. Reagents produced by Sebia. LP-IMM-CZE LP-IMM-PAAT
Urine	Detection of $\beta$ 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
END		