

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189: 2022	North West Anglia NHS Foundation Trust	
	Issue No: 030 Issue date: 17 September 2026	
	Address Pathology Department Department 413 Peterborough City Hospital Edith Cavell Campus Bretton Gate PE3 9GZ	Contact: Kerry Winham-Whyte Tel: +44 (0) 1733678441 E-Mail: kerry.winham-whyte@nhs.net Website: www.peterboroughandstamford.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Pathology Department Department 413 Peterborough City Hospital Edith Cavell Campus Bretton Gate PE3 9GZ Local contact Kerry Winham-Whyte	Clinical Biochemistry Immunology Haematology Coagulation Blood transfusion Molecular microbiology/Virology Bacteriology Mycology Cytopathology Histopathology	PCH
Address Blood sciences Hinchingbrooke Hospital Hinchingbrooke Park Rd, Huntingdon PE29 6NT Local contact Kerry Winham-Whyte	Haematology Coagulation Blood transfusion	HH



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
Peterborough City Hospital Mortuary	Mortuary services Body store	PCH
Stamford and Rutland Hospital Ryhall Road Stamford PE9 1UA	Phlebotomy	SRH
Ramsay Fitzwilliam Hospital Milton Way South Bretton Peterborough Cambridgeshire PE3 9AQ	Blood storage only Fridge managed by laboratory	RFH



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	PCH
Serum/heparinised plasma	<u>Clinical Biochemistry</u> Albumin Alkaline Phosphatase ALT Amylase Bicarbonate Bilirubin C Reactive Protein Cholesterol Creatine Kinase (CK) Creatinine Gamma GT HDL Cholesterol Inorganic Phosphate Lithium Magnesium Paracetamol Salicylate T.Cal/Correct Cal Total Protein Triglyceride Urea Uric Acid Alpha 1 Antitrypsin ACE AST Bile Acids B2 Microglobulin C3 C4 Caeruloplasmin Direct Bilirubin Iron Immunoglobulins (IgA, IgG, IgM) Unsaturated Iron Binding Capacity Lactate Dehydrogenase Rheumatoid Factor	Roche Cobas 702 module - multi assay photometry unit BIO-LP-Cobas8000 BIO-LP-ALB BIO-LP-ALP BIO-LP-ALT BIO-LP-AMY BIO-LP-CO2 BIO-LP-TBIL BIO-LP-CRP BIO-LP-CHOL BIO-LP-CPK BIO-LP-CRT BIO-LP-GGT BIO-LP-HDL BIO-LP-IPH BIO-LP-LIT BIO-LP-MAG BIO-LP-PARA BIO-LP-SAL BIO-LP-CAL BIO-LP-TPR BIO-LP-TG BIO-LP-UREA BIO-LP-UIC BIO-LP-AAT BIO-LP-ACE BIO-LP-AST BIO-LP-BILAC BIO-LP-B2M BIO-LP-C3 BIO-LP-C4 BIO-LP-CAER BIO-LP-DBIL BIO-LP-FE BIO-LP-IGA BIO-LP-IGG BIO-LP-IGM BIO-LP-UIBC BIO-LP-LDH BIO-LP-RF	



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	PCH
	<u>Clinical Biochemistry</u> (cont'd)	Roche Cobas 702 module - multi assay photometry unit BIO-LP-Cobas8000	
EDTA Plasma	Glucose Lactate Ammonia	BIO-LP-GLU BIO-LP-LACT BIO-LP-NH3	
Serum/heparinised plasma	Therapeutic Drugs: Carbamazepine Digoxin Ethanol Gentamicin Phenytoin Phenobarbitone Theophylline Tobramycin Vancomycin	BIO-LP-CMZ BIO-LP-Digoxin BIO-LP-ETOH BIO-LP-GENT BIO-LP-PNT BIO-LP-PNO BIO-LP-Theophylline BIO-LP-TOB BIO-LP-VANC	
Urine	Calcium Amylase Creatinine Magnesium Microalbumin Phosphate Urea Uric Acid Urine Protein	Roche Cobas C702 module - multi assay BIO-LP-CAL BIO-LP-AMY BIO-LP-CRT BIO-LP-MAG BIO-LP-MALB BIO-LP-IPH BIO-LP-UREA BIO-LP-UIC BIO-LP-TPUC	
CSF CSF CSF	Protein Lactate Glucose	BIO-LP-TPUC BIO-LP-LACT BIO-LP-GLU	
		Roche Cobas 8000 Ion Selective Electrode Unit	
Serum/heparinised plasma, urine	Electrolytes: Sodium Potassium Chloride	BIO-LP-Cobas8000 BIO-LP-ISE BIO-LP-ISE BIO-LP-ISE	PCH



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Clinical Biochemistry</u> (cont'd)		
Faeces	Faecal Haemoglobin (FIT)	Roche Cobas C702 module - multi assay photometry unit BIO-LP-Cobas8000 BIO-LP-FIT	PCH
Serum/heparinised plasma		Roche C801 immunoassay module Electrochemiluminescence for sandwich and competitive immunoassays	PCH
	A-TPO B12 CA15-3 Folate Ferritin Free T3 Free Thyroxine IGF1 NT Pro BNP Testosterone SHBG Troponin T (HS) TSH AFP BHCG CA 125 CEA Cortisol FSH LH Progesterone TPSA CA 19.9 C-Peptide HGH Oestradiol Prolactin Macroprolactin 25OH Vitamin D	BIO-LP-TPO BIO-LP-B12 BIO-LP-CA153 BIO-LP-FOL BIO-LP-FER BIO-LP-FT3 BIO-LP-FT4 BIO-LP-IGF1 BIO-LP-proBNP BIO-LP-TT BIO-LP-SHBG BIO-LP-TROP BIO-LP-TSH BIO-LP-AFP BIO-LP-hCG BIO-LP-CA125 BIO-LP-CEA BIO-LP-COR BIO-LP-FSH BIO-LP-LH BIO-LP-PROG BIO-LP-tPSA BIO-LP-CA199 BIO-LP-CPEP BIO-LP-GH BIO-LP-E2 BIO-LP-PROL BIO-LP-MPROL BIO-LP-VITD	
FI-EDTA Plasma Whole Blood (EDTA)	PTH Immunosuppressant analysis: Tacrolimus Cyclosporin	BIO-LP-PTH BIO-LP-TAC BIO-LP-CYC	PCH



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Clinical Biochemistry</u> (cont'd)		
Urine (acidified with glacial acetic acid)	Metanephrines and normetanephrine	Recipe kit using Waters Alliance/Agilent 1100 HPLC system BIO-LP-Alliance, BIO-LP-Aligent BIO-LP-MET	PCH
Urine (acidified with glacial acetic acid)	5-Hydroxyindoleacetic acid (5-HIAA)	Chromosystems kit using Waters Alliance/Agilent 1100 HPLC system BIO-LP-Alliance, BIO-LP-Aligent BIO-LP-HIAA	PCH
Serum and Urine	Osmolality	Vitech Osmo1 Osmometer BIO-LP-Osmometer	PCH
Urine	Detection of hCG (Pregnancy Test)	Invitech kit (thin-layer chromatography dual antibody immunoassay) BIO-LP-Pregnancy Tests	
CSF	Haem Pigments	Spectrophotometer.	PCH
Calculated tests	eGFR (Estimated glomerular filtration rate)		PCH
	AKI stage (Acute Kidney Injury)		
	Free Testosterone		
	Adjusted Calcium		
	Non-HDL Cholesterol		
	LDL		
Whole blood	HbA1c	TOSOH G11 using SOP BIO-LP-HbA1c	PCH
Urine	Porphobilinogen screen	Manual Hoesch test (DMAB) BIO-LP-PBG	PCH



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Clinical Biochemistry</u> (cont'd)		
Serum/heparinised plasma	Sodium	Roche Cobas 6000 c501 BIO-LP-ISE	HH
	Potassium	BIO-LP-ISE	
	Chloride	BIO-LP-ISE	
	Creatinine	BIO-LP-CRT	
	Acetaminophen	BIO-LP-PARA	
	Albumin	BIO-LP-ALB	
	Alkaline phosphatase	BIO-LP-ALP	
	ALT	BIO-LP-ALT	
	Ammonia	BIO-LP-NH3	
	Amylase	BIO-LP-AMY	
	Bilirubin	BIO-LP-TBIL	
	Direct bilirubin	BIO-LP-DBIL	
	Calcium	BIO-LP-CAL	
	Cholesterol	BIO-LP-CHOL	
	CK	BIO-LP-CPK	
	CRP	BIO-LP-CRP	
	Ethanol	BIO-LP-ETOH	
	Gamma GT	BIO-LP-GGT	
	Gentamicin	BIO-LP-GENT2	
	Glucose	BIO-LP-GLU	
	HDL cholesterol	BIO-LP-HDL	
	Iron	BIO-LP-FE	
	Magnesium	BIO-LP-MAG	
	Phosphate	BIO-LP-IPH	
	Salicylate	BIO-LP-SAL	
	Theophylline	BIO-LP-THEOPHYLLINE	
	Total protein	BIO-LP-TPR	
	Triclycerides	BIO-LP-TG	
	Urea	BIO-LP-UREA	
	Uric acid	BIO-LP-UIC	
	Unsaturated iron binding capacity	BIO-LP-UIBC	
	Vancomycin	BIO-LP-VANC	



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Clinical Biochemistry</u> (cont'd)		
Calculated tests	eGFR (Estimated glomerular filtration rate) AKI stage (Acute Kidney Injury) Adjusted Calcium LDL Non-HDL Cholesterol Cholesterol :HDL ratio	Roche Cobas 6000 c501	HH
Urine	Amylase Calcium Creatinine Magnesium Phosphate Protein Urea Uric acid Potassium Sodium	Roche Cobas 6000 c501 BIO-LP-AMY BIO-LP-CAL BIO-LP-CRT BIO-LP-MAG BIO-LP-IPH BIO-LP-TPUC BIO-LP-UREA BIO-LP-UIC BIO-LP-ISE BIO-LP-ISE	HH
CSF	<u>Protein glucose</u>	Roche Cobas 6000 c501 BIO-LP-TPUC Roche Cobas 6000 c501	HH
Serum/heparinised plasma	Beta HCG Digoxin Ferritin Free T3 Free T4 Troponin T TSH	BIO-LP-HCG BIO-LP-DIG BIO-LP-FER BIO-LP-FT3 BIO-LP-FT4 BIO-LP-TROP BIO-LP-TSH	HH
Serum/Urine	<u>Osmolality</u>	Advanced Micro Osmometer BIO-LP-Osmometer	HH



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Serum	<u>Immunology</u> Specific IgE testing Total IgE testing Mast Cell Tryptase testing Specific IgG testing Anti-Cardiolipin antibodies B2GP1 antibodies CCP antibodies CTD assay dsDNA antibodies ENA profile antibodies ENA Screen GBM antibodies MPO/PR3 antibodies Intrinsic factor antibodies TSH receptor antibodies TTG antibodies (IgA) TTG antibodies (IgG) Faecal Calprotectin	ImmunoCAP 250 – ImmunoCAP and ELiA technology (IMM-LP-IC250) IMM-LP-CAP-ALLERGY IMM-LP-CAP-ALLERGY IMM-LP-CAP-Tryptase IMM-LP-CAP-SIGG IMM-LP-EIA-ACA IMM-LP-EIA-B2G IMM-LP-EIA-CCP IMM-LP-EIA-CTD IMM-LP-EIA-DNA IMM-LP-EIA-ENAP IMM-LP-EIA-ENAS IMM-LP-EIA-GBM IMM-LP-EIA-EANCA IMM-LP-EIA-IFS IMM-LP-EIA-TRAB IMM-LP-EIA-TTG IMM-LP-EIA-TTG IMM-LP-EIA-CALPRO	PCH
Serum	GAD Antibodies Interferon-gamma released from T cells (Latent TB testing)	Dynex DS2 ELISA Automated Platform using IMM-LP-EIA-DS2 And kits as stated: Euroimmun kit - IMM-LP-EIA-GAD Qiagen QFT kit - IMM-LP-EIA-QTFG	PCH PCH
Serum	ANCA Liver autoantibodies Gastric parietal cell antibodies Pancreatic islet cell antibodies Paraneoplastic antibodies Skin antibodies Endomysial antibodies ANA antibodies (HEp-2) dsDNA antibodies (Crithidia)	Indirect Immunofluorescence, Werfen Quantalyser 3000 Indirect Immunofluorescence automated platform IMM-LP-IIF-QL3000 IMM-LP-IIF-ANCA IMM-LP-IIF-LABPAB IMM-LP-IIF-TissueAAB	PCH PCH



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	PCH
Serum	Liver Antibodies	Immunoblot IMM-LP-EIA-Liver Lineblot	PCH
Serum	Paraneoplastic antibodies	Immunoblot IMM-LP-EIA-PNP Lineblot	PCH
Serum	Serum Free Light Chains	Binding site Optilite- immunoturbidmetric IMM-LP-Optilite IMM-LP-SFLC	PCH
Serum	Detection and quantification of paraproteins	Capillary Zone Electrophoresis using Sebia Capillarys 3 Octa Electrophoresis and Immunofixation IMMUNO-LP-SERUMEPS/IMMUNO-LP-IMMUNOFIX	PCH
Urine	Detection and quantification of Bence Jones Protein	Sebia Phoresis system Electrophoresis and Immunofixation IMMUNO-LP-UrineEPS/IMMUNO-LP-IMMUNOFIX	PCH
Serum	Cryoglobulin	IMMUNO-LP-CRYO	PCH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Haematology</u>		
Whole Blood: EDTA	Haemoglobinopathy Screen * Quantification of: HbA2 HbF HbD HbE HbS HbC Haemoglobin variants	Biorad Variant 2 - HPLC HAE-LP HAE 351, HAE-LP HAE 355, HAE-LP HAE 357	PCH
Whole Blood: EDTA	Haemoglobin Electrophoresis Confirmation of haemoglobin variants	Sebia hydrasys using Sebia Alkaline and Acid Gel plates HAE-LP HAE 357	PCH
Plasma: Citrate	Coagulation Screen: APTT and mixing studies PT QFA Thrombin Thrombin time	Instrumentation Laboratories ACL TOP 550 photometry / turbidity HAE-LP HAE 005, HAE-LP HAE 102 HAE-LP HAE 004, HAE-LP HAE 101 HAE-LP HAE 006, HAE-LP HAE 103 HAE-LP HAE 011	PCH
Citrated plasma	Coagulation Screen: APTT and mixing studies PT and mixing studies INR Fibrinogen D Dimer TT	Sysmex CS-2500 using clot based, chromogenic and immunologic assays HH-HAE-LP-203//205/206/202	HH
Citrated Plasma	Anti-Xa	Sysmex CS-2500 using clot based, chromogenic and immunologic assays HH-HAE-LP-208	HH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Haematology</u> (cont'd)	Instrumentation Laboratories ACL TOP 550 photometry / turbidity	
Plasma: Citrate	D-Dimer INR Factor Assays: Intrinsic VIII, IX, XI and XII Extrinsic II, V, VII, X Factor XIII	HAE-LP HAE 007 HAE-LP HAE 004, HAE-LP HAE 101 HAE-LP HAE 010 HAE-LP HAE 019 HAE-LP HAE 025	PCH
Plasma: Citrate	Von Willebrand screens; Von Willebrand factor antigen quantitation and ristocetin cofactor activity (RiCof) levels as %	HAE-LP HAE 017	PCH
Plasma: Citrate	Thrombotic Screens (Antithrombin, Protein C, Protein S and Activated protein C Resistance)	HAE-LP HAE 015	PCH
Plasma: Citrate	Lupus Screens; Investigation of antiphospholipid syndromes by quantitation of antiphospholipid inhibition antibody (Weak Moderate or Strong)	HAE-LP HAE 009	PCH
Plasma: Citrate	Low Molecular Weight Heparin Screens	HAE-LP HAE 021	PCH
Plasma: Citrate	Direct Xa Inhibitors: Rivaroxaban Apixaban Endoxaban	HAE-LP HAE 024 HAE-LP-HAE-026 HAE-LP-HAE-027	PCH PCH PCH PCH
Plasma: EDTA	Infectious Mononucleosis screen (qualitative) – detection of Epstein-Barr Virus (EBV) antibodies	Accusay Mono-antibody capture HAE-LP HAE 223	PCH HH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Haematology (cont'd)</u>		
Blood	Morphological appearance	Sysmex SP50 automated staining HAE-LP-HAE 261/237/212	PCH
Blood	Morphological appearance	Sysmex SP-10 automated staining HH-HAE-LP-105/009	HH
Bone Marrow	Morphological appearance	Sysmex SP50 automated staining HAE-LP-HAE 238/261	PCH
Whole Blood: EDTA Thick and thin films	Detection of Malarial parasites, % parasitaemia	Romanowski staining and microscopy HAE-LP HAE 217, HAE-LP HAE 219	PCH
	Malarial confirmation and species identification: Falciparum, P.Vivax, P.Ovale or P.Malariae.	Care US antibody capture HAE-LP HAE 218 HH-HAE-LP-020	PCH HH
Whole Blood: EDTA	G6PD screen	Biotech fluorescence HAE-LP HAE 224	PCH
Whole blood: EDTA	Detection of HbS (Sickle Solubility Screen)	Sickledex Kit HAE-LP HAE 369 HH-HAE-LP-006	PCH HH
	<u>Haematology Molecular Markers</u>		
Whole blood: EDTA	V Leiden/Prothrombin	Dx System – Gene Xpert – PCR HAE-LP HAE 517	PCH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Whole blood: EDTA	<u>Haematology Leucocyte Subtyping</u>		PCH
Whole blood: EDTA	CD3,4 &8 counts	HAE-LP HAE 305, HAE-LP HAE 311	PCH
	T and B cell and NK subsets	HAE-LP HAE 305, HAE-LP HAE 311	PCH
	Immune deficiency incorporating CD3,4,8 analysis (HIV monitoring- CD3,4 &8 counts)	SOP-HAE-LP-HAE-366	PCH
	<u>Haematology Cont'd</u>		
Whole Blood EDTA	FBC	Using the Sysmex XN 10, Sysmex XN 20 using Photometry, Fluorescence and Impedance HAE-LP-HAE 259/290/262	PCH
	Reticulocytes	HH-HAE-LP 102 HAE-LP-HAE 259/290 HH-HAE-LP 102	HH PCH HH
		Sysmex interliner	PCH
Whole Blood EDTA	ESR	HAE-LP-HAE 263	PCH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Whole blood: EDTA	<u>Blood Transfusion</u> Group and Antibody Screening • ABO groups and RhD typing • Rhesus blood group antibodies: anti-Cw anti-C, anti-c, anti-D, anti-E, anti-e • Kell system blood group antibodies: antiK, anti-k, anti Kpa • Kidd blood group antibodies: anti-Jka anti-Jkb • Duffy blood group antibodies: anti-Fya anti-Fyb • Lutheran blood group antibodies: anti-Lua • MNS blood group antibodies: anti-M, anti-N, anti-S, anti-s, • Lewis blood group antibodies: anti-Lea anti-Leb • P blood group antibodies: anti-P1	Ortho Vision column agglutination T	PCH
Whole blood: EDTA	Rh & Kell phenotyping	Manual Column Agglutination in Bio-Vue cards TRA-LP 0052	PCH
Whole blood: EDTA	Foetal Maternal Haemorrhage Estimation – quantitation of foetal bleed in maternal circulation	Beckman Coulter Navios Flow cytometer – fluorescence detection HAE-LP HAE 328 Manual Acid elution (Kleihauers) TRA-LP 017 Manual Acid elution TRA-LP 017	PCH
Plasma: EDTA	Cross Matching	Manual Column Agglutination in Bio-Vue cards TRA-LP 052, TRA-LP080	PCH



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	<u>Blood Transfusion</u> (cont'd)		
Whole blood EDTA	Blood Grouping A B and O groups RhD groups	Grifols Eflexis automated analysers and manual Grifols card technology TRA-LP-318 TRA-LP-320	HH
Whole blood EDTA	Red Cell Antibody Screening and identification	Grifols Eflexis automated analysers and manual Grifols card technology TRA-LP-321 TRA-LP-320	HH
Whole blood EDTA	Red cell phenotyping of antigens of the following systems: Rh- C,D,E,c,e ,Kell-K	Grifols Eflexis automated analysers and manual Grifols card technology TRA-LP-323	HH
Whole blood EDTA	DAT	Grifols Eflexis automated analysers and manual Grifols card technology TRA-LP-322	HH
Whole blood EDTA	Compatibility testing or patients plasma with donor cells	Manual serological crossmatching using Grifols card technology TRA-LP-327	HH
Whole blood EDTA	FMH screening	Acid elution techniques TRA-LP-324	HH
Plasma: EDTA	NHSBT Antibody Panels Panel 1 ICT + ENZ Panel 2 ICT	Manual Column Agglutination in Bio-Vue cards TRA-LP 052	PCH
Whole blood: EDTA	Direct Coombs Test	Ortho Vision and manual column agglutination TRA-LP 050, TRA-LP052	PCH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Serology/Virology</u>		
Serum	Hepatitis BsAg HIV Ag-Ab Testing Syphilis testing Hepatitis C Ab Epstein-Barr Virus (IgM, IgG, EBNA) Hepatitis Bc IgM Anti-HBc Hepatitis Be Ag Anti-HBe CMV IgM Hepatitis A IgM Rubella IgG	Abbott Architect analyser Measurement principle CMIA V051 and to include Documented in-house methods to meet the requirements of the NHS Infectious diseases in pregnancy screening programme as defined in July 2018 NHS Infectious diseases in pregnancy screening programme: laboratory quality assurance evidence requirements.	PCH
Serum	Hepatitis BsAg Anti- HBs Hepatitis C Ab Toxoplasma IgG Rubella IgG/M Varicella Zoster IgG	Biomerieux VIDAS Measurement principle ELFA V045	PCH
Serum	HIV I/II confirmation	BioRad Geenius HIV I/II immunochromatographic assay and Geenius Reader SOP V035	PCH
Serum	Syphilis RPR	RPR charcoal agglutination V034	PCH
Serum	Syphilis TPPA	TPPA – haemagglutination in microtitre plate V034	PCH
Serum	Rheumatoid factor	RF latex agglutination V045	PCH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Molecular microbiology/virology</u>		
Faeces	Clostridium difficile toxin genes	Cepheid GeneXpert PCR V050	PCH
Sputum, bronchial aspirates/lavages.	Mycobacterium tuberculosis complex plus rifampicin resistance specific genes	Cepheid GeneXpert PCR M001, M009	PCH
Virology respiratory (nose or throat) swabs	Influenza A/B/Swine influenza RNA	ABI Prism - and GeneXpert M001, M005, M007	PCH
Virology Respiratory (nose swabs, throat swabs, sputum, PNS, Bronchial aspirate, Broncho-alveolar lavage)	Influenza A,B,H1N1, Coronaviruses (NL63,229E,0C43,HKU1),Parainfluenza 1-4, Human metapneumovirus A&B, Rhinovirus, RSV A&B, Adenovirus, Enterovirus, Parechovirus, Bocavirus, Mycoplasma pneumoniae	Extraction via Qiagen EZ1XL using magnetic bead extraction Target amplification and detection by ABI Prism 7500 using PCR amplification and dye detection. SOPs: M008 – Molecular Extraction Methods M016 – ABI 7500 M015 – Respiratory Multiplex PCR	PCH
Plasma and VTM	Chlamydia/Gonorrhoea - Hepatitis C viral load PCR - Hepatitis B viral load	Abbott Alinity-M Molecular PCR testing MIC-LP-M004	PCH
Plasma and VTM	PCR - Respiratory 4-Plex PCR (Flu A/B RSV & SarsCoV-2)	Abbott Alinity-M Molecular PCR testing MIC-LP-M018	PCH
Nasopharyngeal swab/ Anterior nasal swab	SARS-CoV-2, influenza A, influenza B and RSV RNS	Cepheid GeneXpert using RT PCR MIC-LP-M018	HH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Molecular microbiology/virology (cont'd)</u>		
Nasopharyngeal and combined Nose/throat swabs in viral transport media (VTM)	Detection of SARS-CoV-2 RNA (COVID-19) specific gene sequences, orf1ab and E gene RNA	RNA Extraction via Qiagen EZ1XL using magnetic bead extraction Target amplification and detection by ABI Prism 7500 using PCR amplification and dye detection, using Launch Biosphore PCR assay. MIC- LP-M018	PCH
CSF Samples	Molecular testing of clinical samples for Herpes simplex 1&2, Varicella zoster virus, Mumps virus, Enterovirus, Human Parechovirus	Extraction via Qiagen EZ1XL using magnetic bead extraction Target amplification and detection by ABI Prism using PCR amplification and dye detection SOPs: M008 – Molecular Extraction Methods M016 – ABI 7500 M013 – CSF Virology	PCH
Vesicle swabs in virus transport medium, Vesicle fluid	Molecular testing of clinical samples for Herpes simplex 1&2, Varicella zoster virus	Extraction via Qiagen EZ1XL using magnetic bead extraction Target amplification and detection by ABI Prism using PCR amplification and dye detection SOPs: M008 – Molecular Extraction Methods M016 – ABI 7500 M014 – HSV & VZV PCR	PCH
Swabs or urine in Abbott Multicollect kits	Confirmation of positive Neisseria gonorrhoeae screening results in clinical samples	extractions are via the Qiagen EZ1-XL using magnetic beads. Target amplification and detection by ABI Prism using PCR amplification and dye detection SOPs: M008 – Molecular Extraction Methods M016 – ABI 7500 M004 – Chlamydia and Neisseria gonorrhoea	PCH



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Swabs Sterile Fluids Drains Tissue Faeces Line/catheter tips Spinal fluid Sputum/respiratory	<u>Bacteriology</u> Isolation and Identification of pathogens	Microscopy & culture B015 (Routine), B012 (Faeces), B014 (Respiratory)	PCH
Bacterial Cultures	Antibiotic sensitivity testing	Sensitivity by disc diffusion (EUCAST standards) B015 B028 Sensitivity by break point strips (E-Tests, MICE) B011 (Blood cultures)	
Bacterial Cultures	Identification of microorganisms	Bruker MALDI-ToF using Mass Spectrometry ionisation	PCH
Bacterial Cultures	Identification of micro organisms	Confirmation tests: catalase, Staph latex agglutination, tube coagulase, strep grouping, agglutinating sera, API tests, Rapid ANA, Auxocolour (based on biochemical tests and sugar utilisation tests) B019	PCH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Bacteriology</u>		
Whole Blood in blood culture bottles	Detection of micro organisms of pathogenic significance	Biomerieux BacT/ALERT Virtuo: Detection of pH changes due to CO ₂ B011 (followed by manual culture, sensitivity and identification as above)	PCH
Urine	Urine Microscopy and Culture	Menarini Sedimax for microscopy Mast Uriplus microtitre plate culture B017	PCH
Sputum Bronchial washings/aspirate Tissue Urines	Detection of Mycobacterium spp.	BD Diagnostic Systems MGIT. Detects growth by fluorescent detection of oxygen B016, B026 Manual methods: slope cultures, microscopy B016	PCH
Faeces	Helicobacter Antigen tests GDH	Launch Diagnostics DS2; EIA V048, V039	PCH
Swabs Urine	Isolation of Methicillin Resistant <i>Staph aureus</i> (MRSA)	Culture using Chromogenic media B015	PCH
Faeces	Presence of ova, cysts and parasites	Direct microscopy and microscopy following faecal concentration method	PCH



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	<u>Bacteriology</u> (cont'd)		
Urine	Detection of Schistosoma haematobium ova	Microscopy following urine concentration method B012 – Faeces bench	PCH
	<u>Mycology</u>		
Nail Hair Skin	Isolation and identification of pathogenic fungi	Fluorescent microscopy, wet-film microscopy, plate culture SOP: B013	PCH
	<u>Cytopathology</u>		
Body fluids / Fine needle aspirations	Diagnostic Cytology examination for cell morphology changes/abnormalities and diagnosis for the purposes of disease identification	Centrifugation, staining and microscopy Hereas centrifuge CP-N-014 Thermo cytopspin CP-N-016 Routine Papanicolaou stain CP-H-314 Diff-Quick staining CP-N-009 MGG staining CP-H-400	PCH
	Reading and interpretation of slides from processed fluids	Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-C-002 Non-gynae reporting CP-CLIN-N001	PCH PCH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Histopathology</u>		
Human tissue samples/ organs, cell blocks formalin fixed	Examination to identify cell morphology changes/abnormalities, and diagnosis for the purposes of disease identification	Specimen dissection: SOP Dissection Protocols CP-H-036 Decalcification CP-H-011	PCH PCH
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Routine staining for identification of basophilic and eosinophilic structures	Tissue processing: Thermo Excelsior tissue processor CP-MAN-013 Fixation and Processing Tissue Protocols CP-H-009 Leica Peloris tissue processor CP-MAN-001 Microtomy: Leica / Thermo microtomes CP-H-280	PCH PCH
	Special staining for identification of:	Routine H&E staining: Sakura Prisma staining machine and film coverslipper CP-H-314	PCH
		Manual staining	
	Acid mucins	Alcian Blue CP-H-400	PCH
	Glycogen, Neutral and Acid Mucins	Alcian Blue/ Periodic Acid Schiffs CP-H-400	PCH
	Neutral and Acid Mucins	Alcian Blue/ Periodic Acid Schiffs with Diastase CP-H-400	PCH
	Amyloid	Stoke's Congo Red CP-H-400	PCH
	Elastic Fibres	Elastic Van Gieson CP-H-400	PCH
	Helicobacter pylori	Modified Giemsa for H. pylori CP-H-400	PCH
	Gram +ve&-ve bacteria	Gram CP-H-400	PCH
	Melanin and argentaffin granules	Masson Hamperl CP-H-400	PCH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
	<u>Histopathology (cont'd)</u>		
	Special staining for identification of (cont'd):	Manual staining (cont'd)	
Human tissue samples/ organs, cell blocks (cont'd)	Glycogen, Fungi and Neutral Mucins	Periodic Acid Schiff CP-H-400	PCH
	Fungi and Neutral Mucins	Periodic Acid Schiff with Diastase CP-H-400	PCH
	Identification of Fungi	Grocott stain using commercial kit	PCH
	Ferric Iron	Perl's Prussian Blue CP-H-400	PCH
	Insoluble Calcium Salts	Von Kossa CP-H-400	PCH
	Mycobacterium tuberculosis	Ziehl Neelsen CP-H-400	PCH
Human tissue samples/ organs, cell blocks (cont'd)	Immunohistochemistry for identification of:	Immunohistochemistry: Roche Benchmark Ultra platform SOPs CP-H-700, CP-H-701, CP-H-701a, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:	
	Normal/neoplastic tissue epithelial in origin	AE1/3	PCH
	Companion test for lung carcinoma	ALK	PCH
	Follicular lymphomas and various diffuse lymphoproliferative diseases	Bcl-2	PCH
	Adenocarcinoma vs malignant mesothelioma	BerEP4	PCH
	Classification of prostate adenocarcinomas	AMACR	PCH



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Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology</u> (cont'd)		
	Immunohistochemistry for identification of:	Immunohistochemistry: Roche Benchmark Ultra platform SOPs CP-H-700, CP-H-701, CP-H-701a, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:	
	Identification of neoplasms in liver and thyroid papillary carcinoma	CK-19	PCH
	Identification of malignant lymphatic endothelium, epithelioid mesotheliomas and seminomas	D2-40	PCH
	Identification of unknown primary carcinomas where carcinomas of breast and bladder are possible	GATA-3	PCH
	Detection of Her-2 antigen	Her2 (Gastric)	PCH
	Aid in the interpretation of high grade cervical intraepithelial neoplasia	P16	PCH
	Aids in the investigation of p53 accumulation in neoplasia	P53	PCH
	Identifies plasma cells, benign or malignant	CD138	PCH
	Aids in the investigation of pulmonary squamous cell carcinoma and adenocarcinoma	p40	PCH



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Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology</u> (cont'd)		
	Immunohistochemistry for identification of:	Immunohistochemistry: Roche Benchmark Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:	
	Medullary thyroid carcinoma	Calcitonin	PCH
	Malignant mesothelioma	Calretinin	PCH
	T-cells and T-cell Lymphomas	CD3	PCH
	Mature T-cells and T-cell lymphomas	CD5	PCH
	Mature B-cells, Burkitt's lymphoma, Follicular lymphoma, Clear cell renal cell carcinoma	CD10	PCH
	B-cells and B-cell Lymphomas	CD20	PCH
	ALCL, Reed Sternberg cells, Hodgkin's disease	CD30	PCH
	Identify vascular origin of neoplasms	CD31	PCH
	Vascular and lymphatic tumours	CD34	PCH
	Neuroendocrine cells, NK cells	CD56	PCH
	T-cells, NK cells, Thymocytes	CD68	PCH
	Stem cells. Melanocytes, Mast cells, germ cells, Skin basal cells	CD117	PCH



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Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology</u> (cont'd)		
	Immunohistochemistry for identification of:	Immunohistochemistry: Roche Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-H-702, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:	
	GI origin of metastatic adenocarcinomas	CDX2	PCH
	Surface of GI cells, colon carcinomas	CEA (mono)	PCH
	Secretory granules of endocrine cells	CHROMOGRANIN	PCH
	Squamous epithelium and Neoplasms of type	CK5/6	PCH
	Glandular and transitional epithelia and neoplasia of type	CK7	PCH
	Normal GI epithelia and urothelium and neoplasia of type	CK20	PCH
	Rhabdomyosarcomas, Leiomyomas, Mesotheliomas	Desmin	PCH
	Ductal breast carcinomas	E-cadherin	PCH
	Normal and neoplastic neoplasia	EMA	PCH



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Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology</u> (cont'd)		
	Immunohistochemistry for identification of:	Immunohistochemistry: Roche Benchmark Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:	
	hCG containing cells and cells with trophoblastic elements	HCG	PCH
	Mesothelial cells	HBME-1	PCH
	Melanocytes, Melanomas	HMB45	PCH
	Proliferative cells	Ki67	PCH
	Leucocytes	LCA	PCH
	Melanocytes, Melanomas	Melan A	PCH
	MMR proteins in HNPCC	MLH-1	PCH
	Normal/neoplastic tissue epithelial in origin	MNF116	PCH
	MMR proteins in HNPCC	MSH2	PCH
	MMR proteins in HNPCC	MSH6	PCH



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Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology</u> (cont'd)		
	Immunohistochemistry for identification of:	Immunohistochemistry: Roche Benchmark Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:	
	Basal epithelial cells	p63	PCH
	Companion test for NSCLC	PD-L1	PCH
	Neuroendocrine tumours	PGP	PCH
	MMR proteins in HNPCC	PMS2	PCH
	Normal and neoplastic prostate epithelia	PSA	PCH
	Malignant melanoma, chondroblastoma, Schwannoma	S100	PCH
	Smooth muscle cells, myoepithelial cells, Leiomyosarcomas	SMA	PCH
	Neuroendocrine cells and neoplasms	Synaptophysin	PCH
	Thyroid carcinomas	Thyroglobulin	PCH



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Human tissue samples/ organs, cell blocks (cont'd)	<u>Histopathology</u> (cont'd)		
	Immunohistochemistry for identification of:	Immunohistochemistry: Roche Benchmark Ultra Platform SOPs CP-H-700, CP-H-701, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:	
	Normal and neoplastic lung and thyroid cells	TTF-1	PCH
	Wilms tumour, Malignant mesotheliomas	WT-1	PCH
	Expression of ER containing cells, e.g. Normal and neoplastic breast cells	ER	PCH
	Expression of progesterone cells in breast tissue	PR	PCH
	Detection of Her-2 antigen	Her2	PCH
	Determination of Her2 gene status	DDISH	PCH
	Reading and interpretation of slides from processed tissue and fluids	Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001	PCH
Prepared slides from FFPE tissues	Morphological assessment and interpretation/diagnosis	Diagnostic digital pathology using Philips UFS scanners and Glissando scanner linked to Philips image management software (IMS3.3).	PCH
END			