issued by

**United Kingdom Accreditation Service** 

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



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

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



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## Schedule of Accreditation issued by United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

### North West Anglia NHS Foundation Trust

Issue No: 027 Issue date: 04 April 2025

#### DETAIL OF ACCREDITATION

	DETAIL OF AGOREDITATION		
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
HUMAN BODY FLUIDS	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	
	Clinical Biochemistry	Roche Cobas 702 module - multi assay photometry unit BIO-LP-Cobas8000	
Serum/heparinised plasma	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	BIO-LP-ALB $BIO-LP-ALT$ $BIO-LP-ALT$ $BIO-LP-AMY$ $BIO-LP-CO2$ $BIO-LP-CRP$ $BIO-LP-CPK$ $BIO-LP-CPK$ $BIO-LP-CRT$ $BIO-LP-GGT$ $BIO-LP-HDL$ $BIO-LP-HDL$ $BIO-LP-HTH$ $BIO-LP-ARA$ $BIO-LP-ARA$ $BIO-LP-CAL$ $BIO-LP-TG$ $BIO-LP-TG$ $BIO-LP-UIC$ $BIO-LP-JREA$ $BIO-LP-AAT$ $BIO-LP-AAT$ $BIO-LP-BILAC$ $BIO-LP-BILAC$ $BIO-LP-CAER$ $BIO-LP-C4$	

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UKAS MEDICAL 8055	North West Anglia NHS Foundation Trust Issue No: 027 Issue date: 04 April 2025	
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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)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Clinical Biochemistry (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
		Roche Cobas C702 module - multi assay
Urine	Calcium Amylase Creatinine Magnesium Microalbumin Phosphate Urea Uric Acid Urine Protein	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

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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)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Faeces	<u>Clinical Biochemistry</u> (cont'd) Faecal Haemoglobin (FIT)	Roche Cobas C702 module - multi assay photometry unit BIO-LP-Cobas8000 BIO-LP-FIT Roche C801 immunoassay module Electrochemiluminescence for sandwich and competitive immunoassays
Serum/heparinised plasma	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 $BIO-LP-B12$ $BIO-LP-CA153$ $BIO-LP-FOL$ $BIO-LP-FCR$ $BIO-LP-FT3$ $BIO-LP-FT4$ $BIO-LP-IGF1$ $BIO-LP-IGF1$ $BIO-LP-PrOBNP$ $BIO-LP-TT$ $BIO-LP-SHBG$ $BIO-LP-TROP$ $BIO-LP-TSH$ $BIO-LP-AFP$ $BIO-LP-AFP$ $BIO-LP-CA125$ $BIO-LP-CA125$ $BIO-LP-CAR$ $BIO-LP-CAR$ $BIO-LP-CAR$ $BIO-LP-FSH$ $BIO-LP-FSH$ $BIO-LP-PROG$ $BIO-LP-CPEP$ $BIO-LP-CPEP$ $BIO-LP-CPEP$ $BIO-LP-CPEP$ $BIO-LP-PROL$ $BIO-LP-PROL$ $BIO-LP-VITD$
FI-EDTA Plasma Whole Blood (EDTA)	PTH Immunosuppressant analysis: Tacrolimus Cyclosporin	BIO-LP-PTH BIO-LP-TAC BIO-LP-CYC
Serum/Heparinised plasma	Anti-SARS-CoV-2 ab	BIO-LP-ACOV

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ISO 15189:2022		
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Clinical Biochemistry (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
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
Serum and Urine	Osmolality	Vitech Osmo1 Osmometer BIO-LP-Osmometer
Urine	Detection of hCG (Pregnancy Test)	Invitech kit (thin-layer chromatography dual antibody immunoassay) BIO-LP-Pregnancy Tests
CSF	Haem Pigments	Spectrophotometer.
Calculated tests	eGFR (Estimated glomerular filtration rate)	
	AKI stage (Acute Kidney Injury)	
	Free Testosterone	
	Adjusted Calcium	
	Non-HDL Cholesterol	
	LDL	
Whole blood	HbA1c	TOSOH G11 using SOP BIO-LP-HbA1c
Urine	Porphobilinogen screen	Manual Hoesch test (DMAB) BIO-LP-PBG

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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)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Serum	Immunology	ImmunoCAP 250 – ImmunoCAP and ELiA technology (IMM-LP-IC250)
	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	IMM-LP-CAP-ALLERGY IMM-LP-CAP-ALLERGY IMM-LP-CAP-Tryptase IMM-LP-CAP-SIGG IMM-LP-EIA-ACA IMM-LP-EIA-ACA IMM-LP-EIA-CCP IMM-LP-EIA-CTD IMM-LP-EIA-CTD IMM-LP-EIA-ENAP IMM-LP-EIA-ENAS IMM-LP-EIA-BM IMM-LP-EIA-FAB IMM-LP-EIA-TRAB IMM-LP-EIA-TRAB IMM-LP-EIA-TTG IMM-LP-EIA-TTG IMM-LP-EIA-CALPRO Dynex DS2 ELISA Automated Platform using IMM-LP-EIA-DS2 And kits as stated:
Serum	GAD Antibodies Interferon-gamma released from T cells (Latent TB testing)	Euroimmun kit - IMM-LP-EIA-GAD Qiagen QFT kit - IMM-LP-EIA-QTFG
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



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HUMAN BODY FLUIDS (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Serum	Liver Antibodies	Immunoblot IMM-LP-EIA-Liver Lineblot
Serum	Paraneoplastic antibodies	Immunoblot IMM-LP-EIA-PNP Lineblot
Serum	Serum Free Light Chains	Binding site Optilite- immunoturbidmetric IMM-LP-Optilite IMM-LP-SFLC
Serum	Detection and quantification of paraproteins	Capillary Zone Electrophoresis using Sebia Capillarys 3 Octa Electrophoresis and Immunofixation IMMUNO-LP-SERUMEPS/IMMUNO-LP- IMMUNOFIX
Urine	Detection and quantification of Bence Jones Protein	Sebia Phoresis system Electrophoresis and Immunofixation IMMUNO-LP-UrineEPS/IMMUNO-LP- IMMUNOFIX
Serum	Cryoglobulin	IMMUNO-LP-CRYO
HUMAN BODY FLUIDS AND TISSUES	<u>Haematology</u>	
Whole Blood: EDTA	Haemoglobinopathy Screen	Biorad Variant 2 - HPLC HAE-LP HAE 351, HAE-LP HAE 355, HAE-LP HAE 357
Whole Blood: EDTA	Haemoglobin Electrophoresis	Sebia hydrasys using Sebia Alkaline and Acid Gel plates HAE-LP HAE 357
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



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

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Blood	Morphological appearance	Sysmex SP50 automated staining HAE-LP-HAE 261/237/212
Bone Marrow	Morphological appearance	Sysmex SP50 automated staining HAE-LP-HAE 238/261
Whole Blood: EDTA Thick and thin films	Detection of Malarial parasites, % parasitaemia	Romanowski staining and microscopy HAE-LP HAE 217, HAE-LP HAE 219
	Malarial confirmation and species identification: Falciparum, P.Vivax, P.Ovale or P.Malariae.	Care US antibody capture HAE-LP HAE 218
Whole Blood: EDTA	G6PD screen	Biotech fluorescence HAE-LP HAE 224
Whole blood: EDTA	Detection of HbS (Sickle Solubility Screen)	Sickledex Kit HAE-LP HAE 369 to also include Documented in-house methods to meet the requirements of the NHS Sickle Cell and Thalassaemia screening programme in pregnancy as defined in July 2018 NHS Sickle Cell and Thalassaemia screening programme in pregnancy laboratory quality assurance evidence requirements.
	Haematology Molecular Markers	
Whole blood: EDTA	V Leiden/Prothrombin	Dx System – Gene Xpert – PCR HAE-LP HAE 517

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Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Haematology Leucocyte Subtyping	
Leukaemia immunophenotyping - % positivity of gated cells of interest	Beckman Coulter Aquios CL Flow cytometer system with Aquios System software and the Aquios Tetra Combo Test Immunophenotyping – fluorescence detection HAE-LP HAE 308 (Acute Leukaemia Panel) HAE-LP HAE 309 (Chronic Leukaemia Panel)
CD3,4 &8 counts	HAE-LP HAE 305, HAE-LP HAE 311
T and B cell and NK subsets	HAE-LP HAE 305, HAE-LP HAE 311
Immune deficiency incorporating CD3,4,8 analysis (HIV monitoring- CD3,4 &8 counts)	SOP-HAE-LP-HAE-366
<u>Haematology Cont'd</u> FBC Reticulocytes	Using the Sysmex XN 10, Sysmex XN 20 using Photometry, Fluorescence and Impedance HAE-LP-HAE 259/290/262 HAE-LP-HAE 259/290
	Sysmex interliner
ESR	HAE-LP-HAE 263
	2 Pine Trees, Chertsey Lan         North West Ar         Issue No: 02         Type of test/Properties measured/Range of measurement         Examination activities for the purpose of clinical diagnosis         Haematology Leucocyte Subtyping         Leukaemia immunophenotyping - % positivity of gated cells of interest         CD3,4 &8 counts         T and B cell and NK subsets         Immune deficiency incorporating CD3,4,8 analysis (HIV monitoring- CD3,4 &8 counts)         Haematology Cont'd         FBC Reticulocytes

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Whole blood: EDTA	<ul> <li><u>Blood Transfusion</u></li> <li>Group and Antibody Screening <ul> <li>ABO groups and RhD typing</li> <li>Rhesus blood group antibodies: anti-Cw anti-C, anti-c, anti-C, anti-C, anti-E, anti-E</li> <li>Kell system blood group antibodies: antiK, anti-k, anti Kpa</li> <li>Kidd blood group antibodies:anti-Jka anti-Jkb</li> <li>Duffy blood group antibodies:anti-Fyb</li> <li>Lutheran blood group antibodies: anti-Lua</li> <li>MNS blood group antibodies:anti-N, anti-S, anti-S, anti-N, anti-S, anti-S,</li> <li>Lewis blood group antibodies:anti-Lea anti-Leb</li> </ul> </li> </ul>	Ortho Vision column agglutination T

#### P blood group antibodies: anti-P1 Whole blood: EDTA Manual Column Agglutination in Bio-Vue cards Rh & Kell phenotyping TRA-LP 0052 Foetal Maternal Haemorrhage Estimation – quantitation of Whole blood: EDTA Beckman Coulter Navios Flow cytometer fluorescence detection foetal bleed in maternal HAE-LP HAE 328 circulation Manual Acid elution (Kleihauers) TRA-LP 017Manual Acid elution TRA-LP 017 Manual Column Agglutination in Bio-Vue cards TRA-LP 052, TRA-LP080 Plasma: EDTA **Cross Matching**

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Blood Transfusion (cont'd)	
Plasma: EDTA	NHSBT Antibody Panels Panel 1 ICT + ENZ Panel 2 ICT	Manual Column Agglutination in Bio-Vue cards TRA-LP 052
Whole blood: EDTA	Direct Coombs Test	Ortho Vision and manual column agglutination TRA-LP 050, TRA-LP052
	Serology/Virology	
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.
Serum	Hepatitis BsAg Anti- HBs Hepatitis C Ab Toxoplasma IgG Rubella IgG/M Varicella Zoster IgG	Biomerieux VIDAS Measurement principle ELFA V045
Serum	HIV I/II confirmation	BioRad Geenius HIV I/II immunochromatographic assay and Geenius Reader SOP V035
Serum	Syphilis RPR	RPR charcoal agglutination V034
Serum	Syphilis TPPA	TPPA – haemagglutination in microtitre plate V034
Serum	Rheumatoid factor	RF latex agglutination V045

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Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Molecular microbiology/virology	
Clostridium difficile toxin genes	Cepheid GeneXpert PCR V050
Mycobacterium tuberculosis complex plus rifampicin resistance specific genes	Cepheid GeneXpert PCR M001, M009
Influenza A/B/Swine influenza RNA	ABI Prism - and GeneXpert M001, M005, M007
Influenza A,B,H1N1, Coronaviruses (NL63,229E,0C43,HKU1),Para influenza 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
	United Kingdon 2 Pine Trees, Chertsey Lan North West Am Issue No: 027 Type of test/Properties measured/Range of measurement <u>Examination activities for the</u> purpose of clinical diagnosis <u>Molecular</u> microbiology/virology Clostridium difficile toxin genes Mycobacterium tuberculosis complex plus rifampicin resistance specific genes Influenza A/B/Swine influenza RNA Influenza A,B,H1N1, Coronaviruses (NL63,229E,0C43,HKU1),Para influenza 1-4, Human metapneumovirus A&B, Rhinovirus, RSV A&B, Adenovirus, Enterovirus, Parechovirus, Bocavirus,

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Molecular microbiology/virology (cont'd)	
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
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
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
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

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	
Swabs Sterile Fluids Drains Tissue Faeces Line/catheter tips Spinal fluid Sputum/respiratory	Bacteriology Isolation and Identification of pathogens	Microscopy & culture B015 (Routine), B012 (Faeces), B014 (Respiratory)	
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	
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	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	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 )
Urine	Urine Microscopy and Culture	Menarini Sedimax for microscopy Mast Uriplus microtitre plate culture B017
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
Faeces	Helicobacter Antigen tests GDH	Launch Diagnostics DS2; EIA V048, V039
Swabs Urine	Isolation of Methicillin Resistant <i>Staph aureus</i> (MRSA)	Culture using Chromogenic media B015
Faeces	Presence of ova, cysts and parasites	Direct microscopy and microscopy following faecal concentration method

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
Urine	Bacteriology (cont'd) Detection of Schistosoma haematobium ova	Microscopy following urine concentration method B012 – Faeces bench
Nail Hair Skin	Mycology Isolation and identification of pathogenic fungi	Fluorescent microscopy, wet-film microscopy, plate culture SOP: B013
Body fluids / Fine needle aspirations	Cytopathology Diagnostic Cytology examination for cell morphology changes/abnormalities and diagnosis for the purposes of disease identification Reading and interpretation of slides from processed fluids	Centrifugation, staining and microscopy Hereas centrifuge CP-N-014 Thermo cytospin CP-N-016 Routine Papanicolau stain CP-H-314 Diff-Quick staining CP-N-009 MGG staining CP-H-400 Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-C-002 Non-gynae reporting CP-CLIN-N001

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis Histopathology	In house documented methods incorporating manufacturers' instructions where relevant	
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	
		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	
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Routine staining for identification of basophilic and eosinophilic structures	Routine H&E staining: Sakura Prisma staining machine and film coverslipper CP-H-314	
	Special staining for identification of:	Manual staining	
	Acid mucins	Alcian Blue CP-H-400	
	Glycogen, Neutral and Acid Mucins	Alcian Blue/ Periodic Acid Schiffs CP-H-400	
	Neutral and Acid Mucins	Alcian Blue/ Periodic Acid Schiffs with Diastase CP-H-400	
	Amyloid	Stoke's Congo Red CP-H-400	
	Elastic Fibres	Elastic Van Gieson CP-H-400	
	Helicobacter pylori	Modified Giemsa for H. pylori CP-H-400	
	Gram +ve&-ve bacteria	Gram CP-H-400	
	Melanin and argentaffin granules	Masson Hamperl CP-H-400	

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UKAS MEDICAL 8055 Accredited to ISO 15189:2022		
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant
	Histopathology (cont'd) 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
	Fungi and Neutral Mucins	Periodic Acid Schiff with Diastase CP-H-400
	Ferric Iron	Perl's Prussian Blue CP-H-400
	Insoluble Calcium Salts	Von Kossa CP-H-400
	Mycobacterium tuberculosis	Ziehl Neelsen CP-H-400
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
	Companion test for lung carcinoma	ALK
	Follicular lymphomas and various diffuse lymphoproliferative diseases	Bcl-2
	Adenocarcinoma vs malignant mesothelioma	BerEP4

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Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	
Histopathology (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	
Malignant mesothelioma	Calretinin	
T-cells and T-cell Lymphomas	CD3	
Mature T-cells and T-cell lymphomas	CD5	
Mature B-cells, Burkitt's lymphoma, Follicular lymphoma, Clear cell renal cell carcinoma	CD10	
B-cells and B-cell Lymphomas	CD20	
ALCL, Reed Sternberg cells, Hodgkin's disease	CD30	
Identify vascular origin of neoplasms	CD31	
Vascular and lymphatic tumours	CD34	
Neuroendocrine cells, NK cells	CD56	
T-cells, NK cells, Thymocytes	CD68	
Stem cells. Melanocytes, Mast cells, germ cells, Skin basal cells	CD117	
	United Kingdon         2 Pine Trees, Chertsey Land         North West Am         Issue No: 021         Type of test/Properties measured/Range of measurement         Examination activities for the purpose of clinical diagnosis         Histopathology (cont'd)         Immunohistochemistry for identification of:         Medullary thyroid carcinoma         Malignant mesothelioma         T-cells and T-cell Lymphomas         Mature T-cells and T-cell lymphoma, Follicular lymphoma, Clear cell renal cell carcinoma         B-cells and B-cell Lymphomas         ALCL, Reed Sternberg cells, Hodgkin's disease         Identify vascular origin of neoplasms         Vascular and lymphatic tumours         Neuroendocrine cells, NK cells         T-cells, NK cells, Thymocytes	

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Accredited to ISO 15189:2022			
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	
Human tissue samples/ organs, cell blocks (cont'd)	Histopathology (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	
	Surface of GI cells, colon carcinomas	CEA (mono)	
	Secretory granules of endocrine cells	CHROMOGRANIN	
	Squamous epithelium and Neoplasms of type	CK5/6	
	Glandular and transitional epithelia and neoplasia of type	CK7	
	Normal GI epithelia and urothelium and neoplasia of type	СК20	
	Rhabdomyosarcomas, Leiomyomas, Mesotheliomas	Desmin	
	Ductal breast carcinomas	E-cadherin	
	Normal and neoplastic neoplasia	EMA	

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8055			
Accredited to ISO 15189:2022			
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	
	Histopathology (cont'd)		
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-704, CP-C- 036) using the following monoclonal, polyclonal and cocktail antibodies:	
	hCG containing cells and cells with trophoblastic elements	HCG	
	Mesothelial cells	HBME-1	
	Melanocytes, Melanomas	HMB45	
	Proliferative cells	Ki67	
	Leucocytes	LCA	
	Melanocytes, Melanomas	Melan A	
	MMR proteins in HNPCC	MLH-1	
	Normal/neoplastic tissue epithelial in origin	MNF116	
	MMR proteins in HNPCC	MSH2	
	MMR proteins in HNPCC	MSH6	

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MEDICAL 8055	North West Anglia NHS Foundation Trust		
Accredited to	Issue No: 02	7 Issue date: 04 April 2025	
ISO 15189:2022			
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	
	Histopathology (cont'd)		
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-704, CP-C- 036) using the following monoclonal, polyclonal and cocktail antibodies:	
	Basal epithelial cells	p63	
	Companion test for NSCLC	PD-L1	
	Neuroendocrine tumours	PGP	
	MMR proteins in HNPCC	PMS2	
	Normal and neoplastic prostate epithelia	PSA	
	Malignant melanoma, chondroblastoma, Schwannoma	S100	
	Smooth muscle cells, myoepithelial cells, Leiomyosarcomas	SMA	
	Neuroendocrine cells and neoplasms	Synaptophysin	
	Thyroid carcinomas	Thyroglobulin	

United Kingdom Accreditation Service           2 Pine Trees, Chertisey Lane, Staines-upon-Thames, TW18 3HR, UK           Soft Accredited to iso 1stes:2022           Materials/Products tested         Type of test/Properties measurement         Standard specifications/ Equipment/Techniques used           HUMAN BODY FLUIDS AND TISSUES (cont'd)         Examination activities for the purpose of clinical diagnosis         In house documented methods incorporating manufacturers' instructions where relevant           Human tissue samples/ organs, cell blocks (cont'd)         Expression of Expression of Expression of Expression of Expression of Progesterone cells in breast tissue         TTF-1           Human tissue samples/ organs, cell blocks (cont'd)         Expression of Expression of Expression of Her2 antigen mecosterone cells in breast tissue and thyroid cells         Re           Prepared slides from FFPE tissues         Detection of Her2 antigen and interpretation of slides from processed tissue and fluids         PR           Prepared slides from FFPE tissues         Morphological assessment and interpretation/diagnosis         Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001		Schedule of Accreditation issued by		
Medical 8055 Accreatided to ISO 15189:2022North West Anglia NHS Foundation Trust Issue Ac: 04 April 2025Materials/Products testedType of test/Properties measured/Range of measurementStandard specifications/ Equipment/Techniques usedHUMAN BODY FLUIDS AND TISSUES (cont'd)Examination activities for the purpose of clinical diagnosis Histopathology (cont'd)In house documented methods incorporating manufacturers' instructions where relevantHUMAN BODY FLUIDS AND TISSUES (cont'd)Examination activities for the purpose of clinical diagnosis Histopathology (cont'd)In house documented methods incorporating manufacturers' instructions where relevantHuman tissue samples/ organs, cell blocks (cont'd)Normal and neoplastic lung and thyroid cellsTTF-1Human tissue samples/ organs, cell blocks (cont'd)Expression of ER containing neoplastic breast cellsERPrepared slides from FFPE tissuesDetermination of Her2 gene statusPRPrepared slides from FFPEt tissuesMorphological assessment and interpretation/diagnosisDiagnostic digital pathology using Philips UFS scanners and Glissando scanner linked to Philips image management software (IMS3.3).	$(\mathfrak{S})$	United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK		
Materials/Products tested         measured/Range of measurement         Standard specifications/ Equipment/Techniques used           HUMAN BODY FLUIDS AND TISSUES (cont'd)         Examination activities for the purpose of clinical diagnosis         In house documented methods incorporating manufacturers' instructions where relevant           Histopathology (cont'd)         Immunohistochemistry for identification of:         Inmunohistochemistry: Roche Benchmark Ultra Platform SOPS CP-H-700, CP-H-701, CP-H-704, CP-C- 036) using the following monocional, polyclonal and cocktail antibodies:           Human tissue samples/ organs, cell blocks (cont'd)         Expression of ER containing cells, e.g. Normal and neoplastic breast cells         ER           Human tissue samples/ organs, cell blocks (cont'd)         Expression of FR containing cells in breast tissue         PR           Detection of Her-2 antigen status         Her2         DDISH           Prepared slides from FFPE tissues         Morphological assessment and interpretation/diagnosis         Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001	MEDICAL 8055 Accredited to	North West Anglia NHS Foundation Trust		
AND TISSUES (cont'd)       purpose of clinical diagnosis       manufacturers' instructions where relevant         Histopathology (cont'd)       Immunohistochemistry for identification of:       Immunohistochemistry: Roche Benchmark Ultra Platform SOPS CP-H-700, CP-H-704, CP-C-036) using the following monoclonal, polyclonal and cocktail antibodies:         Human tissue samples/       Normal and neoplastic lung and thyroid cells       TTF-1         Human tissue samples/       Expression of ER containing cells, e.g. Normal and neoplastic breast cells       ER         Expression of Progesterone cells in breast tissue       PR         Detection of Her-2 antigen       Her2         Determination of Her2 gene status       DDISH         Reading and interpretation of slides from FFPE       Morphological assessment and fluids       Diagnostic Microscopy: Olympus/Leica/Nikon microscopes cCP-CLIN-H001         Prepared slides from FFPE       Morphological assessment and interpretation/diagnosis       Diagnostic digital pathology using Philips UFS scanners and Glissando scanner linked to Philips image management software (IMS3.3).	Materials/Products tested	measured/Range of		
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Human tissue samples/ organs, cell blocks (cont'd)Expression of ER containing cells, e.g. Normal and neoplastic breast cellsERExpression of progesterone cells in breast tissuePRDetection of Her-2 antigenHer2Determination of Her2 gene statusDDISHReading and interpretation of slides from processed tissue 			TTF-1	
organs, cell blocks (cont'd)       cells, e.g. Normal and neoplastic breast cells         Expression of progesterone cells in breast tissue       PR         Detection of Her-2 antigen       Her2         Determination of Her2 gene status       DDISH         Reading and interpretation of slides from processed tissue and fluids       Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001         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).			WT-1	
cells in breast tissue       Detection of Her-2 antigen       Her2         Determination of Her2 gene status       DDISH         Reading and interpretation of slides from processed tissue and fluids       Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001         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).		cells, e.g. Normal and	ER	
Determination of Her2 gene status       DDISH         Reading and interpretation of slides from processed tissue and fluids       Diagnostic Microscopy: Olympus/Leica/Nikon microscopes CP-CLIN-H001         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).			PR	
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slides from processed tissue and fluidsmicroscopes CP-CLIN-H001Prepared slides from FFPE tissuesMorphological assessment and interpretation/diagnosisDiagnostic digital pathology using Philips UFS scanners and Glissando scanner linked to Philips image management software (IMS3.3).		-	DDISH	
tissues and interpretation/diagnosis scanners and Glissando scanner linked to Philips image management software (IMS3.3).		slides from processed tissue		
END			scanners and Glissando scanner linked to	