


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<b>Royal United Hospitals Bath NHS Foundation Trust</b>	
	<b>Issue No: 015 Issue date: 29 September 2023</b>	
	<b>Department of Pathology</b> <b>Combe Park</b> <b>Bath</b> <b>BA1 3NG</b>	<b>Contact: Wayne Vietri</b> <b>Tel: +44 (0)1225 821770</b> <b>Fax: +44 (0)1225 826272</b> <b>E-Mail: wayne.vietri@nhs.net</b> <b>Website: http://www.ruh.nhs.uk</b>
<b>Testing performed by the Organisation at the locations specified below</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity
<p><b>Address</b>                      Department of Blood Sciences                      Royal United Hospitals NHS Foundation Trust                      Combe Park                      Bath                      BA1 3NG</p> <p><b>Local contact</b>                      Wayne Vietri                      Tel: +44 (0) 1225 821770</p>	Routine Haematology Routine Biochemistry Blood Transfusion Coagulation Immunology Microbiology
<p><b>Address</b>                      Department of Histopathology                      Royal United Hospitals NHS Foundation Trust                      Combe Park                      Bath                      BA1 3NG</p> <p><b>Local contact</b>                      Wayne Vietri                      Tel: +44 (0) 1225 821770</p>	Routine Histopathology Special Stains Immunohistochemistry Diagnostic non-gynae cytology Interpretation and reporting Intra-operative frozen sections Mortuary services (body receipt, storage and release)



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

Location details	Activity
Royal United Hospitals, address as above: A&E Theatres William Budd (Haem/Oncology) Princess Anne Wing (Maternity)	Blood storage only Fridge managed by laboratory
Royal United Hospitals, address as above: Oncology Ward	FBC using XNL-550 POCT Analyser
Royal United Hospitals NHS Foundation Trust Combe Park Bath BA1 3NG	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 (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house procedures with manufacturer's instructions
Urine	pH (dipstick)	Whatman pH indicator papers using visual interpretation of an indicator colour change QMC/SOP/MAN/59
Sweat	Sweat Conductivity	3120 Sweat-Chek Analyser using electrical conductivity QMS/SOP/CH/MAN/61
CSF	Xanthochromia	Perkin-Elmer Lambda 25 uv spectrophotometer using spectrophotometry and WinLab Software QMS/SOP/CH/MAN/43
Urine	Bence Jones Protein confirmation and typing	Immunofixation using Sebia Hydrasys 2 using agarose gel electrophoresis and visual interpretation QMS/SOP/CH/MAN/16



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house procedures with manufacturer's instructions
Urine, serum	Paraprotein bands identification and classification	
Serum	Paraprotein bands identification and classification	Sebia Capillarys 2 flex using immunosubtraction and Phoresis software QMS/SOP/CH/MAN/62
Serum	Serum Protein Electrophoresis: Monoclonal protein band identification and quantitation	Sebia Capillarys 2 flex using capillary zone electrophoresis and Phoresis Software (endo-osmotic flow) QMS/SOP/CH/MAN/62
Whole Blood	Bilirubin (Total)	Roche Omni S blood gas machine using co-oximetry spectrophotometry QMS/SOP/POCT/15
Whole Blood	Carboxyhaemoglobin	
Whole Blood	Oxyhaemoglobin	
Whole Blood	Total Haemoglobin	
Serum, plasma, whole blood	Ionised calcium	Roche Omni S blood gas machine using potentiometry QMS/SOP/POCT/15
Whole Blood	pCO <sub>2</sub>	
Whole Blood	pH	
Serum, plasma, whole blood	Potassium (Direct ISE)	
Serum, plasma, whole blood		
Whole Blood	Sodium (Direct ISE)	
Whole blood	pO <sub>2</sub>	Roche Omni S blood gas machine using a Clark electrode and O <sub>2</sub> reduction QMS/SOP/POCT/15



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in house procedures with manufacturer's instructions
Serum, plasma	Automation Calculated Tests	Calculated
Serum, plasma	Adjusted calcium	
Serum, plasma	AKI	
Serum, plasma	Cholesterol HDL ratio	
Serum, plasma	eGFR	
Serum, plasma	Globulin	
Serum, plasma	Iron saturation	
Serum, plasma	LDL Cholesterol	
Serum, plasma	Macroprolactin	
Serum, plasma	PSA (log)	
Serum, plasma	Non-HDL Cholesterol	
Serum, plasma	TIBC	
	Manual Laboratory Calculated Tests:	
Urine	Albumin creatinine ratio	
Urine	Albumin excretion	
Urine	Amylase creatinine ratio	
Whole blood, serum, plasma	Base excess	
Urine	BJP excretion	
Urine	Calcium creatinine ratio	
Urine	Calcium excretion	
Serum, plasma, urine	Calcium excretion index	
Urine	Creatinine clearance	
Urine	Creatinine excretion	
Whole blood, serum, plasma	ctCO <sub>2</sub> (P)	
Urine	Magnesium excretion	
Serum, plasma	Osmolality (calc)	
Urine	Phosphate excretion	
Urine	Potassium excretion	
Urine	Protein excretion	
Urine	Protein creatinine ratio	
Urine	Sodium excretion	
Serum, plasma, urine	TMP/GFR	
Urine	Urate excretion	
Urine	Urea excretion	



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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>Immunological examination activities for the purposes of clinical diagnosis</u>	<u>Documented in – house procedures with manufacturer's instructions</u>
Blood - serum	anti-nuclear antibody screen and titre (IgG) HEp-2 autoimmune profile (AIP) – ANA, AMA, ASMA, AGPC, LKM-1 (IgG) anti-dsDNA (crithidia luciliae) (IgG) pemphigus/pemphigoid antibody screen and titre (IgG and IgA) endomysial antibodies (IgA and IgG) anti-neutrophil cytoplasmic antibodies (ANCA) (IgG)	Inova Diagnostics Quantalyser 240 using indirect immunofluorescence and Fluorescent Microscope  SOP/IMM/GEN/5 SOP/IMM/GEN/29 SOP/IMM/GEN/103 SOP/IMM/GEN/6 SOP/IMM/GEN/3 SOP/IMM/GEN/8
Blood - serum	anti-dsDNA IgG anti-extractable nuclear antigen (ENA) screen IgG (anti-Ro, La, U1-RNP, Sm, Scl-70, Jo-1) anti-tissue transglutaminase (tTG) IgA anti-intrinsic factor antibody (IFA) screen IgG ANCA anti-myeloperoxidase (MPO) IgG ANCA anti-proteinase-3 (PR3) IgG anti-thyroid peroxidase (TPO) IgG anti-cardiolipin (ACL) IgG and IgM rheumatoid factor (IgM)	DYNEX DS2 using enzyme linked immunosorbent assay SOP/IMM/GEN/31



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood - serum</p>	<p><u>Immunological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>scleroderma (nucleolar) associated antibody profile Ig G(anti-ScI-70, CENP-A, CENP-B, fibrillarin (U3-RNP), RNAP III, NOR-90, Th/To, PM-ScI, Ku, PDGFR, Ro-52) anti-glomerular basement membrane (GBM), anti-myeloperoxidase (MPO) anti-proteinase-3 (PR3) anti-M2 anti-LKM-1 anti-LC-1 anti-nuclear antibody profile IgG (anti-nRNP/Sm, Sm, RNP70, RNPA, RNPC, SS-A(Ro-60), Ro-52, SS-B(La), ScI-70, PM-ScI, Jo-1, CENP-B, PCNA, dsDNA, nucleosomes, histones, ribosomal-P, AMA-M2) myositis associated antibody profile IgG (anti- Mi-2a and b, TIF1g, MDA5, NXP2, SAE, Ku, PM-ScI 75 and 100, Jo-1, SRP, PL-7, PL-12, EJ, OJ, Ro-52)</p>	<p>Documented in – house procedures with manufacturer's instructions</p> <p>Automated immunoblotting using Euroblot One SOP/IMM/GEN/129</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis.</u> <u>Automated - General Haematology</u> (cont'd)	Documented in – house procedures with manufacturer's instructions
Whole blood – EDTA	Blood film – detecting microscopic cell contents and abnormality	Sysmex SP10 using a May-Grunwald Giemsa (MGG) stain and Light Microscope: semi-automated SOP/IT/GE/40 SOP/HA/ML/60 Slide Maker & Stainer SP10
Whole blood – EDTA	Plasma Viscosity	Benson BV using Capillary technique SOP/HA/VI/4
Whole blood – EDTA	Detection of heterophile antibodies specific to Infectious Mononucleosis (IM)	MONOLATEX using a latex immunodiagnostic technique: manual SOP/HA/ML/3
Whole blood – EDTA	Malarial Parasites screening for the the detection of: <i>P. falciparum</i> <i>P. Ovale</i> <i>P. Vivax</i> <i>P. Malariae</i>	BINAX NOW using a immunodiagnostic technique: manual SOP/HA/CY/18
Whole blood – EDTA	Detection and identification of: <i>P. falciparum</i> <i>P. Ovale</i> <i>P. Vivax</i> <i>P. Malariae</i>	Manual staining technique of Thick and Thin films (using MGG, Giemsa and Fields stain) with examination by light microscopy SOP/HA/CY/5
Bone marrow aspirate	Detection of abnormalities	Manual staining technique (using MGG stain) with examination by light microscopy SOP/HA/SP/15
Bone marrow aspirate	Detection of abnormalities	Manual staining technique (using Clin Tech Perls Prussian Blue) with examination by light microscopy SOP/HA/CY/4





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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis. Automated - General Haematology (cont'd)</u>	Documented in – house procedures with manufacturer's instructions
Cerebral Spinal Fluid (CSF)	White blood cells	Shandon Cytospin III with staining on Sysmex SP10 (using MGG) and examination by light microscopy: semi-automated SOP/IMM/GEN/13
Urine	Haemosiderin	Manual staining technique (using Iron Stain with examination by light microscopy SOP/HA/CY/13
Whole blood – EDTA	Sickle cell Solubility screen	Clin Tech turbidometric technique: manual SOP/HA/SP/11
Whole blood – EDTA	G6PD Screen	Trinity Biotech – Spectrophotometry: semi – automated SOP/HA/SP/2
Whole blood – EDTA	HbA1c	Menarini 9210 using an automated Boronate affinity high performance liquid chromatography (HPLC) technique SOP/HA/HPLC/8



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis.</u> <u>Automated - General Haematology</u> (cont'd)	Documented in – house procedures with manufacturer's instructions
Whole blood – EDTA	Haemoglobinopathy analysis by detection of and quantification haemoglobin variants including: Hb A Hb F HbA2 Hb S Hb C Hb D Hb G Hb E	Tosoh G8 using an automated high performance liquid chromatography (HPLC) technique SOP/HA/HPLC/5
HUMAN BODY SAMPLES	<u>Molecular Haematological examination activities for the purposes of clinical diagnosis</u>	Documented in – house procedures with manufacturer's instructions
DNA	FV Leiden and Prothrombin (FII) mutation detection	DNA extraction, amplification and detection using real-time PCR on Cepheid Genexpert GX16 with Xpert Factor II and Factor V Assay Kits SOP/DNA/41
DNA	B27 (PCR)	Allele-specific priming and gel electrophoresis of amplified products using: Eppendorf PCR Cycler using Olerup HLA-B27 Kit using PCR: semi – automated SOP/HA/DNA/5



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HUMAN BODY FLUIDS	<u>Haematological examination activities for the purposes of clinical diagnosis.</u> <u>Automated – coagulation</u>	Documented in – house procedures with manufacturer's instructions  Sysmex CS5100 using spectrophotometry



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purposes of clinical diagnosis.</u> <u>Automated – coagulation (cont'd)</u>	Documented in – house procedures with manufacturer's instructions  Sysmex CS5100 using spectrophotometry



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis.</u>	Documented in – house procedures with manufacturer's instructions
Whole blood – EDTA (packed red cells & plasma)	Blood Group by detection and identification of antigens: <b>RhD positive</b> A RhD positive B RhD positive O RhD positive AB RhD positive <b>RhD negative</b> A RhD negative B RhD negative AB RhD negative O Rh D negative	Automated using Immucor Neo Iris analyser using Liquid Phase microplate SOP/BB/AUT/16 And Automated using Immucor Echo analyser using Liquid Phase microplate SOP/BB/AUT/14 And Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 and Manual tube spin agglutination using Medion Immuncent III centrifuge: SOP/BB/XM/18
Whole blood – EDTA (packed red cells & plasma)	Antibody Screen by detection of antibodies to:  <b>Rh blood group antibodies:</b> Anti-Cw, anti-C, anti-c, anti-D, anti-E, anti-e <b>Kell system blood group:</b> antibodies: Anti-K, anti-k, anti-Kpa <b>Kidd blood group antibodies:</b> Anti-Jka, anti-Jkb <b>Duffy blood group antibodies:</b> Anti-Fya, anti-Fyb <b>Lutheran blood group antibodies:</b> Anti-Lua, <b>MNS blood group antibodies:</b> Anti-M, anti-N, anti-S, anti-s <b>Lewis blood group antibodies:</b> Anti-Lea, anti-Leb <b>P blood group antibodies:</b> Anti-P1	Automated using Immucor Echo analyser using Solid Phase Red Cell Adherence Indirect Antiglobulin Test (IAT) SOP/BB/AUT/14 and Automated using Immucor Neo Iris analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 and Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 And Manual Diamed Column gel IAT technology SOP/BB/MAN/3



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in – house procedures with manufacturer's instructions
Blood – EDTA (packed red cells)	Red cell phenotyping for Antigens of the following systems: Rh – C,D,E,c,e Kell – K Duffy – Fya, Fyb MNSs – M,N,S,s Lewis – Lea, Leb	Automated using Immucor Echo analyser using Liquid Phase microplate SOP/BB/AUT/14 And Automated using Immucor Neo Iris analyser using Liquid Phase microplate SOP/BB/AUT/16 And Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 And Manual tube spin agglutination using Medion Immuncent III centrifuge: SOP/BB/XM/18 And Manual Diamed Column gel IAT technology SOP/BB/MAN/3
Blood – EDTA (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 Lutheran – Lua, Lub Lewis – Lea, Leb P –P1	Automated using Immucor Echo analyser using Solid Phase Red Cell Adherence Indirect Antiglobulin Test (IAT) SOP/BB/AUT/14 and Automated using Immucor Neo Iris analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 And Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16 and Manual Diamed Column gel IAT technology SOP/BB/MAN/3



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in – house procedures with manufacturer's instructions
Blood – EDTA (packed red cells)	Direct Antiglobulin Technique (DAT)	Diamed Column gel IAT technology SOP/BB/MAN/14
Whole Blood – EDTA	Feto-Maternal Haemorrhage Estimation (FMH) – Kleihauer	Clin -Tech Shepard's Kit acid elution & Eosin counterstain with examination by Nikon Eclipse 50i microscope: Manual SOP/BB/MAN/4
Whole blood – EDTA (packed red cells & plasma)	Compatibility testing of patients plasma with donor cells	Cross matching using automated methods: Immucor Echo analyser using solid phase red cell adherence IAT SOP/BB/AUT/14 and Immucor Neo Iris analyser using solid phase red cell adherence IAT SOP/BB/AUT/16 and Automated using Immuncor Echo Lumina analyser using Solid Phase Red Cell Adherence IAT SOP/BB/AUT/16  And manual methods: Manual Diamed Column gel IAT technology SOP/BB/MAN/3
Whole blood – EDTA (packed red cells & plasma)	Transfusion Reaction	Various manual and automated methods – described above (panel includes Cross-match, DAT, Automated Blood Group & Screen, Antibody identification). SOP/BB/MAN/8
	Reading and recording of all Manual Investigations using the Banjo-ID reader	Documented in – house procedures with manufacturer's instructions Banjo ID-reader – SOP/BB/MAN/18



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HUMAN BODY FLUIDS (cont'd)	Molecular examination activities for the purpose of clinical diagnosis	Documented in-house methods and manufacturer's operating instructions to support clinical diagnosis
Throat swab and nasopharyngeal aspirate	Detection of Flu A & B and RSV	Real-time PCR using Cepheid GeneXpert, QMS/SOP/MIC/10/2
Faeces	Detection of Clostridium difficile	Real-time PCR using Cepheid GeneXpert, QMS/SOP/MIC/3/3
Faeces and Vomit samples	Detection of Norovirus	Real-time PCR using Cepheid GeneXpert, QMS/SOP/MIC/4/3
Faeces	Microbiology examination activities for the purpose of clinical diagnosis Detection of Clostridium difficile toxin A & B	Manual EIA using Meridian Immunocard, QMS/SOP/MIC/5/2
HUMAN BODY TISSUE	<u>Histological 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:
Tissue Samples: Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	Routine Histopathology examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis	Macroanalysis and dissection using documented in house procedure Technical cut-up - HI-170 Specimen Dissection - HI-182 Decalcification using documented in house procedure HI-337  Processing Using: Thermofisher Excelsior Processors - HI-229  Embedding Using: Tissue Tek 5 Embedding Centres - HI-156





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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Formalin Fixed Paraffin wax blocks of processed tissue		Sectioning Using: Leica Rotary Microtomes models RM2235 (5) and RM2245 - HI-167
Fresh Tissue		Cryotomy intra-operative frozen sections Using: Leica C1850 and C1750 cryostats HI-128 HI-304 HI-11 HI-223
Formalin fixed paraffin embedded (FFPE) and frozen section slides	Routine morphological staining for the detection of:  Basophilic and eosinophilic tissue structures	Routine Haematoxylin and Eosin (H&E) staining  Automated using: Thermofisher Gemini AS Stainer - HI-162 & 163 and Thermofisher Clearvue Coverslipper – HI-311  Manual: H&E staining – HI-78 Frozen section staining (Manual H&E) - HI-11
FFPE sections	Special stains to detect the following:  Acid mucins  Acid mucins, alkaline mucins  Amyloid  Elastic Fibres  Granular inclusions	Manual special staining techniques using documented in house procedures for staining with:  Alcian Blue Periodic Acid Schiff's Stain – HI-48  Alcian Blue Periodic Acid Schiff's Stain with Diastase – HI-49  Congo Red – HI-63  Elastin van Gieson – HI-70  Giemsa – HI-74



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Special stains to detect the following: (cont'd)	Manual special staining techniques using documented in house procedures for staining with:
	Helicobacter Pylori	Giemsa method for Helicobacter – HI-75
	Demonstration of fungi	Grocott's Modification of Gomori's Methenamine Silver - SOP-HI-77
	Gram positive and gram negative bacteria	Hucker Conn/Twort – HI 82
	Connective Tissues	Martius Scarlet Blue – HI-90
	Melanin	Masson Fontana – HI-91
	Muscle and Collagen	Masson Trichrome – HI-92
	Basement Membranes	Methenamine silver for basement membranes – HI-94
FFPE and Frozen sections	Iron	Perls Prussian Blue – HI-102
	Glycogen/mucin	Periodic Acid Schiff – HI-103
	Reticulin Fibres	Reticulin stain – modified Gomori – HI-106
	Copper	Rhodanine – HI-107
	Metachromasia (mast cells, cartilage matrix, some connective tissue, mucopolysaccharides)	Toluidine Blue for Metachromasia – HI-108
	Copper associated protein	Rubeanic Acid – HI-110
	Calcium	Von Kossa – HI-112
	Hepatitis B	Shikata's Orcein – HI-114
	Amyloid	Siruis Red – HI-116



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Special stains to detect the following: (cont'd)	Manual special staining techniques using documented in house procedures for staining with:
	Epithelial mucin	Southgates Mucicarmine – HI-118
	Tubercule bacilli	Ziehl Neelsen – HI-122
	Nuclei collagen and muscle	Van Gieson
	Helicobacter and Spirocaetes	Warthin and Starry – HI-126
	M.leprae and other mycobacteria	Wade Fite – HI-125
FFPE sections	Immunohistochemistry to detect the following:	Immunohistochemistry using documented in-house procedures: HI-307 SOP/Hi/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	Pan-cytokeratin - cytoplasmic	AE1/3
	Normal Epithelia - cytoplasmic	34 BE12
	Small B lymphocytes in the mantle and marginal zones and many T cells – cytoplasmic to demonstrate follicular lymphomas	BCI-2
	High expression in B-lymphoid lineage cells. Present in germinal centres, B cell lymphomas	BCL-6



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures: HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	All epithelia except the superficial layers of squamous epithelia	Ber EP4
	Mucinous adenocarcinomas of ovary, breast, colon and lung	CA 125
	Smooth muscle and myoepithelial cells	Caldesmon
	Smooth muscle and myoepithelial cells	Calponin
	Mesothelial cells	Calretinin
	Normal secretory epithelium	CAM 5.2
	T cells	CD3
	T cells, some B cell lymphomas	CD5
	Immature B and T cell precursors and proliferating B cells	CD10
	Mature granulocytes and monocytes, Reed-Sternberg cells	CD15
	B cells	CD20



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures: HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	B cells follicular dendritic cells	CD21
	Follicular dendritic cells. Some B cell lymphomas	CD23
	Hodgkins/Reed-Sternberg cells	CD30
	Endothelium	CD31
	Endothelium	CD34
	Leukocytes	CD45
	Neuroendocrine cells, some use in lymphoma pathology	CD56
	Macrophages	CD68
	B cells	CD79a
	Plasma cells	CD138
	GI tract mucosa, adenocarcinomas and carcinoids of the GI tract	CDX2
	Secretory granules of neuroendocrine cells	Chromogranin



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures: HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	Mesothelial cells	CK5/6
	CK7 usually used as a panel to identify primary site of carcinomas	CK7
	CK20 usually used as a panel to identify primary site of carcinomas	CK20
	Lymphoma diagnosis	C-myc
	Mantle cell lymphoma	Cyclin D1
	Skeletal, cardiac and smooth muscle	Desmin
	Normal/neoplastic epithelial	EMA
	Dendritic cells, dermatofibromas	Factor 13a
	Glandular and ductal cells of normal breast, primary and metastatic breast carcinoma	GCDFP-15
	Trophoblastic cells	hCG
	Activated melanocytes, some melanomas	HMB45



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures:
	Kappa-expressing lymphocytes	HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	Proliferating cells	Kappa
	Lambda-expressing lymphocytes	Ki67
	Melanocytes, melanomas	Lambda
	Pan cytokeratin	MART-1
	Some B cell lymphomas/classical Hogkin's lymphoma.	MNF116
	P53 mutated tumours	MUM1
	Basal epithelial cells	P53
	Germ cell tumours	P63
	Benign and malignant prostate	PLAP
	Most prostate carcinomas	PSA
	Neurons, fat cells, melanocytes	Racemase (AMACR)
	Smooth muscle	S100
		SMA



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures: HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	Neurons, neuroendocrine cells	Synaptophysin
	Thyroid, lung carcinomas	TTF-1
	Widespread intermediate filament	Vimentin
	Ovarian adenocarcinomas, Wilm's tumour, malignant mesotheliomas	WT1
	Breast hormone receptor expression	Oestrogen receptor
	Breast hormone receptor expression	Progesterone receptor
Histological sections prepared in house as above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy (qualitative analysis) using in house procedures and in accordance with manufacturers' instructions for microscopes: Leica DM4000, Leica DMRBE and Olympus BX43 HI-168 Histology Quality Control HI-188 Reporting Results HI-193 Internal Referrals HI-320 Intradepartmental Consultation





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HUMAN BODY TISSUE (cont'd)	<u>Non-gynaecological cytology 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:
Human non-gynaecological fluids	Examination of basic cellular components in order to identify or exclude morphological and cytological abnormalities	Sample preparation and processing using procedures: CY-34 CY-107 CY-156 in conjunction with manufacturer's instructions using: Cytospin 4 - CY-25 Centrifuge - CY-12
	Demonstration of : Cells (nuclei and cytoplasm) and micro organisms	Staining Using in-house procedures: CY-34 Papanicolaou – CY-33 May Grunwald Giemsa – CY-33 In conjunction with manufacturer's instructions using: Thermofisher Gemini Stainer - CY-33 Sakura – coverslipper - CY-158
Cytological sections prepared in house from samples listed above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy (Qualitative analysis) Using in house procedures: CY-112 In conjunction with manufacturer's instructions for: Leica DMLB, Olympus BX45 and Nikon Eclipse Microscopes



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy</u> Detection of sperm	Manual method using centrifugation and manual microscopy and documented in-house procedure SOP CY-138
Semen	<u>Fertility testing</u>  Volume Sperm morphology <b>excluding</b> TZI scoring Sperm concentration Sperm motility Sperm vitality	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method using documented in-house procedure SOPs CY-60, 61, 94, 99  Volume/weight Stained slides (Papanicolau) microscopy (Bright field) Microscopy (Phase contrast) Microscopy (Phase contrast) Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)
END		