


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8140</p> <p>Accredited to ISO 15189:2022</p>	<h3>NHS Grampian</h3> <p>Issue No: 013 Issue date: 16 March 2026</p>	
	<p>Room 16 Laboratory Administration Annex Orange Zone Aberdeen Royal Infirmary AB25 2ZN</p>	<p>Contact: Glenn Ross Tel: +44 (0) 1224 553891 Email: glenn.ross@nhs.scot Website: http://www.nhsgrampian.org</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address Ground Floor Microbiology Department Aberdeen Royal Infirmary</p> <p>Local contact: Lesley Beveridge Tel: +44 (0)1224 552445 Email: lesley.beveridge2@nhs.scot</p>	<p>General Bacteriology Mycology Virology Serology Molecular Microbiology</p>	A
<p>Address GUM Clinic Health Village Frederick Street Aberdeen</p> <p>Local contact: As above</p>	<p>Microscopy</p>	B
<p>Address 1st Floor Aberdeen Royal Infirmary Aberdeen AB25 2ZN United Kingdom</p> <p>Local contact: Ann Milne Tel: +44 (0)1224 552407 Email: Ann.milne2@nhs.scot</p>	<p>Core and special clinical biochemistry</p>	C
<p>Address David Anderson Building Foresterhill Road Aberdeen AB25 2ZP</p> <p>Local contact: Ann Milne Tel: 01224 552407 Email: Ann.milne2@nhs.scot</p>	<p>Diabetic clinic</p>	D
<p>Address Out Patients Department Royal Aberdeen Children's Hospital Westburn Road Foresterhill Aberdeen AB25 2ZG</p> <p>Local contact: Ann Milne Tel: 01224 552407 Email: Ann.milne2@nhs.scot</p>	<p>Sweat test</p>	E



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Location details	Activity	Location code
<p>Address 2nd Floor Link Building Aberdeen Royal Infirmary Aberdeen AB25 2ZD United Kingdom</p> <p>Local contact: Sonja Wright Tel: +44 (0)1224 553843 Fax: +44 (0)1224 554827 Email: sonja.wright2@nhs.scot</p>	<p>Haematology Haemoglobinopathies Coagulation Flow Cytometry</p>	F
<p>Address 2nd Floor Link Building Aberdeen Royal Infirmary Aberdeen AB25 2ZD United Kingdom</p> <p>Local contact: Alison Gall Tel: +44 (0)1224 553792 Email: alison.gall@nhs.scot</p>	<p>Immunology Flow Cytometry</p>	G
<p>Address 3rd Floor, Link Building Aberdeen Royal Infirmary Aberdeen AB25 2ZD United Kingdom</p> <p>Local contact: Wendy Leaper Tel: +44 (0)1224 552858 Fax: +44 (0)1224 663002 Email: wendy.leaper@nhs.scot</p>	<p>Routine Histopathology Special Stains Immunocytochemistry Immunofluorescence Frozen Section Histology Cytology -Diagnostic</p>	H
<p>Address Medical Genetics Department Polwarth Building Aberdeen Royal Infirmary Cornhill Road Aberdeen AB25 2ZD</p> <p>Local contact: Christine Bell Tel: +44 (0)1224 550681 Email: christine.bell@nhs.scot</p>	<p>Cytogenetics Molecular Pathology Molecular Genetics</p>	J
<p>Address Medical Laboratory Sciences Dr Grays Hospital Elgin IV30 1SN United Kingdom</p> <p>Local contact: Emma Parkins Tel: +44 (0)1343 567522 Fax: +44 (0)1343 567831 Email: emma.parkins@nhs.scot</p>	<p>Haematology Coagulation Core biochemistry</p>	K



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Address</p> <p>Aberdeen Royal Infirmary Aberdeen AB25 2ZD United Kingdom</p> <p>Local Contact</p> <p>Sonja Wright Tel: +44 (0)1224 553843 Fax: +44 (0)1224 554827 Email: sonja.wright@nhs.scot</p>	<p><u>Sampling-Phlebotomy</u> Collection of blood specimens by venepuncture in adults</p>	L
<p>Old Laundry room Woodend Hospital Eday road Aberdeen AB15 6XS</p> <p>Local Contact</p> <p>Wendy Leaper Tel: +44 (0)1224 552858 Fax: +44 (0)1224 663002 Email: wendy.leaper@nhs.scot</p>	<p>Storage of blocks slides and request forms- no testing performed at this site.</p>	M



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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>General Bacteriology</u>		
	Examination activities for the purposes of clinical diagnosis	In-house documented procedures based on PHE UK SMIs	
Swabs from eyes, wounds, nose, throat, ears, genital sites, tissue and fluids	General isolation and characterisation of micro-organisms of clinical significance	Manual culture using SOPs MMLP WOUND series, MMLP Genital Series and MMLP Upper Respiratory Series	A
Respiratory fluids (sputum, bronchial washings)	General isolation and characterisation of micro-organisms of clinical significance, including mycobacteria	Manual culture using SOPs MMLP RESPIRATORY series	A
Swabs from nose, perineum and wound sites	Isolation of MRSA	Manual culture on chromogenic agar using SOP MMLP INFCON series	A
Rectal swab	Screening for Carbapenamase producing Enterobacteriaceae	Manual culture using MMLPINFCON SERIES	A
CSF and CAPD fluids	Quantification of white and red blood cells and bacteria	Manual microscopy using Tuerk's fluid and SOP MMLP CSF SERIES and MMLP WOUND SERIES	A
	Detection and characterisation of microorganisms	Staining (Gram) and Microscopy	A
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	SOP MMLP URINE Series in conjunction with equipment manual using IQ200 Urine analyser	A
Urine	General isolation and characterisation of micro-organisms of clinical significance	SOP MMLP EXAM 012 – manual culture using SOP	A



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HUMAN BODY SAMPLES	<u>General Bacteriology</u>		
Urine	Examination activities for the purposes of clinical diagnosis Detection of <i>Legionella pneumophila</i> serotype 1 antigen	In-house documented procedures based on PHE UK SMIs SOP MMLP URINE EIA 001 in conjunction with manufacturer's instructions –screening using BinaxNOW kit and confirmation using DS2	A
Faeces	Examination activities for the purposes of clinical diagnosis General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> 0157 and other enteric pathogens	In house documented procedures based on PHE SMIs Manual culture methods using selective agar and SOP MMLP ENTERIC SERIES series	A
Blood cultures	Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance	SOP MMLP BC series in conjunction with manufacturer's instructions for automated system BACTEC Fx	A
Sputum BAL CSF Urine Pus	Detection of positive Mycobacteria culture	Manual microscopy using auramine and Ziehl Neelsen stains SOP MMLP MYCOBACTERIA SERIES series in conjunction with manufacturer's instructions for automated system BACTEC MGIT	A
Bacterial cultures (isolated in-house)	Identification and Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC)	SOP MMLP AST series in conjunction with manufacturer's instructions for VITEK 2 automated antimicrobial testing system. VITEK MS Prime (MALDI ToF), matrix assisted laser desorption/ionisation time of flight mass spectrometry. SOP: MMLP ID SERIES	A A



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HUMAN BODY FLUIDS (cont'd)	<u>General Bacteriology</u> (cont'd)		
Genital samples	Detection of microbes of clinical significance	Manual microscopy with reference to MMLP GUM SERIES	B
	<u>Mycology</u>		
	Examination activities for the purposes of clinical diagnosis	In-house documented procedures based on PHE SMIs	
Skin scrapings and nail clippings	General isolation and characterisation of fungi of clinical significance	Manual method using MMLP MYCOLOGY 001series by direct microscopy of KOH digested samples and culture on non-chromogenic selective media	A
	<u>Serology</u>		
	Examination activities for the purposes of clinical diagnosis (cont'd)	In house documented procedures based on manufacturer's instructions	
Serum/plasma	Detection of :- Treponema Pallidum Particle Agglutination Syphilis RPR	MMLP VIROL SER Series (MMLP VIROL SER 16, MMLP VIROL SER A10, MMLP VIROL SER L10, MMLP VIROL SER SC2, MMLP VIROL SER SC3) series in conjunction with manufacturers' kit inserts; manual ELISA detection of viral antigens using V KL1 series kits	A



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HUMAN BODY FLUIDS (cont'd)	<u>Serology</u>		
Faeces	Detection of :- Rotavirus and Adenovirus	MMLP MOLEC FEIA series in conjunction with manufacturer's kit inserts; CerTest one step combo card rapid immunoassay	A
Serum/plasma	Hepatitis A virus IgG Hepatitis A virus IgM Hepatitis B virus antibody Hepatitis B surface antigen Qualitative II Hepatitis B surface antigen Qualitative II (confirmatory) Hepatitis B core antibody Hepatitis B core IgM Hepatitis C virus antibody CMV IgG CMV IgM EBV EBNA IgG EBV VCA IgG EBV VCA IgM HIV Ag/Ab combo Syphilis antibody Toxoplasma IgG Toxoplasma IgM	Abbott Alinity I using Immunoassay SOP MMLP VIROL series	A
Serum/plasma	Hepatitis B virus antibody Hepatitis B surface antigen quantification Hepatitis C antibody HIV Ag/Ab Lyme IgG Measles IgG Parvovirus B19 IgG Parvovirus B19 IgM Syphilis antibody Varicella zoster IgG	Diasorin Liaison XL using Immunoassay. MMLP VIROL series	A
Venous blood (serum),	Hepatitis E IgG and Hepatitis E IgM	Chemiluminescent immunoassay on the Diasorin Liaison using MUREX Anti-HEV IgG and IgM assays	A
EDTA blood (plasma)	Hepatitis E IgG and Hepatitis E IgM	Chemiluminescent immunoassay on the Diasorin Liaison using MUREX Anti-HEV IgG and IgM assays	A



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular Biology</u>		
Human samples	Examination activities for the purposes of clinical diagnosis	In house documented procedures based on manufacturer's instructions	
Faeces, swabs (various sites) urines, CSFs, nasopharyngeal aspirates, broncho-alveolar lavages, fluids and tissues specified .	Detection of:- Herpes Simplex Type 1 & 2 Varicella Zoster Adenovirus, CMV,EBV, BK, Erythrovirus B19, B. Pertussis, Syphilis Mycoplasma pneumoniae Influenza A & B, RSV, Humanmetapneumovirus, Parainfluenza Types1-4, Corona viruses 229E,NL63,OC43 & HKU1, Rhino/enterovirus Norovirus, Measles ,Mumps Parechovirus,Enterovirus	Automated extraction using the KingFisher Flex system Real-time PCR using SOP MMLP MOLEC 14-01 series using Luminex MAGPIX and 7500 thermocyclers.	A
Serum/plasma	Hepatitis C viral load HIV viral load	Abbott Alinity M using PCR MMLP MOLEC series	A
Plasma	Quantitative detection of: CMV viral load EBV viral load		
Genital swabs and urine	Detection of Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis	Abbott Alinity M using PCR MMLP STI series	A
Oropharyngeal and rectal swabs	Detection of Chlamydia trachomatis and Neisseria gonorrhoeae	Abbott Alinity M using RT- PCR MMLP STI series	A
Urogenital swabs and urine	Detection of Mycoplasma genitalium	Abbott Alinity M using RT- PCR MMLP STI series	A



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Respiratory Samples (including Throat and Nasopharyngeal swabs)</p> <p>Excluding samples from immunocompromised patients</p>	<p><u>Molecular Biology</u></p> <p>Viral and Bacterial Nucleic Acid Targets</p> <p>Influenza A (RNA)</p> <p>Influenza A H1 (RNA)</p> <p>Mycoplasma pneumoniae, (DNA)</p> <p>Influenza A H3, (RNA)</p> <p>Influenza B (RNA)</p> <p>Respiratory Syncytial Virus A (RNA)</p> <p>Respiratory Syncytial Virus B (RNA)</p> <p>Coronavirus 229E, (RNA)</p> <p>Coronavirus OC43, (RNA)</p> <p>Coronavirus NL63 (RNA)</p> <p>Coronavirus HKU1 (RNA)</p> <p>Human Metapneumovirus (RNA)</p> <p>Rhinovirus (RNA)</p> <p>Enterovirus (RNA)</p> <p>Adenovirus (DNA)</p> <p>Parainfluenza type 1-4 (RNA)</p>	<p>Automated extraction using the KingFisher Flex system</p> <p>Luminex Magpix system using NxTAG respiratory pathogen panel using RT-PCR</p> <p>Qualitative results based on hybridised bead counting</p> <p>SOP MMLP EQUIP MGP 01</p>	<p>A</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	Documented In-house methods using:	
Venous Blood: Citrated	Blood Coagulation	ACL TOP 750 SOP H LP 200 086	F
		ACL TOP 350 SOP H LP 200 246	K
	Prothrombin time INR Activated Partial Thromboplastin Time Fibrinogen estimation Derived Clauss Thrombin Time including correction with protamine sulphate	Turbidimetric method Clot detection by optical rate of change of absorbance end point being the maximum rate of change INR – 200 105 SOP 200 090 SOP 200 089	F and K
	D-Dimers	SOP's 200 104, latex immunoassay	
	Antithrombin 3	SOP 200 094 chromogenic assay	F
	Anti Xa	SOP 200 098 chromogenic assay	F
	VWF: Ag	SOP 200 096- immunoturbidimetric assay	F
	vWF:RCo	SOP 200 119- Latex Immunoassay	F
	Anti- Xa for direct Xa inhibitors	SOP 200 113 chromogenic assay for Direct Oral Anticoagulants (DOAC)	
	Factor assay • V • VII • X • VIII • IX • XI • XII	Turbidometric method. Clot detection by optical rate of change of absorbance end point being the maximum rate of change Extrinsic Factors SOP 200 088 Intrinsic Factors SOP 200 087	F



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented In-house methods using:	
Venous Blood: Citrated (cont'd)	Blood coagulation	ACL TOP 750	F
	Lupus anticoagulant Protein C Protein S	SOP 200 091 Turbidometric SOP 200 092- chromogenic assay SOP 200 093 latex immunoassay	F
	Factor VIII inhibitor Factor IX inhibitor	Turbidometric method SOP 200 097	F
	Heparin Induced Thrombocytopenia	ELISA PF4 IgG assay SOP 200 069	F
Venous whole blood: EDTA	FBC	Abbott Alinity hq series LP 100 107	F and K
	Haemoglobin estimation	Photometric	
	Red cell and platelet counts	Flow Cytometry	
	Differential white cell count		
	Reticulocyte		
	Nucleated Red Cells (NRBC)		
	HCT	Calculate parameters	
Venous whole blood :EDTA	Film reporting and WBC Differential	Wright Giemsa blood smears by Alinity hs SOP's 100 094, and Microscopy- SOP's 100 089	F
	Malaria Parasite detection P.falciparum P.vivax P.ovale P.malariae P knowlesi	Giemsa stain and microscopy - SOP 300 014	F



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Urine	Haemosiderin	Perl's Prussian Blue staining-microscopy- SOP 300 007	F
Serum	Haematinics <ul style="list-style-type: none"> • B12 • Ferritin • Serum folate 	Abbott Alinity I immunoassay analyser LP 400 027	F
Serum	Haptoglobins	Immunoturbidimetry on the Abbott Alinity C LP 500 034	F
Venous whole blood :EDTA	Haemoglobinopathies and Thalassemia	BioRad Variant II, HPLC SOP 500 017	F
	Haemoglobin S	Detection of decreased solubility of haemoglobin S with HD supplies kit SOP 500 023	F
Venous whole blood :EDTA	G6PD	Appearance of fluorescence in red cell substrate mixtures SOP 500 024	F
Venous whole blood :EDTA	Plasma Viscosity	Benson BV 200 analyser- by flow resistance SOP 500 025	F



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Blood	Infectious Mononucleosis	Monogen Kit using SOP: LP300 013	F
Venous whole blood/ bone marrow in EDTA	<u>Flow Cytometry</u> Immunophenotyping of haematological disorders for chronic lymphoproliferative disorders Chronic B cell 1 (CB1) <ul style="list-style-type: none"> • CD5 • CD19 • CD20 • CD23 • CD38 • CD45 • CD79b • CD200 • FMC7 	Navios Flow Cytometer Cellular analysis by flow cytometry using SOP: LP-300-025	F
Venous whole blood, bone marrow in EDTA, fine needle aspirate, ascitic and pleural fluids	Immunophenotyping of haematological disorders for chronic lymphoproliferative disorders Chronic B cell 2 (CB2) <ul style="list-style-type: none"> • CD10 • CD11c • CD19 • CD22 • CD43 • CD45 • HLA-DR • IgM 	Navios Flow Cytometer Cellular analysis by flow cytometry using SOP: LP-300-025, <u>H-LP 300 035</u>	F



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Venous whole blood, bone marrow in EDTA, fine needle aspirate, ascitic and pleural fluids</p>	<p><u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Flow Cytometry</u> (cont'd)</p> <p>Immunophenotyping of haematological disorders for chronic lymphoproliferative disorders (cont'd)</p> <p>T Cell</p> <ul style="list-style-type: none"> • TCR alpha/beta • TCR gamma/delta • CD2 ECD • CD5 PC5.5 • CD7 APC • CD16 PC7 • CD56 AA750 • HLA-DR PB • CD45 KO <p>Lymphocyte Screening Tube (LST)</p> <ul style="list-style-type: none"> • CD3 • CD4 • CD8 • CD19 • CD25 • CD34 • CD45 • Kappa • Lambda <p>CD34 (Stem cell harvesting)</p> <p>Paroxysmal Nocturnal Haemoglobinuria(PNH) RBC and WBC CD 59 expression</p>	<p>Documented In-house methods using:</p> <p>Navios Flow Cytometer Cellular analysis by flow cytometry using SOP: LP-300-025, <u>H-LP 300 035</u></p> <p>SOP:-300 031</p> <p>SOP:- 300 032</p>	<p>F</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Venous whole blood, bone marrow in EDTA</p>	<p><u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Immunophenotyping of haematological disorders for acute leukaemia.</p> <p>Acute Screening Tube (AST)</p> <ul style="list-style-type: none"> • CD13 • CD33 • CD34 • CD10 • CD7 • CD117 • CD19 • HLA-DR • CD45 <p>Acute Myeloid Tube (AM1)</p> <ul style="list-style-type: none"> • CD15 • CD56 • CD14 • CD11c • CD34 • CD38 • CD64 • HLA-DR • CD45 <p>Acute Lymphoid Tube (AL2)</p> <ul style="list-style-type: none"> • CD9 • IgM • CD34 • CD10 • CD20 • CD22 • CD38 • CD19 • CD45 	<p>Documented In-house methods using:</p> <p>Navios Flow Cytometer Cellular analysis by flow cytometry using SOP: LP-300-037</p>	<p>F</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Venous whole blood, bone marrow in EDTA(cont'd)</p>	<p>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</p> <p>Immunophenotyping of haematological disorders for acute leukaemia.</p> <p>Acute Permeabilised Panel</p> <ul style="list-style-type: none"> • CD3 • CD22 • MPO • TdT • IgM • CD79a • CD19 • CD34 • CD45 	<p>Documented In-house methods using:</p> <p>Navios Flow Cytometer Cellular analysis by flow cytometry using SOP: LP-300-037</p>	<p>F</p>



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HUMAN BODY FLUIDS and TISSUES	<u>Diagnostic Cytology examinations to assist in clinical investigations</u>	In House documented procedure & manufacturer's instructions using the following	
Wet Fixed Preparations – Body fluids, urine, CSFs, washings, brushings, EUSFNA	Processing and Staining of Diagnostic Specimens for detection of abnormal cells	Manual Processing – Documented procedures – PCD 03, PCD 11, PCD 13, PCD 36 Documented procedure & manufacturer's instructions using Hologic T5000 sample processor – PCD 37, PCD 08, PCD 26, PCD 27, PCD 33, PCD 34 Papanicolaou - Documented procedure & manufacturer's instructions using Leica Autostainer Ultra – PCSt 13 Papanicolaou-Manual method using documented procedure - PCSt 02	H
Air Dried Preparations - Body fluids, CSFs	Processing and Staining of Diagnostic Specimens for detection of abnormal cells	Manual Processing – Documented procedures – PCD 03, PCD 11, PCD 13, PCD 36 May Grunwald Giemsa (MGG) Manual method using documented procedure – PCSt 03	H
Cell Block Preparations - Body fluids, urine, CSFs, washings, brushings, EUSFNA, needle washings from, Thyroid, Lymph node FNAs Etc	Preparation of cell block from Diagnostic Specimens for detection of abnormal cells	Documented procedure – PCD 19	H



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Frozen Section Histology examinations to assist in clinical investigations</u>	In House documented procedure & manufacturer's instructions using the following	
Tissue samples	Detection of abnormal cells	Documented in the range PCBR 101 - 109 Leica Cryostat (Cryostar NX50 & CM1860 UV Cryostat) PCBR102 &109	H
Tissue samples	<u>Routine Histopathology examinations to assist in clinical investigations</u>	In House documented manual methods and manufacturer's instructions	
	Specimen Dissection	Manual method using documented procedures in the range PHD101 – 117. Dissections performed on AFOS Ventilated Specimen Table.	H
	Tissue processing	Documented procedure & manufacturer's instructions using Leica Peloris PPR103	
	Tissue Processing	Documented Procedure & Manufacturers Manual for P EX 107 Tissue-Tek Sakura VIP Vacuum Infiltration Processor, PPR115	H
	Tissue embedding	Manual method using documented procedure PPR107	
	Tissue sectioning	Manual method using documented procedure PRL104 (Leica Microtome RM 2125 RTS, Leica Microtome RM 2235, Leica Histocore Autocut Rotary Microtome, Histocore Biocut microtome & Tissue-TEK AutoSection Automated Microtome).	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Routine Histopathology examinations to assist in clinical investigations</u> (cont'd)	In House documented manual methods and manufacturer's instructions	
Tissue samples	Basophilic and eosinophilic structures	Automated Haematoxylin and eosin staining using Dako coverstainer and Leica Histocore Spectra with reference to PRL131	H
Tissue samples	<u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities</u>	In House documented procedure of manual methods using series PSSSt 101 – 140	H
	Acid Fast Tubercle Bacilli	Ziehl Neelson	
	Basophil/Eosinophil/Neutrophil granules	Giemsa	
	Calcium	Von Kossa	
	Connective tissue/Collagen/Muscle	Masson Trichrome Picro Sirius Red Van Gieson	
	Connective tissue/Collagen/Muscle/Fibrin	Martius Scarlet Blue (MSB)	
	Elastic Fibres	Elastic Haematoxylin & Eosin Elastic Stain	
	General Architecture	Toluidine blue Stain (Resin Sections)	
	Histopathological examination activities for the purposes of clinical diagnosis		
	Morphological assessment and interpretation/diagnosis.	Microscopy with reference to SOPS: PHRR13 PHRR12	H



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u>	In House documented procedure & manufacturer's instructions using the following (cont'd)	
Tissue samples (cont'd)	Gram +ve & Gram -ve Organisms	Gram Stain	H
	Helicobacter/Micro-organisms	Modified Giemsa	
	Hepatitis B affected Cells/Copper associated protein	Shikata's Orcein	
	Lipid	Oil Red O	
	Mast Cells	Toluidine Blue	
	Melanin/Argentaffin/Chromaffin/some Lipofuscin	Masson Fontana	
	Mycobacterium Leprae	Wade-Fite	
	Nuclei	Celestin Blue-Haematoxylin	
	pH2.5 Acid Mucins	Alcian Blue (pH2.5)	
	Spirochetes	Warthin Starry	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities</u>	Automated special stains using Dako Artisan Link Pro with reference to PSSt 149	H
Tissue samples (cont'd)	Acid and Neutral Mucins Amyloid Fungi Acid mucopolysaccharides Basement Membranes Glycogen/Neutral Mucins/Fungi Haemosiderin Reticulin Fibres	Alcian Blue ABPAS Congo Red Grocott Gomori Methenamine Silver Hales Colloidal Iron Jones Methenamine Sliver PAS/ PASD Perls Prussian Blue Gordon & Sweet's Reticulin	



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>Tissue samples & Cell blocks</p>	<p><u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u></p> <p>Embryonic cells in normal tissues and germ tumours</p> <p>Smooth muscle cells, myoepithelial cells</p> <p>Anaplastic Large Cell Lymphoma's (ALCL's)</p> <p>Androgen Receptor positive cells</p> <p>B cells, follicular lymphomas</p> <p>B cells, lymphomas</p> <p>B cells, plasma cells</p> <p>Ovarian epithelial malignancies, seminal vesical carcinoma, anaplastic lymphoma</p> <p>Parafollicular cells in thyroid and medullary thyroid carcinomas</p> <p>Smooth muscle cells</p> <p>Marker for mesotheliomas</p> <p>Mature B cells, follicular dendritic cells, CALLA</p>	<p>In house documented procedures & manufacturer's instructions using Dako Omnisystem – SOP PICC 211-213</p> <p>Using antibodies to and microscopy;-</p> <p>a-1-Fetoprotein</p> <p>Actin, smooth muscle</p> <p>ALKinase</p> <p>Androgen Receptor</p> <p>Bcl-2 (Dako)</p> <p>Bcl-6 Protein</p> <p>Bob-1 (C20)</p> <p>CA125</p> <p>Calcitonin</p> <p>Caldesmon, Calponin (cell marque)</p> <p>Calretinin</p> <p>CD10 (CALLA)</p>	<p>H</p>



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u>	In House documented procedure & manufacturer's instructions using the following (cont'd)	H
Tissue samples & Cell blocks (cont'd)	Various - mast cells, stem cells, Cajal cells, melanocytes, basal cells (skin) and mammary duct epithelium	CD117	
	Granulocytes, monocytes and various non- hematopoietic	CD13	
	Plasma cells	CD138	
	Monocytes, macrophages and Langerhans cells	CD14	
	Granulocytes, Reed-Sternberg cells	CD15	
	Monocytes	CD163	
	Langerhans cells	CD1a	
	T cells	CD2, CD3	
	B cell	CD20	
	Mature B cells, Follicular dendritic cell	CD21	
	B cells, some T cell	CD23	
	Reed-Sternberg cells, plasma cells	CD30	
	Endothelial cells	CD31 CD34	
	Myeloid cells	CD33	
	Erythrocytes, leukocytes, glomerular podocytes and follicular dendritic cells	CD35	
	T cells (helper & mature)	CD4	



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>Tissue samples & Cell blocks (cont'd)</p>	<p><u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u></p> <p>Platelets, megakaryocytes</p> <p>T and B cell Lymphoma's</p> <p>Leucocytes</p> <p>T cell (membranous) & B Cell (mantel zone of secondary follicle)</p> <p>Natural killer cells, neuroendocrine tissues</p> <p>Platelets, megakaryocytes, macrophages, endothelial cells</p> <p>Macrophages, monocytes, myeloid cells</p> <p>T cells. Natural killer cells, thymocytes</p> <p>B cells</p> <p>T cells</p> <p>Wide range of tumours including Ewing's Sarcoma, & T cell lymphoma</p> <p>Intestinal epithelial cells, colorectal + other adenocarcinomas</p> <p>CEA glycoproteins</p> <p>Tissues of neuroendocrine origin</p> <p>Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma</p>	<p>In House documented procedure & manufacturer's instructions using the following (cont'd)</p> <p>CD42b</p> <p>CD43</p> <p>CD45</p> <p>CD5</p> <p>CD56</p> <p>CD57</p> <p>CD61</p> <p>CD68</p> <p>CD7</p> <p>CD79a</p> <p>CD8 CD99 CDX2</p> <p>CEA</p> <p>Chromagranin A</p> <p>CK, HMW</p>	<p>H</p>



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>Tissue samples & Cell blocks (cont'd)</p>	<p><u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u></p> <p>Expressed in variety tumours</p> <p>Pan cytokeratin (broad range)</p> <p>Epithelial cells</p> <p>Epithelial cells including ductal and glandular epithelia</p> <p>Adenocarcinomas, columnar epithelial cells</p> <p>Stratified squamous epithelium, basal cells, mesotheliomas</p> <p>Normal and neoplastic epithelia</p> <p>Pan cytokeratin (broad range)</p> <p>Epithelial cells</p> <p>Cytomegalovirus</p> <p>Lymphatic vessels</p> <p>Striated and smooth muscle cells</p> <p>Gastro Intestinal Stromal tumours (GIST)</p> <p>Normal duct epithelial cells, ductal carcinoma</p>	<p>In House documented procedure & manufacturer's instructions using the following (cont'd)</p> <p>Cyclin D1</p> <p>Cytokeratin, MNF116</p> <p>Cytokeratin 14</p> <p>Cytokeratin 19</p> <p>Cytokeratin 20</p> <p>Cytokeratin 5/6</p> <p>Cytokeratin 7</p> <p>Cytokeratin AE1/AE3</p> <p>Cytokeratin, Cam 5.2</p> <p>Cytomegalovirus</p> <p>D2-40</p> <p>Desmin</p> <p>DOG-1</p> <p>E-Cadherin</p>	<p>H</p>



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u>	In House documented procedure & manufacturer's instructions using the following (cont'd)	
Tissue samples & Cell blocks (cont'd)	Normal epithelium, over expression in various cancers	EGFR	H
	Normal and neoplastic epithelium	EMA	
	Epithelial cells, most adenocarcinomas	EP4	
	Nuclei of cells containing a high level of oestrogen	Estrogen Receptor	
	V.W factor in endothelial cells	Factor XIIIa	
	G Cell hyperplasia	Gastrin	
	Schwann cells, enteric glial cells, astrocytomas, ependymomas	GFAP	
	Erythrocytes	Glycophorin A and Glycophorin C	
	T cell lymphoma's	GMP-17 (TIA-1)	
	Cytotoxic T Lymphocytes, Natural Killer cells	Granzyme B	
	Hairy cell leukaemia's	Hairy Cell Leukaemia	
	Placental trophoblasts	hCG	
	Breast carcinoma's expressing HER-2	HER – 2	



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>Tissue samples & Cell blocks (cont'd)</p>	<p><u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u></p> <p>B cells, monocytes, macrophages, myeloid/erythroid precursors activated T cells and some epithelial cells</p> <p>Melanoma, melanocyte differentiation</p> <p>Sex chord stromal tumours</p> <p>Insulin</p> <p>Proliferating Cells</p> <p>B cells and plasma cells</p> <p>B cell follicles</p> <p>Melanoma marker</p> <p>Colon adenocarcinoma</p> <p>Granulocytes and monocytes</p> <p>Urothelium</p> <p>Lympho-haemopoietic tumours</p> <p>Rhabdomyosarcoma</p> <p>Smooth muscle cells</p>	<p>In House documented procedure & manufacturer's instructions using the following (cont'd)</p> <p>HLA-DR</p> <p>HMB45</p> <p>Inhibin, alpha</p> <p>Insulin</p> <p>Ki67/p16-MIB-1(Ki67)</p> <p>Kappa</p> <p>Lambda</p> <p>Melan A</p> <p>MLH1</p> <p>MPO</p> <p>MUC-4</p> <p>MUM1</p> <p>MyoD1 and Myogenin</p> <p>Myosin (Skeletal Fast)</p>	<p>H</p>



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u>	In House documented procedure & manufacturer's instructions using the following (cont'd)	H
Tissue samples & Cell blocks (cont'd)	myoepithelial cells	Myosin Heavy Chain (Smooth muscle)	
	Neutrophils	Neutrophil Elastase	
	Neuro, endocrine and neuro-endocrine tumours	NFP	
	Peripheral nerves, neuroendocrine tumours	NSE	
	B Cell lymphomas, germinal centre derived lymphomas	Oct 2	
	Germ cell tumours, seminomas	OCT 3/4	
	Various tumours	P16 Protein	
	Squamous and Basal Cell Carcinoma's	P40	
	Breast, colon, lung and urothelial carcinoma's	P53	
	Prostate basal cells, proliferative cells, glandular epithelium	P63	
	Non-small cell lung carcinoma differentiation	P63/CK7	
	B Cells	PAX-5	
	Neurones and ganglion cells	Peripherin	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u>	In House documented procedure & manufacturer's instructions using the following (cont'd)	H
Tissue samples & Cell blocks (cont'd)	Neurons and neuro-endocrine cells	PGP9.5	
	Germ cell tumours, seminomas	Plac Alk Phos	
	Colon adenocarcinoma	PMS2	
	Nuclei of cells showing expression of Progesterone	Progesterone	
	Metastatic prostatic tumours	Pros Acid Phos	
	Prostate secretory and ductal epithelium	PSA poly	
	Prostate adenocarcinoma	Racemace	
	High Grade PIN	S-100	
	Schwann cells, nerve processes, S100 positive neoplasms		
	Simian Virus 40	SV40	
	Neuroendocrine cells	Synaptophysin	
	Lung adenocarcinoma	TAG-72	
	T & B Lymphocytes, Leukaemias, acute lymphocytic lymphomas	TdT	
	Thyroglobulin containing cells	Thyroglobulin	
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1	



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>Tissue samples & Cell blocks (cont'd)</p>	<p><u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u></p> <p>Small cell differentiation in Lung cancer</p> <p>Cells of mesenchymal origin Epithelial cells and smooth muscle in fallopian tube.</p> <p>Wilms' tumour</p> <p>Epstein Barr Encoded RNA expressing cells</p> <p>Complement C4d in allograft rejection</p> <p>Myeloid cells</p> <p>Non-small Cell Lung Carcinoma's (NSCLC)</p> <p>Non-small-cell Lung Carcinoma (NSCLC)</p>	<p>In House documented procedure & manufacturer's instructions using the following (cont'd)</p> <p>TTF-1/CK5/6</p> <p>Vimentin</p> <p>Wilms' Tumour (WT1)</p> <p>EBER ISH</p> <p>C4d</p> <p>CD33</p> <p>In house documented procedures & manufacturer's instructions using Roche Ventana Benchmark Ultra system – SOP PICC 201-209 Using antibodies to and microscopy;-</p> <p>Lung ALK</p> <p>ROS-1</p>	<p>H</p>



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u>	In House documented procedure & manufacturer's instructions using the following (cont'd)	
FFPE Lung tissue	Non-small cell lung carcinoma differentiation	PD-L1 via the DAKO AS 48 autostainer using SOP: PBioR 405	H
Acetone fixed Fresh Skin and Renal tissue	Immunoglobulins and complement factors	Immunofluorescent detection of IgA, IgG, IgM, C3 via the Roche Ventana Benchmark Ultra system using SOP: PICC 210	H



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HUMAN BODY FLUIDS (cont'd) Plasma and Serum (cont'd)	<u>Immunology examinations for the purpose of clinical diagnosis (cont'd):</u> Allergy (cont'd) Chicken meat Chilli pepper Chlorohexidine Coconut Cod fish Cow dander Crab Cucumber Dog dander Eurogyphus maynei Egg white Egg yolk Glycyphagus domesticus Garlic Ginger Gluten Green pepper Hazel nut Horse dander House dust mite Isocyanate HDI Isocyanate MDI Isocyanate TDI Kiwifruit Lepidoglyphus destructor Latex Lemon Lentil lupin seed Lysozyme Macademia Maize Mango Melon Milk Morphine Mosquito Mushroom Mustard Mutton Oat Omega-5 gliadin Onion Orange	In-house documented procedures based on equipment manuals as relevant Immunocap-Phadia 250 by fluorescence detection of strength of antibody/antigen reactions I-AIA-IP-06 SOP: I-AIA-LP-07 SOP: I-AIA-LP-08 SOP: I-AIA-LP-09 SOP: I-AIA-LP-10	G



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	G
Plasma and Serum (cont'd)	Allergy (cont'd) Paprika Pea Peach Peanut Pear Pecan Penicillin G Penicillin V Pineapple Pinenut Pistachio Poppy seed Pork Potato Pumpkin seed Rape pollen Rape seed oil Raspberry Red kidney bean Rice Rye Salmon Scallop Sesame seed Sheep Dander Shrimp Soya bean Strawberry Sunflower seed Suxamethonium Tyrophagus putrescentiae Tomato Tuna fish Walnut Wasp venom Wheat Yeast	Immunocap-Phadia 250 by fluorescence detection of strength of antibody/antigen reactions I-AIA-IP-06 SOP: I-AIA-LP-07 SOP: I-AIA-LP-08 SOP: I-AIA-LP-09 SOP: I-AIA-LP-10	



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Plasma and Serum (cont'd)</p>	<p><u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Allergy (cont'd) Allergen components rAra-h-2 rAra-h-8 rAra-h-9 rCor a 1 PR-10 nCor a 9 rCor a 14</p> <p>Allergen mixes Guinea pig/rabbit/hamster/rat/mouse</p> <p>Goose/chicken/duck/ turkey feathers</p> <p>Budgerigar/canary/parakeet/parr ot feathers</p> <p>Grass pollen: Anthoxanthum odoratum/lolium perenne/phleum pratense/Secale cereal/Holcus lanatus</p> <p>Tree pollen: Acer negundo/Betula verrucosa/ Corylus avellana/Quercus alba/Salix caprea</p> <p>Weed pollen: Artemisia vulgaris/Plantago lanceolata/Chenopodium album/ Solidago virgaurea/ urtica dioica</p> <p>Orange/lemon/grapefruit/mand arin</p> <p>Peanut/hazelnut/brazil nut/almond/coconut</p> <p>Pecan/cashew/pistachio/walnut</p> <p>Egg/white/milk/fish/wheat/pean ut/soybean</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Immunocap-Phadia 250 by fluorescence detection of strength of antibody/antigen reactions I-AIA-IP-06 SOP: I-AIA-LP-07 SOP: I-AIA-LP-08 SOP: I-AIA-LP-09 SOP: I-AIA-LP-10</p>	<p align="center">G</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Plasma and Serum (cont'd)	Wheat/oat/maize/sesame seed/buckwheat, Fish/shrimp/blue mussel/tuna/salmon Kiwi/melon/banana/peach/pine apple Mould: Penicillium chrysogenum/ Cladosporium herbarum/Aspergillus fumigatus/ Alternaria alternate	Immucap-Phadia 250 by fluorescence detection of strength of antibody/antigen reactions I-AIA-IP-06 SOP: I-AIA-LP-07 SOP: I-AIA-LP-08 SOP: I-AIA-LP-09 SOP: I-AIA-LP-10	G
	Autoimmunity Antibodies to;- <ul style="list-style-type: none"> • Cardiopilin • CCP • CTD • dsDNA • ENAs <ul style="list-style-type: none"> ○ CenpB ○ Jo-1 ○ La ○ RNP ○ RNP70 ○ Scl-70 ○ Sm • GBM • IgA & IgG Anti-Tissue Transglutaminase (TTG) antibodies • MPO • PR3 • Intrinsic Factor • TPO • TSH-Receptor 	Immucap-Phadia 250 by fluorescence detection of strength of antibody/antigen reactions using ELIA kits I-AIA-LP-16 I-AIA-LP-50 I-AIA-LP-57 I-AIA-LP-19 I-AIA-LP-39 I-AIA-LP-15 I-AIA-LP-55 I-AIA-LP-60 I-AIA-LP-13 I-AIA-LP-14 I-AIA-LP-61 I-AIA-LP-12 I-AIA-LP-38	G



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Serum	Ro52 antibody Ro60 antibody	Immucap-Phadia 250 by immunoassay I-AIA-IP-06 I-AIA-LP-19	G
	<u>Cellular Immunity</u>	Beckman Coulter Navios EX Flow Cytometry enumeration of cells.	
Whole Blood	Lymphocyte phenotyping;- • CD3 • CD4 • CD8 • CD19 • CD16/CD56	SOP I-CEL-IP-07 SOP I-CEL-LP-20 SOP I-CEL-LP-22	G
Whole Blood	DHR Neutrophil Oxidative Burst Assay	Beckman Coulter Navios EX Flow Cytometry. SOP I-CEL-IP-07 SOP I-CEL-LP-23	G
Serum	Determination of: Complement • C3 • C4 Rheumatoid Factor Anti- Streptolysin O (ASO) Beta 2 Microglobulin C1 inhibitor (quantitative) IgG subclasses (IgG 1-4)	The Binding Site- Optilite Immunoturbometric I-AIA-IP-18 in conjunction with: I-AIA-LP-04 I-AIA-LP-05 I-AIA-LP-01 I-AIA-LP-02 I-AIA-LP-03 I-AIA-LP-06	G
Plasma and serum	Auto Immune Antibodies to: • C1q • Haemophilus Influenza • Pneumococcal • Tetanus • Functional C1-inhibitor	Manual ELISAs read on Tecan Sunrise ELISA reader using optical density I-AIA-LP- 54 I-AIA-LP-40 I-AIA-LP-42 I-AIA-LP-41 I-AIA-LP-56	G



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HUMAN BODY FLUIDS	<u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Serum	Classical Pathway Complement Assay Alternative Pathway Complement Assay	Weislab Complement System ELISA read on TECAN Sunrise ELISA plate reader I-AIA-IP-08, I-CEL-LP-25 I-AIA-IP-08, I-CEL-LP-26	G
Serum	Detection of the following antibodies: <ul style="list-style-type: none"> • Anti-Neutrophil Cytoplasmic • Anti-Nuclear (Hep-2) • Adrenal Antibodies • Anti-Mitochondrial • Anti-Gastric Parietal Cell • Anti-LKM • Anti-Smooth Muscle • Anti-Endomysial IgA • Anti-ds-DNA (Crithidia) • Anti-Skin (bullous) antibodies 	Indirect Immunofluorescence, QuantalLyser 3000. SOPs I-AIA-IP-20 plus: I-AIA-LP-21 I-AIA-LP-22 I-AIA-LP-27 I-AIA-LP-59 I-AIA-LP-59 I-AIA-LP-59 I-AIA-LP-28 I-AIA-LP-44 I-AIA-LP-34	G



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HUMAN TISSUE AND FLUIDS	Cytogenetics		
Whole Blood Amniotic Fluid CVS Foetal blood Products of conception Tissue biopsy	Chromosome analysis for: Constitutional disorders Prenatal Diagnosis Reproductive Medicine Disorders Developmental Disorders Chromosome Breakage Disorders	Documented in-house methods for Chromosome culture by in-house procedures CYT PND 002, 005, 006, 007, 008, 014, 015, 021, 023; CYT BLO 002, 003 CYT INST 001-006 Followed by: Preparation of material for chromosome analysis by manual harvest using procedures CYT PND 019, CYT BLO 004, CYT INST 001-006 CYT GEN 012	J J
Whole Blood Amniotic Fluid CVS Foetal blood Products of conception Tissue biopsy (cont'd)	Chromosome analysis for: Constitutional disorders Prenatal Diagnosis Reproductive Medicine Disorders Developmental Disorders Chromosome Breakage Disorders (cont'd)	The above followed by any combination of the following and Applied Spectral Imaging Image Analysis System SOP : CYT ANAL 003, 004, 005 a) G Banding - Microscopic detection using procedures CYT GEN 013 b) Solid Staining and SCE staining with Microscopic detection using procedures CYT GEN 008 CYT INST007 c) Fluorescence In situ Hybridisation (FISH) Documented in house methods using commercial kits from Abott (Vysis), Cytocell, Kreatech, and TCAG and in-house manual processing - Microscopic detection CYT FISH 018	J



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<p>HUMAN TISSUE AND FLUIDS</p> <p>Bone marrow Whole blood Pleural Infusions Any malignant fluid</p>	<p><u>Molecular Pathology</u></p> <p>Chromosome analysis for haemato-oncology and other oncology disorders</p>	<p>Chromosome culture by in-house procedures CYT ACQ 002, 014, 015</p> <p>Followed by: Preparation of material for chromosome analysis by manual harvest using in-house methods CYT ACQ 009 CYT GEN 012</p> <p>and one or both of the following:</p> <p>a) G-Banding - Microscopic detection CYT GEN 013 b) Fluorescence In situ Hybridisation (FISH) by documented in house methods using Abott (Vysis), Cytocell and Kreatech kits and in-house manual processing – Microscopic detection CYT FISH 018</p>	<p>J</p>
<p>Paraffin embedded tissue sections</p>		<p>Treatment of FFPE sections by documented in house manual method CYT FISH 020, 021</p> <p>Followed by: Fluorescence In situ Hybridisation (FISH) using documented in house methods and Abott (Vysis), Cytocell, Kreatech, and Zytolight kits with in-house manual processing – Microscopic detection CYT FISH 018</p>	<p>J</p>



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HUMAN TISSUE AND FLUIDS (cont'd) Bone marrow Lymph node Whole blood Pleural Infusions Any malignant solid body tumour or fluid FFPE	<u>Molecular Pathology</u> (cont'd) DNA and RNA-based molecular analysis for haemato-oncology disorders	Documented methods for DNA and RNA extraction using in-house procedures for manual or robotic extraction using QIASymphony, Biorobot EZI XL, and Maxwell 16 IVD kits Manual CYT ACQM 003 Robotic MOL EXTR 009, 019 FFPE LEV DNA Extraction SOP: MOL EXTR 017	J
	Mutation detection in the diagnosis and management of: AML / MDS CML / MPN ALL	PCR and RT PCR amplification of DNA / RNA (cDNA) using in house techniques. CYT ACQM 012, 002, 016, 018, 027 Followed by one of the following: a) Agarose gel electrophoresis MOL ELECT 004 b) Fragment analysis by capillary electrophoresis on ABI3730 MOL EQUIP 009 MOL FLA 001 Followed by Data analysis using GeneMarker CYT ACQM 023, 028	J
	CML / MPN ALL	(RT-q) PCR amplification of DNA / RNA (cDNA) using in house method and Qiagen kit with RotorGene 6000 CYT ACQM 006, 019, 024	J
Bone marrow Lymph node Whole blood Pleural Infusions Any malignant solid body tumour or fluid	MYD88 L265P Mutation	Realtime PCR and RotorgeneQ SOP:-CYT ACQM 020	J



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular Pathology</u> (cont'd)		
DNA	FLT3-TKD mutations	Fragment length polymorphism-mediated PCR assay (PCR followed by enzyme EcoRV digest and resolution by fragment analysis ABI3730) CYT ACQM 027, 028, MOL EQUIP 009, MOL FLA 001	J
DNA	Clonality assessment of suspected lymphoproliferative disorders	Commercial kit (InVivoScribe) Fragment analysis on ABI3730 Data analysis using GeneMarker CYT ACQM 005, 026	J
Paraffin embedded tissue sections	Mutation detection and screening: Lung cancer Colorectal cancer Melanoma Ovarian cancer Breast cancer	PCR amplification of DNA/RNA (cDNA) using in house methods and commercial kits MOL PCR 001 MOL PATH 003 Using a combination of techniques below: a) Fragment length analysis (FLA) using ABI 3730 capillary electrophoresis MOL EQUIP 009 MOL FLA 001 MOL PATH 002 MOL PATH 006 b) Sequence analysis on ABI3730 platform. Data analysis Mutation Surveyor MOL SEQ 001 MOL EQUIP 009 MOL PATH 002, 006 c) Mutation detection on the Cobas platform using kits as below Roche Cobas EGFR Roche Cobas KRAS Roche Cobas BRAF V600 MOL PATH 001, 003, 006	J



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular Pathology</u> (cont'd)		
Plasma	cfDNA	Roche Cobas cfDNA preparation kit For downstream EGFR testing on Cobas SOPs: MOL EXTR 015, 016 Roche Cobas EGFR SOPs: MOL PATH, 001, 003, 006	J
DNA from FFPE	Micro satellite instability (MSI)	In house methodology for evaluation of colo-rectal tumour samples only SOP: MOL PATH 001, 004, 006	J
DNA extracted from FFPE tissue	Solid Tumour Panel Detection of hotspots in solid tumours	Thermo Fisher Oncomine Focus NGS DNA panel Library preparation on Ion Chef and sequencing on Ion GeneStudio S5. Analysis using commercial Torrent Suite and Ion Reporter Analysis Pipeline. SOP: MOL PATH 001, 006; MOL NGS 003, 013, 015, 018	J
RNA extracted from FFPE tissue	Detection of fusions in solid tumour cancers, including: <ul style="list-style-type: none"> • ALK, ROS1, NTRK1,2,3 RET and MET skipping	Automated library preparation and sequencing using Genexus Integrated Sequencer NGS platform and Oncomine Precision assay. Analysis using customised workflow and Genexus server. SOPs: MOL PATH 001, MOL PATH 006, MOL NGS 024, MOL NGS 025	J



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular Pathology</u> (cont'd)		
DNA	Myeloid Panel Detection of mutations in MDS, AML, and CLL	Thermo Fisher Myeloid Oncomine NGS DNA panel Set up on Ion Chef) and sequencing by Ion Torrent S5. Analysis through commercial Ion Reporter Analysis Pipeline SOP: MOL NGS 003, 013, 015, 018	J
RNA /cDNA	Myeloid Panel Detection of fusion gene / translocation detection in haematological malignancies	Thermo Fisher Oncomine Myeloid RNA Assay Set up on Ion Chef and sequencing by Ion Torrent S5. Analysis through commercial Ion Reporter Analysis Pipeline. SOP: MOL NGS 003, 013, 015, 018	J
DNA	Fragment size data	Agilent Tapestation 4200 for QC and DNA NGS Libraries MOL NGS 017	J



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Whole Blood Foetal Blood Mouth washes Amniotic Fluid CVS Products of Conception Fresh tissue (tumour, muscle, liver, lymph nodes etc) Bone Marrow Wax embedded tissue Slide sections DNA Culture fibroblasts</p>	<p><u>Molecular Genetics</u></p> <p>DNA and RNA (cDNA)-based detection of abnormal sequences for common and rare genetic disease conditions</p>	<p>Documented in-house methods for DNA and RNA extraction using in-house procedures using commercial kits and manual or robotic extraction using QIASymphony, QIA EZ1, and Maxwell 16 IVD instruments and kits</p> <p><u>Manual</u> MOL EXTR 005, 006, iGENATAL DNA extraction MOL 021</p> <p><u>Robotic</u> MOL EXTR 009, ,019</p> <p>FFPE LEV DNA extraction kit Maxwell 16 IVD Tissue Kit SOP:MOL EXTR 017</p> <p>PCR amplification of DNA/RNA (cDNA) using in house methods and commercial kits MOL PCR 001, MOL QFPCR 015, MOL EXTR 018</p> <p>Followed by (as appropriate): Capillary electrophoresis by in house methods using ABI 3730 genetic analyser MOL SEQ 001 MOL EQUIP 009 MOL FLA 001</p>	<p>J</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Whole Blood, Foetal Blood Mouth washes, Amniotic Fluid CVS, Products of Conception Fresh tissue (tumour, muscle, liver, lymph nodes etc), Bone Marrow Wax embedded tissue, Slide sections, DNA</p> <p>DNA extracted from whole blood (EDTA preserved), amniotic fluid, chorionic villus sampling, saliva.</p> <p>Whole Blood, Foetal Blood Mouth washes, Amniotic Fluid CVS, Products of Conception Fresh tissue (tumour, muscle, liver, lymph nodes etc), Bone Marrow Wax embedded tissue Slide sections, DNA</p>	<p><u>Molecular Genetics</u> (cont'd)</p> <p>DNA and RNA (cDNA)-based detection of abnormal sequences for common and rare genetic disease conditions (cont'd)</p> <ul style="list-style-type: none"> Rapid Prenatal diagnosis of Trisomies <p>Deletion and duplication detection</p> <ul style="list-style-type: none"> Breast/ovarian cancer HMSN/HLPP Hyperlipidaemia Li-Fraumeni PTEN Hamartoma Tumour syndrome (PHTS) <p>Detection of specific wild type and mutant alleles in the CFTR gene</p> <p>Unstable repeat measurement and Specific mutation detection:</p> <ul style="list-style-type: none"> Myotonic Dystrophy types 1 and 2, Fragile X Torsion dystonia GRA 	<p>Using Elucigene kits as below QST*R plus QST*R 13 QST*R 18 QST*R 21 MOL QFPCR 015</p> <p>Multiplex Ligation Probe Amplification (MLPA) and fragment length analysis to detect characteristic mutations and larger intragenic deletions and duplications using MRC-Holland kit MOL MLPA 001, 002, MOL FLA 001</p> <p>Fragment length analysis on ABI3730 platform with data analysis on GeneMarker MOL CF 004 MOL FLA 001</p> <p>Fragment length analysis (FLA)ABI 3730 capillary electrophoresis MOL EQUIP, 009 MOL FLA 001 MOL ELECT 001</p> <p>MOL DM 003, MOL DM 004MOL FRAX 001 MOL DYT 001 MOL GRA 001</p>	<p>J</p> <p>J</p> <p>J</p> <p>J</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Whole Blood, Foetal Blood Mouth washes, Amniotic Fluid CVS, Products of Conception Fresh tissue (tumour, muscle, liver, lymph nodes etc), Bone Marrow Wax embedded tissue Slide sections, DNA (cont'd)</p>	<p><u>Molecular Genetics</u> (cont'd)</p> <p>Mutation detection by DNA sequencing:</p> <ul style="list-style-type: none"> • Breast/ovarian cancer • Cardiac disorders • PTEN Hamartoma Tumour syndrome (PHTS) • Haemochromatosis • HMSN (all types) • Hyperlipidaemia • Sickle cell mutation EB7 • Thrombophilia <p>Rare disorders:</p> <ul style="list-style-type: none"> • Non-syndromic X-linked mental retardation • Trimethylaminuria • Familial Mediterranean fever 	<p>Sequence analysis on ABI3730 platform. Data analysis Mutation Surveyor MOL EQUIP 009 MOL SEQ 001, 008 With specific reference to the procedures below as appropriate</p> <p>MOL IN CAN 001 MOL CARD 001 MOL PTEN 003</p> <p>MOL HFE 001 MOL HMSN 002 MOL FH 006 MOL APOE 001 MOL TRIG 001 MOL SICK 001 MOL THROM 001</p> <p>MOL RARE 001 MOL TMA 001 MOL FMF 001</p>	<p>J</p>
<p>DNA</p>	<p>DYPD SNP screening for SNPs associated with 5FU chemotherapy toxicity</p>	<p>Sanger sequencing using universal primers and capillary electrophoresis on the ABI3730 genetic analyser. Results analysis using commercial Mutation Surveyor software SOP: MOL DPYD 001, MOL FORM 205, MOL PCR 001, MOL ELECT 004, MOL EQUIP 007, MOL SEQ 001, MOL SEQ 008, MOL SEQ 010</p>	<p>J</p>



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular Genetics</u> (cont'd)		
DNA extracted from whole blood, amniotic fluid, CVS, cultured cells, saliva, bone marrow, fresh tissue and formalin fixed paraffin embedded (FFPE) tissue	Detection of copy number variants associated with: <ul style="list-style-type: none"> developmental delay dysmorphic features with or without congenital anomalies acute lymphoblastic leukaemia (ALL) renal cell carcinoma	ThermoFisher CytoScan 750K Suite microarray instruments and Chromosome Analysis Software (ChAS) programme SOP: CYT ARRAY 005, 008, 009, 010, 011, 012, 013 and 014.	J
DNA	Mutation detection by Next-Generation DNA sequencing		
	Cardiac Arrhythmias Sub panels <ul style="list-style-type: none"> Atrial Fibrillation Brugada Syndrome Catecholaminergic polymorphic ventricular tachycardia (CPVT) Heart Block Long QT Long QT – Andersen syndrome Sudden Cardiac Death 	Custom Cardio Solution NGS panel for Cardiac Arrhythmias, sequencing by MiSeq and analysis of sub-panels through commercial SOPHiA DDM pipeline. MOL NGS 006, 016, 022, 034, , MOL CARD 001	J
DNA	Hereditary Cancer Solution for breast and ovarian cancer,	Breast and ovarian cancer, sequencing by MiSeq and analysis through commercial SOPHiA DDM pipeline (Germline). MOL IN CAN 001 MOL NGS 006, 016, 022, MOL NGS 034	J



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular Genetics</u> (cont'd)		
DNA	Mutation detection by Next-Generation DNA sequencing SPIDeR SEQ panel	(Scottish Primary Immune Deficiency and Rheumatology NGS SEQ panel) - custom design kit based on Twist Custom Design library preparation, sequencing by MiSeq and analysis by commercial Sophia DDM pipeline (CVID). SOP: MOL NGS 031 ,MOL NGS 022, MOL MIR 001	J
DNA extracted from FFPE tissue	Mutation detections detected by Devyser assay:	Next generation sequencing: Devyser BRCA kit for library preparation NGS using Illumina NextSeq 550 Analysis using SOPHiA DDM SOP: MOL sBRCA 001, MOL NGS 020, MOL NGS 021	
DNA from blood, saliva, fresh tissue	<ul style="list-style-type: none"> • BRCA1 • BRCA2 • Familial hypercholesterolaemia 	SOP: MOL FH 006, MOL NGS 023	



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HUMAN BODY FLUIDS body fluids and tissue	Clinical Chemistry examination activities for the purpose of clinical diagnosis	In house methods using manufacturers instructions	
Serum/Plasma/Urine/Fluid	Amylase	Abbott Alinity c Photometry, using SOPs: C-LP 350 008	C, K
Serum/Plasma/Urine	Chloride Sodium Potassium Urea Uric Acid Magnesium	C-LP 350 058 C-LP 350 070 C-LP 350 069 C-LP 350 045	
Serum/Urine	Albumin Alkaline Phosphatase Calcium Creatinine Enzymatic	C-LP 350 002 C-LP 350 004 C-LP 350 018 C-LP 350 026	
Serum/Plasma	Alcohol Bicarbonate Creatinine Kinase Gamma GT HDL Lactic Acid Salicylate Total Protein Triglyceride	C-LP 350 003 C-LP 350 014 C-LP 350 025 C-LP 350 034 C-LP 350 037 C-LP 350 041 C-LP 350 055 C-LP 350 065 C-LP 350 067	
Serum	Ammonia Bilirubin Direct Bilirubin total Alanine Aminotransferase Lithium Phosphorous ACE	C-LP-350-007 C-LP 350 029 C-LP 350 064 C-LP 350 001 C-LP 350 043 C-LP 350 039 C-LP 350 009	C
Serum/Plasma	Iron Lactose Dehydrogenase (LDH) Lipoprotein (a) and (b)	C-LP 350 040 C-LP 350 042 C-LP 350 012	
Urine	Microalbumin	C-LP 350 078	C



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HUMAN BODY FLUIDS body fluids and tissue	<u>Clinical Chemistry examination activities for the purpose of clinical diagnosis</u>	In house methods, using manufacturer's instructions	
Serum	Therapeutic drugs Phenytoin Phenobarbitone Theophylline Valproic Acid Carbamazepine	Abbott Alinity c Photometry, using SOPs: C-LP 350 061	C
Urine	Drugs of Abuse Amphetamines Benzodiazepines Cocaine Methadone Opiates THC	C-LP 350 030	C
Serum	Digoxin Antibiotic Assay • Gentamicin • Vancomycin	Abbott Alinity c, PETINA, using SOPs: C-LP 350 028 C-LP 350 010	C C C, K
Serum/Plasma	CRP (high sensitivity) Alpha-1-Antitrypsin Caeruloplasmin Immunoglobulins • IgA • IgG • IgM	Abbott Alinity c, Turbidimetric/Immunoturbidimetric, using SOPs: C-LP 350 024 C-LP 350 005 C-LP 350 017 C-LP 350 071	C, K C
Serum/Plasma	Transferrin	C-LP 350 066	C
Urine/CSF	Albumin	C-LP 350 073	C



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HUMAN BODY FLUIDS body fluids and tissue	<u>Clinical Chemistry examination activities for the purpose of clinical diagnosis</u>	In house methods using manufacturer's instructions	
Plasma/CSF	Glucose	Abbott Alinity c, Enzymatic assay, using SOPs: C-LP 350 035	C, K
Serum/Plasma	AST Acetaminophen Cholesterol Bile Acid	C-LP 350 013 C-LP 350 079 C-LP 350 020 C-LP 350 015	C
Serum/Plasma	Cortisol DHEAs Methotrexate Oestradiol Progesterone Tacrolimus Testosterone	Abbott Alinity I, one step CIMA, using SOPs: C-LP 350 022 C-LP 350 027 C-LP 350 046 C-LP 350 048 C-LP 350 052 C-LP 350 059 C-LP 350 060	C
Serum/Plasma	BHCG AFP ATG NCA125 CEA CSA FT3 FT4 FSH	Abbott Alinity I, two step CIMA, using SOPs: C-LP 350 036 C-LP 350 006 C-LP 350 011 C-LP 350 016 C-LP 350 019 C-LP 350 021 C-LP 350 032 C-LP 350 033 C-LP 350 031	C, K C
Serum/Plasma	HSTNlu PSA (total) PTH SHBG TSH	Abbott Alinity I, Immunoassay using SOPs: C-LP 350 068 C-LP 350 054 C-LP 350 050 C-LP 350 057 C-LP 350 063	C, K C



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HUMAN BODY FLUIDS body fluids and tissue	<u>Clinical Chemistry examination activities for the purpose of clinical diagnosis</u>	In house methods using manufacturer's instructions	
Serum/Plasma	LH Macroprolactin NTBNP Prolactin	Abbott Alinity I, two step Immunoassay using SOPs: C-LP 350 044 C-LP 350 076 C-LP 350 047 C-LP 350 053	C
	Thyroglobulin	Abbott Alinity I, Immunometric assay, using SOPs: C-LP 350 062	C
Whole Blood	HbA1C	Tosoh G11 – HPLC, using SOP: C-LP 200 043	C, K, D
Serum/Plasma/CSF	Amino Acids	Biochrom 30+ Amino acid Analyser using SOP- LP 500 002 Detected by HPLC	C
Serum/Urine	Osmolality	Advanced Instruments Osmometer 1 and 2, using SOP: LP 200 024 Detected by freezing point depression	C, K
Serum/Urine/CSF	Immunofixation Protein Electrophoresis Immunofixation Oligoclonal Bands	Helena SAS 3 and 4, V8 by Detection of paraprotein bands using, SOPs: LP 200 071 LP 200 017LP 200 015	C
CSF	Haemoglobin breakdown products	Uvikon XL Spectrophotometer using SOP: LP 200 057	C
Sweat	Sweat Chloride	Wescor Sweat-Chek 3120, using SOP: LP 650 008	E



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Clinical Chemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house methods using manufacturer's instructions	
Blood/Urine	Ethylene Glycol Methanol	Thermo TRACE GC Ultra Gas Chromatography Mass spectroscopy, using SOPs LP 100 028 & LP 100 061	C
Urine	Porphobilinogen	Porphobilinogen Photometric Complete Kit analysed on Bio UV Spectrophotometer. SOP C LP 200 064	C
END			