


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8407</p> <p>Accredited to ISO 15189:2012</p>	<p>Royal Wolverhampton NHS Trust operating as Black Country Pathology Services</p> <p>Issue No: 002 Issue date: 21 December 2018</p>	
	<p>City Hospital Dudley Road Birmingham B18 7QH</p>	<p>Contact: Julie Evans Tel: +44 (0)121 507 4227 E-Mail: julie.evans10@nhs.net</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 Laboratories City Hospital Dudley Road Birmingham B18 7QH</p> <p>Local contact Julie Evans Pathology Quality Manager Tel: +44 (0)121 507 4227</p>	<p>Microbiology Histopathology & body store Blood Transfusion Essentials Laboratory (Biochemistry & Haematology) Toxicology Body Store</p>	A
<p>Laboratories Sandwell Hospital Lyndon West Bromwich B71 4HJ</p> <p style="text-align: center;">As above</p>	<p>Clinical Biochemistry Haematology Blood Transfusion Immunology Serology Mortuary</p>	B



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Site activities performed away from the locations listed above:

Location details	Activity
Medical Assessment Unit Hemosafe MAU City Hospital Dudley Road Birmingham B18 7QH	Blood storage only
Hemosafe Issue Fridge Annex to Blood Transfusion Lab City Hospital Birmingham B18 7QH	Blood storage only
Hemosafe Issue Fridge Ground floor corridor area in immediate vicinity of Pathology Sandwell Hospital Lyndon West Bromwich B71 4HJ	Blood storage only
Mortuary Sandwell Hospital Lyndon West Bromwich B71 4HJ	Mortuary and body store
Body Store City Hospital Dudley Road Birmingham B18 7QH	Body store
Outpatients Sandwell General Hospital Lyndon West Bromwich B71 4HJ	Phlebotomy
Outpatients Birmingham City Hospital Dudley Road Birmingham B18 7QH	Phlebotomy
Community Services Rowley Regis Hospital Moor Lane Rowley Regis B65 8DA	Phlebotomy



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Location details	Activity
Ann Jones Family Centre 52 Chesterton Road Sparkbrook Birmingham B12 8HE	Phlebotomy
Aston Pride Health Centre 74 Victoria Road Aston Birmingham B6 5HA	Phlebotomy
ENKIM/P Osborn House 55 Terrace Road Birmingham B19 1BP	Phlebotomy
Heathfield Family Centre 133-135Heathfield Road Handsworth Birmingham B19 1HC	Phlebotomy
Laurie Pike HC 2 Fentham Road Aston Birmingham B6 6BB	Phlebotomy
Lyng Centre for Health Frank Fisher Way West Bromwich B70 7AN	Phlebotomy
Malling Health Great Bridge Street West Bromwich B70 0EN	Phlebotomy
Neptune Health Park Sedgley Road West Tipton West Midlands DY4 8PX	Phlebotomy
Oldbury Health centre Albert Road Oldbury B69 4DE	Phlebotomy



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Location details	Activity
Soho H/C 247-25 Soho Road Handsworth Birmingham B21 0RY	Phlebotomy
Summerfield Group Practice Heath Street Winson Green Birmingham B18 7AG	Phlebotomy
The Slieve Handsworth Wood Birmingham B20 2NR	Phlebotomy
Tower Hill Partnership M/P 435 Walsall Road Perry Barr Birmingham B42 1BT	Phlebotomy
Victoria H/C 6 Suffrage Street Smethwick West Midlands B66 3PZ	Phlebotomy
Warwick Road Surgery 35 Warwick Road Sparkhill Birmingham B11 4RA	Phlebotomy



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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
<p>HUMAN BODY FLUIDS and TISSUES</p> <p>Ear swabs Middle ear effusion Eye swabs Nose swabs Throat swabs Mouth Skin swab Swab from superficial wound Swab from non-surgical wound Abscess pus Abscess swab Deep-seated pus swab Post-operative wound Wound exudates Tissue Biopsy Aqueous and vitreous humour Corneal scrapings Fluids Intra-operative samples of bone or bone biopsies</p>	<p><u>General Bacteriology Examination activities for the purposes of clinical diagnosis</u></p> <p>General isolation of micro-organisms of clinical significance</p>	<p>In-house documented procedures</p> <p>Culture onto selected media with reference to documented in-house procedure for inoculation of samples onto culture media</p> <p>PROC-M-Processing Skin, Superficial and non-surgical wound swabs PROC-M-Bacterial Examination of Ear, Mouth, Nose and Throat PROC-M-Examination of CSF for Bacterial pathogens PROC-M-Eye swabs and Canicular Pus PROC-M-Investigation of Intraocular fluid, Corneal scrapes and associated specimens from eye hospital PROC-M-Investigation of Prosthetic Joint Specimens and Bone & Soft tissue associated with Osteomyelitis PROC-M-Investigation of fluids from normally sterile sites PROC-M-Processing Specimens from pus and deep seated infections</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>All genital swabs Aspirates/pus/swabs from tubo-ovarian abscess IUCD, Bartholin's gland Pouch of Douglas</p> <p>Urine</p> <p>Urine</p> <p>Blood</p>	<p>General Bacteriology Examination activities for the <u>purposes of clinical diagnosis</u> (cont'd)</p> <p>General isolation of micro-organisms of clinical significance (cont'd)</p>	<p>In-house documented procedures</p> <p>Culture onto selected media with reference to documented in-house procedure for inoculation of samples onto culture media</p> <p>Manufacturers Media PROC-M-Processing Genital Tract and Associated Specimens</p> <p>Manufacturers media BioMerieux Previolsola</p> <p>PROC-M-Use of the Previolsola PROC-M-Urinalysis</p> <p>BioMerieux UF1000 Flow cytometry</p> <p>PROC-m-Use of UF1000i Automated Urine Analyser</p> <p>PROC-M-Urinalysis</p> <p>Manufacturers media and BacTalert, colourimetric sensor-and-detection</p> <p>PROC-M-Blood Cultures</p>	<p>A</p>



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>General Bacteriology Examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on current PHE SMIs	A
Bacterial cultures isolated in-house	General identification of micro-organisms of clinical significance (cont'd)	BioMerieux VITEK MS Mass spectrophotometry PROC-M-Use & maintenance of VITEK MS	
faeces	<i>Cryptosporidium</i>	OCP preparation (Parasep concentration method) and prep of slides for Cryptosporidium detection. OCP Fluorescence microscopy PROC-M-Stains	
	<i>Trichomonas vaginalis</i>	Acridine orange staining for detection of by Microscopy PROC-M-Stains	
	Cryptococcal antigen:	IMMY lateral flow test PROC-M-CryptoccalAg	
Corneal scrapes, contact lenses and contact lens fluid	Acanthamoeba screening	Detected by Microscopy PROC-M-Eyes	
Faeces	Enteric Pathogens	Serosep -EntericBio PCR-EntericBio realtime Gastro Panel 2 assay Manufacturers media PROC-M- EntericBio Real Time PCR processing of Faeces samples	
Sputum, respiratory fluids	Mycobacteria investigation:	EIA for IGRA Manufacturers media PROC-M- Investigation of Sputum, Bronchial lavage, Pleural fluid and associated respiratory specimens	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>General Bacteriology Examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on current PHE SMIs	A
Sputum, respiratory fluids	Detection of positive Mycobacteria	MGIT and traditional slope cultures preparation Becton Dickenson MGIT Growth based system using fluorometric technology PROC-M-Use of TB MGIT PROC-M-TBCulture Auramine phenol and ZN staining-detection by microscopy PROC-M-Stains	
Swabs	Methicillin-Resistant <i>Staphylococcus aureus</i> MRSA detection	Manufacturers media PROC-M-MRSA screens Culture & Identification	
Faeces	<i>C. difficile</i> GDH and toxin	Alere Techlab <i>C.difficile</i> QuikChek Complete, rapid cassette assay lateral flow PROC-M-Cdiff Quik Chek Techlab <i>C.diff</i> TOX A/B II EIA PROC-M-Cdiff EIA EntericBio real time <i>C.difficile</i> assay on Cepheid GeneXpert PCR PROC-M- Clostridium difficile PCR	
Urine	Legionella urine antigen:	Lateral flow using Meridian Tru-Legionella kit PROC-M-Urinalysis	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>General Bacteriology</u> Examination activities for the <u>purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures	
Bacterial cultures isolated in-house	Antimicrobial susceptibility testing (and determination of minimum inhibitory concentration (MIC))	BioMerieux VITEK 2. Growth based system using colourimetric reagent cards EUCAST disc diffusion preparation and reading Gradient strip test (E-test) PROC-M- Susceptibility Testing	A
faeces	<u>Parasitology</u> Examination for the detection and identification of parasites (ova, cysts, trophozoites and worms) of clinical significance	PROC-M-Processing of samples for Parasitology by Microscopy	A
Nails/ Hair / Skin scrapings	<u>Mycology</u> General isolation and characterisation of fungi of human clinical significance	Cultures and KOH fluorescence microscopy. PROC-M-Mycology	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<p><u>General Serology Examination activities for the purposes of clinical diagnosis</u></p> <p>Detection of</p> <ul style="list-style-type: none"> • HIV • Hepatitis B sAg, cAb, sAb, eAb, eAg, cAgM • Hepatitis C • Hepatitis A IgM & IgG • CMV IgM & IgG • <i>Toxoplasma</i> IgM & IgG • Syphilis Total Ab 	In-house documented procedures	
Serum	<ul style="list-style-type: none"> • HIV • Hepatitis B sAg, cAb, sAb, eAb, eAg, cAgM • Hepatitis C • Hepatitis A IgM & IgG • CMV IgM & IgG • <i>Toxoplasma</i> IgM & IgG • Syphilis Total Ab 	Abbot Architect by CMIA PROC-M-Use of Abbott Architect	B
Blood Spots	<ul style="list-style-type: none"> • HIV • Hep B • Hep C 	PROC-M-Dried Blood Spot testing	
Serum	<ul style="list-style-type: none"> • EBNA • EBV IGG and IgM • HCV • HIV • Hbcore • Mumps IgG • Measles IgG • Hepatitis B sAg confirmation • Hepatitis C Antibody confirmation • Rubella IgG • VZV IgG 	BioMerieux VIDAS 30 ELFA assay principle PROC-M-VIDAS 30 PROC-M-VIDAS Serology	B
	<ul style="list-style-type: none"> • Hepatitis B sAg • Anti Hepatitis B core Total • Anti HCV • HIV 	BioMerieux VIDAS 3 ELFA assay PROC- M-BBV/IDS out of hours PROC-M-URGENT ANC	A
	Mycoplasma	Serodia Myco II particle agglutination test PROC-M-Mycoplasma	B



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>General Serology Examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures	
Serum	Detection of HIV 1 and 2 Confirmation	BioRad Geenius PROC-M-Geenius HIV1/2 Confirmatory Assay BioMerieux VIDAS ELFA assay principle PROC-M-VIDAS Serology	B
	VZV	Alere DS2- Serion VZV IgG EIA PROC-M-Varicella Zoster IgG ELISA	
	Syphilis markers	BioKit RPR Flocculation test Serodia Passive particle agglutination PROC-M- Syphmarkers	
Sputum	Detection of Mycobacteria	Qiagen Quantiferon-TB Gold Plus ELISA Dynex DS2 ELISA PROC-M- Procedure for Detection of Latent TB infection by Quantiferon-TB Gold plus ELISA	
Faeces	Helicobacter pylori detection	Alere DS2 – IDEIA Amplified HP ELISA PROC-M-HP Stool Antigen	A
Swabs	Detection of <ul style="list-style-type: none"> • CT/NG • HSV • TV 	BD Viper Strand Displacement Amplification PROC-M-CT/GC/TV/HSV 1&2 using BD Viper	
	Detection of <ul style="list-style-type: none"> • Flu A/B • RSV • <i>C.difficile</i> 	Cepheid Gene expert Real time PCR PROC-M-Use Gene Xpert	A



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>General Serology Examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on current PHE SMIs	
Swabs	Methicillin-Resistant <i>Staphylococcus aureus</i> MRSA	Cepheid GeneXpert – Real time PCR Xpert MRSA PROC-M- Use of GeneXpert	A
Serum	RSV	Binax Now RSV Lateral flow PROC-M-RSV Testing	B
	ASOT	ASO Biokit Agglutination PROC-M-RheumajetASO (Biokit)	
Faeces	<ul style="list-style-type: none"> • <i>C.difficile</i> • Noro 	Cepheid Gene Xpert Real time PCR PROC-M-Use Gene Xpert	A
Respiratory	<ul style="list-style-type: none"> • NTS, • non direct BAL • Flu A/B/RSV • MTB/RIF 	Cepheid Gene Xpert Real time PCR PROC-M-Use Gene Xpert	A



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HUMAN BODY FLUIDS	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u>	Documented In-house methods using:	
Venous Blood	<p>Blood Grouping</p> <ul style="list-style-type: none"> • A B O • Rhesus: C, c, D, E, e, • Kell 	<p>Immucor NEO and ECHO analyser Liquid Phase Microtitre plate PROC- -BB Operating the NEO PROC- -BB NEO & ECHO Interpreting results PROC-BB-Operating the ECHO</p> <p>Manual tube technique Red cell agglutination. PROC- -BB Issuing of group specific blood PROC- BB-Issuing of blood in an emergency PROC-BB-Tube ABO RhD grouping: Rapid and Full PROC-BB-Antigen typing</p>	A and B
	Antibody Detection	<p>3 cell panels, Biorad Indirect Antiglobulin Test (Anti-IgG) Column agglutination</p> <p>PROC- -BB-Antibody screen: Biorad manual technique</p>	A and B
		<p>Immucor NEO & ECHO analyser Capture solid phase test</p> <p>PROC- -BB Operating the NEO PROC- -BB NEO & ECHO Interpreting results PROC-BB-Operating the ECHO</p>	A and B



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Venous Blood	Antibody Identification <ul style="list-style-type: none"> • A B O • Rhesus:-C^w,C, c, D, E, e, • K • Fya, Fyb • Jka, Jkb • Kpa • Lea, Leb • Lua • M, N, S, s 	11 cell panels Bio-Rad, column tube technology 14 cell panels Immucor NEO & ECHO analyser Capture solid phase test PROC- -BB Operating the NEO PROC-BB-NEO & ECHO Interpreting Results PROC-BB-Operating the ECHO PROC- -BB-Dealing with Positive Antibody Screens PROC- -BB Antibody Investigation in Biorad	A and B
	Blood Grouping <ul style="list-style-type: none"> • A B O • Rhesus:-C^w,C, c, D, E, e, • K • Fya, Fyb • Jka, Jkb • Kpa • Lea, Leb • Lua • M, N, S, s 	Biorad Rh Phenotyping cards Column agglutination PROC- -BB Antigen typing	A and B
	Compatibility testing of patients' plasma with donor cells	Biorad Indirect Antiglobulin Test (Anti-IgG) Column agglutination. PROC- -BB Crossmatch in Biorad cards: Adults & children	A and B



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Venous Blood	Direct Anti-Human Globulin	Biorad DC-Screening II cards Column agglutination. PROC- -BB-DAT in Biorad monospecific cards	A and B
	Estimation of Foetal cells	Kleihauer by Acid Elution using Inverclyde Diagnostics Acid Elution PROC- -BB Kleihauer Demonstration of Foetal Cells	A



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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:	
Venous whole blood: EDTA	Haemoglobinopathy Screening <ul style="list-style-type: none"> • HbA2 • HbF • HbA • HbS 	TOSOH G7 and HPLC PROC-H-TOSOH G7	B
Venous whole blood: EDTA	FBC <ul style="list-style-type: none"> • Haemoglobin estimation • Red cell and platelet counts • Haematocrit • Differential white cell count • Reticulocyte • MCV • MCH • MCHC 	Sysmex XN 9000 track including 3 x Sysmex XN 10 FBC analysers and 1 x Sysmex XN 20 FBC analyser using three primary analysis principles. Fluorescence flow cytometry using a semiconductor laser. Hydro dynamic focusing and impedance testing. Colourimetric Hb detector based on a sodium lauryl sulphate method. PROC- FBC Analysis using Sysmex XN series (XN9000)	B
	FBC <ul style="list-style-type: none"> • Haemoglobin estimation • Red cell and platelet counts • Haematocrit • Differential white cell count • Reticulocytes • MCV • MCH • MCHC 	1 x Sysmex XN10 FBC analyser 1 x Sysmex XN 20 FBC analyser PROC- FBC Analysis using Sysmex XN series (XN9000)	A



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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:	
Venous whole blood: EDTA	Identification of normal and abnormal morphologies including WBC differential count	<p>Sysmex SP10, automated slide preparation unit and stainer using May Grunwald and Giemsa stain PROC- Use of the Sysmex SP slide maker and stainer</p> <p>Sysmex RAL stainer methanol free, chromatic detection for Haematology PROC-H-F2-Use of RAL Stainer</p> <p>Microscopy Use of Microscope (Blood Science 707) PROC- Blood Film Examination and Referral to Consultant Haematologist</p>	A and B B A and B
Whole Blood	<p>Malaria Parasite detection</p> <ul style="list-style-type: none"> • P. Falciparum • Non-falciparum <p>Plasmodium Falciparum parasataemia</p>	CareStart Malaria Rapydtest and monoclonal antibodies PROC-H-F2-Malarial Parasites (thin blood film examination) and use of Rapyd Antigen slide test	A and B
Venous whole blood: EDTA	Infectious Mononucleosis screen (EBV) antibody	Alere Clearview IM and immunoassay. PROC-H-F2-IM Test- Clearview 2	A and B
Venous whole blood: EDTA	Glucose-6-Phosphate Dehydrogenase (G-6-PDH) Deficiency Screen	Trinity Biotech G6PD screen and fluorescence PROC- G6PD Screening Test.	A and B



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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:	
Bone Marrow Aspirate and Trepines	Reporting of normal and abnormal morphologies	<p>Sysmex SP10, automated slide preparation unit and stainer using May Grunwald and Giemsa stain. PROC-H- Use of the Sysmex SP slide maker and stainer</p> <p>Sysmex RAL stainer methanol free, chromatic detection for Haematology. PROC-H-Use of RAL Stainer</p> <p>Manual method and Prussian Blue. PROC-H-F2-Perls stain PROC-H-F2 bone marrow Microscopy</p>	A and B B A and B
Urine	Haemosiderin	Manual method and Prussian Blue. PROC-H-F2-Perls stain Microscopy	A and B
Serum	Haematinics <ul style="list-style-type: none"> • Ferritin • B12 • Folate 	Abbott Architect Immunoassay analyser and immunoassay PROC-H- Serum Ferritin PROC-H- Serum Folate PROC-H- Vitamin B12	B
Whole Blood	Zinc Protoporphyrin	Haematofluorometer Protofluor Z PROC-H-ZPP measurement	B
Serum	EPO	Beckman Coulter Access 2 and two-site immunoenzymatic assay PROC-H-ROUTINE Use of the Access II Immunoassay Analyser PROC-H-Erythropoietin	B



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis</u>	Documented In-house methods using:	B
Serum		Werfen QUANTLYSER 160 (PROC-IMM-QUANTALYSER) Immunofluorescent platforms and Indirect Immunofluorescence and using commercial slides and SOP; PROC-IMM-QUANTALYSER	
	Anti-nuclear antibodies (ANA)	Inova slides	
	Double stranded DNA antibodies screen (dsDNA)	Inova slides	
	Autoantibody screen – mitochondrial, smooth muscle, gastric parietal and liver kidney microsomal antibodies	Biosystems slides	
	Endomysial antibodies	Inova slides	
	Skin antibodies	Inova slides	
	Anti-Neutrophil Cytoplasmic antibodies	Inova slides	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
Serum		Launch Diagnostics DS2 2 plate ELISA platform and commercial ELISAs Using PROC-IMM-DS2 And PROCIMMDS2-VAL	
	Thyroid Peroxidase antibodies	Orgentec ELISA	
	Extractable Nuclear Antigen (ENA) screen and profile (Scl70, Ro, La, Sm, RNP & Jo1)	Orgentec ELISA	
	Cardiolipin antibody screen	Orgentec ELISA	
	Intrinsic factor antibodies	Cambridge Life Sciences ELISA	
	Double stranded DNA antibodies quantitation (dsDNA)	Inova ELISA	
	Myeloperoxidase (MPO) antibodies	Inova ELISA	
	Proteinase 3 (PR3) antibodies	Inova ELISA	
	GAD antibodies	RSR ELISA	
	<ul style="list-style-type: none"> • Tissue Transglutaminase (TTG) antibodies • Glomerular Basement Membrane Antibodies (GBM) • Myeloperoxidase (MPO) antibodies • Proteinase 3 (PR3) antibodies 	Werfen BIOFLASH Chemiluminescence TTG PROC-IMM-BIOFLASH FORM-IMM-BIOFLASHMAINT FORM-IMM-COMP-BIOFLASH	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Serum	<ul style="list-style-type: none"> • Cardioplipin IgG/IgM quantitation • Cyclic Citrullinated Peptide (CCP) antibodies • Avian IgG – Pigeon and Budgie • Aspergillus IgG 	Thermofisher ImmunoCAP 250 and Fluoroenzyme Immunoassay (F EIA) FORM-IMM-IC250	B
	Allergy <ul style="list-style-type: none"> • Specific IgE • Total IgE Mast cell Tryptase	Thermofisher ImmunoCAP 250 and Fluoroenzyme Immunoassay (FEIA) FORM-IMM-IC250	
	ISAC Specific IgE 112 component panel	Thermofisher luminometer SOP: PROC-IMM-ISAC	
	Functional Antibodies to Pneumococcus	In house ELISA SOP: PROC-IMM-PGALC V 1.5	
	<ul style="list-style-type: none"> • Functional Antibodies to HIB Functional Antibodies to Tetanus	Launch Diagnostics DS2 and Binding Site ELISA SOP: PROC-IMM-PGALC V 1.5.	
	Protein Immunochemistry <ul style="list-style-type: none"> • Complement C3 & C4 levels • Rheumatoid Factor B2 Microglobulin	Abbot C16000 Architect Turbidimetry SOP: PROC-IMM-C3C4B2MRHF.	
	T spot	Oxford Immunotec and ELISPOT 7 SOP: PROC-IMM-TSPOT V1.2.	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Documented In-house methods using:	
Serum	Quantification determination of Routine Chemistry <ul style="list-style-type: none"> • Acetaminophen • Alanine transaminase • Alkaline Phosphatase • Ammonia • Amylase • Cholesterol • Creatine Kinase • Ethanol • Gamma G.T • Glucose • Lactate • Lactate dehydrogenase • Magnesium • Potassium • Salicylate • Sodium • Triglycerides • Urea • Uric Acid 	Abbott c4000/Abbott ci4100 and Abbott kits SOP: Routine Operation of the Abbott Architect ci4100 and c4000 (Blood Sciences 274) Enzymatic	A
Urine	<ul style="list-style-type: none"> • Creatinine • Potassium • Sodium • Urea 		
Serum/Plasma	<ul style="list-style-type: none"> • CO2 	Abbott c4000/ci4100 Roche enzymatic	



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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>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Serum/Plasma	Quantification determination of Routine Chemistry <ul style="list-style-type: none"> • Albumin • Calcium • Creatinine • Direct Bilirubin • Lithium • Phosphate • Total Bilirubin • Total Protein 	Abbott c4000/ci4100 SOP: Routine Operation of the Abbott Architect ci4100 and c4000 (Blood Sciences 274) Colourimetric	A
Urine	<ul style="list-style-type: none"> • Calcium • Phosphate 		
Serum/Plasma	<ul style="list-style-type: none"> • CRP • Lpa 	Abbott c4000/ci4100 SOP: Routine Operation of the Abbott Architect ci4100 and c4000 (Blood Sciences 274) Turbimetric	
Serum/Plasma	<ul style="list-style-type: none"> • Amikacin • Tobramycin • Vancomycin • Gentamicin • HDL 	Abbott c4000 PETINIA Abbott c4000 Turbidimetric Inhibition Immunoassay Abbott ci4100 Accelerator selective detergent	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	A
Urine/CSF	Quantification determination of <ul style="list-style-type: none"> • Total Protein 	SOP: Routine Operation of the Abbott Architect ci4100 and c4000 (Blood Sciences 274) Abbott c4000 Benzethonium Chloride	
Serum/Plasma	<ul style="list-style-type: none"> • Chloride • Potassium • Sodium • FT4 • TSH 	ISE c4000 and ci4100 Indirect ISE Abbott ci4100 Chemiluminescence	B
Urine	<ul style="list-style-type: none"> • Acetaminophen • Alkaline phosphatase • Alanine transaminase • Ammonia • Amylase • Aspartate transaminase • Bile Acids • Cholesterol • CK • Ethanol • GGT • Glucose • Lactate • LDH • Magnesium • Salicylate • Triglyceride • Urea • Uric Acid 	Architect c16000 & Abbott kits SOP: Routine Use of the Sandwell Architect c16000 & i2000 analysers at Sandwell (Blood Sciences 303) Enzymatic	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
Serum/Plasma	<ul style="list-style-type: none"> • CO2 	Architect c16000 & Abbott kits SOP: Routine Use of the Sandwell Architect c16000 & i2000 analysers at Sandwell (Blood Sciences 303) Architect c16000 Roche enzymatic	
Serum/Plasma	<ul style="list-style-type: none"> • Albumin • Calcium • Creatinine • Direct Bilirubin • Iron • Lithium • Phosphorus • Total Bilirubin • Total Protein 	Architect c16000 & Abbott kits SOP: Routine Use of the Sandwell Architect c16000 & i2000 analysers at Sandwell (Blood Sciences 303) Colourimetric	
Urine	<ul style="list-style-type: none"> • Calcium 		
Serum/Plasma	<ul style="list-style-type: none"> • Fructosamine • Alpha-1-antitrypsin • Alpha-1-glycoprotein • Ceruloplasmin • CRP • Haptoglobin • IgA • IgG • IgM • Transferrin 	Roche Colourimetric Architect c16000 SOP: Routine Use of the Sandwell Architect c16000 & i2000 analysers at Sandwell (Blood Sciences 303) Immunoturbidimetric	



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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>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
Serum/Plasma/Urine	<ul style="list-style-type: none"> • Digoxin • Gentamicin • Valproic Acid • Vancomycin 	Architect c16000 SOP: Routine Use of the Sandwell Architect c16000 & i2000 analysers at Sandwell (Blood Sciences 303) Turbidimetric Inhibition Immunoassay	
Serum/Plasma	<ul style="list-style-type: none"> • Chloride • Potassium • Sodium 	Abbott c16000 Indirect ISE	
Serum/Plasma	<ul style="list-style-type: none"> • Carbamazepine • Phenobarbital • Phenytoin • Theophylline 	Abbott c16000 Enzyme Immunoassay	
Serum	<ul style="list-style-type: none"> • HDL 	Abbott c16000 Accelerator selective detergent	
Serum	<ul style="list-style-type: none"> • AFP • Ca125 • Ca153 • Ca199 • CEA • Cortisol • DHEAS • FSH • FT3 • FT4 • LH • Oestradiol • Progesterone • Prolactin • PSA • SHBG • Testosterone • TSH 	Abbott i2000: SOP: Routine Use of the Sandwell Architect c16000 & i2000 analysers at Sandwell (Blood Sciences 303) Chemiluminescence	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Documented In-house methods using:	
Urine/CSF	<ul style="list-style-type: none"> Total protein 	Abbott c16000 Benzethonium Chloride	B
Urine	<ul style="list-style-type: none"> Microalbumin 	Abbott c16000 Immunoturbidimetric	
CSF	<ul style="list-style-type: none"> Glucose Lactate 	Abbott c16000 Enzymatic	
	Calculated tests		A and B
	<ul style="list-style-type: none"> AKI eGFR LDL Cholesterol Adjusted calcium 	By Calculation By MDRD Calculation By Friedwald Calculation By Calculation	
CSF	Xanthochromia	Perkin Elmer: SOP: CSF Xanthochromia (PROC-CB-F2.1-MAN/17)	B
Serum/Plasma	<ul style="list-style-type: none"> Troponin T beta-HCG PTH BNP 	Roche Cobas e411: SOP: Maintenance and Daily Operation of Cobas e411 analyser (Blood Sciences 347)	
Serum and Urine	Osmolality	Vitech Scientific: Freezing point depression SOP: Serum and urine osmolality (PROC-CB-F2.1-MAN/16)	
Whole blood	HbA1c	Tosoh G8 HPLC System SOP: Tosoh G8 HPLC HbA1c (PROC-CB-F2.1-MAN/45)	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
Urine	Urine Calculi	Thermo Nicolet 360, Thermo Nicolet iS10, Thermo Nicolet iS5 by FTIR SOP: Stone analysis by FTIR spectroscopy (PROC-CB -F2.1-FTIR/01)	
Serum	Macroprolactin	PEG precepitation SOP: Macroprolactin Screen (PROC-CB-F2.1-FTIR/08) SOP: Routine Use of the Sandwell Architect c16000 & i2000 analysers at Sandwell (Blood Sciences 303)	
Urine	Oxalate	Ilab Aries: Urine Oxalate (PROC-CB-F2.1FTIR/03)	
Serum	Protein band detection	Sebia Capillarys: Protein Electrophoresis Protein Electrophoresis using Sebia Capillarys (PROC-CB-F2.1-MAN/50)	
Serum/Urine	Monoclonal bands	Sebia Hydrasys: Immunofixation & Urine immunofixation, Serum Immunofixation Electrophoresis - Sebia Hydrasys LC (PROC-CB-F2.1-MAN/30),	
Urine	Bence Jones proteins	Bence Jones Protein - Sebia Hydrasys LC (PROC-CB-F2.1-MAN/28)	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
Faeces	Quantification determination of Faecal Calprotectin	ELISA on DS2 Faecal Calprotectin analysis using the DS2 analyser	
Urine	Porphyrin	Spectrophotometric screening test Investigations of Porphyrins (PROC-CB-F2.1-MAN/20)	
Urine	Porphobilinogen PBG	Bio-Rad kit: SOP: Investigations of Porphyrins (PROC-CB-F2.1-MAN/20)	
Urine	<ul style="list-style-type: none"> • Bilirubin • Urobilinogen • pH 	Siemens Multistix 10SG: SOP: Urinary Dipstick Analysis (PROC-CB-F2.1-MAN/15)	
Faeces	Occult blood	Hema screen test kits: Faecal Occult Blood (PROC-CB-F2.1-MAN/9)	
Urine and faeces	Reducing Substances	Benedict's reagent Semi Quantitative analysis of Reducing substances in Urine and Faeces (Chem 957)	
Serum	Adalimumab, Adalimumab Ab	Manual ELISA read using the Thermo Plate reader (Chem 492 and 493)	
	Infliximab, Infliximab Ab,	(Chem 193 and 269)	
Whole Blood	Red Cell Cholinesterase	iLab Aries- enzymatic assay (PROC-CB-MAN/13)	
Serum/Plasma	Serum/ Plasma Cholinesterase	(Chem 915)	



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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>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
	Quantification determination of (cont'd)		
	<u>Trace Metals</u>	Agilent 7500/Agilent 7700x/Thermo Fisher iCAPQ cx by ICPMS	
Blood, serum, plasma, urine	<ul style="list-style-type: none"> • Cobalt • Chromium 	Cobalt & chromium in blood & serum (PROC-CB-TE/19) Cobalt, chromium, nickel & cadmium in urine (PROC-CB-TE/41)	
Blood/Urine	<ul style="list-style-type: none"> • Lead • Manganese • Mercury • Arsenic • Cadmium • Thallium • Antimony • Bismuth • Nickel • Semi-quantitative toxic metals 	Lead in whole blood (PROC-CB-TE/12) Manganese in whole blood (PROC-CB-TE/37) Mercury in whole blood & urine (PROC-CB-TE/16) Arsenic in whole blood (PROC-CB-TE/39) Cadmium in whole blood (PROC-CB-TE/38) Thallium in whole blood (PROC-CB-TE/51) Antimony, barium, bismuth, silver & strontium in whole blood (PROC-TOXI-TE/55) Manganese, arsenic, thallium & lead in urine (PROC-CB-TE/44) Cobalt, chromium, nickel & cadmium in urine (PROC-CB-TE/41)	
Blood	<ul style="list-style-type: none"> • Barium • Silver 	Antimony, barium, bismuth, silver & strontium in whole blood (PROC-TOXI-TE/55)	
Plasma/Serum	<ul style="list-style-type: none"> • Aluminium 	Aluminium in plasma & serum (PROC-CB-TE/10)	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	
Serum/Urine/Plasma	Quantification determination of (cont'd) <u>Trace Metals (cont'd)</u> <ul style="list-style-type: none"> • Copper • Selenium • Zinc 	Agilent 7500/Agilent 7700x/Thermo Fisher iCAPQ cx by ICPMS Copper, zinc and selenium in plasma & serum (PROC-CB-TE/9) Selenium in urine (PROC-CB-TE/42) Copper & zinc in urine (PROC	B
Urine	<ul style="list-style-type: none"> • Gallium • Indium • Iron 	Iron in urine (PROC-TOXI-TE/	
Serum/Plasma	<u>Vitamins</u> <ul style="list-style-type: none"> • D2 • D3 	Waters Acquity UPLC & Xevo/TQD LC MS-MS Measurement of 25-Hydroxy vitamin D (Chem 524)	B
Blood Spots	<ul style="list-style-type: none"> • D2 • D3 	Waters Acquity UPLC & Xevo TQSMS LC MS-MS Measurement of blood spot 25-Hydroxy vitamin D (Chem 527)	
Serum/Plasma	<ul style="list-style-type: none"> • Vitamin A • Vitamin E • α Carotene • β Carotene 	Shimadzu Prominence HPLC Measurement of vitamin A, E and carotenes (Chem 657)	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
Blood	<u>TPMT</u> Thiopurine methyl transferase (TPMT)	Shimadzu HPLC Measurement of whole blood TPMT activity (PROC-CB-F2.5-TPMT)	
	TPMT Genotyping	QIASymphony SP ARMS-PCR SYNGENE InGenius ³ Extraction of DNA from whole blood using the QIA Symphony (Blood Science 911) TPMT genotyping by ARMS-PCR (PROC-CB-F2.1-TPMT/10) Agarose gel electrophoresis for analysis of TPMT ARMS reaction products (PROC-CB-F2.1-TPMT/1)	
	<ul style="list-style-type: none"> 6-thioguanine (TGN) 6-methylmercaptopurine nucleotides (6MMP) 	Shimadzu Prominence HPLC Nexera UPLC Measurement of whole blood 6-TGN and 6-MMP nucleotides (PROC-CB-F2.1-TPMT/21)	
Faeces	Red Cell count (RCC) Haematocrit (HCT)	Sysmex XN-1000 Measurement of Red Blood Cell counts (Chem 663)	
	Elastase	Schebo ELISA kit Measurement of Faecal Elastase (PROC-CB-F2.1-TPMT)	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	B
Blood	<u>TMPT (cont'd)</u> Uridine diphosphoglucose glucuronosyltransferase enzyme (UGT1A1) for Gilbert's syndrome	QIASymphony SP Real-Time PCR Extraction of DNA from whole blood using the QIASymphony SP (Blood Science 911) Gilbert's syndrome: genotyping of UGT1A1 by Real-Time PCR (Chem 313)	
Blood	Haemochromatosis	QIASymphony SP Real-Time PCR and LightMix in vitro diagnostics kit Extraction of DNA from whole blood using the QIASymphony SP (Blood Science 911) Haemochromatosis: genetic screening for C282Y, H63D and S65C mutations (Blood Sciences 338)	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented In-house methods using:	A
Blood	Quantification determination of <u>Toxicology</u> Levetiracetam	HPLC-DAD Dionex Target Absorption/RT Quantitative analysis of drugs in plasma by HPLC-DAD (TOXI 535)	
Blood/urine	<ul style="list-style-type: none"> Amitriptyline nortriptyline 	HPLC-DAD Dionex Target Absorption/RT Quantitative analysis of drugs in plasma by HPLC-DAD (TOXI 535)	
Blood	<ul style="list-style-type: none"> Clozapine & norclozapine Lamotrigine 	HPLC-UV Prominence Absorption maxima/RT Quantitative analysis of clozapine, norclozapine & lamotrigine by Shimadzu HPLC-UV	
Blood/Urine	Ethanol screening & confirmation Methanol screening	Shimadzu headspace- GC-FID Target ions Quantitative analysis of ethanol & methanol (Toxi 649)	
Blood	<ul style="list-style-type: none"> TDM: Quetiapine TDM: Olanzapine 	Waters AquityUPLC-MS/MS Semi-quantitative MRM Quantitative analysis of plasma Olanzapine & Quetiapine by Waters LC-MS/MS (TOXI 540)	
Blood	Ethylene glycol screening	Shimadzu GC 2020 plusGC-FID Target ions Quantitative analysis of ethylene glycol by Shimadzu GC-FIC (TOXI 646)	



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Oral Fluid using Salivette Collection Device</p> <p>Urine</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Quantification determination of (cont'd)</p> <p><u>Toxicology (cont'd)</u></p> <p>Cannabis</p> <ul style="list-style-type: none"> • 6-MAM screen • Methadone metabolite (EDDP) screen • pH • Cannabis 	<p>Documented In-house methods using:</p> <p>Abbot Architect c4000 Colourmetric determination Guide to analysis of samples for drugs of abuse and pH (Blood Sciences 429)</p> <p>Abbott Architect ci4100 Immunoassay Guide to analysis of samples for drugs of abuse and pH (Blood Sciences 429)</p>	<p align="center">A</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Oral Fluid using Salivette Collection Device</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Quantification determination of (cont'd)</p> <p><u>Toxicology (cont'd)</u></p> <p>Drugs of abuse screening:</p> <ul style="list-style-type: none"> • Morphine, • Codeine • Dihydrocodeine, • 6MAM, • Methadone • EDDP • Buprenorphine • Norbuprenorphine • Cocaine, • Benzoylcegonine • Amphetamine • Methamphetamine • MDA, • MDMA, • Diazepam • Nordiazepam • Oxazepam • Temazepam • Lorazepam • Thebaine • Ketamine • Tramadol • Mephedrone, • 4-MEC • Ethylphenidate • Methiopropamine • Adamantyl-NOID 	<p>Documented In-house methods using:</p> <p>Waters Acquity UPLC-MS/MS Semi-quantitative MRM Analysis of Oral Fluid Drugs of Abuse by Waters LC-MS/MS (TOXI 861)</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Urine</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Quantification determination of (cont'd)</p> <p><u>Toxicology (cont'd)</u></p> <p>Drugs of abuse screening:</p> <ul style="list-style-type: none"> • Morphine • Codeine • Dihydrocodeine • 6MAM • Methadone • EDDP • Buprenorphine • Norbuprenorphine • Benzoylcegonine • Amphetamine • Methamphetamine • MDA • MDMA • Diazepam • Nordiazepam • Oxazepam • Temazepam • Lorazepam • Thebaine • Ketamine • N-desmethyltramadol • Mephedrone • 4-MEC • Ethylphenidate • Methiopropamine, • Adamantyl-NOID • Creatinine 	<p>Documented In-house methods using:</p> <p>Waters UPLC-MS/MS Semi-quantitative MRM Analysis of urine drugs of abuse by Waters LC-MS/MS(TOXI 860)</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Urine</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Quantification determination of (cont'd)</p> <p><u>Toxicology (cont'd)</u></p> <p>Drugs of Abuse Confirmation</p> <p>Heroin metabolite 6-Monoacetylmorphine (6MAM)</p> <p>Benzodiazepines</p> <ul style="list-style-type: none"> • Diazepam • Nordiazepam • Temazepam • Oxazepam • Lorazepam <p>Opiates</p> <ul style="list-style-type: none"> • Morphine • Codeine • Dihydrocodeine <p>Cannabis metabolite</p> <ul style="list-style-type: none"> • 11-nor-9-carboxy-delta-9-tetrahydrocannabinol (THC-COOH) <p>Amphetamines</p> <ul style="list-style-type: none"> • Amphetamine • Methamphetamine • MDMA 	<p>Documented In-house methods using:</p> <p>Schimadzu QP2010 GC-MS Target Ions</p> <p>Quantitative analysis of 6-MAM in urine by Shimadzu GC-MS (TOXI 983)</p> <p>Quantitative analysis of Benzodiazepines in Urine by Shimadzu GC-MS (TOXI 986)</p> <p>Quantitative analysis of Opiates in Urine by Shimadzu GC-MS (TOXI 987)</p> <p>Quantitative analysis of Cannabis Metabolite in urine by Shimadzu GC-MS (TOXI 985)</p> <p>Waters Acquity LC-MS/MS Target Ions</p> <p>Quantification of Amphetamine (amphetamine, methamphetamine, MDMA, MDA) Methadone, EDDP and Benzoylcegonine in urine by Waters LC-MS/MS (TOXI 862)</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Urine (cont'd)</p> <p>Biological material</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Toxicology (cont'd)</u></p> <p>Drugs of Abuse Confirmation (cont'd)</p> <p>Methadone and metabolite</p> <ul style="list-style-type: none"> • Methadone • EDDP <p>Cocaine metabolite</p> <ul style="list-style-type: none"> • Benzoylecgonine <p>Unknown toxicology screen: General drugs screen (positive electrospray) as per Waters (Masslynx 4.1 TOF TOX database 1)</p> <p>Unknown toxicology screen: General drugs screen (negative electrospray) as per Waters (Neg-ion-library-201115)</p>	<p>Documented In-house methods using:</p> <p>Waters Acquity LC-MS/MS Target Ions</p> <p>Waters Xevo UPLC-MS/TOF Exact mass/RT Toxicology screening using the Waters Xevo G2 TOF: General drug screening method with positive electrospray (Tox (Confidential) 1014)</p> <p>Toxicology screening using the Waters Xevo G2 TOF: General drug screening method with negative electrospray (Tox (Confidential) 1015)</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Wet fixed Preparations urines, Bronchial specimens, FNA's, Thyroid, body fluids</p> <p>Slides prepared in house as above</p>	<p><u>Diagnostic Cytology examinations to assist in clinical investigations</u></p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Documented In-house methods using:</p> <p>Cytospin Preparation of Cytology Sample PROC-HIS-SWBH-F2-34 Centrifuge PROC-HIS-SWBH-C5,D1-1 Cytology equipment and maintenance T2 Liquid based processing machine PROC-HIS-SWBH-C5,D1-1 Cytology equipment and maintenance Staining machine Papanicolaou Staining on the DRS 2000 Staining Machine PROC-HIS-SWBH-F2-33 Microscope Cytology Internal Quality Control PROC-HIS-SWBH-F3-1</p> <p>SOP PROC-HIS-SWBH-F2G1-1 Microscopy</p>	<p>A</p>



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>Tissue samples</p>	<p><u>Routine Histopathology examinations to assist in clinical investigations</u></p>	<p>In House documented procedure & manufacturer's instructions using the following equipment</p> <p>Leica IP Cassette & slide Writer PROC-HIS-SWBH-Cassette/Slide Writer Maintenance PROC-HIS-SWBH-Routine Specimen Dissection VIP 5 & VIP 6 Tissue Processing Machines PROC-HIS-SWBH-VIP Automated Tissue Processing Machines TissueTek Embedding Centre PROC-HIS-Embedding Processed Tissue Samples Leica RM 2035, Leica RM 2135 & Leica RM 2235 Microtomes PROC-HIS-SWBH-Routine Microtomy Leica Cryostat PROC-HIS-SWBH-Frozen Sections PROC-HIS-SWBH-Decalcifying Tissue</p>	A
<p>Prepared slides as above</p>	<p>Identification of basophilic and eosinophilic structures</p>	<p>Routine staining (H&E) Tissue Tek Prisma automated slide stainer Glas g2 coverslipper PROC-HIS-SWBH-Automated Prisma Stainer and Glas G2 Coverslipper PROC-HIS-SWBH- H&E by hand</p>	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<p><u>Routine Histopathology examinations to assist in clinical investigations (cont'd)</u></p> <p>Frozen Section Histology examinations to assist in clinical investigations Detection of abnormal cells</p> <p>Morphological assessment and interpretation/diagnosis</p> <p><u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities</u></p> <p>Acid and Neutral Mucins</p> <p>Acid Fast Tubercle Bacilli</p> <p>Amyloid</p> <p>Argyrophil cells</p>	<p>In House documented procedure & manufacturer's instructions using the following equipment</p> <p>In House manual methods and manufacturer's instructions Using the Cryostat PROC-HIS-SWBH-F2-14 Frozen Sections PROC-HIS-SWBH-C5.3, D1.2-1 Decontamination of Cryostat</p> <p>SOP PROC-HIS-SWBH-F2G1-1 Microscopy</p> <p>PROC-HIS-SWBH -Alcian Blue PROC-HIS-SWBH- Alcian Blue PAS PROC-HIS-SWBH- Diastase Alcian blue PAS PROC-HIS-SWBH-Diastase Periodic Acid Schiff (DPAS) PROC-HIS-SWBH-Hales colloidal iron stain</p> <p>PROC-HIS-SWBH-Zeihl Neelsen (ZN) for Tubercle Bacilli</p> <p>PROC-HIS-SWBH-Congo Red for Amyloid (Eastwood & Cole modification) PROC-HIS-SWBH-Thioflavin T pH1.4 Staining for Amyloid</p> <p>PROC-HIS-SWBH-Grimelius method for Argyrophil cells especially A cells of pancreas</p>	A



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<p><u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u></p> <p>Basement Membranes</p> <p>Calcium</p> <p>Connective tissue /Collagen / Muscle</p> <p>Connective tissue/ Collagen/Muscle/Fibrin</p> <p>Elastin Fibres</p> <p>Fungi</p> <p>Glycogen/Neutral Mucins/Fungi</p> <p>Gram +ve & Gram -ve Organisms</p> <p>Haemosiderin</p> <p><i>Helicobacter pylori</i></p>	<p>In House documented procedure & manufacturer's instructions using the following equipment</p> <p>PROC-HIS-SWBH-Jones Methenamine Silver</p> <p>PROC-HIS-SWBH-Von Kossa stain</p> <p>PROC-HIS-SWBH-Masson Trichrome stain for connective tissue PROC-HIS-SWBH-Van Gieson stain</p> <p>PROC-HIS-SWBH-Martius Scarlet Blue PROC-HIS-SWBH-Phosphotungstic Acid Haematoxylin</p> <p>PROC-HIS-SWBH-Millers stain for Elastin fibres</p> <p>PROC-HIS-SWBH-Periodic Acid Schiff for Fungi PROC-HIS-SWBH-Grocotts Hexamine Silver method for fungi</p> <p>PROC-HIS-SWBH-Periodic Acid Schiff (PAS) for Neutral Mucins</p> <p>PROC-HIS-SWBH-Grams stain for bacteria (Hucker and Conn) PROC-HIS-SWBH-Gram Twort stain for bacteria</p> <p>PROC-HIS-SWBH-Perls Prussian Blue</p> <p>PROC-HIS-SWBH-Giemsa stain for H pylori</p>	A



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<p><u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u></p> <p>Hepatitis B affected Cells/Copper associated protein</p> <p>Lipid</p> <p>Mast Cells</p> <p>Melanin /Lipofuscin</p> <p>Mycobacterium Leprae</p> <p>Reticular fibres</p> <p>Spirochetes</p> <p>Skin abnormalities</p>	<p>In House documented procedure & manufacturer's instructions using the following equipment</p> <p>PROC-HIS-SWBH-Shikatas Orcein stain for Hep B antigen</p> <p>PROC-HIS-SWBH-Oil Red O</p> <p>PROC-HIS-SWBH-Toluidine blue for mast cells PROC-HIS-SWBH-Modified Giemsa stain for Lymph nodes</p> <p>PROC-HIS-SWBH-Masson Fontana stain for melanin PROC-HIS-SWBH-Melanin Bleach PROC-HIS-SWBH-Zeihl Neelsen (Long ZN) for Lipofuscin</p> <p>PROC-HIS-SWBH-Zeihl Neelsen for M.Leprae</p> <p>PROC-HIS-SWBH-Gordon and Sweets method for Reticular fibres</p> <p>PROC-HIS-SWBH-Warthin and Starry stain</p> <p>PROC-HIS-SWBH-Skin Direct Immunofluorescence</p>	A



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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 and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u>	In house documented procedures & manufacturer's instructions	A
Tissue samples & Cell blocks		Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;-	
	Oestrogen	PROC-HIS-SWBH-Oestrogen Receptor-Quick Score	
	Pan cytokeratin (broad range), Epithelial Cells	AE1/AE3	
	Anaplastic Large Cell Lymphoma	ALK Protein (ALK1)	
	Androgen Receptor positive cells, prostate tumours	Androgen Receptor	
	B cells, follicular lymphomas	BCL-2	
	Follicle centre B-cells, lymphomas	BCL-6	
	Basal cell carcinoma, mesothelioma marker	Ber-EP4	
	Fibromatosis of Breast, DCIS	Beta-catenin	
	B Cells, Hodgkin Lymphoma NLP subtype marker	BOB.1	
	Characterization of various neoplasms including lung, endometrial and ovarian	CA125	
	Pancreatic and GI tumours	CA19-9	
	Thyroid C cells and medullary thyroid carcinoma	Calcitonin	
	Smooth muscle and sarcoma	Caldesmon	



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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 procedures & manufacturer's instructions	A
Tissue samples & Cell blocks (cont'd)		Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;-	
	Pulmonary subtypes - mesothelioma	Calretinin	
	Epithelial cells	CAM5.2	
	Lymphoblastic, Burkitt, and follicular lymphomas	CD10	
	Plasma Cells – Multiple Myeloma	CD138	
	Granulocytes, Reed-Sternberg cells	CD15	
	Langerhans cells	CD1a	
	T cells – normal/neoplastic	CD2	
	B cells – normal/neoplastic	CD20	
	B cells, Follicular dendritic cells	CD21	
	B cells, Follicular dendritic cells	CD23	
	T Cells – normal/neoplastic	CD3	
	Reed-Sternberg cells, plasma cells	CD30	
	Endothelial cells	CD31	



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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 procedures & manufacturer's instructions	A
Tissue samples & Cell blocks (cont'd)	Endothelial cells, GISTs, leukaemia's, and Connective tissue tumours	Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;- CD34	
	Erythrocytes, leukocytes, glomerular podocytes and follicular dendritic cells	CD35	
	T cells (helper & mature)	CD4	
	T Cells – normal/neoplastic	CD43	
	Bladder epithelium	CD44	
	T Cells – normal/neoplastic	CD45RO (UCHL1)	
	T Cells – normal/neoplastic	CD5	
	Natural killer cells, neuroendocrine tissues	CD56	
	Natural Killer cells	CD57	
	Megakaryocytes	CD61	
	Macrophages	CD68	
	T Cells – normal/neoplastic	CD7	
	B cells – normal/neoplastic	CD79a	
	T cells (cytotoxic)	CD8	
	Ewing's Sarcoma	CD99	



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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 procedures & manufacturer's instructions	A
Tissue samples & Cell blocks (cont'd)		Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;-	
	Colonic epithelium – normal/neoplastic	CDX-2	
	Various adenocarcinoma (absent in mesothelioma)	CEA (mono-& polyclonal)	
	Neuroendocrine tumours	Chromogranin A	
	Squamous, basal epithelial cells	CK-14	
	Epithelial cells including ductal and glandular epithelia	CK-19	
	Carcinomas of urothelium, GI and Merkel	CK-20	
	Stratified squamous epithelium, basal cells, mesotheliomas	CK-5/6	
	Macular amyloidosis	CK-5/6/18 (CK-1)	
	Adenocarcinomas, columnar epithelial cells, lung, breast endometria	CK-7	
	Simple and glandular epithelium	CK8/18	
	Gastrointestinal stromal tumours (GISTs), mast cells and their relevant disorders.	c-kit (CD117)	
	Cytomegalovirus infection	CMV	



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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 procedures & manufacturer's instructions	A
Tissue samples & Cell blocks (cont'd)		Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;-	
	Haematopoietic tumours, Ewing's sarcoma	c-MYC	
	Mantle Cell Lymphoma	Cyclin D1	
	Lymphatic endothelium	D2-40	
	Smooth Muscle Cells – Normal/Neoplastic	Desmin	
	Gastrointestinal stromal tumours (GISTs)	DOG-1	
	Normal duct epithelial cells, ductal breast carcinoma	E-Cadherin	
	Tumour subtyping – Skin, Lymphoid	EMA	
	Cellular oestrogen receptor expression	ER	
	Endothelial cells and megakaryocytes	Factor VIII	
	Dermatofibromas	Factor XIIIa	
	Thyroid tumour subtyping	Galectin-3	
	Urothelial / Breast carcinoma marker	GATA-3	
	Breast carcinoma marker	GCDFP15	



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HUMAN BODY FLUIDS and TISSUES (cont'd) Tissue samples & Cell blocks (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u> Erythrocytes - Normal/Neoplastic Cytotoxic T Lymphocytes, Natural Killer cells Thyroid tumour subtyping Placenta and certain trophoblastic tumours Hepatocytes – Normal/Neoplastic Human Herpes Virus 8, Kaposi Sarcoma marker Melanoma, melanocyte differentiation Basal cells in Prostate/Thyroid tumour Subtyping Herpes Simplex Virus Immune-complex disorders/Lymphoid tumour subtyping Immune-complex disorders/Lymphoid tumour subtyping IgG-4 related systemic disease	In house documented procedures & manufacturer's instructions Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;- Glycophorin A (CD125a) Granzyme B HBME-1 hCG Hep-Par1 HHV-8 HMB-45 HMWCK HSV IgD IgG IgG4	A



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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 procedures & manufacturer's instructions	A
Tissue samples & Cell blocks (cont'd)		Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;-	
	Immune-complex disorders/Lymphoid tumour subtyping	IgM	
	Characterisation of various genitourinary tract tumours	Inhibin	
	Distinction between monoclonal (i.e. neoplastic), versus polyclonal (i.e. reactive) proliferation of B lymphoid cells	Kappa	
	Proliferation marker	Ki-67	
	Distinction between monoclonal (i.e. neoplastic), versus polyclonal (i.e. reactive) proliferation of B lymphoid cells	Lambda	
	Lymphoid Cells	LCA	
	Epstein-Barr Virus	LMP-1	
	Melanoma marker	Melan A (MART-1)	
	Pan cytokeratin (broad range)	MNF116	
	B cells – normal/neoplastic	MUM-1 Protein	
	Myeloid cells- Acute Myeloid Leukaemia	Myeloperoxidase	
	Rhabdomyosarcoma	Myogenin	



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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 procedures & manufacturer's instructions	A
Tissue samples & Cell blocks (cont'd)		Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;-	
	Pulmonary adenocarcinoma marker	Napsin A	
	Peripheral nerves, neuroendocrine tumours	NSE	
	B Cells, Hodgkin Lymphoma NLP subtype marker	Oct-2	
	Germ cell tumours, seminomas	Oct-3/4	
	Identification HPV associated neoplastic lesions – Cervix/Oral cavity	P16INK4A	
	Pulmonary squamous cell carcinoma marker	p40	
	Prostate adenocarcinoma, High grade prostatic intraepithelial neoplasm (HGPIN)	P504S	
	Prognostic factor in breast, colon, lung and urothelial carcinomas	p53	
	Malignant prostatic/breast glands, and Squamous cell carcinoma	p63	
	B cells – normal/neoplastic	Pax-5	



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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 procedures & manufacturer's instructions	A
Tissue samples & Cell blocks (cont'd)		Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;-	
	Sub typing tumours of Mullerian origin	PAX8	
	Angioimmunoblastic lymphoma marker	PD-1	
	Neurons and neuroendocrine cells	PGP 9.5	
	Germ cell tumours, seminomas	PLAP	
	Cellular progesterone receptor expression	PR	
	Prostate glands – Normal/Neoplastic	PRAP	
	Prostate glands – Normal/Neoplastic	PSA	
	Renal epithelial tumours	RCC	
	Normal and neoplastic neural tissues and melanoma	S-100	
	Smooth Muscle and Myoepithelial cells	SMA	
	Smooth Muscle and Myoepithelial cells	SMM	
	Neuroendocrine tumours	Synaptophysin	



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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 procedures & manufacturer's instructions	A
Tissue samples & Cell blocks (cont'd)		Roche Ventana Benchmark XT PROC-HIS-SWBH- Immunohistochemistry and antibodies to;-	
	Acute lymphoblastic lymphoma	TdT	
	Renal cell carcinoma with Xp11 translocation	TFE-3	
	Pulmonary subtypes - mesothelioma	Thrombomodulin	
	Thyroid epithelium – normal/neoplastic	Thyroglobulin	
	Primary adenocarcinoma of the Lung, Thyroid epithelium – normal/neoplastic	TTF-1	
	Metastatic Colorectal tumours	Villin	
	Cells of mesenchymal origin, Epithelial cells and smooth muscle in fallopian tube	Vimentin	
	Ovarian tumours, mesothelioma, sarcomas	WT1	
	Hepatic Tumours, histocytes	α- 1-Antitrypsin	
	Hepatocytes & germ cell tumours	α- Fetoprotein	
END			