Schedule of Accreditation

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

8097

Accredited to ISO 15189:2022

The Royal Marsden NHS Foundation Trust

Issue No: 018 **Issue date:** 12 August 2026

Pathology Services
The Royal Marsden NHS Foundation Trust
Fulham Road
Chelsea
SW3 6JJ

Contact: Zanell Lategan
Tel: +44 (0) 20 3186 5082
E-Mail: Zanell.Lategan@rmh.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Blood Sciences Laboratory The Royal Marsden NHS Foundation Trust Fulham Road Chelsea SW3 6JJ	**Local contact** Mr Paul Wadham Tel: 02086 613354 ext. 1328 E-Mail:paul.wadham@rmh.nhs.uk	Biochemistry Haematology Blood Transfusion Automated Chemistry Manual Chemistry Blood component issue	A
Blood Sciences Laboratory The Royal Marsden NHS Foundation Trust Downs Road Sutton SM2 5PT	**Local contact** Gopyraj Sundararajah Tel: 020 7808 2606 E-Mail: Gopyraj.Sundararajah@rmh.nhs.uk	Biochemistry Haematology Blood Transfusion Automated Chemistry Endocrinology Tumour markers Manual Chemistry Endocine/Haematinics/Cardiac/Thyroid/ Drugs Blood component issue (as above) Blood storage & issue	B
Blood Sciences Laboratory 19a Cavendish Square London W1G 0PL	**Local Contact** Mr Paul Wadham Tel: 020 7808 2606 E-Mail: paul.wadham@rmh.nhs.uk	Biochemistry Haematology	C
Microbiology Department The Royal Marsden NHS Foundation Trust McElwain Building Oakleaf Avenue Sutton Surrey SM2 5GP	**Local Contact** Komal Vaghela Tel: 020 8661 3787 E-Mail: Komal.Vaghela@rmh.nhs.uk	Bacteriology Virology Molecular	B

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Location details		Activity	Location code
Cellular Pathology Department The Royal Marsden NHS Foundation Trust Fulham Road London SW3 6JJ United Kingdom	**Local contact** Coralie Pennaneac'h Tel: 020 7808 2632 E-Mail: Coralie.Pennaneach@rmh.nhs.uk	Histology Non-Gynae Cytology Immunohistochemistry In-situ Hybridisation OSNA	A
Histo/Cytopathology Department The Royal Marsden NHS Foundation Trust The Centre for Molecular Pathology 10 Oakleaf Avenue Sutton Surrey SM2 5GP	**Local contact** Natalie Peters Tel: 020 895 6549 E-mail: natalie.peters@rmh.nhs.uk	Histology Immunohistochemistry In-situ Hybridisation OSNA	B
Clinical Genomics The Royal Marsden NHS Foundation Trust The Centre for Molecular Pathology 10 Oakleaf Avenue Sutton Surrey SM2 5GP	**Local contact** Mikel Valganon Petrizan Tel: 020 861 3354 E-Mail: Mikel.ValganonPetrizan@rmh.nhs.uk	Solid tumours Haematological malignancies Molecular testing Cytogenetics Bioinformatics	B
Immunophenotyping Department The Royal Marsden NHS Foundation Trust The Centre for Molecular Pathology 10 Oakleaf Avenue Sutton Surrey SM2 5GP	**Local contact** Alan Dunlop Tel: 020 8915 6512 E-Mail: Alan.Dunlop@rmh.nhs.uk	Haematological malignancies Minimal residual disease monitoring Stem cell enumeration Immune monitoring	B

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Theatre Fridge The Royal Marsden NHS Foundation Trust Fulham Road Chelsea SW3 6JJ	Blood storage & issue Fridge managed by Haematology	A

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES	Biochemistry examination activities for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
	Quantification of:	Ortho Clinical Diagnostics VITROS 5600 with MicroSlide Technology BSCHEMSOP300	
Serum	Alanine Transaminase (ALT)		A, B
Serum	Aspartate Transaminase (AST)		A, B
Serum	Amylase		A, B
Serum	Albumin		A, B
Serum	Alkaline Phosphatase (AP)		A, B
Serum	Bicarbonate		A, B
Serum	Total Bilirubin		A, B
Serum, CSF*	Total Protein		A, B*
Serum	Calcium		A, B
Serum	Chloride		A, B
Serum	Creatinine Kinase (CK)		A, B
Serum, urine*	Creatinine		A, B*
Urine	Creatinine clearance		B
Serum	Gamma Glutamyl Transferase (γGT)		A, B
Serum, CSF*	Glucose		A, B*
Serum	Cholesterol		B
Serum	LDL Cholesterol		B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
	Quantification of: (cont'd)	Ortho Clinical Diagnostics VITROS 5600 with MicroSlide Technology BSCHEMSOP300	
Serum	HDL Cholesterol		B
Serum	Iron		A, B
Serum	Lactate Dehydrogenase (LDH)		A, B
Serum	Lipase		A, B
Serum	Magnesium		A, B
Serum, Urine*	Phosphate		A, B*
Serum, Urine*	Potassium		A, B*
Serum, Urine*	Sodium		A, B*
Serum	Triglycerides		B
Serum	Uric Acid (Urate)		A, B
Serum	Urea		A, B
Urine	Total protein		B
Serum	Adjusted calcium		A, B
Serum	AKI		A, B
Serum	HDL/LDL ratio		B
Serum	Transferrin saturation		B
Serum	Free PSA / Total PSA ratio		A, B
Serum	Alpha Fetoprotein		A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
	Quantification of: (cont'd)	Ortho Clinical Diagnostics VITROS 5600 with MicroSlide Technology BSCHEMSOP300	
Serum	beta Human Chorionic Gonadotrophin (HCG)		A, B
Serum	Carbohydrate Antigen 125 (CA125)		A, B
Serum	Carbohydrate Antigen 15.3(CA15.3)		A, B
Serum	Carbohydrate Antigen 19.9 (CA19.9)		A, B
Serum	Carcinoembryonic antigen (CEA)		A, B
Serum	Cortisol		A, B
Serum	Ferritin		A, B
Serum	Folate		B
Serum	Free Prostate Specific Antigen (PSA)		A, B
Serum	Follicle Stimulating Hormone (FSH)		A, B
Serum	Free Tri-iodothyronine (Free T3)		A, B
Serum	Free Thyroxine (Free T4)		A, B
Serum	Luteinising Hormone (LH)		A, B
Serum	Testosterone		A, B
Serum	Total PSA		A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
	Quantification of: (cont'd)	Ortho Clinical Diagnostics VITROS 5600 with MicroSlide Technology BSCHEMSOP300	
Serum	Troponin I		A, B
Serum	Thyroid Stimulating Hormone (TSH)		A, B
Serum	25 OH Vitamin D		B
Serum	Vitamin B12		A, B
Serum	Intact PTH		B
Serum	Vancomycin		B
Serum	Gentamicin		B
Serum	Haptoglobin		B
Serum	Immunoglobulin A		B
Serum	Immunoglobulin G		B
Serum	Immunglobulin M		B
Serum	Transferrin		B
Serum	C-reactive protein (CRP)		A, B
Serum	Amikacin		B
Serum	B2 Microglobulin		B
Serum	Ciclosporine		B
Serum	Methotrexate		B
Serum	NT proBNP		B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
	Quantification of: (cont'd)	Ortho Clinical Diagnostics VITROS XT3400 with MicroSlide Technology BSCHEMSOP500	
Serum	Albumin		B, C
Serum	ALP		B, C
Serum	ALT		B, C
Serum	Amylase		B, C
Serum	AST		B, C
Serum	Bicarbonate		B, C
Serum	Calcium		B, C
Serum	Chloride		B, C
Serum	Creatinine Kinase (CK)		B, C
Serum	Creatinine		B, C
Serum	C Reactive Protein (CRP)		B, C
Serum	Gamma GlutamylTransferase (GGT)		B, C
Serum	Glucose		B, C
Serum	LDH		B, C
Serum	Lipase		B, C
Serum	Magnesium		B, C
Serum	Phosphate		B, C
Serum	Potassium		B, C

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
	Quantification of: (cont'd)	Ortho Clinical Diagnostics VITROS XT3400 with MicroSlide Technology BSCHEMSOP500	
Serum	Sodium		B, C
Serum	Total Bilirubin		B, C
Serum	Total Protein		B, C
Serum	Urea		B, C
Serum	Uric Acid		B, C
	Quantification of	Ortho Clinical Diagnostics VITROS ECIQ BSCHEMSOP 501	
Serum	Alpha feto Protein (AFP)		C
Serum	Human Chorionic Gonadotrophin (bHCG)		C
Serum	CA125		C
Serum	CA199		C
Serum	Carcinoembryonic antigen (CEA)		C
Serum	Cortisol		C
Serum	Prostate Specific Antigen (PSA)		C
Whole blood	Haemoglobin A1c	Biorad D-10 HPLC Ion Exchange BSCHEM91	B
Serum	Paraprotein identification and quantitation	Sebia Capillarys 2 Capillary Electrophoresis BSCHEMSOP100	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Urine	Paraprotein identification	Sebia Hydrasys Gel Electrophoresis BSCHEM42	B
Serum, urine	Isotype confirmation	Gel Electrophoresis/ Immunofixation BSCHEM42	B
Serum	Light Free Chains (Kappa and Lambda)	Binding site Optilite Turbidmetric detection BSCHEMSOP001	B
Serum	Kappa and Lambda ratio	Binding site Optilite calculation BSCHEMSOP001	B
Urine	Urinalysis (Dipstick) Glucose Bilirubin Ketone Specific Gravity Blood pH Protein Urobilinogen Nitrite Leucocytes	Siemens-Clintek Siemens Photometric detection BSCHEMSOP009	A, B
Serum, urine	Osmolality	Advanced Instruments Osmometer OSMO1 Freezing point depression BSCHEMSOP038	A, B
Urine	Qualitative detection of bHCG (pregnancy)	Launch Diagnostics Accusay hCG Immunoassay BSCHEMSOP007	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Serum	Quantification of: Thyroglobulin Thyroglobulin Antibody Thyroglobulin recovery	Beckman Coulter Access II using Chemiluminescent microparticle immunoassay (CMIA) detection BSCHEMSOP011	B
Blood	DPYD deficiency testing	DPYD LAMP Assay using: MIC qPCR MYRA liquid handler BSCHEMSOP013	B
EDTA (plasma)	ACTH	DiaSorin Liaison XL chemiluminescent immunoassay (CLIA) technology BSCHEMSOP029	B
Serum	Calcitonin	DiaSorin Liaison XL chemiluminescent immunoassay (CLIA) technology BSCHEMSOP028	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Blood Transfusion examinations to assist in clinical investigations	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Venous blood	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative O Rh D Negative Transitional (during BMT) groups	BioRad IH500 using gel card technology BSBBSOP089	A, B
Venous blood	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh D Negative AB Rh D Negative B Rh D Negative O Rh D Negative Transitional (during BMT) groups	Manual methods using BioRad gel card technology BSBBSOP044.	A, B
Venous blood	Blood group by detection and identification of antigens A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh D Negative AB Rh D Negative B Rh D Negative O Rh D Negative Transitional (during BMT) groups	Manual methods using tube technique BSBBSOP009	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Blood Transfusion examinations to assist in clinical investigations (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Venous blood	Detection of Rh+K red cell Phenotyping by detection and identification of antigens: C c E e K	BioRad IH500 using gel card technology BSBBSOP089	A, B
Venous blood	Detection of Rh+K red cell Phenotyping by detection and identification of antigens: C c E e K	Manual methodology using BioRad gel card technology BSBBSOP022	A, B
Plasma	Antibody Screen by detection and identification of antibodies to: Rh MNS P Lutheran Kell Lewis Duffy Kidd	BioRad IH500 using gel card technology BSBBSOP089	A, B
Blood	Antibody Screen by detection and identification of antibodies to: Rh MNS P Lutheran Kell Lewis Duffy Kidd	Manual methodology using BioRad gel card technology BSBBSOP010 BSBBSOP011	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Blood Transfusion examinations to assist in clinical investigations (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Plasma	Emergency issue of red cells	Manual tube method Saline immediate spin BSBBSOP105	A, B
Plasma	Compatibility testing of patients' plasma with donor cells	Manual BioRad IAT method: using gel card technology BSBBSOP105	A, B
Plasma	Compatibility testing of patients' plasma with donor cells	Manual prewarmed BioRad IAT 37oC method using gel card technology BSBBSOP105	A, B
Plasma	Routine compatibility testing of patients' plasma with donor cells	BioRad IH500 IAT method using gel card technology BSBBSOP089	A, B
Venous blood	Direct Anti-globulin Test- DAT Polyspecific AHG IgG C3d	BioRad IH500 using gel card technology BSBBSOP089	A, B
Venous blood	Direct Anti-globulin Test- DAT Polyspecific AHG IgG C3d	Manual BioRad method using gel card technology BSBBSOP019	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haematology examinations to assist in clinical investigations	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Whole blood (EDTA)	Full Blood Count (FBC) analysis of the following parameters: WBC WBC 5 part differential: Neutrophils Lymphocytes Monocytes Eosinophils Basophils RBC HGB HCT MCV MCH MCHC	Sysmex XN automated analysers, using spectrophotometry, impedance particle counting and laser light scatter BSHAEMSOP014	A, B, C
Whole Blood (EDTA)	Preparation of blood films for Identification of normal and abnormal morphologies	Sysmex SP-50 Slide Maker BSHAEMSOP007	A, B
Blood film on glass slide	Identification of normal and abnormal morphologies including WBC differential count	Morphological review of blood films BSHAEMSOP002	A, B
Whole Blood (EDTA)	Haemoglobin S Screening	Manual Solubility test using Streck Sickle Test kit BSHAEMSOP011	A, B
Whole Blood (EDTA)	Glucose-6-phosphate dehydrogenase (G6PD) screening test	Rapid Immunoassay manual test using Binax NOW G6PD kit BSHAEMSOP010	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
	Routine Coagulation testing for:	Sysmex CS2500 automated analyser, photo-optical	
Blood (Plasma)	Prothrombin Time (PT)	H095	A, B
Blood (Plasma)	Activated Partial Thromboplastin Time (APTT)	H095	A, B
Blood (Plasma)	INR	H095	A, B
Blood (Plasma)	Fibrinogen	H095	A, B
Blood (Plasma)	Corrected APTT	H095	A, B
Blood (Plasma)	Anti-Xa	BSHAEMSOP009	A, B
Blood (Plasma)	D-Dimer	H098	A, B
Venous blood	Corrected PT	H095	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Swabs of tissue and fluids from various body sites including but not limited to pus, drain fluids, duodenal aspirates, sputum, bronchial lavage, ascitic fluids, pleural fluids, CSF, voice prosthesis	General isolation of micro-organisms of clinical significance	Manual culture onto selected media BACT 2 BACT 5 BACT 6 BACT 8 BACT 26 BACT 29 BACT 41 BACT 48 BACT 49 BACT 50 BACT 51 BACT 52 BACT 54 BACT 55 BACT 56 BACT 57 BACT 60	B
Bacterial cultures isolated in-house	General identification of micro-organisms of clinical significance	General kit based biochemical identification methods BACT 7 BACT 14 BACT 18 BACT 22 BACT 23 BACT 53	B
Bacterial cultures isolated in-house	General identification of micro-organisms of clinical significance	Matrix assisted laser desorption / ionisation using: Bruker MALDI-ToF Microflex MALDI Biotyper® sirius System BACT43	B
Bacterial cultures isolated in-house	General identification of micro-organisms of clinical significance	VITEK 2 Compact BACT 40	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Bacterial cultures isolated in-house	Antimicrobial susceptibility testing	Manual testing using antimicrobial discs and EUCAST guidelines BACT 36 BACT 36A	B
Bacterial cultures isolated in-house	Antimicrobial susceptibility testing	Manual testing using antimicrobial discs and EUCAST guidelines BACT 36 BACT 36A	B
Bacterial cultures isolated in-house	Antimicrobial susceptibility testing	Manual MIC determination using gradient strips and EUCAST guidelines BACT 36	B
Fungal cultures isolated in house	Antifungal susceptibility testing	MIC Gradient strips FUN 2	B
CSF Ascitic fluid Pleural fluids	Quantification of white and red blood cells and qualitative demonstration of Bacteria	Light microscopy using fast read counting chambers and glass slides followed by manual culture onto selected media BACT 2 BACT 26	B
Swabs from various sites	Screening for and isolation of Methicillin-Resistant *Staphylococcus aureus* (MRSA)	Manual culture onto chromogenic selective media BACT 33	B
Duodenal aspirates	Detection and identification of Giardia lamblia cysts and trophozoites	Manual light microscopy BACT 5 MICRO 14	B
Sputum Bronchial lavage	Identification of acid-fast bacilli	Staining and Microscopy using Auramine Phenol staining BACT 7	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Urine	Quantification of white and red blood cells, epithelial cells and qualitative demonstration of Bacteria, crystals and casts	Light microscopy using fast read counting chambers followed by manual culture onto selected media BACT 35	B
Blood	Detection of microbial growth and isolation of micro-organisms of clinical significance	Automated culture using BACT/Alert followed by culture onto selected media BACT 16 BACT 59	B
Faeces	General isolation of Aeromonas *Salmonella sp*, *Shigella sp, CampyloBACTer sp* & E. coli 0157, *Vibrio sp*. and *Yersinia sp.*	Manual culture onto selective media BACT 38	B
Faeces	Screening and isolation of multi-drug resistant Bacteria	Manual culture onto selective media BACT 38	B
Faeces	Identification of *Cryptosporidium sp*	Staining and Microscopy using Auramine Phenol and ZN BACT 7	B
Faeces	*Clostridioides* (formerly *Clostridium*) *difficile* GDH and toxin A/B	Manual enzyme immunoassay using Alere QuikChek BACT 24	B
Faeces	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Concentration using Midi Parasep Faecal Parasite Concentrator followed by identification using light microscopy MICRO 14	B
Faeces	Detection of Rotavirus/Adenovirus	Certest kit BACT 27	B
Faeces	Detection of Norovirus I/II	Ridaquick kit BACT 27	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods based on related UK standards for Microbiology Investigations (SMIs) and manufacturers' operating instructions.	
Skin Nail	General isolation and characterisation of fungi of human clinical significance	Manual culture onto selective culture media and microscopic / macroscopic identification FUN 1	B
Serum	Serology for the detection of:	DiaSorin Liaison XL SERO 23	
	Hepatitis A IgM	LIAISON® HAV IgM	B
	Hepatitis B Surface Antigen	LIAISON® MUREX HBsAg Quant	B
	Hepatitis B Core antibody	LIAISON® Anti-HBc	B
	Hepatitis B Surface antibody	LIAISON® MUREX Anti-HBs	B
	Hepatitis C antibody	LIAISON® MUREX HCV Ab	B
	HIV-1 & HIV-2 Antibodies and HIV-1 p24 Antigen.	LIAISON® MUREX HIV Ab / Ag	B
	HTLV I/II IgG	LIAISON® MUREX recHTLV-I/II	B
	Cytomegalovirus IgG antibody	LIAISON® CMV IgG II	B
	Rubella IgG antibody	LIAISON® Rubella IgG II	B
	Treponema total antibody	LIAISON® Treponema Screen	B
	Toxoplasma IgG antibody	LIAISON® Toxo IgG II	B
	Epstein Barr Virus VCA IgG	LIAISON® VCA IgG	B
	EBV nuclear antigen (EBNA) IgG	LIAISON® EBNA IgG	B
	Measles IgG	LIAISON® Measles IgG	B
	Varicella zoster (VZV) IgG	LIAISON® VZV IgG HT	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis	In house documented methods incorporating manufacturer's instructions where relevant	
Tissue samples: Fixed & fresh, including bone barrow trephines.	The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	Macroscopic and Microscopic examination Supported by:	A, B
Non-gynae cytology cell blocks Frozen sections		CYTO 2 HIST 17	A
Fresh tissue only		Manual Tissue dissection HIST 164 HIST CMP 146	A, B
		Cryomicrotomy and intraoperative frozen sections using Thermo Scientific HM525NX Cryotostat NX50 HIST 17	A
		Tissue processing using Sakura Tissue Tek VIP6, VIP 6 AI HIST 1A	A
		Tissue processing using Sakura Tissue Tek VIP6 HIST CMP 01	B
		Embedding using Sakura Tissue Tec5 HIST SD 06	A
		Embedding using Sakura Tissue TEC-6 HIST SD 06	B
		Section Cutting using Leica Microtome RM 2235, BioCut, Epredia Slide Mate AS + Slide Mate Pro HIST SD 05 HIST 149 HIST SD 17	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
		Cassette Printers: PI SMART HIST 264	A
		Cassette Printer: Thermo Scientific PrintMate AS HIST SD 17	B
Stained Formalin-fixed paraffin embedded tissue slides	Morphological assessment and interpretation/diagnosis	Microscopy HIST MAN 09 HIST 26	A, B
Formalin-fixed paraffin embedded tissue slides	Demonstration of:	Special Tinctorial Histochemical Staining (Special Stains) methods using manual techniques:	
	Basophilic and eosinophilic structures	Routine H&E staining Leica HistoCore SPECTRA HIST SD 21	A, B
	Basophilic and eosinophilic structures	Hand staining H&E HIST 131 (manual) HIST SD 13	A, B
	Acid mucins	Alcian Blue Technique HIST 59	A, B
	Acid and Neutral mucins	Alcian Blue – Periodic Acid-Schiff ± Diastase HIST SD 01	A, B
	Amyloid	Congo Red (Highman) HIST CMP 70	B
	Bone marrow cell differentiation	Giemsa Stain HIST CMP 67	B
	Glycogen	PAS ± Diastase HIST SD 14	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Demonstration of: (cont'd)	Special Tinctorial Histochemical Staining (Special Stains) methods using manual techniques:	
	M. Tuberculosis	Ziehl Neelsen HIST CMP 91	B
	Haemosiderin	Perl's Prussian Blue Stain HIST CMP 83	B
	Reticulin Fibres	Gordon and Sweet Stain HIST CMP 85	B
	Immunohistochemistry for the detection of:	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Glandular and stratified squamous epithelium	AE1/3	A, B
	Germ cell tumours, with high frequency in yolk sac tumours	Alpha Fetoprotein	A
	Anaplastic lymphoma kinase large cell lymphoma.	ALK-1 (DAKO)	A, B
	Anaplastic lymphoma kinase large cell lymphoma.	ALK-1 (VMS)	A, B
	Prostatic carcinoma	Alpha-methylacyl-CoA racemase (AMACR)	A
	Osteosarcoma, and in prostatic carcinoma	Androgen Receptor	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Human tumorigenesis, and in colorectal cancer	B-Catenin	A
	Presence and loss of nuclear staining in melanocytes, moderate nuclear staining of epithelial and lymphoid cells	BAP1	A
	Malignant rhabdoid tumour (MRT) of the liver	BAF-47	A
	Follicular and diffused large cell lymphomas from reactive lymph nodes	BCL2	A, B
	Diffuse large B cell lymphomas and Burkitt's lymphoma and Reed Sternberg cells in Hodgkin's disease	BCL6	A, B
	Epithelial Cells of the Colon	BerEP4	A
	B cells, plasma cells	BOB-1	A, B
	Cytoplasmic staining in BRAF mutated tumour cells	BRAF V600E	A
	Nuclear staining/loss of expression correlates to tumour staging	BRG1	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Membranous staining in RCC and normal normal Gall bladder/ Stomach epithelium	CA IX	A
	Seminal vesicle carcinoma and anaplastic lymphoma	CA125	A
	Gastrointestinal and pancreatic cancers	CA19.9	A
	Endocrine tumour, medullary thyroid carcinoma (MTC),	Calcitonin	A
	Smooth muscle tumours	Caldesmon	A
	Smooth muscle of prostate, bowel and aorta	Calponin	A
	Mesothelial cells, steroid producing cells	Calretinin	A
	Carcinomas from malignant tumours of non-epithelial origin	Cam5.2	A, B
	Langerhans cells in skin	CD1a	A, B
	T cell lymphomas	CD2	B
	Normal and neoplastic T cells from thymocytes to mature T cells	CD3	A, B
	Inducer T cells both normal and neoplastic	CD4	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	T cell lymphomas and mantle cell lymphoma	CD5	A, B
	Peripheral blood T lymphocytes NK cells Thymocytes	CD7	B
	T cells cytotoxic / suppressor	CD8	A, B
	All germinal centre cells – tonsil Renal cell carcinoma	CD10	A, B
	Hairy cell leukaemia	CD11c	B
	Myeloid antigen	CD13	B
	Monocyte differentiation antigen	CD14	B
	Granulocytes, Reed-Sternberg cells	CD15	A, B
	Natural killer cells	CD16	B
	Common B cell marker, expressed by B cells and follicular dendritic cells	CD19	B
	B cells	CD20	A, B
	Follicular dendritic cells	CD21	A, B
	B cell marker	CD22	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Small B cell lymphocytic lymphoma	CD23	A, B
	Activated T lymphocytes; Natural Killer cell	CD25	B
	Post germinal centre B cell marker	CD27	B
	Reed Sternberg cells in Hodgkin's lymphoma, anaplastic large cell lymphoma and plasma cells	CD30	A, B
	Endothelial cells. Benign and malignant vascular disorders	CD31	A, B
	Myeloid marker	CD33	B
	Leucocyte differentiation	CD34	A, B
	Erythrocytes, leukocytes, glomerular podocytes and follicular dendritic cells	CD35	A, B
	Thymocytes, germinal centre B cells, activated T cells, plasma cells, monocytes	CD38	B
	T and B cell lymphomas	CD43	A, B
	Malignant cells in epithelial, mesothelial and hemopoiesis tissues	CD44	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	All Leucocytes	CD45	A, B
	Neural / neuroendocrine tissue and natural killer cells	CD56	A, B
	Mononuclear cells, natural killer and neuroectodermal cells	CD57	A, B
	Identify platelets, megakaryocytes and platelet thrombi	CD61	B
	T cells. Natural killer cells, thymocytes	CD68 (KPI)	A, B
	T cells. Natural killer cells, thymocytes	CD68 (PGM1)	A, B
	Red blood cell marker	CD71	B
	B cells all stages	CD79a	A, B
	T- Lymphocytes, granulosa cells ovary, pancreatic islet cells, CNS ependymal cells and Sertoli's, Ewing's sarcoma	CD99	A, B
	Membrane staining of intraepithelial T-cells and some periphery regulatory T cells	CD103 (clone EP206)	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	KIT protein in gastro-intestinal stromal tumours	CD117	A, B
	Plasma cells	CD138	A, B
	Macrophages	CD163	B
	Lung carcinoma	CDK4	A
	Surface of the villus, crypts and in sporadic colorectal cancers	CDX2	A
	Mucosal epithelia of the adult colon	Carcinoembryonic antigen (CEA)	A
	Neuroendocrine tumours	Chromogranin (CG)	A
	Epithelial tumour cells	CK5/6	A
	Adenocarcinomas of breast, lung, endometrium, ovary, thyroid and carcinomas of bladder and renal cell	CK7	A
	Neoplasms of squamous cell	CK14	A
	Squamous cell carcinomas of the lung, cervix and oral cavity	CK17	A
	Adenocarcinomas of colon, stomach, pancreas, biliary tract, liver and breast	CK19	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Columnar cell epithelium	CK20	A
	Prostate carcinoma	CK903	A
	Cytomegalovirus infected cells	CMV	A
	Oncogene	cMYC	B
	Basement membranes associated with Alport syndrome and Goodpasture's syndrome	Collagen IV	A
	Plasma biomarker for germinal centre activity, peritoneal macrophages, Kuppfer cells	CXCL13	B
	Mantle cell lymphomas and breast	Cyclin D1	A, B
	Lymphatic vessels	D240	A, B
	Hairy cell leukaemia	DBA44	B
	Smooth and striated muscle tumours	Desmin	A
	Gastro-intestinal stromal tumours	DOG-1	A
	Adenocarcinoma from mesothelioma and ductal vs lobular cancer of the breast	E-Cadherin	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Epstein Barr Encoded RNA expressing cells	EBER ISH	B
	Variety of normal and neoplastic epithelia	EMA	A, B
	Oestrogen receptors breast carcinoma	ER	A
	Prostate carcinoma	ERG	A
	Endothelia cells	Factor VIII	A
	Bone marrow dermal dendritic cells, distinct from Langerhans cells	Factor XIIIa	A
	Dendritic cells and Hodgkin's disease	Fascin	B
	Ewing sarcoma, Angiosarcoma	Fli-1	A
	B cell marker	Fox-P1	B
	T cell regulatory cells marker	Fox-P3	B
	Cytoplasmic staining in hepatocytes, loss in germline mutations	Fumarate Hydratase (FH)	A
	T-cells and endothelial cells	GATA-3	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Immuno-reactive cells, associated with mucous glands	Gastrin	A
	Breast Carcinoma	GCDFP	A
	Germinal centre B cell marker	GCET-1	B
	Astrocytes, Schwann cells	GFAP	A
	Erythrocytes	Glycophlorin C (Ret 40)	B
	Erythrocytes	Glycophlorin A (CD235a)	A, B
	Cytotoxic granules	Granzyme	B
	Mesothelial cells benign and malignant	HBME-1	A
	Hepatocellular carcinoma, hepatoblastoma, melanoma, testicular germ cell tumours and Wilms tumour	Glypican 3	A
	Placental secreting trophoblasts	HCG	A
	Membrane staining of MHS class II complex Leukaemia marker	HLA-DR (TAL-1B5)	B
	Helicobacter pylori protein	H Pylori	A, B
	Human Herpes Virus 8	HHV8	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Marker of Her2 amplification in breast tumours.	Her2	A
	Marker of Her2 amplification in breast tumours.	Her2 DDISH	A
	Hepatocellular carcinoma	HepaR1	A
	Melanoma cells	HMB45	A
	T cell Follicular helper cells	ICOS	B
	Plasma cells and related lymphoid cells containing IgA	IgA	A, B
	Plasma cells and related lymphoid cells containing IgD	IgD	A, B
	Plasma cells and related lymphoid cells containing IgG	IgG	A, B
	Plasma cells and related lymphoid cells containing IgG4	IgG4	A, B
	Plasma cells and related lymphoid cells containing IgM	IgM	B
	Leydig and Sertoli cells testis	Inhibin	A
	Immunoglobulins	J chain	B
	B cells and plasma cells	Kappa	A, B
	B cells and plasma cells	Lambda	A, B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Langerhans cells	Langerin	B
	Nuclear staining associated with chromosomal aberration in T-ALL	LMO2	B
	Melanoma	Melan A	A
	Mast cells	MCT	B
	Proliferating cells in germinal B cells	MIB-1	A, B
	Colorectal carcinoma	MLH-1	A
	Cytokeratins 5, 6, 8, 17, 19 (All epithelia)	MNF116	A, B
	Myeloperoxidase in Neutrophils, eosinophils, monocytes	MPO	A, B
	Colorectal carcinoma	MSH2	A
	Colorectal carcinoma	MSH6	A
	Breast carcinoma	MUC-1	A
	Gastric carcinoma	MUC-2	A
	Epithelial cells	MUC-4	A
	Gastric carcinoma	MUC-5ac	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Epithelial cells	MUC-6	A
	Expressed in plasma cells germinal centre B cells activated T cells and Reed Sternberg cells	MUM-1	A, B
	Normal and neoplastic skeletal and cardiac muscle cells	MyoD1	A
	Rhabdomyosarcomas, Wilms tumour	Myogenin	A
	Napsin A, expressed in type II pneumocytes, kidney and foetal lung	Napsin A	A
	Neuronal intermediate filament	NF	A
	Seminiferous ducts	NUT	A
	Central and peripheral neuroendocrine cells	NSE	A
	B Cell lymphomas, germinal centre derived lymphomas	OCT-2	A, B
	Seminoma / germ cell tumour	OCT-4	A
	Pre-B cells	PAX5	A, B
	Human immunodeficiency virus disease	P24	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	P40 protein in squamous cell carcinomas (lung, urothelial, head and neck)	P40	A
	Thyroid follicular carcinomas and atypical follicular thyroid adenomas.	Pax8	A
	Pancreas islets of Langerhans cells positive	PGP 9.5	A
	Membranous and nuclear staining	PRAME	A
	Cytoplasmic/nuclear staining of tumour cells	P16	A
	Wild type and mutant forms of human p53	P53	A, B
	Normal proliferating cells; poorly differentiated squamous cell carcinoma, basal cells; abluminal cells	P63	A
	Hepatocellular carcinoma	PCEA	A
	Systemic lupus erythematosus, T-cells in germinal centres, mantle zones and interfollicular zones	PD1	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	PD-L1 protein expression	PD-L1 (SP142 & SP263)	A
	Cytoplasmic granules of cytolytic T-lymphocytes	Perforin	B
	Placental trophoblasts	PLAP	A
	Plasma cells	Plasma cell (V538c)	B
	Breast carcinoma	PMS2	A
	Breast carcinoma	Progesterone receptor	A
	Prostate secretory and ductal epithelium	PSA	A
	Glandular prostatic epithelium	PSAP	A
	Renal tumours	RCC	A
	Squamous cell carcinoma	SALL-4	A
	Gastrointestinal carcinoma	Serotonin	A
	Schwann cells, adipocytes, cartilage	S100	A, B
	Smooth muscle, myoepithelial and other contractile cells	Smooth muscle actin (SMA)	A
	Melanoma marker- especially spindle cell type	Sox-10	A
	Mantle cell lymphoma	Sox11	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Formalin-fixed paraffin embedded tissue slides (cont'd)	Immunohistochemistry for the detection of: (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Location A = Roche/Ventana Benchmark Ultra (HIST 32) Location B = Leica Bond III (HIST CMP 15)	
	Stat6 (signal transducers and activators of transcription)	STAT-6	A
	Synaptic vesicle protein (neurones; neuroendocrine cells)	Synaptophysin	A
	T cell subtyping	TCR beta	B
	Leukaemia's, acute lymphoblastic	Tdt	B
	Cytotoxic granules	TIA1	B
	Tartrate resistant acid phosphatase in Hairy cell leukaemia	TRAP	B
	Lymphomas in lung and thyroid.	TTF-1	A
	Cells of mesenchymal origin	Vimentin	A
	Mesenchymal cells, Wilms tumour, Serous ovarian adenocarcinoma	WT-1	A
Formalin-fixed paraffin embedded tissue slides	PDL-1 (22C3)	Documented in-house procedure in conjunction with manufacturer's instructions for Dako Autostainer 48 and Dako PT Link HIST CMP 6	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant	
Sentinel lymph node tissue	Detection of Cytokeratin 19 (CK19) mRNA in breast carcinoma (OSNA)	OSNA (One Step Nucleic Acid Amplification) Documented in-house procedures In conjunction with manufacturer's instructions for Sysmex RD210, Eppendorf minispin. HIST SD 08	A, B
	Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis	Macroscopic and microscopic examination	
Serous fluids Fine Needle Aspirations Cerebro-spinal fluid CSF) Sputum Bronchio-alveolar lavage Bronchial washings	The examination of body fluid/fine needle aspirate samples to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	Documented in-house procedures in conjunction with manufacturer's instructions for Cytopsin, Gemini Shandon Varistain. Tinctorial stains (Special stains) Papanicolaou (PAP) May-Grunwald Giemsa (MGG) CYTO 23 CYTO 2 CYTO 15 CYTO 16	A
TIC sentinel lymph node	Demonstration of cells (nuclei and cytoplasm) and micro-organisms	Tinctorial stains (Special Stains): Diff Quick CYTO 17	A
Samples as above	Preparation of cell blocks for histology processing and staining	CYTO 2	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer DNA/RNA Extraction, quantification, and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Documented in house procedures incorporating manufacturer's instructions (where relevant): Manual semi-automated and automated DNA /RNA extraction and quantification using: **Cell Fraction:**	
Blood Bone marrow		Cell Separation for Chimerism AutoMACS Pro Separator GEN-SOP 149	B
Blood Bone marrow		Cell Separation for Chimerism MultiMACS Cell24 Separator Plus GEN-SOP 183	B
		DNA Extraction:	
Blood		Manual - QIAmp Midi and Mini kits GEN-SOP 207	B
Blood Bone Marrow		Automata workflow Kingfisher extraction platform Promega Maxwell HT Genomic DNA kit (A6050) GEN-SOP 930	B
Blood Bone Marrow		Kingfisher extraction platform Promega Maxwell HT Genomic DNA kit (A6050) GEN-SOP 930	B
Saliva		Automata workflow Kingfisher extraction platform Promega Maxwell HT Genomic DNA kit (A6050) GEN-SOP 881	B
Saliva		Automated - Promega Maxwell GEN-SOP 600	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
	DNA/RNA Extraction, quantification, and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Manual semi-automated and automated DNA /RNA extraction and quantification using:	
Lyophilised cells CD3, CD15 and CD138 cells		Automated - Qiagen QIAsymphony GEN-SOP 156	B
Unfixed (fresh or frozen) tissue/cells		Manual- QIAmp mini kit GEN-SOP 223	B
Formalin fixed paraffin embedded tissues (FFPE)		Automated - Promega Maxwell RSC GEN-SOP 185	B
		DNA Extraction:	
Plasma	Isolation of cfDNA	Manual - QIAmp circulating NA kit GEN-SOP 215	B
Plasma	Isolation of cfDNA	Manual - Roche Cobas sample preparation kit GEN-SOP 122	B
Plasma	Isolation of cfDNA	Automated - Qiagen QIAsymphony GEN-SOP 128	B
Plasma	Isolation of cfDNA	Automated - Marsden360 QIAsymphony cfDNA Extraction kit GEN-SOP 711	B
		DNA Extraction:	
Plasma		Automated - Marsden360 GEN-SOP 712	B
		RNA Extraction:	
Blood		Manual - Qiagen RNeasy mini kit GEN-SOP 125	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
Blood Bone marrow Fixed cells Lyophilised cells		Automated - Promega Maxwell RSC 48 Instrument Simply RNA Blood Kit GEN-SOP 173	B
	DNA/RNA Extraction, quantification, and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	**Nucleic Acid quantification for QC purposes:**	
Nucleic acid		QUBIT GEN-SOP 212	B
Nucleic acid		Agilent 4200 Tapestation GEN-SOP 213	B
Nucleic acid		QUBIT FLEX GEN-SOP 858	B
Nucleic acid		Automated - DNA Quantification Thermo Scientific™ Varioskan Lux™ Microplate Fluorometer Quant-It dsDNA High Sensitivity/Broad Range Assay Kit GEN-SOP 169	B
RNA Extracted from peripheral Blood, Bone Marrow Biological Fluids, Unfixed Tissue Formalin fixed paraffin embedded tissues (FFPE)	Generation of cDNA by reverse transcriptase for subsequent in-house Analysis (see below)	Manual Method - Applied Biosystems Reverse Transcription Kit (SuperScript II).: GEN-SOP 131	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
Genomic RNA (cDNA) extracted in house from the sample types listed above and received as primary samples from external sources	Quantitative analysis of known gene fusions events for the monitoring of malignancies for the purpose of clinical diagnosis of cancer and cancer MRD. Analysis of acute leukaemia, chronic myeloid leukaemia, and translocations [Definitive list in GEN-DOC 707]	**Quantitative Real Time PCR** ABI 7500 Fast sequence detection system real time system: RQ-PCR for detection and MRD monitoring of translocations and NPM1 mutations in leukaemias GEN-SOP 8 GEN-SOP 9 GEN-SOP 170	B
Genomic DNA (extracted in house) from the sample types listed above or received from external sources	Multiplex Ligation-dependent Probe Amplification for the detection of DNA methylation analysis	**Quantitative Real Time PCR** ABI 3500 genetic analyser GEN-SOP 200 ABI 3730xl genetic analyser GEN-SOP 204 Thermal Cyclers GEN-SOP 202 MS-MLPA for MLH1 Promoter Methylation Detection GEN-SOP 674 GEN-SOP 678	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
Genomic DNA extracted in house from the sample types listed above and received as primary samples from external sources	Qualitative Genotype analysis for SNV's Indels and Fusion transcripts [Definitive list in GEN-DOC 707]	**Quantitative Real Time PCR** Cobas z analyser 480 Detection of EGFR mutations Cobas® EGFR mutation test GENSOP 210 Detection of BRAF and NRAS mutations Cobas Mutation Test (LSR) GEN-SOP-139 Detection of KRAS mutations Cobas mutation test (LSR) for DNA from plasma and FFPET GEN-SOP 165 QIAgility GEN-SOP-170	B
Genomic DNA & RNA extracted in house from the sample types listed above and received as primary samples from external sources	Detection of DNA sequence variants, Copy number Variants and Indels [Definitive list in GEN-DOC 707]	**ddPCR (digital drop PCR)** QX200 Automated Droplet Generator PX1™ PCR plate sealer DG32™ Automated Droplet Generator Cartridges C1000 Touch Thermal Cycler with 96-Deep Well Reaction Module QX200 Droplet Reader PC and QuantaSoft Rare Mutations Detection using ddPCR GEN-SOP 225 SMD161_MYC amplification ddPCR assay GEN-SOP 161 CNV Detection of MDM2 using Droplet Digital PCR GEN-SOP 11	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
Genomic DNA extracted in house from the sample types listed and samples received as primary samples from external sources. Unless otherwise stated testing is undertaken on DNA	Detection of fragment length size, deletions, known mutations, repeat expansions, MSI, - Linkage markers, IG and TCR Gene re-arrangements. [Definitive list in GEN-DOC 707]	**Fragment length analysis** ABI 3500 genetic analyser GEN-SOP 200 ABI 3730xl genetic analyser GEN-SOP 204 Thermal Cyclers GEN-SOP 202 Genescan: B and T-cell clonality GEN-SOP 126 NPM1 GEN-SOP 138 FLT3 ITD GEN-SOP 123 Genemapper Analysis GEN-SOP 193 Post Transplant Chimerism Analysis using the Powerplex 16 kit (Promega) GEN-SOP 12 GEN-SOP 14 RNA Pan-Cancer GEN-SOP-175 The Promega OncoMate™ MSI Dx Analysis System GEN-SOP 598	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
Genomic DNA & RNA extracted in house from the sample types listed above and received as primary samples from external sources	Detection of DNA sequence variants - SNVs and Indels and Ig Variable regions [Definitive list in GEN-DOC 707]	**Sanger Sequencing** Thermal Cyclers GEN-SOP 202 ABI 3500 Genetic analyser GEN-SOP 200 ABI 3730 Genetic Analyser GEN-SOP 204 Mutational status of IGHV gene GEN-SOP 159	B
Genomic DNA, ctDNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources	Gene Screening of Large gene panels for genetic variants: [Definitive list is in GEN-DOC 707] SNV's Indels, Structural variants and Copy Number Variants.	**Next Generation Sequencing: Library Preparation Kits** Illumina Trusight (Pan cancer) KAPA/Nimblegen Baits Nonacus/Baits DNA library preparation using KAPA DNA HyperPlus Kit GEN-SOP 219 Targeted Capture of DNA using Nonacus Library Prep Kit and Baits GEN-SOP 176	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
Genomic DNA, ctDNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources	Gene Screening of Large gene panels for genetic variants: [Definitive list is in GEN-DOC 707]	**Next Generation Sequencing: Manual Process** Concentrating DNA: Eppendorf Concentrator Plus (Speedvac) GEN-SOP 214 PCR: ABI 7500 Fast Real-Time PCR System GEN-SOP 198 Thermal Cyclers GEN-SOP 202 DNA quantification: QUBIT GEN-SOP 212 Agilent Tapestation 4200 GEN-SOP 213 Thermo Scientific™ Varioskan Lux™ Microplate Fluorometer & Quant-IT dsDNA High Sensitivity/Broad Range Assay kit GEN-SOP 169 Sequencing: Illumina NextSeq 500 Illumina NextSeq 550Dx GEN-SOP 144 Illumina NovaSeq 6000 GEN-SOP 164	B
Genomic DNA, ctDNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources	Gene Screening of Large gene panels for genetic variants: [Definitive list is in GEN-DOC 707]	**NGS - Library preparation Automated:** Hamilton STARlet Liquid Handler Hamilton NGS STAR Liquid Handler STAR KAPA Prep Marsden360 GEN-SOP 174 GEN-SOP 710	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
Genomic DNA, ctDNA and RNA extracted in house from the sample types listed and samples received as primary samples from external sources (cont'd)	Gene Screening of Large gene panels for genetic variants: [Definitive list is in GEN-DOC 707] (cont'd)	**NGS - Library preparation** **Analysis:** Somatic Mutation report Pipeline HPC (High-Performance Cluster/Computer) Somatic Mutations Report MarsGen Reporter Alamut Variant Studio Variant Interpretation and Classification Marsden360 BIP Results Marsden360 QIAGEN Clinical Insights Interpret GEN-SOP 152 GEN-SOP 167 GEN-SOP 142 GEN-SOP 143 GEN-SOP 713 GEN-SOP 715	B
DNA extracted from Formalin-Fixed Paraffin-Embedded (FFPE) tissue Bone marrow Blood.		**Bioinformatics** Pipeline: Illumina's DRAGEN (Dynamic Read Analysis for Genomics) Post pipeline software: Pipeline Somatic Mutations Report using MarsGen Reporter GEN-SOP 167	B
RNA extracted from Formalin-Fixed Paraffin-Embedded (FFPE) tissue Unfixed (fresh or frozen) tissue/cells Bone marrow Blood Cell lines		**Bioinformatics** Pipeline: RNA fusion calling Pipeline Arriba and StarFusion combination RNA Pan-Cancer Analysis GEN-SOP 718	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer</u> (cont'd)	Documented in house procedures incorporating manufacturer's instructions (where relevant):	
Whole blood collected in Streck cell-free DNA Blood collection tubes	Cell free DNA (cfDNA) NGS for tumour profiling in advanced cancers (stage III and IV) 74 genes targeted panel – examined for single nucleotide variants (SNV) and insertions/deletions (indels) 18 genes for copy number variants (CNV) 6 genes for fusions	**Next Generation Sequencing:** DNA extraction: QiasymphonySP Instrument Marsden360 QIAsymphony cfDNA Extraction kit GEN-SOP 711 Automated Library preparation: Hamilton Microlab STARlet Hamilton Microlab STAR GEN-SOP 710 PCR for library preparation: Veriti Thermocycler GEN-SOP 710 Library quantification: Agilent 4200 Tapestation GEN-SOP 710 Sequencing: NextSeq 550 GEN-SOP 710 Software: Qiagen Clinical Insights (QCI) Interpret Software GEN-SOP 715	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Cytogenetic examinations for the purpose of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant.	
Whole blood Bone marrow	Cytogenetics analyses for: Haemato-oncology disorders, including prognostic markers for multiple myeloma	Cell culture using commercial media and harvesting GEN-SOP 38 GEN-SOP 55 GEN-SOP 60 GEN-SOP 61 GEN-SOP 63 GEN-SOP 68	B
		Isolation of highly purified cell populations (CD138 Positive cells for multiple myeloma) Using AutoMacsPro by Miltenyi Biotec GEN-SOP 97	B
		Microscopic analysis and reporting of G Banding and karyotype against considered normal pattern/profile. GEN-SOP 36 GEN-SOP 56 GEN-SOP 60 GEN-SOP 16	B
		Fluorescent in-situ hybridisation (FISH) using in-house procedures and Cytocell, Vysis and Zytovision commercial kits GEN-SOP-52 GEN-SOP-53 GEN-SOP-56 GEN-SOP-60 GEN-SOP 61 GEN-SOP 79	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Cytogenetic examinations for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant.	
Paraffin embedded tissue	Haemato-oncology disorders and Solid tumours	Fluorescent in-situ hybridisation (FISH) using in-house procedures and Cytocell, Vysis and Zytovision commercial kits GEN-SOP 52 GEN-SOP 53 GEN-SOP 54 GEN-SOP 56 GEN-SOP 60 GEN-SOP 61	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	<u>SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant.	
Blood, Bone Marrow, CSF, Biopsies including fine needle aspirates and other body fluids: pericardial fluid, peritoneal fluid, pleural fluid, ascitic fluid, vitreous fluid, BAL fluid and EBUS	Diagnosis and monitoring of Chronic Lymphoid Neoplasms using the following antibodies: Screening tube CD8, Kappa, CD56, Lambda, CD5, CD19, CD3, CD38, CD20, CD4, CD45, CD33, CD34, CD10, TRBC1 B-cell follow on and Hairy Cell Markers CD81, ROR1, CD5, CD23, CD10, CD79b, CD19, CD200, CD43, CD20, CD45 CD103, CD11c, CD123, CD25, CD43, CD305, CD19, CD45, CD20 Ki67, BCL2, CD10, CD19 T-cell follow on CD4 CD25, CD26, CD3, CD10, CD2, CD7, CD4, CD5, CD8, CD45, TRBC1	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using either Cellmek automated cell preparation analysers or manual red cell lysis sample preparation and in-house methods Immuno No. 10 Immuno No. 22 Immuno No. 87 Immuno No. 88 Immuno No. 89 Immuno no. 91 Immuno No. 8 Immuno No. 64	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant.	
Blood, Bone Marrow, CSF, Biopsies including fine needle aspirates and other body fluids.	Diagnosis and monitoring of Chronic Lymphoid Neoplasms using the following antibodies:	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using either Cellmek automated cell preparation analysers or manual red cell lysis sample preparation and in-house methods	B
	T-cell follow on CD8 CD57, TCR alpha/beta, CD3, TCR gamma/delta, CD56, CD30, CD4, CD16, CD8, CD45, TRBC1 TCL1 tube CD52, CD25, CD3, CD2, TCL1, CD19, CD4, CD45 FNA tube CD15, CD30, CD2, CD45, CD20, EPCAM, 7AAD	Immuno No. 10 Immuno No. 22 Immuno No. 87 Immuno No. 88 Immuno No. 89 Immuno no. 91	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant.	
Blood, Bone Marrow, CSF, Biopsies including fine needle aspirates and other body fluids: pericardial fluid, peritoneal fluid, pleural fluid, ascitic fluid, vitreous fluid, BAL fluid and EBUS.	Diagnosis and monitoring of Acute Leukaemia, MDS and Chronic Lymphoid Neoplasms using the following antibodies: ALOT tube MPO, CD79a, CD34, CD7, CD19, CytCD3, MembraneCD3, CD45 AML Tube 1 CD7, CD56, CD13, CD117, CD34, CD33, CD38, CD11b, HlaDr, CD45, CD19, CD123 AML Tube 2 CD16, CD300e, CD117, CD13, CD105, CD34, CD14, CD33, CD36, CD45, CD64, CD71, CD10 B-ALL tube CD81, CD66c, CD20, CD123, CD73, CD34, CD10, CD19, CD38, CD45, CD304, CD22 T-ALL tubes TCR gamma/delta, CD4, CD2, CD56, CD5, CD34, CD7, CD8, CD3, CD45, CD33, CD99 CD1a, CD5, CD45 TDT, CytCD3, CD45 Mast cell tubes CD2, CD25, CD34, CD117, CD33, CD38, HlaDr, CD45 HlaDr, CD30, CD34, CD117, CD123, CD38, CD45	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using either Cellmek automated cell preparation analysers or manual red cell lysis sample preparation and in-house methods Immuno No. 10 Immuno No. 22 Immuno No. 87 Immuno No. 88 Immuno No. 89 Immuno no. 91	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant.	
Blood, Bone Marrow, CSF, Biopsies including fine needle aspirates and other body fluids: pericardial fluid, peritoneal fluid, pleural fluid, ascitic fluid, vitreous fluid, BAL fluid and EBUS.	Diagnosis and Monitoring of Plasma cell dyscrasia: CD38,CD138,CD45,CD19,CD 117, CD27,CD81,CD56,Kappa,Lam bda	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using either Cellmek automated cell preparation analysers or manual red cell lysis sample preparation and in-house methods	B
Blood, Bone Marrow, CSF, Biopsies including fine needle aspirates and other body fluids: pericardial fluid, peritoneal fluid, pleural fluid, ascitic fluid, vitreous fluid, BAL fluid and EBUS.	MRD assessment in AML	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using either Cellmek automated cell preparation analysers or manual red cell lysis sample preparation and in-house methods	B
Peripheral Blood (EDTA)	Diagnosis and monitoring of PNH: WBC FLAER, CD157, CD64, CD15, CD45 RBC CD59, CD235a, CD71 AML Tube 1 CD7, CD56, CD13, CD117, CD34, CD33, CD38, CD11b, HlaDr, CD45, CD19, CD123 AML Tube 2 CD16, CD300e, CD117, CD13, CD105, CD34, CD14, CD33, CD36, CD45, CD64, CD71, CD10	Immuno No. 66 Immuno No. 10 Immuno No. 22 Immuno No. 87 Immuno No. 88 Immuno No. 89 Immuno no. 91 Immuno No. 10 Immuno No. 22 Immuno No. 87 Immuno No. 88 Immuno No. 89 Immuno no. 91	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant.	
Blood, Bone Marrow, CSF, Biopsies including fine needle aspirates and other body fluids: pericardial fluid, peritoneal fluid, pleural fluid, ascitic fluid, vitreous fluid, BAL fluid and EBUS.		Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using either Cellmek automated cell preparation analysers or manual red cell lysis sample preparation and in-house methods	B
	MRD Assessment in T and B ALL B-ALL tube CD81, CD66c, CD20, CD123, CD73, CD34, CD10, CD19, CD38, CD45, CD304, CD22	Immuno No. 10 Immuno No. 22 Immuno No. 87 Immuno No. 88 Immuno No. 89 Immuno no. 91	
	MRD assessment in CLL CD81, ROR1, CD5, CD23, CD10, CD79b, CD19, CD200, CD43, CD20, CD45	Immuno No. 10 Immuno No. 22 Immuno No. 87 Immuno No. 88 Immuno No. 89 Immuno no. 91	
Peripheral Blood, PBSCH, Bone Marrow	CD34 enumeration for the purposes of stem cell transplant. CD45, CD34, 7AAD	Beckman DX Acquios Immuno No. 64 Immuno No. 93	B
Bone Marrow	CD3 enumeration for the purposes of stem cell transplant. CD45,CD34,7AAD	Beckman DX Flex Immuno No. 64	B
Peripheral Blood	Immune Monitoring (CD3, CD4, CD8, CD19 and CD56 percentage and absolute counts)	Beckman Acquios Immuno No. 93	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant.	
Blood, bone marrow, CSF, Biopsies including fine needle aspirates, other body fluids: pericardial fluid, peritoneal fluid, pleural fluid, ascitic fluid, vitreous fluid, BAL fluid and EBUS.	Diagnosis and monitoring of haematological malignancy and bone marrow failure syndromes	Microscopic examination/morphological assessment of stained material using Gemini autostainer machine using modified Wright's stain and iron stain Shandon Cytocentrifuge II Immuno 4 Immuno 5 Immuno 18 Immuno 22 Immuno 67	B
Bone marrow	Morphological assessment of iron stores in blood films	Perl's Prussian Blue stain performed using the Gemini Autostainer Immuno No. 67	B
Blood Bone marrow CSF Biopsies including fine needle aspirates Body fluids	Morphological assessment of blood films	May Grunwald Giemsa stain performed using the Gemini Autostainer Immuno No 96	B
END			