Schedule of Accreditation

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HSL (Analytics) LLP

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Testing performed at the above address only

Site activities performed away from the locations listed above:

Location details		Activity
Ambulatory Care QE2 Hospital Howlands Welwyn Garden City Hertfordshire AL7 4HQ		Blood storage & issue Fridge managed by Haematology
Blood Transfusion Department Lister Hospital Coreys Mill Lane Stevenage Hertfordshire SG1 4AB		Blood storage & issue Fridge managed by Haematology
Hertford Hospital North Road Hertford SG14 1LP	**Local contact** Elaine Stokes	Phlebotomy services
Lister Hospital Coreys Mill Lane Stevenage Hertfordshire SG1 4AB	**Local contact** Elaine Stokes	Phlebotomy services
QE2 Hospital Howlands Welwyn Garden City Hertfordshire AL7 4HQ	**Local contact** Elaine Stokes	Phlebotomy services

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood Plasma	Antibody Identification by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Automated using Grifols Gel Column Technology DG Gel Coombs Cards, SOP BTSOP1822 (The use of Grifols Erytra SOP BTSOP1827 (Antibody Identification [manual interpretation of results
Blood Plasma	Antibody Identification by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Manual using Grifols DG Gel Coombs Cards SOP BTSOP1829 (Grifols Manual Techniques
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 Including the presence of A2 antigens	Automated using Grifols Gel Column Technology SOP BTSOP 1822 (The use of the Grifols Erytra

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (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:
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 Including the presence of A2 antigens	Manual using Grifols DG Gel ABO/Rh (2D + Kell Cards SOP BTSOP 1829 (Grifols Manual Techniques) Manual tube techniques using Lorne Antisera for possible subgroups of A using SOP BTSOP1403 Equivocal ABO and Rh(D) Grouping Results with Sub-Groups of A
Blood Plasma	Antibody Screen by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Automated using Grifols Gel Column Technology SOP BTSOP 1822
Blood Plasma	Antibody Screen by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb	Manual using Grifols DG Gel Coombs Cards SOP BTSOP1829 (Grifols Manual Techniques)
Blood Plasma	Compatibility testing of patients plasma with donor cells	Cross matching using manual indirect anti globulin test using Grifols Gel column technology and SOP BTSOP 1830
Blood Plasma	Compatibility testing of patients plasma with donor cells	Cross matching using Grifols serological tesing using SOP BTSOP1822

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (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:
Blood Plasma	Compatibility testing of patients plasma with donor cells	Electronic cross match using BTSOP 1510
Blood Plasma	Direct Antiglobulin Test (DAT)	Automated using Grifols Gel Column technology SOP BTSOP 1822 (The use of the Grifols Erytra) and BTSOP1839 (Direct Antiglobulin Test)
Blood Plasma	Foetal Maternal Haemorrhage	Manual Kleihauer Acid Elution Technique using SOP BTSOP 1707
Blood Plasma	Red cell phenotyping for Rh and Kell antigens	Automated using Grifols Gel Column Technology SOP BTSOP 1822 (The use of Grifols Erytra) SOP BTSOP 1825 (Red Cell Phenotyping
Blood Plasma	Red Cell phenotyping for RBC antigens other than Rh and Kell	Manual using Grifols DG Gel Coombs Cards and manual tube methods using Lorne Antisera; SOP BTSOP 1825 (Red Cell Phenotyping)
	Haematological 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:
Blood	HbA1c	ArkayHA8180 HPLC using SOP BSLSOPHAEM24 (Procedure on the Use of Arkay HA-8180

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematological examinations 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:
Blood	Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: Hb A2 Hb F	Documented In-House Methods to meet the requirements of the SCT screening programme as defined in the July 2018 sickle cell and thalassaemia screening: laboratory QA evidence requirements ArkayHA8180 HPLC using SOP BSLSOPHAEM24 (Procedure on the Use of Arkay HA-8180) BSLSOPHAEM25 (Haemoglobinopathy Screening (ANEP))
Blood	Erythrocyte Sedimentation Rate (ESR)	Red blood cell sedimentation rate using sediplus s2000 analyser and M2000 mixer and SOP BSL SOP HAEM7
Blood Bone marrow	Blood / Bone marrow film analysis in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis	Manual Romanowsky stain using SOP BSLSOPHAEM 4 Perl's Prussian blue reaction using SOP BSLSOPHAEM6
Blood	Blood film analysis, Detection of normal and abnormal blood cell morphology and manual differential	Automated slide and stain maker (Sysmex SP-10) which methanol fixes and stains films by Romanowsky method SOP BSLSOPHAEM 33, 3, 4 and 5.
Blood	FBC and reticulocyte count: WB Differential Hb Platelets RBC MCV MCH MCHC Hct nRBC	Sysmex XN cytometry and spectrophotometry using SOP BSLSOPHAEM31 and BSLSOPHAEM32

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Haematological examinations 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:
Blood	G6PD qualitative screen	Manual fluorescence technique using the Trinity Biotech Kit 203-A BSLSOPHAEM18
Blood	Detection of IM Hetrophile antibodies-Glandular Fever Screen	Manual antibody-antigen latex agglutination using the Monogen Biokit, for IM Hetrophile antibodies. BSLSOPHAEM17
Blood	Partial detection & speciation of malaria parasites:	Preparation of thin films, manual Giemsa staining and light microscopy using SOP BSLSOPHAEM8
Blood	Malarial antigens of malarial parasites spp Plasmodium falciparum HRP2 & P. falciparum, P. vivax, P. ovale, P. malariae Pan LDH	Malaria CareUS Test Kit Immunoassay BSLSOPHAEM43 CareUS Rapydtest Malaria Screen
Blood	Insolubility of HbS Sickle cell screen	Qualitative solubility using the TCS Biosciences Sickle-Check screening kit. SOP BSLSOPHAEM14
Urine	Haemosiderin	Perl's Prussian blue reaction using SOP BSLSOPHAEM10
Blood	Coagulation testing PT INR Fibrinogen APTT/APTT ratio DDimer Clauss Fibrongen (QFA Quantitated fibrinogen assay)	Sysmex CS-2500 using SOP BSLSOPHAEM37, BSLSOPHAEM38 & BSLSOPHAEM39

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis:	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
	Quantitative determination of:	Roche Cobas e601 Module
Blood	Beta HcG	Electrochemiluminecence-immunoassay sandwich assay BSLSOPBIO21
Serum	Cortisol	Competitive Chemiluminescence Immunoassay using BSLSOPBIO72
Blood	Digoxin	ECL Competitive immunoassay, using BSLSOPBIO38 –
Blood	Ferritin	Sandwich assay using BSLSOPBIO64
Serum	Folate	Competition assay using BSLSOPBIO63 serum folate
Blood	FSH	Sandwich immunoassay BSLSOPBIO66
Blood	FT3	Competition principle BSLSOPBIO62
Blood	FT4	Competition principle BSLSOPBIO59
Blood	LH	Sandwich immunoassay BSLSOPBIO67
Serum	Oestradiol	Competitive Chemiluminescence Immunoassay using BSLSOPBIO70
Serum	PlGF – Placental Growth Factor	ECLIA using BSLSOPBIO084
Serum	Procalcitonin	BRAHMS Sandwich Assay using BSLSOPBIO083
Serum	Progesterone	Competitive Chemiluminescence Immunoassay using BSLSOPBIO71
Blood	PRL	Sandwich immunoassay BSLSOPBIO68
Serum	PSA	Competitive Chemiluminescence Immunoassay using BSLSOPBIO73

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
	Quantitative determination of:	Roche Cobas e601 Module
Serum	Free PSA	Competitive Chemiluminescence Immunoassay using BSLSOPBIO74
Serum	sFlt-1 - Soluble fms-Like Tyrosine Kinase-1	ECLIA using BSLSOPBIO84
Serum	Testosterone	Competitive Chemiluminescence Immunoassay using BSLSOPBIO69
Blood	Troponin T	Electrochemiluminescence immunoassay sandwich assay BSLSOPBIO27
Blood	TSH	Sandwich Immunoassay BSLSOPBIO
Blood	Vitamin B12	Competition assay BSLSOPBIO
	Quantitative determination of:	Roche Cobas c501 module
Blood	Albumin	BCG method using SOP BSLSOPBIO15 Cobas Albumin
Urine	Albumin	Immunoturbidmetric using BSLSOPBIO79
Blood	ALP	Amp buffer (IFCC) BSLSOPBIO7 Cobas Alkaline Phosphatase (ALP)
Blood	ALT	Tris buffer without PLP (IFCC) BSLSOPBIO8 Cobas Alanine Aminotransferase (ALT)
Blood	AST	ASAT/GOT UV without P5P, using BSLSOPBIO6 – Cobas Aspartate Aminotransferase (AST).
Blood	Ammonia	Glutamate Dehydrogenase Infinity direct enzymatic method BSLSOPIO4

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis: (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
	Quantitative determination of:	Roche c501
Blood	Amylase	Kinetic G7PNP Substrate (IFCC) BSLSOPBIO5
Blood	Bicarbonate (CO2)	PEP Carboxylase method BSLSOPBIO9
Blood	Bilirubin (Direct)	3rd Party Wako Vanadate Oxidation method, using BSLSOPBIO31-WAKO Conjugated Bilirubin on Coba
Blood	Bilirubin (Total)	Diazo method BSLSOPBIO35
Blood	Calcium	NM-BAPTA Method BSLSOPBIO10
Blood	Carbamazapine	Immunoassay/turbidimetry BSLSOPBIO12
Urine	Creatinine	Spectrophotometeric Enzymatic using BSLSOPBIO17
Blood	CRP	Immunoturbitimetry using BSLSOPBIO18
Blood	Phenytoin	KIMS method BSLSOPBIO46
Blood	Theophylline	KIMS method BSLSOPBIO25
Blood	Chloride	Indirect ISE BSLSOPBIO22
Blood	Potassium	Indirect ISE BSLSOPBIO22
Blood	Sodium	Indirect ISE BSLSOPBIO22
Blood	Cholesterol	Enzymatic Cholesterol Oxidase BSLSOPBIO13
Blood	HDL Cholesterol	Enzymatic Cholesterol Esterase BSLSOPBIO13
Blood	CK	Enzymatic UV Test NAC (IFCC), using BSLSOPBIO14
Blood	Creatinine	Enzymatic method BSLSOPBIO17

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers instructions for
	Quantitative determination of:	Roche C501
Blood	Ethanol	Enzymatic UV BSLSOPBIO16
Blood	Salicylate	Enzymatic method BSLSOPBIO24
CSF	CSF Protein	Turbidimetry BSLSOPBIO19
Blood	Gentamicin	CEDIA Method, using BSLSOPBIO48
Blood	GGT	Carboxynitroanilide (IFCC) BSLSOPBIO39
Blood/CSF	Glucose	Hexokinase + G6PD BSLSOPBIO40
Blood	Iron	Ferrozine/Ferene BSLSOPBIO41
Blood/CSF	Lactate	Enzymatic colourimeteric BSLSOPBIO43
Blood	LDH	L to P Glucamine (IFCC) BSLSOPBIO42
Blood	Lithium	Colourimetric method BSLSOPBIO32
Blood	Paracetamol	Colourimetric method, using BSLSOPBIO45
Blood	Magnesium	Xylidyl Blue (M&Y) BSLSOPBIO44
Blood	Phosphate	Phosphomolybdate UV BSLSOPBIO47
Blood	Protein (Total)	Biuret method BSLSOPBIO32
Urine	Protein	Spectrometric using BSLSOPBIO19
Blood	Triglyceride	Total glycerol GPO BSLSOPBIO26
Blood	Urea	Kinetic Urease BSLSOPBIO28

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturers instructions for
	Quantitative determination of:	Roche c501
Urine	Urea	Spectrophotometeric Enzymatic using BSLSOPBIO28
Blood	Uric Acid (Urate)	Enzymatic Uricase BSLSOPBIO29
Blood	Valproic Acid	Enzyme immunoassay BSLSOPBIO30
Blood	Vancomycin	Two point end assay using BSLSOPBIO60
Fluid/Urine	Urine pH	Ph/Mv/Temperature meter model 3510 BSLSOPBIO37
Whole Blood	Blood Gas Analysis pH pCO2 pO2 tHb & derivatives	Siemens RapidPoint 500e Series Blood gas analyser (Potentiometry, amperometry and conductance) BSLSOPBIO87
Serum Urine	Osmolality	Advanced Instrument Osmometer 3320 Freezing point depression BSLSOPBIO1
Faeces	Faecal Haemoglobin	Quantitive faecal immunoturbidmetry (FIT) using Eiken OC-Sensor IO BSLSOPBIO76
	Calculated determination of:	
Blood	eGFR	Calculated in Winpath
Blood	Adjusted Calcium	Adjusted in Winpath
Serum	sFlt1 / PlGF Ratio	Calculated from Roche Cobas e601 Using BSLSOPBIO084

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Histopathological examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Tissue: biopsy, excision, resection, and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	HISSOP111 – receipt and processing of post mortem specimens HISSOP112 – receipt of POC samples Specimen Dissection using: HISSOP81 – Cut up set up HISSOP78 – BMS cut up HISSOP64 – Assigning BMS cut up HISSOP41 – Cut up of large specimens by the pathologist – Bladder HISSOP51 – Cut up of large specimens by the pathologist – Prostate HISSOP60 – Cut up of large specimens by the pathologist – Penis HISSOP37 – Cut up of large specimens by the pathologist – Gall bladder HISSOP39 – Cut up of large specimens by the pathologist – Parathyroid HISSOP38 – Cut up of large specimens by the pathologist – Thyroid HISSOP40 – Cut up of large specimens by the pathologist – Small bowel

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Tissue: biopsy, excision, resection, and post-mortem specimens (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	HISSOP54 – Cut up of large specimens by the pathologist – Uterus and cervix HISSOP42 – Cut up of large specimens by the pathologist – Salivary gland HISSOP45 – Cut up of large specimens by the pathologist – Ovary HISSOP46 – Cut up of large specimens by the pathologist – Fallopian tube HISSOP44 – Cut up of large specimens by the pathologist – Placenta HISSOP43 – Cut up of large specimens by the pathologist – Lymph node HISSOP57 – Cut up of large specimens by the pathologist – Vulva HISSOP55 – Cut up of large specimens by the pathologist – Colon HISSOP49 – Cut up of large specimens by the pathologist – laparotomy for lymphoma HISSOP56 – Cut up of large specimens by the pathologists – Skin

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Tissue: biopsy, excision, resection, and post-mortem specimens (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	HISSOP59 – Cut up of large specimens by the pathologist – Breast HISSOP52 – Cut up of large specimens by the pathologist – Spleen HISSOP47 – Cut up of large specimens by the pathologist – Bone HISSOP48 – Cut up of large specimens by the pathologist – Kidney HISSOP53 – Cut up of large specimens by the pathologist – Appendix
Tissue: biopsy, excision, resection, and post-mortem specimens. Cytology clots	Tissue processing	Tissue Processing using Sakura VIP and HISSOP69 – Processing VIP1&2 HISSOP85 – VIP 1&2 maintenance HISSOP66 – Processing VIP3 HISSOP88 – VIP3 maintenance CPF80 – VIP usage maintenance log HISSOP65 – Removal of blocks from VIPs HISSOP84 – VIP failure

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
Tissue: biopsy, excision, resection, and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	
	De-calcification	De-calcification using HISSOP70 – De-calcification CPF69 – Decal end point test
	Tissue embedding	Tissue Tek 5EC and HISSOP10 – Embedding procedure
Formalin Fixed Paraffin wax blocks of processed tissue	Microtomy	Tissue sectioning using Tissue Tek and Leica microtomes and HISSOP9 – The sectioning procedure CPF18 – Histology cutting list
Tissue for frozen sections	Cryotomy	Cryotomy Intra-operative frozen sections using Bright Cryostat and HISSOP1 – Frozen section procedure HISSOP50 – Cut up of large specimens by the pathologist - Neurosafe

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Routine morphological staining For the detection of:	
	Basophilic and eosinophilic structures	Routine morphological staining using Sakura Tissue Tek Prisma and HISSOP64 – Operation of the Prisma stainer and cover slipper HISSOP1 – Frozen section procedure
FFPE slides	Special stains for the detection of:	Documented in-house procedures for manual special stains
	Acid mucopolysaccharides	Alcian Blue/PAS using HISSOP14 – Alcian Blue PAS
	Acid and Neutral Mucopolysaccharides	Alcian Blue using HISSOP17 – Alcian Blue
	Helicobacter Pylori	Cresyl Violet Acetate using HISSOP16 – Cresyl Violet Acetate
	Neutral Mucopolysaccharides, glycogen and fungus	Diastase PAS using HISSOP19 – Diastase PAS
	Elastic fibres and connective tissue	Elastic van Gieson using HISSOP 11 – Elastic Van Gieson
	Helicobacter/Microorganisms	Giemsa using HISSOP30 – Giemsa
	Gram positive and negative micro-organisms	Gram using HISSOP20 – Gram
	Fungi (Aspergillus) and Pneumocystis	Grocott using HISSOP13 – Grocott
	Elastic fibres and connective tissue	Haematoxylin Van Gieson using HISSOP12 – Haematoxylin Van Gieson

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides (cont'd)	Special stains for the detection of: (cont'd)	Documented in-house procedures for manual special stains
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana using HISSOP21 – Masson Fontana
	Melanin	Melanin Bleach using HISSOP113 – Melanin bleach
	Connective tissue and fibrin	Martius Scarlett Blue using HISSOP25 – MSB
	Copper assoc. Protein and Hepatitis B	Orcein using HISSOP26 – Orcein
	Neutral Mucopolysaccharides, glycogen and fungus	PAS using HISSOP18 – PAS
	Reticulin fibres	Reticulin using HISSOP28 – Reticulin
	Mast cells	Toludine Blue using HISSOP114 – Toluidine blue
	Calcium	Von Kossa using HISSOP29 – Von Kossa
	Tubercle bacilli	Ziehl Neelson using HISSOP23 – Ziehl Neelson

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides (cont'd)	Immunohistochemistry to detect the following:	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation Incorporating the following antibodies
	Smooth muscle cells, myofibroblasts, myoepithelial cells, Diagnosis of leiomyomas, leiomyosarcomas	Actin
	Broad band cytokeratin marker, epithelial cell carcinomas	AE1/3
	HGPIN, prostate adenocarcinoma	AMACR/P63
	BCL-2 oncoprotein	BCL-2
	BCL-6 gene	BCL-6
	Epithelial cell types	BerEP4
	Ovarian cancer	CA125
	Carcinomas, RCC	CA-IX
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	Calretinin
	T cells	CD3
	Mature T cells, T cell lymphomas	CD5
	Granulocytes Reed-Sternberg cells	CD10
	Mature B cells, Follicular dendritic cells	CD20
	B cells, some T cells	CD21

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation Incorporating the following antibodies
	B Cells, Reed-Sternberg cells	CD23
	Reed-Sternberg cells and ALCL	CD30
	Haematopoietic cells, vascular endothelium	CD31
	T cells and some soft tissue	CD34
	Leukocyte common antigen	CD45
	Neuroendocrine cells	CD56
	Macrophages	CD68
	B lymphocytes	CD79
	GIST	CD117
	Plasma cells	CD138
	Adenocarcinoma and carcinoid (intestinal epithelium)	CDX-2
	CEA glycoproteins in adenocarcinoma	CEA
	Neuroendocrine tumours	Chromogrannin
	Stratified squamous epithelium, basal cells, mesotheliomas	CK5
	Normal and neoplastic epithelia	CK7

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation Incorporating the following antibodies
	Glandular and transitional epithelium	CK8/18
	Basal cell carcinoma, squamous cell carcinoma	CK14
	Adenocarcinomas	CK19
	Adenocarcinomas, columnar epithelial cells	CK20
	Striated and smooth muscle cells	Desmin
	GIST	DOG-1
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin
	Normal and neoplastic epithelium	EMA
	Nuclei of cells containing a high level of oestrogen	ER
	V.W factor in endothelial cells	Factor VIII
	Mesothelial Cells Thyroid carcinomas	HBME-1
	Melanoma, melanocyte differentiation	HMB45
	Proliferating Cells	Ki67

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation Incorporating the following antibodies
	B cells and plasma cells	Kappa
	B cells and plasma cells	Lambda
	Melanoma marker	Melan A
	Epithelial tissue from glandular to stratified squamous	MNF116
	Peripheral nerves, neuroendocrine tumours	NSE
	Seminomas	Oct3/4
	HPV driven tumour eg Squamous cell carcinoma	P16
	Neoplastic cells in epithelium	P53
	Squamous epithelium	P63
	Nuclei of cells showing expression of Progesterone	PR
	Prostate secretory and ductal epithelium	PSA
	Prostate secretory and ductal epithelium	PSAP
	Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma	S100

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation Incorporating the following antibodies
	Smooth muscle cells, myoepithelial cells	SMM
	Neuroendocrine cells	Synaptohphysin
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF1
	Cells of mesenchymal origin	Vimentin
	Plasma cells	VS38c
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	WT1
		Interpretive/diagnostic microscopy Using HISSOP95 – Reporting of Cellular Pathology requests CPM24 – Procedure for issuing an amended report HISSOP100 – Giving results over the telephone CPM23 – Authorisation of cellular Pathology results

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Fine needle aspirates –Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Diagnostic cytology (Non-gynae) in house documented manual procedures for preparation and screening and reporting using Hologic-T2000, Sakura DRS 2000
	Demonstration of : Cells (nuclei and cytoplasm) and micro organisms	CYTSOP5 – General procedure for the receipt and processing of non-gynaecological specimens CYTSOP15 – Preparation of breast samples CYTSOP16 – Preparation of Bronchoscopy specimens CYTSOP17 – Preparation of cerebrospinal fluid (CSF) CYTSOP18 – Preparation of EBUS samples CYTSOP19 – Preparation of Head and Neck samples CYTSOP20 –Preparation of Lymph node aspirates CYTSOP21 – Preparation of natural and induced clots CYTSOP22 – Preparation of Serous fluids CYTSOP23 – Preparation of Sputum samples CYTSOP24 – Preparation of Urine samples

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Fine needle aspirates –Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples (cont'd)	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities (cont'd)	Diagnostic cytology (Non-gynae) in house documented manual procedures for preparation and screening and reporting using Hologic-T2000, Sakura DRS 2000
	Demonstration of: Cells (nuclei and cytoplasm) and micro organisms (cont'd)	CYTSOP5 – General procedure for the receipt and processing of non-gynaecological specimens CYTSOP11 – Operation of the centrifuge CYTSOP12 – Operation of the safety cabinet CYTSOP13 – Operation of the Thin Prep 2000 processor CYTSOP30 –Screening of non-gynaecological preparations CYTSOP14 – Operation of the tissue tek DRS staining machine Papanicalou stain for non-gynae specimens and CYTSOP33 – Papanicolaou staining method May-Grunwald Giemsa staining for air dried slides using CYTSOP7 – May Grunwald Giemsa staining method Diff Quick staining technique using CYTSOP2 – Diff - quick staining procedure for FNA's

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