Schedule of Accreditation

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HSL (Analytics) LLP

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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
Address Haematology Department Watford General Hospital Vicarage Road Watford Hertfordshire WD18 0HB	**Local contact** Krupa Amin Kanval Ali Chris Hessey	Haematology Coagulation Blood Transfusion	A
Address Haematology Department Pathology Department Hemel Hempstead General Hospital Hillfield Road Hemel Hempstead Hertfordshire HP2 4AD	**Local contact** Krupa Amin Kanval Ali Chris Hessey	Haematology Coagulation Blood Transfusion Immunology	B
Address Lister Hospital Coreys Mill Lane Stevenage Hertfordshire SG1 4AB	**Local Contact** Andrew Clarke	Haematology Coagulation Blood Transfusion Histopathology Biochemistry	D

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Address: Blood fridge, WGH Main Theatre Haematology Department Watford General Hospital Vicarage Road Watford Hertfordshire WD18 0HB	**Local contact:** Chris Hessey	Satellite Blood Issue Fridge for storage of blood and products	
Address: Blood fridge, WGH Maternity Delivery Suite Haematology Department Watford General Hospital Vicarage Road Watford Hertfordshire WD18 0HB	**Local contact:** Chris Hessey	Satellite Blood Issue Fridge for storage of blood and products	
Address: Blood fridge, WGH Helen Donald Unit Haematology Department Watford General Hospital Vicarage Road Watford Hertfordshire WD18 0HB	**Local contact:** Chris Hessey	Satellite Blood Issue Fridge for storage of blood and products	
Address: WGH Phlebotomy Haematology Department Watford General Hospital Vicarage Road Watford Hertfordshire WD18 0HB	**Local contact:** Islay Lawton	Phlebotomy	
Address: Blood fridge, Main Theatres St Albans City Hospital Waverly Road St Albans Hertfordshire AL3 5PN	**Local contact:** Chris Hessey/ Matt Ginger	Satellite Blood Issue Fridge for storage of blood and products	

Location details	Activity	Location code
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	
Address: Phlebotomy St Albans City Hospital Waverly Road St Albans Hertfordshire AL3 5PN **Local contact:** Nadene Short	Phlebotomy	
Address: Blood fridge, Immunology corridor Hemel Hempstead Hospital Pathology Department Hemel Hempstead General Hospital Hillfield Road Hemel Hempstead Hertfordshire HP2 4AD **Local contact:** Chris Hessey/ Matt Ginger	Satellite Blood Issue Fridge for storage of blood and products	
Address: Phlebotomy Hemel Hempstead General Hospital Pathology Department Hillfield Road Hemel Hempstead Hertfordshire HP2 4AD **Local contact:** Nadene Short	Phlebotomy	

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Blood Transfusion		
HUMAN BODY FLUIDS	Blood Transfusion examination activities for the purposes of clinical diagnosis	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
Venous whole blood	Blood Group (ABO & RhD) and antibody Detection Blood groups detected: A Rh D positive A Rh D negative O Rh D positive O Rh D negative B Rh D positive B Rh D negative AB Rh D positive AB Rh D negative	Automated method Ortho Vision Swift; microcolumn gel (cassette) method SOP BTF-RFRR-60, 52 Manual method Ortho manual workstation and ortho cassetes SOP BTF-RFRR-60, 52	A
Venous whole blood	Atypical antibody Identification • Rh: C, c, D, , e, C^w • Kell: K, k, Kpa, Kpb, Jsa, Jsb • Kidd: Jk^a, JK^b Duffy:Fy^a, Fy^b • MNS: M, N, S, s • P: P1 • Lewis: Le^a, Le^b • Luth: Lua, Lub • Xg: Xga	Manual method Ortho manual workstation and ortho cassetes SOP BTF-RFRR-60, 52 Automated method Ortho Vision Swift; microcolumn gel (cassette) method SOP BTF-RFRR-60, 52	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Blood Transfusion (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
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 Erytra, Grifols Gel Column Technology DG Gel Coombs Cards, SOP BTSOP1822 (The use of Grifols Erytra SOP BTSOP1827 (Antibody Identification [manual interpretation of results Manual using Grifols DG Gel Coombs Cards SOP BTSOP1829 (Grifols Manual Techniques	D
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 GrifolsErytra and Gel Column Technology SOP BTSOP 1822 Manual using Grifols DG Gel Coombs Cards SOP BTSOP1829 (Grifols Manual Techniques)	D
Venous whole blood	Direct Antiglobulin Test (DAT)	Manual method Ortho manual workstation with microcolumn gel cassettes SOP: HASOPBT210 Automated method Ortho Vision Swift; microcolumn gel (cassette) method SOP BTF-RFRR-60, 52	A
Venous whole blood	Estimation of fetal bleed in maternal circulation (Kleihauer Screen)	Light Microscopy, Kleihauer Acid Elution Methodology (Clin-Tech) (SOP: HASOPBT905)	A
Venous whole blood	Compatibility testing of patient's plasma with donor cells (Serological Crossmatch)	Ortho vision manual workstation, microcolumn gel crossmatch SOPHASOPBT303	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Blood Transfusion (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
Venous whole blood	Red cell phenotyping: Rh & K blood group antigens: C, c, E, e, Cw, K	Ortho Vision Swift automated method and NHSBT Antibody identification 10-cell panel	A
Venous whole blood	Red cell phenotyping: Rh & K blood group antigens: C, c, E, e, Cw, K	Manual method using Ortho workstation and Ortho cassettes	A
	Haematology		
HUMAN BODY FLUIDS	Haematology examination activities for the purposes of clinical diagnosis	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
EDTA whole blood	Full blood count: Haemoglobin (Hb) Red cell count (RBC), Platelet count, Haematocrit, White blood cell count (WBC) Differential white blood cell count (Neutrophil, Lymphocyte, Monocyte, Eosinophil, Basophil), NRBC count, MCV MCH	Sysmex XN analysers (XN-10 and XN-20) fluorescence flow cytometry and electrical impedance SOP HAE-RFRR-15	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Haematology (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
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 Erytra and Gel Column Technology SOP BTSOP 1822 (The use of the Grifols Erytra 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	D
EDTA whole blood	Automated Reticulocyte Count	Sysmex XN analysers (XN-10 and XN-20) using fluorescence flow cytometry, SOP HAE-RFRR-15	A
EDTA whole blood	Erythrocyte Sedimentation Rate (ESR)	Automated method Starssed Interliner, modifid Westergren method SOP HAE-60RR-55	A
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	D
Blood Plasma	Compatibility testing of patients plasma with donor cells	Cross matching using Grifols serological tesing using SOP BTSOP1822	D
Blood Plasma	Compatibility testing of patients plasma with donor cells	Electronic cross match using BTSOP 1510	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Haematology (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
Blood Plasma	Direct Antiglobulin Test (DAT)	Automated using Grifols Erytra, Grifols Gel Column technology SOP BTSOP 1822 (The use of the Grifols Erytra) and BTSOP1839 (Direct Antiglobulin Test)	D
Blood Plasma	Foetal Maternal Haemorrhage	Manual Kleihauer Acid Elution Technique using SOP BTSOP 1707	D
Blood Plasma	Red cell phenotyping for Rh and Kell antigens	Automated using Grifols Erytra Grifols Gel Column Technology SOP BTSOP 1822 (The use of Grifols Erytra) SOP BTSOP 1825 (Red Cell Phenotyping	D
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) Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	D
Blood	HbA1c	Arkay HA8180 HPLC using SOP BSLSOPHAEM24 (Procedure on the Use of Arkay HA-8180	D
EDTA whole blood	Detection of Malarial Parasites and Speciation on thin films : *Plasmodium falciparum* *Plasmodium malariae* *Plasmodium ovale* *Plasmodium vivax* *Plasmodium knowesi*	Fields and Dilute Giemsa staining with light microscopic detection. (SOP: HASOPHA51/HASOPHA01)	A B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Haematology (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Haematology 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:	
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	D
		Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
EDTA whole blood	Examination of Peripheral Blood Films, detection of normal and abnormal morphology and white cell differential count	Manual Peripheral Blood film staining May-Grunwald-Giemsa (MGG) stain (SOP: HASOPHA30)	A B
		Automated Peripheral Blood film staining May-Grunwald-Giemsa (MGG) stain using Beckman Coulter Light Microscopy on MGG stained slides (SOP: HASOPHA27)	B A B
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	D
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.	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Haematology (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
BM aspirate	Examination of Bone Marrow Films, detection of normal and abnormal morphology	Manual Bone Marrow film staining May-Grunwald-Giemsa (MGG) stain (SOP: HASOPHA30)	A B
		Automated Bone Marrow film staining May-Grunwald-Giemsa (MGG) stain using Beckman Coulter SMS (SOP: HASOPHA62)	B
EDTA whole blood	Sickle Screening Test	Sickle Solubility test kit(Sickledex) Qualitative assessment of Haemoglobin S (SOP: HASOPSH27)	A B
Blood	Insolubility of HbS Sickle cell screen	Qualitative solubility using the TCS Biosciences Sickle-Check screening kit. SOP BSLSOPHAEM14	D
	Thalassaemia and Abnormal Haemoglobin Screening	Documented in-house methods to meet the requirements of the SCT screening programme as defined in the 'NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements'.	
EDTA whole blood	Quantitation of HbA_2 Quantitation of HbF Quantitation of HbS Variant Hb	BioRad Variant II HPLC liquid Chromatography (SOP: HASOPSH09)	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Haematology (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
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 sickle cell and thalassaemia screening: laboratory QA evidence requirements Arkay HA8180 HPLC using SOP BSLSOPHAEM24 (Procedure on the Use of Arkay HA-8180) BSLSOPHAEM25 (Haemoglobinopathy Screening (ANEP))	D
EDTA whole blood	Glandular Fever Screen	Clearview II kit, qualitative, lateral flow immunoassay for the detection of IM heterophile antibodies (SOP: HASOPHA26)	A B
Bone Marrow/Urine	Iron stain	Light microscopy of Perls Prussian Blue reaction, qualitative assessment of Hemosiderin by ferric ferrocyanide (SOP: HASOPHA29)	A B
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	D
Blood	G6PD qualitative screen	Manual fluorescence technique using the Trinity Biotech Kit 203-A BSLSOPHAEM18	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Haematology (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
Blood	Detection of IM Hetrophile antibodies-Glandular Fever Screen	Manual antibody-antigen latex agglutination using the Monogen Biokit, for IM Hetrophile antibodies. BSLSOPHAEM17	D
Blood	Partial detection & speciation of malaria parasites:	Preparation of thin films, manual Giemsa staining and light microscopy using SOP BSLSOPHAEM8	D
Urine	Haemosiderin	Perl's Prussian blue reaction using SOP BSLSOPHAEM10	D
	Coagulation		
Citrated Whole Blood	Prothrombin Time/ INR Warfarin control	Sysmex CN3000 using optical clot detection SOP: HAE-NWP5-46	A
Citrated Whole Blood	Activated Partial Thromboplastin Time (APTT)/ Heparin Ratio	Sysmex CN3000 using optical clot detection SOP: HAE-NWP5-46	A
Citrated Whole Blood	Thrombin time	Sysmex CN3000 using optical clot detection SOP: HAE-NWP5-46	A
Citrated Whole Blood	Fibrinogen/QFA Assay	Sysmex CN3000 using optical clot detection SOP: HAE-NWP5-46	A
Citrated Whole Blood	D-Dimer Assay	Sysmex CN3000 using optical clot detection SOP: HAE-NWP5-46	A
Blood	Coagulation testing PT INR Fibrinogen APTT/APTT ratio DDimer Clauss Fibrongen (QFA Quantitated fibrinogen assay)	Sysmex CS-2500 using SOP BSLSOPHAEM37, BSLSOPHAEM38 & BSLSOPHAEM39	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Immunology		
HUMAN BODY FLUIDS	Immunology examination activities for the purposes of clinical diagnosis	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
Blood (Serum)	Specific IgE: House dust mite Cat dander Dog dander Egg white Milk Fish (cod) Wheat Peanut Soya bean Hazel nut Brazil nut Almond Pecan nut Cashew nut Pistachio Walnut Nut mix Mixed grass pollen Aspergillus fumigatus Mould mix Common silver birch Mixed tree pollen Penicilloyl G Penicilloyl V Amoxicilloyl Horse dander Guinea pig epithelium Budgerigar feathers Rabbit epithelium Hamster epithelium Milk (Bos d 6) Parrot feathers Barley Oat Rice Sesame seed Pea White bean Crab Tomato	Enzyme Immunoassay using Phadia 250 (SOP: HASOPIM20)	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Immunology (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
	Specific IgE (cont'd): Pork Beef Carrot Orange Potato Blue Mussel Tuna Salmon Haddock Strawberry Yeast Garlic Onion nShrimp Coconut Apple Egg yolk Milk (Bos d 4) Milk (Bos d 5) Milk (Bos d 8) Gluten Lobster Cheese, cheddar type Chicken meat Kiwi Melon Mustard Mango Banana Cacao Pear Peach Avocado Mackerel Lemon Pineapple Mushroom Paprika (Sweet pepper) Pumpkin seed Egg (nGal d 2) Egg (nGal d 1)	Enzyme Immunoassay using Phadia 250 (SOP: HASOPIM20)	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	**Immunology** (cont'd) <u>Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd) Specific IgE (cont'd): Lentil Cherry Pine nut Plaice Squid (Atlantic) Grape Aubergine (eggplant) Chilipepper Goat milk Chick pea Rape seed Egg (nGal d 3) Raspberry Macadamia nut Peanut (rAra h 8) rBer e 1 (Brazil nut) Wheat (Tri a 19 Omega-5 Gliadin) rPru P 3 LTP (Peach) Peanut (rAra h 1) Peanut (rAra h 2) Peanut (rAra h 3) Hazel nut (Cor a 8) Peanut (rAra h 9) Hazel nut (Cor a 1) Hazel nut (Cor a 14) Hazel nut (Cor a 9) Walnut (Jug r 1) Walnut (Jug r 3) Cashew nut (Ana o 3) Seafood mix Food mix Timothy grass Budgerigar mix Pigeon mix Micropolyspora faeni IgG Thermactinomyces vulgaris IgG Honey Bee Common Wasp	Documented in-house procedures in conjunction with manufacturer's equipment manuals: Enzyme Immunoassay using Phadia 250 (SOP: HASOPIM20)	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Immunology (cont'd)		
HUMAN BODY FLUIDS (cont'd)	Immunology examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's equipment manuals:	
	Specific IgE (cont'd): Yellow hornet Latex Sunflower seed Penicillium chrysogenum Cladosporium herbarum Alternaria alternata Weed mix Total IgE Specific IgG Mast Cell Tryptase Anti-Thyroid Peroxidase Ab Anti-ENA Ab Screen Anti-dsDNA Ab Anti-MPO Ab Anti-PR3 Ab Anti-GBM Ab Anti-Cardiolipin Ab (IgG) Anti-Cardiolipin Ab (IgM) Anti-β2-Glycoprotein 1 (IgG) Anti-tTG Ab (IgA) Anti-CCP Ab	Enzyme Immunoassay using Phadia 250 (SOP: HASOPIM20)	B
Faecal sample	Calprotectin	Enzyme Immunoassay using Phadia 250 (SOP: HASOPIM20)	B
Blood (Serum)	Anti-nuclear Antibody (ANA) Smooth Muscle Antibody (SMA) Anti-Mitochondrial Antibody (AMA) Gastric Parietal Cell Antibody (GPC) Crithidia Antibody Islet Cell Antibody Endomysial Antibody (IgA + IgG)	Immunofluorescence-HTZ 320 Automated Slide processor and fluorescent microscopy, (SOP: HASOPIM41)	B
Blood (Serum)	Mitochondrial (AMA-M2) Antibody	ImmunoBlots-Blue Diver methodology (SOP: HASOPIM38)	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Clinical Biochemistry		
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:	D
	Quantitative determination of:	Roche Cobas e601 Module	D
Blood	Beta HcG	Electrochemiluminecence-immunoassay sandwich assay BSLSOPBIO21	D
Serum	Cortisol	Competitive Chemiluminescence Immunoassay using BSLSOPBIO72	D
Blood	Digoxin	ECL Competitive immunoassay, using BSLSOPBIO38 –	D
Blood	Ferritin	Sandwich assay using BSLSOPBIO64	D
Serum	Folate	Competition assay using BSLSOPBIO63 serum folate	D
Blood	FSH	Sandwich immunoassay BSLSOPBIO66	D
Blood	FT3	Competition principle BSLSOPBIO62	D
Blood	FT4	Competition principle BSLSOPBIO59	D
Blood	LH	Sandwich immunoassay BSLSOPBIO67	D
Serum	Oestradiol	Competitive Chemiluminescence Immunoassay using BSLSOPBIO70	D
Serum	PlGF – Placental Growth Factor	ECLIA using BSLSOPBIO084	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Clinical Biochemistry (cont'd)		
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: (cont'd)	Roche Cobas e601 Module	
Serum	Procalcitonin	BRAHMS Sandwich Assay using BSLSOPBIO083	D
Serum	Progesterone	Competitive Chemiluminescence Immunoassay using BSLSOPBIO71	D
Blood	PRL	Sandwich immunoassay BSLSOPBIO68	D
Serum	PSA	Competitive Chemiluminescence Immunoassay using BSLSOPBIO73	D
Serum	Free PSA	Competitive Chemiluminescence Immunoassay using BSLSOPBIO74	D
Serum	sFlt-1 - Soluble fms-Like Tyrosine Kinase-1	ECLIA using BSLSOPBIO84	D
Serum	Testosterone	Competitive Chemiluminescence Immunoassay using BSLSOPBIO69	D
Blood	Troponin T	Electrochemiluminescence immunoassay sandwich assay BSLSOPBIO27	D
Blood	TSH	Sandwich Immunoassay BSLSOPBIO	D
Blood	Vitamin B12	Competition assay BSLSOPBIO	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Clinical Biochemistry (cont'd)		
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: (cont'd)	Roche Cobas c501 module	D
Blood	Albumin	BCG method using SOP BSLSOPBIO15 Cobas Albumin	D
Urine	Albumin	Immunoturbidmetric using BSLSOPBIO79	D
Blood	ALP	Amp buffer (IFCC) BSLSOPBIO7 Cobas Alkaline Phosphatase (ALP)	D
Blood	ALT	Tris buffer without PLP (IFCC) BSLSOPBIO8 Cobas Alanine Aminotransferase (ALT)	D
Blood	AST	ASAT/GOT UV without P5P, using BSLSOPBIO6 – Cobas Aspartate Aminotransferase (AST).	D
Blood	Ammonia	Glutamate Dehydrogenase Infinity direct enzymatic method BSLSOPIO4	D
Blood	Amylase	Kinetic G7PNP Substrate (IFCC) BSLSOPBIO5	D
Blood	Bicarbonate (CO2)	PEP Carboxylase method BSLSOPBIO9	D
Blood	Bilirubin (Direct)	3rd Party Wako Vanadate Oxidation method, using BSLSOPBIO31-WAKO Conjugated Bilirubin on Coba	D
Blood	Bilirubin (Total)	Diazo method BSLSOPBIO35	D
Blood	Calcium	NM-BAPTA Method BSLSOPBIO10	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Clinical Biochemistry (cont'd)		
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:	D
	Quantitative determination of: (cont'd)	Roche Cobas c501 module	D
Blood	Carbamazapine	Immunoassay/turbidimetry BSLSOPBIO12	D
Urine	Creatinine	Spectrophotometeric Enzymatic using BSLSOPBIO17	D
Blood	CRP	Immunoturbitimetry using BSLSOPBIO18	D
Blood	Phenytoin	KIMS method BSLSOPBIO46	D
Blood	Theophylline	KIMS method BSLSOPBIO25	D
Blood	Chloride	Indirect ISE BSLSOPBIO22	D
Blood	Potassium	Indirect ISE BSLSOPBIO22	D
Blood	Sodium	Indirect ISE BSLSOPBIO22	D
Blood	Cholesterol	Enzymatic Cholesterol Oxidase BSLSOPBIO13	D
Blood	HDL Cholesterol	Enzymatic Cholesterol Esterase BSLSOPBIO13	D
Blood	CK	Enzymatic UV Test NAC (IFCC), using BSLSOPBIO14	D
Blood	Creatinine	Enzymatic method BSLSOPBIO17	D
Blood	Ethanol	Enzymatic UV BSLSOPBIO16	D
Blood	Salicylate	Enzymatic method BSLSOPBIO24	D
CSF	CSF Protein	Turbidimetry BSLSOPBIO19	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Clinical Biochemistry (cont'd)		
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: (cont'd)	Roche Cobas c501 module	D
Blood	Gentamicin	CEDIA Method, using BSLSOPBIO48	D
Blood	GGT	Carboxynitroanilide (IFCC) BSLSOPBIO39	D
Blood/CSF	Glucose	Hexokinase + G6PD BSLSOPBIO40	D
Blood	Iron	Ferrozine/Ferene BSLSOPBIO41	D
Blood/CSF	Lactate	Enzymatic colourimeteric BSLSOPBIO43	D
Blood	LDH	L to P Glucamine (IFCC) BSLSOPBIO42	D
Blood	Lithium	Colourimetric method BSLSOPBIO32	D
Blood	Paracetamol	Colourimetric method, using BSLSOPBIO45	D
Blood	Magnesium	Xylidyl Blue (M&Y) BSLSOPBIO44	D
Blood	Phosphate	Phosphomolybdate UV BSLSOPBIO47	D
Blood	Protein (Total)	Biuret method BSLSOPBIO32	D
Urine	Protein	Spectrometric using BSLSOPBIO19	D
Blood	Triglyceride	Total glycerol GPO BSLSOPBIO26	D
Blood	Urea	Kinetic Urease BSLSOPBIO28	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Clinical Biochemistry (cont'd)		
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: (cont'd)	Roche Cobas c501 module	D
Urine	Urea	Spectrophotometeric Enzymatic using BSLSOPBIO28	D
Blood	Uric Acid (Urate)	Enzymatic Uricase BSLSOPBIO29	D
Blood	Valproic Acid	Enzyme immunoassay BSLSOPBIO30	D
Blood	Vancomycin	Two point end assay using BSLSOPBIO60	D
Fluid/Urine	Urine pH	Ph/Mv/Temperature meter model 3510 BSLSOPBIO37	D
Whole Blood	Blood Gas Analysis pH pCO2 pO2 tHb & derivatives	Siemens RapidPoint 500e Series Blood gas analyser (Potentiometry, amperometry and conductance) BSLSOPBIO87	D
Serum Urine	Osmolality	Advanced Instrument Osmometer 3320 Freezing point depression BSLSOPBIO1	D
	Calculated determination of:		
Blood	eGFR	Calculated in Winpath	D
Blood	Adjusted Calcium	Adjusted in Winpath	D
Serum	sFlt1 / PlGF Ratio	Calculated from Roche Cobas e601 Using BSLSOPBIO084	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology		
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	D
		HISSOP112 – receipt of POC samples	
		Specimen Dissection using: HISSOP81 – Cut up set up	D
		HISSOP78 – BMS cut up	D
		HISSOP64 – Assigning BMS cut up	D
		HISSOP41 – Cut up of large specimens by the pathologist – Bladder	D
		HISSOP51 – Cut up of large specimens by the pathologist – Prostate	D
		HISSOP60 – Cut up of large specimens by the pathologist – Penis	D
		HISSOP37 – Cut up of large specimens by the pathologist – Gall bladder	D
		HISSOP39 – Cut up of large specimens by the pathologist – Parathyroid	D
		HISSOP38 – Cut up of large specimens by the pathologist – Thyroid	D
		HISSOP40 – Cut up of large specimens by the pathologist – Small bowel	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
		HISSOP42 – Cut up of large specimens by the pathologist – Salivary gland	D
		HISSOP45 – Cut up of large specimens by the pathologist – Ovary	D
		HISSOP46 – Cut up of large specimens by the pathologist – Fallopian tube	D
		HISSOP44 – Cut up of large specimens by the pathologist – Placenta	D
		HISSOP43 – Cut up of large specimens by the pathologist – Lymph node	D
		HISSOP57 – Cut up of large specimens by the pathologist – Vulva	D
		HISSOP55 – Cut up of large specimens by the pathologist – Colon	D
		HISSOP49 – Cut up of large specimens by the pathologist – laparotomy for lymphoma	D
		HISSOP56 – Cut up of large specimens by the pathologists – Skin	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
		HISSOP52 – Cut up of large specimens by the pathologist – Spleen	D
		HISSOP47 – Cut up of large specimens by the pathologist – Bone	D
		HISSOP48 – Cut up of large specimens by the pathologist – Kidney	D
		HISSOP53 – Cut up of large specimens by the pathologist – Appendix	D
Tissue: biopsy, excision, resection, and post-mortem specimens. Cytology clots	Tissue processing	Tissue Processing using Sakura VIP 6 and Sakura VIP6 AI 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	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
	Tissue embedding	Tissue Tek 5EC and HISSOP10 – Embedding procedure	D
Formalin Fixed Paraffin wax blocks of processed tissue	Microtomy	Tissue sectioning using Tissue Tek, Histocore Biocut and Leica RM 2235 microtomes and HISSOP9 – The sectioning procedure CPF18 – Histology cutting list	D
Tissue for frozen sections	Cryotomy	Cryotomy Intra-operative frozen sections using Bright Cryostat (OTF5000) and HISSOP1 – Frozen section procedure HISSOP50 – Cut up of large specimens by the pathologist - Neurosafe	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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:		D
	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	D
FFPE slides	Special stains for the detection of:	Documented in-house procedures for manual special stains	D
	Acid mucopolysaccharides	Alcian Blue/PAS using HISSOP14 – Alcian Blue PAS	D
	Acid and Neutral Mucopolysaccharides	Alcian Blue using HISSOP17 – Alcian Blue	D
	Helicobacter Pylori	Modified manual Giemsa HISSOP30 – Giemsa	D
	Neutral Mucopolysaccharides, glycogen and fungus	Diastase PAS using HISSOP19 – Diastase PAS	D
	Elastic fibres and connective tissue	Elastic van Gieson using HISSOP 11 – Elastic Van Gieson	D
	Helicobacter/Microorganisms	Giemsa using HISSOP30 – Giemsa	D
	Gram positive and negative micro-organisms	Gram using HISSOP20 – Gram	D
	Fungi (Aspergillus) and Pneumocystis	Grocott using HISSOP13 – Grocott	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
FFPE slides (cont'd)	Special stains for the detection of: (cont'd)	Documented in-house procedures for manual special stains	D
	Elastic fibres and connective tissue	Haematoxylin Van Gieson using HISSOP12 – Haematoxylin Van Gieson	D
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana using HISSOP21 – Masson Fontana	D
	Melanin	Melanin Bleach using HISSOP113 – Melanin bleach	D
	Connective tissue and fibrin	Martius Scarlett Blue using HISSOP25 – MSB	D
	Copper assoc. Protein and Hepatitis B	Orcein using HISSOP26 – Orcein	D
	Neutral Mucopolysaccharides, glycogen and fungus	PAS using HISSOP18 – PAS	D
	Reticulin fibres	Reticulin using HISSOP28 – Reticulin	D
	Mast cells	Toludine Blue using HISSOP114 – Toluidine blue	D
	Calcium	Von Kossa using HISSOP29 – Von Kossa	D
	Tubercle bacilli	Ziehl Neelson using HISSOP23 – Ziehl Neelson	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
		Incorporating the following antibodies	D
	Smooth muscle cells, myofibroblasts, myoepithelial cells, Diagnosis of leiomyomas, leiomyosarcomas	Actin	D
	Broad band cytokeratin marker, epithelial cell carcinomas	AE1/3	D
	HGPIN, prostate adenocarcinoma	AMACR/P63	D
	BCL-2 oncoprotein	BCL-2	D
	BCL-6 gene	BCL-6	D
	Epithelial cell types	BerEP4	D
	Ovarian cancer	CA125	D
	Carcinomas, RCC	CA-IX	D
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	Calretinin	D
	T cells	CD3	D
	Mature T cells, T cell lymphomas	CD5	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
		Incorporating the following antibodies	D
	Granulocytes Reed-Sternberg cells	CD10	D
	Mature B cells, Follicular dendritic cells	CD20	D
	B cells, some T cells	CD21	D
	B Cells, Reed-Sternberg cells	CD23	D
	Reed-Sternberg cells and ALCL	CD30	D
	Haematopoietic cells, vascular endothelium	CD31	D
	T cells and some soft tissue	CD34	D
	Leukocyte common antigen	CD45	D
	Neuroendocrine cells	CD56	D
	Macrophages	CD68	D
	B lymphocytes	CD79	D
	GIST	CD117	D
	Plasma cells	CD138	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
		Incorporating the following antibodies	D
	Adenocarcinoma and carcinoid (intestinal epithelium)	CDX-2	D
	CEA glycoproteins in adenocarcinoma	CEA	D
	Neuroendocrine tumours	Chromogrannin	D
	Stratified squamous epithelium, basal cells, mesotheliomas	CK5	D
	Normal and neoplastic epithelia	CK7	D
	Glandular and transitional epithelium	CK8/18	D
	Basal cell carcinoma, squamous cell carcinoma	CK14	
	Adenocarcinomas	CK19	D
	Adenocarcinomas, columnar epithelial cells	CK20	D
	Striated and smooth muscle cells	Desmin	D
	GIST	DOG-1	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
		Incorporating the following antibodies	D
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin	D
	Normal and neoplastic epithelium	EMA	D
	Nuclei of cells containing a high level of oestrogen	ER	D
	V.W factor in endothelial cells	Factor VIII	D
	Mesothelial Cells Thyroid carcinomas	HBME-1	D
	Melanoma, melanocyte differentiation	HMB45	D
	Proliferating Cells	Ki67	D
	B cells and plasma cells	Kappa	D
	B cells and plasma cells	Lambda	D
	Melanoma marker	Melan A	D
	Epithelial tissue from glandular to stratified squamous	MNF116	D
	Seminomas	Oct3/4	D
	HPV driven tumour eg Squamous cell carcinoma	P16	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopathology (cont'd)		
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	D
		Incorporating the following antibodies	D
	Neoplastic cells in epithelium	P53	D
	Squamous epithelium	P63	D
	Nuclei of cells showing expression of Progesterone	PR	D
	Prostate secretory and ductal epithelium	PSA	D
	Prostate secretory and ductal epithelium	PSAP	D
	Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma	S100	D
	Smooth muscle cells, myoepithelial cells	SMM	D
	Neuroendocrine cells	Synaptohphysin	D
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF1	D
	Cells of mesenchymal origin	Vimentin	D
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	WT1	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)	**Histopathology** (cont'd) <u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified 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	D
END			