Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

9862

Accredited to ISO 15189:2022

Leeds Teaching Hospitals NHS Trust

Issue No: 022 **Issue date:** 19 August 2026

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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Local Contact information:

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Laboratory locations:

Location details	Department	Activity	Location code
Address Centre for Laboratory Medicine St James's University Hospital Becket Street Leeds LS9 7TF	Microbiology	Bacteriology (including molecular), Mycology Blood culture incubation & detection of microbial growth	CfLM
Chancellor Wing St James's University Hospital Beckett Street LS9 7TF	Cellular Pathology	non-gynaecological cytology Reporting of the above Muscle / nerve histopathology, enzyme histochemistry	SJUH
Bexley Wing St James' University Hospital Beckett Street Leeds LS9 7TF	Cellular Pathology Genetics	Routine diagnostic service for histopathology (including neuropathology and paediatric pathology) Reporting of the above and non-gynae cytology Out of hours on call service for urgent frozen sections / diagnosis FISH testing, DNA extraction and quantification, NGS library preparation	BEX
Seacroft Hospital York Road Leeds West Yorkshire LS14 6UH	Cellular Pathology	Andrology (post vasectomy and infertility investigation).	SEA
Clinical Sciences Building St James's University Hospital Becket Street Leeds LS9 7TF	Genetics	NGS library preparation and sequencing	CSB
Yorkshire and North East Genomic Laboratory Hub Central Lab Ashley Wing St James's University Hospital Leeds LS9 7TF	Genetics	Molecular and Cytogenetics testing	ASH

Additional site activity performed away from the laboratory:

Location details	Activities
On-site Mortuary and Body Store, St James' University Hospital On-site Mortuary and Body Store, Leeds General Infirmary	Storage of bodies Viewing facilities Record keeping (body identification and audit trail)

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS	Microbiological examination activities for the purpose of clinical diagnosis	In-house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMIs) and incorporating manufacturer's instructions where relevant	
Routine samples: Swabs, fluids and tissues	Isolation of microorganisms of clinical significance	Manual or automated (WASP) inoculation and manual or automated incubation SOPs: MIC-BAC-EP-1 MIC-BAC-EP-2 MIC-BAC-EP-4 MIC-BAC-EP-5 MIC-BAC-EP-7 MIC-BAC-EP-9 MIC-BAC-EP-10 MIC-BAC-EP-12 MIC-BAC-EP-14 MIC-BAC-EP-15 MIC-BAC-EP-16 MIC-BAC-EP-17 MIC-BAC-EP-26 MIC-BAC-EP-27 Gram staining and Microscopic examination of sterile fluids and tissues for bacteria and white cells	CfLM
Cerebrospinal fluid	Quantification and differentiation of white and red cells Isolation of microorganisms of clinical significance	Manual cell count using modified Fuchs-Rosenthal chamber Manual inoculation and incubation MIC-BAC-EP-18 MIC-BAC-EP-15	CfLM
Cellular and fluid material contained on swabs	Screening for Methicillin-Resistant *Staphylococcus aureus* (MRSA)	Automated processing, incubation and digital plate imaging using Brilliance culture media and WASP or manual culture methods using Brilliance culture media SOP: MIC-BAC-EP-20	CfLM

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMIs) and incorporating manufacturer's instructions where relevant	
Blood	Detection of microbial growth Isolation & characterisation of microorganisms of clinical significance	Liquid media culture using Using Bactec FX and Bactec FX40 Subsequent manual culture and Gram staining SOP: MIC-BAC-EP-23	CfLM
Respiratory samples: Sputum, Broncho-alveolar lavage, Bronchial Washings, Naso-pharyngeal Aspirate Naso-pharyngeal swabs, Sinus/Antral Washout	Isolation of microorganisms of clinical significance	Manual inoculation and media culture SOPs: MIC-BAC-EP-3 MIC-BAC-EP-13 MIC-BAC-EP-6	CfLM
Urine	Detection, identification and quantification of: White blood cells Red blood cells Squamous epithelial cells Bacterial cells	Detection by microscopy and culture Sysmex UF-5000 SOP: MIC-BAC-EP-25	CfLM
Faeces	Isolation, identification and antimicrobial susceptibility of bacterial pathogens: *Campylobacter* spp. *Escherichia coli O*157 *Salmonella* sp. *Shigella* spp. *Vibrio* spp. *Yersinia* spp. *Pleisiomonas* spp. *C.perfringens* *B.cereus* *B.subtilis* *B.lichenformans* *S.aureus*	Manual inoculation and media culture SOP: MIC-BAC-EP-21	CfLM

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMIs) and incorporating manufacturer's instructions where relevant	
Female genital tract liquid swabs	General isolation and characterisation of micro-organisms of clinical significance	Automated processing, incubation and digital plate imaging (WASP) QASPLab WebAPP SOP: MIC-BAC-EP-19	CfLM
Cultures isolated in-house from all samples listed above	Identification of microorganisms of clinical significance	Using manual biochemical methods SOPs: MIC-BAC-TP-5 MIC-BAC-TP-11 MIC-BAC-IP-16 And Automated BD Maldi-Tof Matrix-assisted laser desorption/ionisation SOP: MIC-BAC-TP-2	CfLM
Bacterial cultures isolated in-house from all samples listed above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual antimicrobial susceptibility testing using EUCAST methodology and manual Reading SOP: MIC-BAC-EP-28	CfLM
Bacterial cultures of Staphylococci isolated in-house from all samples listed above	Antimicrobial susceptibility testing of Staphylococci spp.	Semi-automated antimicrobial susceptibility testing using VITEK SOP: MIC-BAC-BG-123	CfLM
Faeces CSF, Bile, Pus, Duodenal/Jejunal Aspirate, Sputum, Tissue (where appropriate)	Detection of clinically significant ova, cysts and parasites (OCP)	Faecal concentration using Mini system Total-Fix kit and direct Microscopic examination SOP: MIC-BAC-EP-22	CfLM
Clear adhesive tape' slide/perianal swab	Detection of *Enterobius vermicularis* larvae and ova	Direct Microscopic examination SOP: MIC-BAC-EP-22	CfLM
Urine	Detection of *Schistosoma haematobium* ova	Sedimentation of Urine and Microscopic Identification SOP: MIC-BAC-EP-22	CfLM

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMIs) and incorporating manufacturer's instructions where relevant	
Sputum, broncho-alveolar lavage/washings. Gastric Aspirates/Washings Sterile body fluids Pus and pus swabs Skin or tissue including lymph nodes Bone Faeces Urine BAL Blood	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. Mycobacterium spp.)	Liquid culture, auramine phenol staining and incident-light fluorescence microscopy Using BD BacTec MGIT 960 (fluorescence) BD BacTec FX40 SOP: MIC-BAC-EP-24	CfLM
Faeces	C. difficile toxin B and binary toxin genes	Cepheid Gene Xpert Real-time PCR. SOP: MIC-BAC-BG-174	CfLM
Faeces Rectal Swabs	Detection of Carbapenemase Genes (KPC, VDM, OXA-48, IMP1 & VIM)	Cepheid Gene Xpert Real-time PCR SOP: MIC-BAC-OP-6 MIC-BAC-IP-10	CfLM
Blood/serum, bronchoalveolar lavage (BAL)	Aspergillus antigen	Manual ELISA Platelia Antigen Kit SOP: MIC-MYC-YP-8 MIC-MYC-EP-5	CfLM
Blood/serum	Qualitative detection of Beta D glucan	ACC Fungitell (kinetic) Assay and ELX 808 Ultra Microplate Reader SOP: MIC-MYC-TP-12	CfLM
Blood/serum, CSF	Cryptococcal antigen	Latex agglutination (IMMY lateral flow kit) SOP: MIC-MYC-TP-9	CfLM

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Microbiological examination activities for the purpose of clinical diagnosis (cont'd)	In-house documented procedures following current UK Health Security Agency (UKHSA) Standards for Microbiological Investigations (SMIs) and incorporating manufacturer's instructions where relevant	
Hair Nail Skin	Isolation and identification of clinically significant dermatophyte fungi	Manual inoculation, media culture, and macroscopic & microscopic examination (stained (lactophenol cotton blue, KOH/Calcoflour white & unstained) SOP: MIC-MYC-EP-1 MIC-MYC-TP-2	CfLM
Mould isolates Fluid from normally sterile sites, bile, pus and swabs, antral washout	Isolation and identification of clinically significant moulds	Culture. Macroscopic and microscopic identification using lactophenol cotton blue for staining SOPs: MIC-MYC-TP-2 MIC-MYC-EP-2 MIC-MYC-EP-3 MIC-MYC-EP-4	CfLM
Yeast isolates Fluid from normally sterile sites, bile, pus and swabs, antral washout, oral rinse, urine Skin, tissue biopsies Corneal Scrapes Swabs from genito-urinary tract	Isolation, identification and susceptibility testing of clinically significant yeasts	Culture on chromogenic agar SOPs: MIC-MYC-EP-2, MIC-MYC-EP-4	CfLM
CSF, tissue, sputum, Bile Acid, fluids, gastric aspirate	Detection of Mycobacterium tuberculosis complex DNA and detection of rifampicin resistance associated mutations	Real-time PCR using Cepheid GeneXpert MTB/RIF Ultra assay SOP: MIC-BAC-EP-24	CfLM

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Body fluids / Fine needle aspirations, urines and bronchial/ sputum samples	Diagnostic Non Gynae Cytopathology	Sample preparation (Rotina 380 centrifuge, Shandon cytospin 4): CPATH-SOP-CYTO-2 Preparation of Non Gynae Samples	SJUH
		CPATH-SOP—HP-107 Preparation of Cell blocks	SJUH
	Visualisation of nuclear detail in cells present	CPATH-SOP-CYTO-15 H&E (automated using Jung Autostainer) CPATH-COSHH-10 Papanicolaou (automated using Jung Autostainer) CPATH-COSHH-12 Rapid Romanowsky Stain	SJUH
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	CPATH-SOP-CYTO-8 Medical reporting of Non-Gynae cytology	BEX

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue / organs	Histopathology	Tissue dissection: CPATH-SOP-HP-156 Cut Up of Specimens by Biomedical Scientists HPSOP 0305 Cut Up of Specimens by Medical Staff CPATH-SOP-HP-125 CPATH-REC-527 Guidelines for Inflating a Lung CPAYH-SOP-HP-65 Handling of CJD Specimens CPATH-SOP-HP-125 Further Blocks CPATH-REC-526 Guidelines for Opening a Fresh Uterus CPATH-REC-527 Guidelines on Opening a Kidney CPATH-SOP-HP-66 Renal Biopsy Procedure CPATH-SOP-MED-1 Dissection of gall bladder resection specimens CPATH-SOP-MED-2 Dissection of appendiceal resection specimens CPATH-SOP-MED-30 Cut up of gynae specimens	BEX

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue / organs (cont'd)	Histopathology (cont'd)	Tissue dissection: CPATH-SOP-MED-31 Operations for Hirschsprung's Disease and Other Motility Abnormalities CPATH-SOP-MED-32 Handling paediatric tumours in the laboratory CPATH-SOP-MED-33 Reporting of placental examination (unaccompanied by a fetus) X-ray/photography (Breast cases only) (Faxitron): Decalcification: CPATH-SOP-HP-24 Decalcification of Specimens CPATH SOP-HP-24 X-raying of Decalcification Samples CPATH-SOP-HP-24 Chemical End Point Testing of Decalcification Samples Tissue processing: CPATH-SOP-HP-26 Processing tissue using the Leica Peloris tissue processor (routine & big blocks & long process)	BEX BEX BEX

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue / organs (cont'd)	Histopathology (cont'd)	Tissue processing: CPATH-SOP-HP-160 Processing tissue using the Sakura X-Press (small urgent biopsies and neuropath specimens) Embedding: CPATH-SOP-HP-109 Embedding paraffin wax impregnated tissues Microtomy: CPATH-SOP-HP-114 Sectioning using rotary microtome CPATH-SOP-HP-28 Sectioning using automated microtome CPATH-SOP-HP-28 Sectioning of Problem Blocks CPATH-SOP-HP-27 Sections/levels required for particular tissue types Frozen Sections: CPATH-SOP-HP-22 Leica 1950 cryostat CPATH-SOP-HP-23 Specimens Requiring Frozen Sections CPATH-SOP-HP-18 Preparation of Split Skin Biopsies for Immunofluorescence	BEX BEX BEX

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue / organs (cont'd)	Histopathology (cont'd)	Frozen Sections: CPATH-SOP-HP-23 Processing and Embedding of Alopecia Cases and other Paraffins CPATH-SOP-MED-43 Protocol for Transplant Donor Lesion Biopsies – Frozen Sections	BEX
Tissue	Identification of basophilic and eosinophilic structures	Routine Haematoxylin and Eosin Staining Automated: CPATH-SOP-HP-63 Use and maintenance of Spectra Autostainer/coverslipper Manual: CPATH-SOP-HP-4 Mayers haematoxylin and eosin for rapid method for frozen sections	BEX
Tissue	Histopathology - Identification of: Acid and neutral mucins Diastase resistance acidic and neutral mucins Mucins, glycogen Diastase resistance mucin Basement membranes, fungi	Automated: CPATH-SOP-HP-54HPSOP 657 Use of theAgilent Artisan Link Pro for Special stain techniques ABPAS ABPAS+D PAS DPAS ExPAS	BEX

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue (cont'd)	Histopathology - Identification of: (cont'd)	Automated: CPATH-SOP-HP-54 Use of the Artisan Link Pro for Special stain techniques	BEX
	Basement membranes, fungi	ExDPAS	
	Fungi	Grocott	
	Iron (ferric)	Perls	
	Reticulin fibers	Retic	
	Spirochettes, H.Pylori	Warthin & Starry	
	Amyloid	Congo Red	
		Manual staining:	
	Copper/Hepatitis B	Orcein	
	Sulphated acid mucins	CPATH-SOP-HP-29 Alcian blue pH1.0	
	Acid mucins	CPATH-SOP-HP-30 Alcian blue pH2.5	
	Acid mucins/connective tissue	CPATH-SOP-HP-31 Alcian blue van gieson	
	Acid mucins/connective tissue/elastic	CPATH-SOP-HP-53 Alcian blue elastic van gieson	
	AL amyloid	CPATH-SOP-HP-32 Congo red potassium permanganate	
	Nissl granules and neurones	CPATH-SOP-HP-33 Cresyl violet	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue (cont'd)	Histopathology - Identification of (cont'd):	Manual special staining:	BEX
	Elastic/connective tissue	CPATH-SOP-HP-34 Elastic van gieson	
	H Pylori	CPATH-SOP-HP-35 Giemsa- modified	
	Bone marrow	CPATH-SOP-HP-37 Giemsa- overnight	
	Gram positive bacteria	CPATH-SOP-HP-37 Grams technique	
	Gram positive and negative bacteria	CPATH-SOP-HP-38 Gram twort	
	General tissue morphology	CPATH-SOP-HP-4 Mayers Haematoxylin and Eosin	
	Collagen/muscle	CPATH-SOP-HP-39 Haematoxylin van gieson	
	Acid mucin	CPATH-SOP-HP-52 Hales colloidal iron	
	Myelin	CPATH-SOP-HP-40 Luxol fast blue Haematoxylin and Eosin	
	Melanin	CPATH-SOP-HP-41 Masson Fontana	
	Muscle/collagen	CPATH-SOP-HP-42 Masson Trichrome	
	Paired sections identifies melanin pigment	CPATH-SOP-HP-43 Melanin bleach	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue (cont'd)	Histopathology - Identification of (cont'd):	Manual special staining:	BEX
	Fibrin/connective tissue	CPATH-SOP-HP-44 MSB	
	Copper	CPATH-SOP-HP-45 Rhodanine technique	
	Fat	CPATH-SOP-HP-46 Sudan IV	
	Mast cells	CPATH-SOP-HP-48 Toluidine blue	
	Calcium	CPATH-SOP-HP-49 Von Kossa	
	Mycobacterium leprae	CPATH-SOP-HP-50 Wade fite	
	Tubercle bacilli	CPATH-SOP-HP-50 Ziehl Neelsen	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks	Histopathology – identification of:	Automated Immunohistochemical staining, PTLink/Autostainer CPATH-SOP-HP-55 Preparation of Primary antibodies and associated reagents CPATH-SOP-HP-56 DAKO Autostainer Link 48 CPATH-SOP-HP-57 DAKO PTLinks for antigen retrieval Using the following monoclonal, polyclonal and cocktail antibodies:	BEX
	Amyloid deposits	AMYLOID-A	
	Lung cancer	PDL-1	
	Marker of normal throid/lung tumours	TTF-1	
		Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies: CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	A1-AT deiciency	A1-AT	
	Pituitary hormone	ACTH	
	Epithelial marker	AE1/3	
	Primary liver tumours/yolk sac tumours	AFP	
	Prostate cancer	AMACR	
	Prostate/breast marker	ANDROGEN R	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	Lewy bodies /Parkinsons disease	A-SYN	
	Melanocytic lesions	BAP1	
	Neuronal damage	BAPP	
	Marker for apoptosis	BCL-2	
	Epithelial marker	BER-EP4	
	Senile plaques in Alzheimers disease	B-AMYLOID	
	Fibromatous lesions	B-CATENIN	
	Germ cell tumours	B-HCG	
	Marker of breast tumours	BRST-2 (GCDFP15)	
	Marker of ovarian tumours	CA125	
	Tumours of GI tract and pancreas	CA19.9	
	Marker of thyroid tumours	CALCITONIN	
	Marker of smooth nuscle	CALDES	
	Marker for mesothelioma	CALRET	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	Marker of rejection in renal/liver transplants	C4D	
	Langerhan cells	CD1A	
	T lymphocytes	CD3	
	T helper lymphocytes	CD4	
	T supressor lymphocytes	CD8	
	Lymphoid/endometrial malignancies	CD10	
	Hogkins lymphoma	CD15	
	B lymphocytes	CD20	
	Lymphoma marker	CD21	
	Hogkins lymphoma	CD30	
	Endothelial marker	CD31	
	Endothelial marker	CD34	
	Lymphocyte marker	CD45	
	Marker of nerve/neuroendocrine tumours	CD56	
	Histiocytes/macrophages	CD68	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	B lymphocytes	CD79a	
	Ewings sarcoma	CD99	
	Mesothelioma marker	CD141	
	Histiocytes/macrophages	CD163	
	GI tract tumours	CDX2	
	Epithelial marker	CEA-M	
	Epithelial marker/liver tumour marker	CEA-P	
	Neuroendocrine cells	CHROMO	
	Epithelial marker	CK5	
	Epithelial marker	CK5/6	
	Epithelial marker	CK7	
	Epithelial marker/mallory bodies	CK8/18	
	Epithelial marker	CK14	
	Epithelial marker	CK19	
	Epithelial marker	CK20	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	Gastrointestinal stromal tumour marker	C-KIT (CD117)	
	Cytomegalovirus infection	CMV	
	Marker of basement membrane	COLL IV	
	Marker of lymphatic channels	D2-40	
	Pan muscle marker	DES	
	Gastrointestinal stromal tumour marker	DOG-1	
	Cell adhesion molecule	E-CAD	
	Epidermal growth factor receptor	EGFR	
	Epithelial marker	EMA	
	Estrogen receptor/ prognostic breast marker	ER	
	Vascular tumours	ERG	
	Pituitary hormone	FSH	
	Marker of gastrin producing tumours	GASTRIN	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	Glial cells benign and malignant	GFAP	
	Pituitary hormone	GH	
	Pancreatic tumour typing	Glucagon	
	Pancreatic tumour typing	Glucagon	
	Adenoma v HCC	Glutamine Synthetase	
	Liver adenoma/HCC	Glypican-3	
	Hepatitis B infected cells	HEP B c	
	Hepatitis B infected cells	HEP B s	
	Marker of normal/malignant hepatocytes	HEPAR 1	
	Marker of Her2 amplification in breast tumours.	HER 2	
	Melanoma marker	HMB45	
	Epithelial marker	HMC	
	Marker for H pylori	HP	
	Marker for teratoma	HPL	
	Herpes simlex 1 infection	HSV 1	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	Brain tumours	IDH1	
	Lymphoma markers	IgA IgG IgM	
	IgG4 disease marker	IgG4	
	Granulosa cell tumours Mucinous epithelial ovarian tumours	Inhibin	
	Paediatric tumours	INI-1	
	Pancreatic tumours	Insulin	
	Lymphoma marker	KAPPA	
	Proliferation marker	KI67	
	Lymphoma marker	Lambda	
	Pituitary hormone	LH	
	Head and Neck tumour	Mammaglobin	
	Melanoma marker	MEL-A	
	Mismatch repair protein	MLH 1 MSH 2 MSH6	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	Epithelial marker	MNF	
	MUC4 in tumours	MUC4	
	Marker for rhabdomyosarcoma	MYOD 1	
	Marker for rhabdomyosarcoma	MYOGENIN	
	Neuronal marker	N52	
	Neuronal marker	NEU N	
	Neuronal marker	NFP	
	Neuroectodermal marker	NSE	
	Epithelial gynae tumours	PAX-8	
	Marker of CIN	P16	
	Marker of wild type P53 in malignancy	P53	
	Marker of molar pregnancy	p57	
	Marker in breast/prostate tumours	p63	
	Infection with parvo virus	PARVO	
	Marker of neuroblastoma	Phox 2B	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	Marker of germ cell tumours	PLAP	
	Mismatch repair protein	PMS2	
	Polyoma virus infection I renal transplant patients	POLYOMA SV40	
	Pituitary hormone	PROLACTIN	
	Progesterone receptor/prognostic breast marker	PR	
	Marker of normal/malignant prostate	PSA	
	Marker of normal/malignant prostate	PSAP	
	Marker of parthyroid tumours	PTH	
	Marker of ovarian malignancy	R1(inhibin)	
	Marker of primary renal carcinoma	RCC	
	Nerve sheath, neural marker	S100	
	Marker of serotonin producing tumours	SEROT	
	Pancreatic tumours	SOMAT	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	BEX
	Smooth muscle marker	SMA	
	Smooth muscle marker	SMM	
	Marker of neural cells/neuroendocrine tumors	SYNAPT	
	Stat6 Expression	STAT6	
	Tangles in Alzheimers disease	TAU	
	Marker of normal/malignant thyroid	THYROG	
	Pituitary hormone	TSH	
	Tangles, plaques and inclusions in dementia	UBIQ brain	
	Marker of Mallory bodies.	UBIQ liver	
	Mesenchymal tumours	Vimentin	
	Wilms tumour/mesothelioma	WT-1	
	Desmoplastic cell tumour	WT-1 C19	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) Histopathology	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue (Breast primary)	HER2	Automated Immunohistochemical staining, CPATH-SOP-HP-58: Use of Ventana Benchmark Ultra for HER2 Antibody: anti-HER-2/neu(4B5)	BEX
	Histopathology – Enzyme histochemistry Immuno fluorescence (IF) for identification/demonstration of:		
Tissue (Renal)	Immunoglobulins and complement	CPATH-SOP-HP-20 Immunofluorescence staining of renal biopsies Using antibodies IgA IgG IgM C3C C1q Kappa Lambda	BEX
Tissue (Skin)	Immunoglobulins and complement	CPATH-SOP-HP-21 Sectioning & Immunofluorescence Staining of Skin/ Oral/Neuro frozen sections Using antibodies in IgA IgG IgM C3C Fibrinogen	BEX
	Histopathology – Morphological assessment and interpretation/diagnosis:	Using light microscopy and SOPs:	BEX
Slides prepared in house as above (Breast)		CPATH-SOP-MED-5 Dissection and Reporting of Breast Specimens	
Slides prepared in house as above (Gastrointestinal)		CPATH-SOP-MED-6 Reporting of colonic resection specimens with vascular pathology CPATH-SOP-MED-7 Reporting of ileo-colic resection specimens	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
	Histopathology – Morphological assessment and interpretation/diagnosis: (cont'd)	Using light microscopy and SOPs:	BEX
Slides prepared in house as above (Gastrointestinal) (cont'd)		CPATH-SOP-MED-8 Reporting of small intestinal resection specimens CPATH-SOP-MED-9 Reporting of Colorectal Cancer Specimens CPATH-SOP-MED-10 Reporting of resections for pancreatic, ampullary and bile duct carcinoma CPATH-SOP-MED-11 Reporting of stomach resection specimens CPATH-SOP-MED-12 Reporting of oesophageal resection specimens CPATH-SOP-MED-47 Reporting of endomucosal resection specimens (EMR) CPATH-SOP-MED-39 Reporting of liver resections not transplant	
Slides prepared in house as above (Thoracic, skin)		CPATH-SOP-MED-13 Reporting of skin specimens, biopsies and resections CPATH-SOP-MED-14 Reporting of lung resection specimens	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
	Histopathology – Morphological assessment and interpretation/diagnosis (cont'd):	Using light microscopy and SOPs:	BEX
Slides prepared in house as above (Thoracic, skin) (cont'd)		CPATH-SOP-MED-15 Reporting of Thoricic lung biopsies and segmental excisions CPATH-SOP-MED-48 Reporting of Soft Tissue tumours specimens, core biopsies, excisions, amputations	
Slides prepared in house as above (Head & neck)		CPATH-SOP-MED-16 Reporting of oral mucosal specimens for tumours CPATH-SOP-MED-17 Reporting of thyroid specimens CPATH-SOP-MED-18 Reporting of small mucosal specimens CPATH-SOP-MED-19 Reporting of small bone specimens CPATH-SOP-MED-20 Reporting of salivary gland specimens for tumours CPATH-SOP-MED-21 Reporting of radical neck dissection specimens CPATH-SOP-MED-22 Reporting of maxillectomy specimens for tumours	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) Histopathology – Morphological assessment and interpretation/diagnosis (cont'd):	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: Using light microscopy and SOPs:	
Slides prepared in house as above (Head & neck) (cont'd) Slides prepared in house as above (Neuropathology) Slides prepared in house as above (Urology)		CPATH-SOP-MED-23 Reporting of laryngectomy specimens for tumours CPATH-SOP-MED-24 Reporting of Globes CPATH-SOP-MED-25 Reporting the examination of orbital exenterations CPATH-SOP-MED-26 Reporting of wedge excisions - eyelid lesions CPATH-SOP-MED-27 Reporting of Temporal Artery Specimens CPATH-SOP-MED-28 Reporting of Trabeculectomy Specimens CPATH-SOP-MED-29 Reporting a penetrating keratoplasty (Cornea) CPATH-SOP-MED-34 Prostatic biopsies, transurethral or open prosatic resections and radical prostatectomies CPATH-SOP-MED-35 Adult renal parenchymal tumours CPATH-SOP-MED-36 Penile biopsies and resections	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) Histopathology – Morphological assessment and interpretation/diagnosis (cont'd):	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: Using light microscopy and SOPs:	
Slides prepared in house as above (Urology) (cont'd)		CPATH-SOP-MED-37 Testicular biopsies and resections, retroperitoneal lymph node dissections CPATH-SOP-MED-38 Urinary bladder, ureteric, renal pelvic and urethral specimen	
Slides prepared in house as above (Skin)		CPATH-SOP-HP-21 Screening of skin biopsies by Immunofluorescence	
Digital images from slides prepared in house as above	Histopathology – Morphological assessment and interpretation/diagnosis (cont'd):	Using digital pathology (slide scanners and viewing software): Slide Scanning CPATH-SOP-HP-166 Scanning Digital Cases Using Leica GT450 Scanners Slide Reporting CPATH-SOP-HP-64 Reporting digital slides using Sectra IDs 7	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue	Muscle / Nerve Histopathology		SJUH
		Frozen section preparation Leica CM 1950 CPATH-SOP-23 Cryostat Section Preparation for Histochemistry Sample preparation techniques: CPATH-COSHH-32 Tissue Quenching for Histochemistry CPATH-SOP-SPH-12 CPATH-SOP-SPH-13 Specimen Handling for Muscle, Nerve, Rectal, Skin and Conjunctival Biopsies	
	Identification of basophilic and eosinophilic structures	CPATH-SOP-HP-4 Haematoxylin and Eosin Staining Method (cryostat sections)	SJUH
	Muscle / Nerve Histopathology - Identification of:	Manual special staining techniques:	SJUH
	Glycogen	CPATH-SOP-HP-8 Periodic Acid Schiff (PAS) and Diastase-PAS Staining Method for Cryostat Sections	
	Mitochondria and their distribution	CPATH-SOP-HP-3 Gomori Trichrome CPATH-SOP-HP-16 Succinate Dehydrogenase Demonstration	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue (Muscle)	Muscle / Nerve Histopathology - Identification of normal /abnormal muscle fibre elements	CPATH-SOP-HP-15 Immunocytochemical Sarcolemmal Staining Method (Real) Using the following monoclonal, polyclonal and antibodies: Dystrophin 1 Dystrophin 2 Dystrophin 3 Alpha Sarcoglycan BetaSarcoglycan Gamma Sarcoglycan Delta Sarcoglycan Emerin Dysferlin Merosin Spectrin	SJUH
	Identification of nucleated cells	MHC-1 (HLA-ABC)	
Tissue (Surgical and MH muscle)	Muscle Histopathology - identification /demonstration of:	Enzyme histochemical staining CPATH-SOP-SPH-12 Specialist Histopathology Staining Panels	SJUH
	Acid Phosphatase	CPATH-SOP-HP-1 Acid Phosphatase – Naphthol AS-BI Phosphate	
	Fibres with abnormal COX activity	CPATH-SOP-HP-16 Combined Demonstration of Cytochrome Oxidase & Succinate Dehydrogenase CPATH-SOP-HP-2 Cytochrome Oxidase Demonstration	
	Myoadenylate Deaminase	CPATH-SOP-HP-5 Myoadenylate Deaminase Demonstration	
	Adenosine triphosphatase	CPATH-SOP-HP-6 Myosin ATPase Staining Method	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue (Surgical and MH muscle) (cont'd)	Muscle / Nerve Histopathology - identification /demonstration of: (cont'd)	Manual tinctorial Stain techniques for:	SJUH
	NADH	CPATH-SOP-HP-7 NADH - Tetrazolium Reductase Demonstration	
	PFK and Aldolase activity	CPATH-SOP-HP-9 Phosphofructokinase and Aldolase Demonstration	
	Myophosphorylase in muscle	CPATH-SOP-HP-13 Phosphorylase Demonstration	
	Presence and distribution of lipid in muscle	CPATH-SOP-HP-10 P-Phenylene diamine Staining Method CPATH-SOP-HP-14 Sudan Black B Staining Method	
Slides prepared in house as above	Muscle / Nerve Histopathology - Morphological assessment and interpretation/diagnosis	CPATH-SOP-MED-3 Reporting of muscle biopsy specimen examination and handling	BEX
		CPATH-SOP-MED-4 Reporting of peripheral nerve biopsy specimen examination	BEX
	Molecular Pathology		
FFPE sections prepared in house as above	Detection of BRAF mutation at codon 600	RT-PCR CPATH-SOP-HP-60 IdyllaTM System	BEX

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Andrological examination activities for the purposes of clinical diagnosis		
Semen	Post vasectomy: Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy OR wet prep and centrifugation and documented in-house procedure CPATH-SOP-AND-5 Post vasectomy testing	SEA
Semen	Fertility testing:	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method / documented in-house procedures: CPATH-SOP-AND-1 Infertility testing CPATH-SOP-AND-2 Sperm density CPATH-SOP-AND-3 Motility testing CPATH-SOP-AND-4 Sperm morphology	SEA
	Volume	Volume/weight	
	pH	Colorimetric strips	
	Sperm morphology excluding TZI scoring	Stained slides (H&E) microscopy (Bright field)	
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Genetics		
HUMAN TISSUE AND FLUIDS	Molecular genetic examinations for the purpose of clinical diagnosis (including predictive and prenatal) for a range of disorders:	In house documented methods incorporating manufacturers' instructions where relevant	
Human DNA / RNA Blood, saliva, tissue, paraffin embedded tissue amniotic fluid, chorionic villus sampling (CVS) Extracted DNA from external sources	DNA/RNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Using a combination of the methods listed below, supported by: 1. DNA Extraction by: Automated EZ1 robot: (LG-SR-SOP-1) 2. Automated Chemagic and Chemagic 360i: ((LG-SR-SOP-2)) 4. Automated extraction using Maxwell RSC 48 extraction robot SOP LG-SR-SOP-4 5. DNA Quantification by Nanodrop spectrophotometer and Tecan plate reader F200 (PicoGreen) or Qubit: LG-SR-SOP-5	BEX
		6. Amplification by Polymerase Chain Reaction/PCR (Thermocyclers: LG-PCR-SOP-12, Tecan Robot: LG-NGS-SOP-1) 7. Sanger DNA sequencing (Applied Biosystems (AB) Analysers 3730, 3500XL: LG-PCR-SOP-1) 8. Multiplex Ligation-dependent Probe Amplification, (AB, Thermocyclers: LG-PCR-SOP-12) 9. Gel Electrophoresis (LG-PCR-SOP-3) 10. Fragment analysis (AB): LG-PCR-SOP-4) (Applied Biosystems (AB) Analysers 3730, 3500XL: LG-PCR-SOP-1)	ASH CSB

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Genetics (cont'd)		
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (including predictive and prenatal) for a range of disorders (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Human DNA / RNA Blood, saliva, tissue, paraffin embedded tissue amniotic fluid, chorionic villus sampling (CVS) Extracted DNA from external sources (cont'd)	DNA/RNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage (cont'd)	11.NGS Library preparation: (Sureselect – custom targeting and clinical exomelllumina, Sureselect Library Prep: LG-NGS-SOP-2 Agilent Bravo: LG-NGS-SOP-2 Sciclone SureSelect Library Preparation: LG-NGS-SOP-11 Tecan Liquid Handling SOP: LG-NGS-SOP-1 Agilent Bioanalyser: LG-NGS-SOP-14 Covaris LE220: LG-NGS-SOP-12 Quantitative DNA analysis (PicoGreen): LG-NGS-SOP-20	CSB BEX
		Next Generation Sequencing: sequencing and dosage analysis: 12. NovaSeq 6000	CSB
		13. CFEU2 (Cystic Fibrosis Base - Yourgene) (Thermocyclers, AB: LG-PCR-SOP-5) 14. MFI-Y Plus (Male Factor Fertility Base- Yourgene) (Thermocyclers, AB: LG-PCR-SOP-6)	ASH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd) Human DNA obtained from: A. blood, saliva, tissue, paraffin embedded tissue B. amniotic fluid, chorionic villus sampling (CVS)	Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal) (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	ASH or ASH & CSB, or ASH, CSB & BEX (see techniques 1,2,4-8, 10, 11,12, above)
A, B	Li-Fraumeni syndrome	LG-IC-SOP-6	
A	Selected Gene Panel (Agilent Custom Design) including: Ataxia/Neuropathy panel BOB (Breast, ovarian, bowel) panel Cancer panel Connective tissue disorders panel Core (FH and CF) panel Dystonia/Paroxysmal (DYT) panel Gastrohepatology panel Haematology panel HSP/Degenerative disorders panel LGMD and MH panel Respiratory diseases panel Somatic BRCA panel YNExome panel (includes mitochondrial disorder targets)	LG-IC-SOP-4LG-NGS-SOP-6LG-NGS-SOP-6aLG-NGS-SOP-2	ASH or ASH & CSB, or ASH, CSB & BEX (see techniques 1.2.4-8,10, .11.12 above)
A, B	Variant Confirmation	LG-RD-SOP-33	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal) (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
A. B	Cystic Fibrosis	LG-PCR-SOP-5	ASH or ASH & CSB, or ASH, CSB & BEX (see techniques 1,2,4-8, 10-13 above)
A (Blood only)	Y Chromosome Microdeletions	LG-PCR-SOP-6	ASH, CSB & BEX (See techniques 2, 5, 6, 10, 14 above)
A, B	DNA Profiling	LG-PCR-SOP-7	
FFPE tumour material	SNVs, small indels and fusions associated with Non-Small Cell Lung Cancer	Nucleic Acid Extraction & Quantitation using the Ion Torrent Genexus Purification System Ion Torrent Genexus FFPE DNA/RNA Purification Kit, Genexus Nucleic Acid Quantitation kit Automated Library Preparation using the Oncomine Precision assay and (NGS) sequencing using Integrated Ion Torrent Genexsus Sequencer. Analysis using Integrated Genexsus Software v 6.6 and Alissa Interpret. SOP: LG-NGS-SOP-19, LG-NGS-SOP-18, LG-SO-SOP-31	ASH, BEX, CSB

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal) (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
FFPE Tumour material	Detection of somatic variants (SNVs, small indels and fusions) in DNA or RNA	Extraction using Hamilton automation, bead-based normalisation using Tecan Fluent 780. Next Generation sequencing using Illumina NovaSeq, Analysis in-house bioinformatics DNA and RNA specific pipeline and Alissa Interpret (filtering and evaluation). SOP: LG-NGS-SOP-17, LG-BIO-SOP-29, LG-SO-SOP-21,	ASH, BEX, CSB
DNA or RNA extracted from FFPE tumour material (endometrial, thyroid and cholangiocarcinoma, melanoma, CNS and GIST)	TERT mutations in DNA from Gliomas and Melamonas.	ddPCR for the detection of TERT mutations,Analysis using Bio-Rad Auto DG and QX200 Droplet reader with QX Manager Software Standard Edition V2.1. LG-PCR-SOP-15	ASH, BEX, CSB
Blood (EDTA anticoagulant), amniotic fluid, chorionic villus or solid tissue	Detection of aneupoidy of chromosomes 13, 18, 21, or sex chromosomes	QF-PCR analysis involving DNA extraction using Instagene or EZ1 followed by molecular analysis of DNA dosage for rapid aneuploidy using ABI 3500 or ABI 3730 gene scanner (LG-CF-SOP-24, LG-CF-SOP-30; LG-PP-SOP-1, LG-PP-SOP-15, LG-PP-SOP-17)	ASH & BEX (See techniques 1, 2, 4, 5, 6, 10)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal) (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
FFPE Tumour	Detection of methylation of the MLH1 gene (by DNA sequencing test)	Pyrosequencing involving DNA extraction followed by MLH1 methylation using Pyromark Q48 LG-PCR-SOP-11, LG-PCR-SOP-10, LG-NGS-SOP-5	ASH
Next Generation Sequence data files received from an external source within the NEYGLH	Detection of variant BRAF, KRAS and NRAS point mutations from DNA extraction from FFPE material (curls and slides)	Next Generation Sequencing – Data analysis and reporting only: Analysis using NEYGLH or MSI pipeline and variant interpretation and reporting including variant classification procedures. NGS Molecular Inversion Probes (MIPs). Assay based on multiplex PCR enrichment of 14* short (7 – 12bp) MNR for combined MSI, BRAF and N/KRAS status. LG-NGS-SOP-23	ASH, BEX, CSB
Blood plasma	Mutation testing of circulating tumour DNA - targeted mutation testing of the EGFR gene	Separation of blood plasma from whole blood, DNA extraction from blood plasma. Targeted EGFR mutation detection by real-time PCR using the Qiagen Rotagene Q and Therascreen Plasma RGQ PCR kit (LG-SO-SOP-24)	ASH & BEX (See techniques 3, 5 above)
Bone marrow, Blood	DNA extraction for the purposes of external Whole Genome Sequencing	Automated extraction using Chemagic and Chemagic 360i: (LG-SR-SOP-2)	BEX

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS/TISSUE	Cytogenetics examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	
Amniotic fluid, chorionic villus, solid tissue, blood (lithium heparin), bone marrow	Karyotype	Culture and karyotype analysis using G-banding LG-CF-SOP-3 and light microscope using SOPs: LG-CF-SOP-4, LG-CF-SOP-6, LG-PP-SOP-11, LG-PPSOP-4 (amniotic fluid) LG-CF-SOP-5, LG-CF-SOP-6, LG-PP-SOP-11, LG-PPSOP-4 (chorionic villus) Culture and karyotype analysis using G-banding LG-CF-SOP-3 and image analysis via automatic slide scanner /Cytovision using SOPs: LG-CF-SOP-7, LG-CF-SOP-6, LG-PP-SOP-5, LG-PP-SOP-12, LG-PP-SOP-4 (solid tissue) LG-CF-SOP-1, LG-CF-SOP-14, LG-PP-SOP-9, LG-PP-SOP-3, LG-PP-SOP-5, LG-PP-SOP-12,, LG-PP-SOP-2 (blood) LG-CF-SOP-2, LG-PP-SOP-5, LG-PP-SOP-12, LG-SO-SOP-6 (bone marrow)	ASH
Blood (lithium heparin anticoagulant)	Karyotype	Culture and karyotype analysis using G-banding and image analysis via automatic slide scanner /Cytovision LG-CF-SOP-1, LG-CF-SOP-3, LG-PP-SOP-3, LG-PP-SOP-5, LG-PP-SOP-12, LG-PP-SOP-2	ASH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS/TISSUE (cont'd)	Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Bone marrow	Karyotype	Culture and karyotype analysis using G-banding and image analysis via automatic slide scanner /Cytovision LG-CF-SOP-2, LG-CF-SOP-3, LG-PP-SOP-5, LG-PP-SOP-12, LG-SO-SOP-6	ASH
Illumina Bead Array GTC Files received from ISO 15189 accredited laboratory 9028	Interpretation of data to detect microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number in: Postnatal disorders, prenatal diagnosis, neoplastic genetics	SNP array analysis using Illumina BlueFuse Multi software and SOP LG-RD-SOP-18	ASH
Fixed cells/Formalin Fixed Paraffin Embedded tissue (FFPE) from: Peripheral Blood Bone Marrow Amniotic fluid CVS- Chronic villus samples Solid tissues Solid tumours Buccal smears	Detection of chromosomal aberrations loci changes including confirmation of array CGH findings and rearrangements in the diagnosis of haematological malignancy, bone marrow failure syndromes, constitutional disorders, solid tumours	Pre analytical preparation of tissues for Fluorescent in situ hybridisation procedures (FISH) using Hybrite, Water bath, hot-plate and SOPs: LG-CF-SOP-9 (FFPE slides) (fixed suspension samples) followed by:	BEX
Fixed cells/Formalin Fixed Paraffin Embedded tissue (FFPE) from: Peripheral Blood Bone Marrow Amniotic fluid CVS- Chronic villus samples Solid tissues Solid tumours Buccal smears (cont'd)	Break-apart probes Fusion product probes Single copy probes to detect gain or loss of a specific locus	Fluorescent in situ hybridization (FISH) analysis of metaphase and interphase cells using commercial (and including probe validation/verification) using Cyto-vision analysis system and Fluorescent microscopy as defined in SOP LG-SO-MISC-4 v1.16 in conjunction with SOPs LG-CF-SOP-10, LG-CF-SOP-9, LG-SO-SOP-14, LG-CF-SOP-12, LG-CF-SOP-11	BEX

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS/TISSUE (cont'd)	Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Peripheral Blood (in Lithium heparin)	DNA repair defects (Chromosome breakage)	Cytovision scanner. Measurement Principle – Cytogenetics analysis of SOP: LG-CF-SOP-25	ASH
END			