# **Schedule of Accreditation**

issued by

# **United Kingdom Accreditation Service**

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



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LS1 3EX

Accredited to ISO 15189:2022

## **Leeds Teaching Hospitals NHS Trust**

Issue No: 017 Issue date: 02 October 2025

Leeds General Infirmary

Old Medical School

Great George Street

Contact: Helen Pritchett

Tel: +44 (0)113 39 25697

E-Mail: h.pritchett@nhs.net

Website: https://www.leedsth.nhs.uk/a-z-of-services

Testing performed by the Organisation at the locations specified below

#### Locations covered by the organisation and their relevant activities

#### **Local Contact information:**

Contact information		Department
Wendy Boote	E-Mail: wendy.boote@nhs.net Tel: +44 (0) 113 206 67609	Cellular Pathology
James Steer	E-Mail: leedsth-tr.dna@nhs.net Tel: +44 (0)1132 065205	Genetics

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#### **Laboratory locations:**

Location details	Department	Activity	Location code
Address  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
Yorkshire and North East Genomic Laboratory Hub Central Lab Ashley Wing St James's University Hospital Leeds LS9 7TF United Kingdom	Genetics	Molecular and Cytogenetics testing	ASH

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### 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)

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#### **DETAIL OF ACCREDITATION**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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	<u>Diagnostic Non Gynae</u> <u>Cytopathology</u>	Sample preparation (Rotina 380 centrifuge, , Shandon cytospin 4):	SJUH
		CPATH-SOP-CYTO-2 Preparation of Non Gynae Samples	
		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)	SJUH
		CPATH-COSHH-10 Papanicolaou (automated using Jung Autostainer)	
		CPATH-COSHH-12 Rapid Romanowsky Stain	
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	CPATH-SOP-CYTO-8 Medical reporting of Non-Gynae cytology	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)    Histopathology	Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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		to identify or exclude morphological and cytological abnormalities for the purpose	examination:  Documented in house methods incorporating manufacturers'	
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	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	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 / 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):	BEX
		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	BEX
		Tissue processing:  CPATH-SOP-HP-26 Processing tissue using the Leica Peloris tissue processor (routine & big blocks & long process)	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 / organs (cont'd)	Histopathology (cont'd)		BEX
		Requiring Frozen Sections  CPATH-SOP-HP-18 Preparation of Split Skin Biopsies for Immunofluorescence	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological	Macroscopic and Microscopic examination:	
	abnormalities for the purpose of diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue / organs (cont'd)	Histopathology (cont'd)	Frozen Sections:	BEX
		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	
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	
Tissue	Histopathology - Identification of:	Automated: CPATH-SOP-HP-54HPSOP 657 Use of theAgilent Artisan Link Pro for Special stain techniques	BEX
	Acid and neutral mucins	ABPAS	
	Diastase resistance acidic and neutral mucins	ABPAS+D	
	Mucins, glycogen	PAS	
	Diastase resistance mucin	DPAS	
	Basement membranes, fungi	ExPAS	

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Examination activities in order to identify or exclude morphological and cytological	Macroscopic and Microscopic examination:	
	abnormalities for the purpose of diagnosis (cont'd)	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	
	Elastic/connective tissue	CPATH-SOP-HP-34 Elastic van gieson	

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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	Macroscopic and Microscopic examination:  Documented in house methods	
	of diagnosis (cont'd)	incorporating manufacturers' instructions where relevant:	
Tissue (cont'd)	Histopathology - Identification of (cont'd):	Manual special staining:	BEX
	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'	
Tissue (cont'd)	Histopathology - Identification of (cont'd):	instructions where relevant:  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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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	
	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	Macroscopic and Microscopic examination:	
	abnormalities for the purpose of diagnosis (cont'd)	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 (cont'd):	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	
	Marker of rejection in renal/liver transplants	C4D	

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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 (cont'd):	BEX
	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	
	B lymphocytes	CD79a	
	Ewings sarcoma	CD99	

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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 (cont'd):	BEX
	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	
	Gastrointestinal stromal tumour marker	C-KIT (CD117)	
	Cytomegalovirus infection	CMV	

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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 (cont'd):	BEX
	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	
	Glial cells benign and malignant	GFAP	
	Pituitary hormone	GH	
	Pancreatic tumour typing	Glucagon	

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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 (cont'd):	BEX
	Pancreatic tumour typing	Glucagon	
	Adenoma v HCC	Glutamine Synthetase	
	Liver adenoma/HCC	Glypican-3	
	Hepatitis B infected cells	НЕР В с	
	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	НМС	
	Marker for H pylori	HP	
	Marker for teratoma	HPL	
	Herpes simlex 1 infection	HSV 1	
	Brain tumours	IDH1	
	Lymphoma markers	IgA IgG IgM	
	IgG4 disease marker	IgG4	

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Tissue and cell blocks (cont'd)	Histopathology – identification of (cont'd):	instructions where relevant:  Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	BEX
	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	
	Epithelial marker	MNF	
	MUC4 in tumours	MUC4	
	Marker for rhabdomyosarcoma	MYOD 1	
	Marker for rhabdomyosarcoma	MYOGENIN	
	Neuronal marker	N52	

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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 (cont'd):	BEX
	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	
	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	

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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 (cont'd):	BEX
	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	
	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	

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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 (cont'd):	BEX
	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	
	<u>Histopathology</u>		
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

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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:	
	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	
		CPATH-SOP-MED-8 Reporting of small intestinal resection specimens	
		CPATH-SOP-MED-9 Reporting of Colorectal Cancer Specimens	

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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	Macroscopic and Microscopic examination:	
	abnormalities for the purpose of diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
	Histopathology – Morphological assessment and interpretation/diagnosis: (cont'd)	Using light microscopy and SOPs:	BEX
		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	
		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	

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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	Macroscopic and Microscopic examination:  Documented in house methods	
	of diagnosis (cont'd)	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 (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	
		CPATH-SOP-MED-23 Reporting of laryngectomy specimens for tumours	
Slides prepared in house as above (Neuropathology)		CPATH-SOP-MED-24 Reporting of Globes	
		CPATH-SOP-MED-25 Reporting the examination of orbital exenterations	

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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	Macroscopic and Microscopic examination:	
	abnormalities for the purpose of diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
	Histopathology – Morphological assessment and interpretation/diagnosis	Using light microscopy and SOPs:	
	(cont'd):	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)	
Slides prepared in house as above (Urology)		CPATH-SOP-MED-34 Prostatic biopsies, transurethral or open prosatic resections and radical prostatectomies	
		CPATH-SOP-MED-35 Adult renal parenchymal tumours	
Slides prepared in house as above (Urology)		CPATH-SOP-MED-36 Penile biopsies and resections	
		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	

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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:	
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	

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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	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	

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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	Macroscopic and Microscopic examination:  Documented in house methods	
	of diagnosis (cont'd)	incorporating manufacturers' instructions where relevant:	
	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:	SJUH
Tissue (Muscle)		Dystrophin 1 Dystrophin 2 Dystrophin 3 Alpha Sarcoglycan BetaSarcoglycan Gamma Sarcoglycan Delta Sarcoglycan Emerin Dysferlin Merosin Spectrin	
	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	

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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 /demonstration of:	Manual tinctorial Stain techniques for:	SJUH
Tissue (Surgical and MH muscle) (cont'd)	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

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Andrological examination activities for the purposes of clinical diagnosis		
Semen	Post vasectomy:	Based on 2016 Laboratory	SEA
	Detection of sperm	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	
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	
	рН	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)	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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))  3. Manual extraction of cfDNA from plasma with Qiagen QlAamp kit: (LG-SR-SOP-3))  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

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HUMAN TISSUE AND FLUIDS (cont'd)	examinations for the purpose	In house documented methods incorporating manufacturers' instructions where relevant	
	range of disorders (cont'd)	11.NGS Library preparation: (Sureselect – custom targeting and clinical exomelllumina , Sureselect Library Prep: LG- NGS-SOP-2	CSB BEX
		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	
		Next Generation Sequencing: sequencing and dosage analysis	Next Generation Sequencing: sequencing and dosage analysis:
		12. NovaSeq 6000	
		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

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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)
А, В	Variant Confirmation	LG-RD-SOP-33	

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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	,
Blood (EDTA anticoagulant), amniotic fluid, chorionic villus or solid tissue	Detection of aneupoidy of chromosomes 13, 18, 21	QF-PCR analysis involving DNA extraction 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)
Paraffin embedded Tissue	Human identity testing for detection of specimen mix up	Microsatellite PCR test to identify DNA variation at multiple genomic loci known to be unique to individuals using Thermal cycler, ABI 3500XL or ABI 3730 genetic analyser, LG-SO-SOP-3	ASH & BEX (See techniques 4, 5, 6, 10 above)

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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	
Peripheral Blood	Detection of varients of DPYP gene indicating vulnerability to 5FU toxicity. Eleucie DPYD detection from the following alleles: c.1679T>G c.1905+1G>A c.2846A>T c.483+18G>A c.1129-5923C>G c.1236G>A.	Genotyping: Yourgene DPYD kit and analysis on using ABI 3500XL or ABI 3730 genetic analyser LG-IC-SOP-15	ASH & BEX (See techniques 4, 5, 6, 7, 9 above)
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

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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	
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
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:	ASH
		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)	

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Materials/Products tested	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		
Amniotic fluid, chorionic villus, solid tissue, blood (lithium heparin), bone marrow (cont'd)	Karyotype (cont'd)	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-12,, LG-PP-SOP-2	ASH	
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, hotplate and SOPs: LG-CF-SOP-9 (FFPE slides) (fixed suspension samples) followed by:	BEX	

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### Testing performed by the Organisation at the locations specified

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		
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 Cytovision 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	
END				

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