


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8123</p> <p>Accredited to ISO 15189:2012</p>	<p>Royal Devon University Healthcare NHS Foundation Trust</p> <p>Issue No: 012 Issue date: 05 June 2024</p>	
	<p>Cellular Pathology Royal Devon & Exeter Hospital Church Lane Exeter Devon EX2 5AD United Kingdom</p>	<p>Contact: Leah Riley Tel: +44 (0)1392 402964 Fax: +44 (0)1392 406402 E-Mail: leah.riley1@nhs.net Website: www.exeterlaboratory.com/cellular-pathology/</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
<p>Address</p> <p>Cellular Pathology Department Royal Devon & Exeter Hospital (Wonford) Church Lane Exeter Devon EX2 5AD United Kingdom</p>	<p>Local contact</p> <p>Carina Hume Tel: +44 (0)1392 402964 Fax: +44 (0)1392 406402 Email: carina.hume@nhs.net</p>	<p>Routine Histopathology Special Stains Immunohistochemistry Immunofluorescence Diagnostic Cytology (Non-Gynae)</p> <p>Mohs Clinic Post-Vasectomy Semen Analysis Molecular Genetics testing</p>	A

Site activities performed away from the locations listed above:

Location details		Activity	Location code
<p>Mortuary Royal Devon & Exeter Hospital (Wonford) Church Lane Exeter Devon EX2 5AD United Kingdom</p>		<p>Mortuary Services (body receipt, storage and release)</p>	B
<p>Histology Archives Royal Devon & Exeter Hospital (Heavitree) Gladstone Road Exeter Devon EX1 2ED United Kingdom</p>		<p>Histology Archives Storage of records only Moh's clinic</p>	C



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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	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Tissue: biopsy, excision, resection and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Histology cut up– HISOP058 Monmouth downdraft benches HISOP118	A
	<u>X-Ray analysis of specimens</u>	<u>Faxitron – HISOP 104</u>	A
	Macro Imaging for specimen recording	Pathlite Macro Imaging system – HISOP 112	A
		Tissue processing Manual procedures or using VIP or excelsior Tissue processor (HISOP108, HISOP003, HISOP082, EXTDOC018, HISOP004, EXTDOC007, EXTDOC025, EXTDOC036)	A
		Tissue Embedding Using Leica, Sakura and Histostar embedding stations (HISOP016, EXTDOC090, EXTDOC092)	A
Formalin Fixed Paraffin wax blocks of processed tissue.		Tissue Sectioning Using Leica Microtomes, (HISOP030, HISOP028, EXTDOC028, EXTDOC031,)	A
Skin in Michel's Medium Renal tissue in saline Tissue for frozen sections		Cryotomy Intra-Operative Frozen sections Using Shandon Cryostat (HISOP021, HISOP023, HISOP HISOP014, EXTDOC013)	A



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Tissue for frozen sections - MOHS	Histopathological examination of common skin malignancies to provide assessment of the circumpheral, peripheral and deep margins	Cryotomy Intra-Operative Frozen sections Using Cryostar NX70 Cryostat HISOP147 Leica ST4020 slide stainer HISOP116 HISOP116 Preparation of slides for MOHs Surgery	C
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Routine morphological staining For the detection of: Basophilic and eosinophilic structures	Routine morphological staining Leica Autostainer (HistoCore spectra using Haematoxylin and Eosin (H & E) stains – HISOP143, EXTDOC020& 026 Frozen Section Staining (Handstained H&E) HISOPSS037	A
Frozen Sections	Special stains for the detection of: Lipids	Documented in-house procedures for manual special stains Fat Stains on Frozen Sections (Oil Red O) HISOPSS019	A



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FFPE slides	Acid Mucopolysaccharides	Alcian Blue HISOPSS001	
	Acid and Neutral Mucopolysaccharides	Alcian Blue/PAS HISOPSS002	
	Amyloid	Congo Red HISOPSS032	
	Elastic fibres and connective tissue	Elastic/Haematoxylin Van Gieson (EVG/HVG) HISOPSS017 & 012	
	Helicobacter/Microorganisms haematopoetic cells	Giemsa HISOPSS006	
	Gram positive and Negative microorganisms	Gram HISOPSS009	
	Basophilic and eosinophilic structures	Haematoxylin & Eosin (H&E) HISOPSS037	
	Connective tissue and fibrin	Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) HISOPSS014	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides	Special stains for the detection of:	Documented in-house procedures for manual special stains	A
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana HISOPSS015	
	Connective tissue	Masson's Trichrome HISOPSS016	
	Neutral Mucopolysaccharides, glycogen and fungus	Periodic Acid Schiff (PAS) & Diastase PAS (D/PAS) HISOPSS021	
	Haemosiderin and ferric iron	Perl's Prussian Blue HISOPSS022	
	Reticulin fibres	Reticulin HISOPSS008	
	Mast cells	Toluidine Blue HISOPSS026	
	Tubercle bacilli	Ziehl Nielsen (ZN) HISOPSS031	
	Calcium	Von Kossa HISOPSS028	
	Copper assoc Protein and Hepatitis B	Orcein HISOPSS020	
	Fungi (Aspergillus) and Pneumocystis	Grocott HISOPSS011	
	Helicobacter Pylori	Cresyl Fast Violet HISOPSS005	
	Leprosy	Wade Fite HISOPSS029	
	Plasma Cells e.g. BMT, parasites/bacteria	Giemsa HISOPSS006	
	Carcinoid Tumour	Grimelius HISOPSS010	
	Proteoglycans, hyaluronic acid and acid mucins	Colloidal Iron HISOPSS038	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides	Special stains for the detection of: Spirochetes Basement Membranes	Documented in-house procedures for manual special stains Warthin & Starry HISOPSS035 Jones' Methenamine Silver HISOPSS013	A
frozen sections	IDENTIFICATION OF: Antigens and antibodies in various auto-immune skin diseases Reacts with C3c fragment, native C3 and C3b Specific for alpha chains of human IgA Specific for gamma chains of human IgG Specific for mu chains of human IgM Reacts with C1a fragment, native C1 and C1a Specific for kappa chains Specific for lambda Fibrinogen (Skin only) Specific for fibrinogen (Skin only)	Immunofluorescence technique Documented in-house procedures in conjunction with manufacturer's instructions for Fluorescent Microscope SOPS HISOP025, HISOP026, EXTDOC048, EXTDOC074 C3c complement/FITC IgA/FITC IgG/FITC IgM/FITC C1a/FITC Kappa/FITC Lambda/FITC Fibrinogen/FITC	A



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Macrophages, neutrophils, A1AT accumulation	Alpha 1 Antitrypsin	
	Anaplastic lymphoma kinase receptor (CD246)	ALK- 1	
	Embryonic cell in normal tissues and germ tumours	Alpha Fetoprotein	
	HGPIN, prostate adenocarcinoma	AMACR, Prostate combo, PROSTEIN	
	Amyloid	Amyloid A – MC1	
	Androgen Receptor eg breast tumours	AR	
	Alpha Smooth Muscle Actin	ASMA -	
	Diffuse lymphoproliferative disease and neoplastic cells of follicular lymphomas.	BCL2, BCL6 ,BCL2(E17)	
	Epithelial cell types	Ber EP4, AE1/3	
	T Helper Cells	CD4	
	Ovarian cancer	CA 125	
	Parafollicular cells in thyroid and medullary thyroid carcinomas	Calcitonin	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	Calretinin	
	Smooth Muscle Cells	Caldesmon h-CD	
	Smooth Muscle Cells	Calponin	
	Glandular cells	CAM 5.2	
	T cells	CD3	
	T cells (helper+mature)	CD4	
	Mature T cells, T cell lymphomas	CD5	
	Mature B cells, follicular dendritic cells, CALLA	CD8	
	Granulocytes Reed-Sternberg cells	CD10	
	T Cell, NK cells	CD7	
	Reed-Sternberg and lymphomas	CD15	
	Mature B cells, Follicular dendritic cells	CD20	
	B cells, some T cells	CD21	
	B Cells, Reed-Sternberg cells	CD23	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Reed-Sternberg cells and ALCL	CD30	
	Haematopoietic cells, vascular endothelium	CD31	
	T cells and some soft tissue	CD34	
	Plasma cells and activated T-cells	CD38	
	Reactive urothelium and Lymphocytes	CD44	
	Leukocyte common antigen	CD45	
	Neuroendocrine cells	CD56	
	Hodgkin's and T cell marker	CD57	
	Macrophages	CD68 (KPI)	
	B lymphocytes	CD79 alpha, PAX-5, PAX-8	
	Ewings sarcoma and thymic tumour marker	CD99	
	GIST	CD117/CKIT	
	Plasma cells	CD138	
	Adenocarcinoma and carcinoid (intestinal epithelium)	CDX2	
	Megakaryocytes	CD61	



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FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	CEA glycoproteins in adenocarcinoma	CEA-m / CEA-p	
	Tissues of neuroendocrine origin	Chromogranin	
	CMV	CMV	
	Expressed in variety tumours Eg Mantle cell lymphoma	Cyclin D1	
	Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma	Cytokeratin (HMWCK/34βE12)	
	Epithelial tissue from glandular to stratified squamous	Cytokeratin (MNF116)	
	Stratified squamous epithelium, basal cells, mesotheliomas	Cytokeratin 5/6	
	Normal and neoplastic epithelia	Cytokeratin 7	
	Epithelial cells	Cytokeratin 14	
	Identification of specific tumour cells	Cytokeratin 19	
	Malignant transformation of squamous cells	EGFR	
	Adenocarcinomas, columnar epithelial cells	Cytokeratin 20	



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FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Striated and smooth muscle cells	Desmin	
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin	
	Normal and neoplastic epithelium	EMA	
	V.W factor in endothelial cells	Factor VIII	
	Normal and neoplastic epithelium	Gastrin	
	Cytotoxic T lymphocytes and NK cells for classification of T/NK-cell lymphomas	Granzyme B-GrB	
	Mesothelial Cells	HBME1	
	Placental trophoblasts	HCG	
	Melanoma, melanocyte differentiation	HMB45	
	Sex chord stromal tumours	Inhibin	
	B cells and plasma cells	Kappa K(pcp)	
	Proliferating Cells	Ki 67 (MIB-1)	
	B cells and plasma cells	Lambda L(pcp)	
	Epstein-Barr Virus	LMP	
	Melanoma marker	Melan-A	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Neutrophil granulocytes, monocytes	Myeloperoxidase	
	Colon carcinomas	MLH1, MSH2	
	Granulocytes, monocytes and histiocytes	Lysozyme	
	Breast ductal carcinoma	Mammaglobin	
	Rhabdomyosarcoma and Wilm's tumour	Myogenin	
	Neural tissue	Neurofibrillary protein NFP	
	Peripheral nerves, neuroendocrine tumours	NSE	
	Nuclei of cells containing a high level of oestrogen	Oestrogen Receptors	
	Neoplastic cells in epithelium	P53	
	Squamous epithelium	P63	
	Glandular epithelium	PAP	
	Neurones, melanocytes, neuroendocrine cells	PGP 9.5	
	Germ cell tumours	PLAP	
	Mantle cell lymphoma	SOX-11	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Nuclei of cells showing expression of Progesterone	Progesterone Receptors	
	Lung Carcinoma	P40	
	Pro/pre/Mature B cells	PAX 5 (BSAP)	
	Prostate secretory and ductal epithelium	PSA-P PSA-M PSMA	
	Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma	S100	
	Smooth muscle cells, myoepithelial cells	Smooth Muscle Myosin (SMM)	
	Neuroendocrine cells	Synaptophysin	
	Lining blood vessels, lymphatic vessels, mesothelial cells	Thrombomodulin	
	Thyroglobulin containing cells	Thyroglobulin	
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1	
	Cells of mesenchymal origin	Vimentin	
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	WT-1	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	
	Renal rejection markers	C4d, CMV	
	Langerhans cells	CD1a	
	Subtyping germ cell tumours and molar pregnancies	CD61	
	Lymphoid cells	D2-40	
	Collagen V	COL	
	Identification of HPV associated neoplastic lesions, cervix and oral cavity	F13A	
	Breast carcinoma	GCDFP, GATA3	
	Malignant prostatic gland/breast glands and SCC	GFAP	
	Glycogen	GLYC	
	H.pylori	HP	
	Herpes Simplex Virus	HSV	
	Hepatocyte specific Antigen	HSA	
	Thyroid epithelium – normal/neoplastic	IgA, IgG, IgM, IgD	
	Primary adenocarcinoma lung/thyroid epithelium normal/neoplastic	IgG4	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	
	Mismatch repair genes and proteins	MSH6, PMS2	
	Mitochondria	MIT	
	Gastrointestinal stromal tumours, mast cells and their disorders	MOC-31	
	Programmed death marker/ligand	PD1 / PDL-1	
	c-Myc regulator gene	C-MYC	
	B cells normal/neoplastic	MUM-1	
	B cells/ B Cell derived lymphomas	OCT 2, OCT 3/4	
	COS-1 and WOP cells transfected with CD68 cDNA	PG-M1	
	Renal Cell carcinoma	RCC	
	Precursor B/T cell ALL and thymoma	TdT	
	T-cell diseases	TIA-1	



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FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	
	Vascular endothelial cells (homeostasis and angiogenesis)	ERG (Erythrocyte transformation specific ETS related gene)	
	Desmoid tumours, colorectal cancer and colon adenoma	B-CAT	
	Differential diagnosis T-cell lymphoma vs. B-cell lymphoma	CD2	
	Herpes Simplex Virus	HSV	
	Desmoplastic and spindle cell melanomas	SOX 10	
	Colorectal carcinoma	SATB2	
FFPE	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC015)	
	Spindle cell tumours	STAT6	
	Synovial sarcoma	TLE-1	
	Pancreatic Adenocarcinoma	MUC4	
	Melanoma	PRAME	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides	Immunohistochemistry to detect the following:	ROCHE Ventana ULTRA HISOPIHC016-Routine Ultra operation	
	ALK Lung	ALK-1	
	HPV driven tumour eg Squamous cell carcinoma	P16	
	Mast cells	DOG-1	
	Pan melanoma Cocktail	PMC	
	B lymphocytes	PAX-8	
	Renal rejection marker	SV-40 (BKV)	
	EBV	EBER ISH	
	Range of B cell Lymphocytes	BOB-1	
	PD-L1 in tumour cells	PD-L1 Clone SP142	
		HISOPIHC019; HISOPIHC018; HISOPIHC017; HISOPIHCPDL1	
	<u>Andrology examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Semen (Post Vasectomy)	Detection of spermatozoa	Documented in house manual method CYNG14, CYSA09, CY01, CYNG24, CYNG27 for examination of direct wet preparation and centrifuged pellet based on 2016 Laboratory guidelines for postvasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons	A
		Boeco U320 Centrifuge CYNG09 CYNG22	



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HUMAN BODY FLUIDS	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Fine needle aspirates – sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples.	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Screening and Reporting CYNG02, CYNG03, CYNG04, CYNG05, CYNG06, CYNG07, CYNG08, CYNG09, CYNG10, CYNG11, CYNG11a, CYNG15, CYNG24, CYNG26, Cell Block Preparation CYNG20, Cytofoam Cell Block Preparation CYNG29 Preparation of LBC bronchial brushing specimens CYNGLBC01 Screening and reporting of non gynae cytology slides CYNG01	A
	Demonstration of: Cells (nuclei and cytoplasm) and micro organisms	Papanicolaou stain for Non-Gynae Specimens CYNG24 May-Grunwald & Giemsa stain for air dried slides CYNG08 Diff-Quick Staining Technique CYNG18 Papanicolaou staining on the Leica autostainer/ coverslipper CYLBC03	A



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

Royal Devon University Healthcare NHS Foundation Trust

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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
Synovial Aspirate (Synovial Fluid for Cytology)	Detection and identification of Crystals	Preparation and examination of joint fluids -CYNG 19 using polarising microscopy	A
Non-gynae slide preparations (respiratory samples, oesophageal brushings and paucicellular urine samples)	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Non-Gynae-cytology preparation, Boeco U320 Centrifuge CYNG09, CYNG22 Hologic T2000 Processor CYLBC01 Preparation of urine specimens CYNG06	A
Slides prepared in-house from sample types listed above	<u>Molecular Genetics examination activities for the purpose of clinical diagnosis</u>	Interpretive/diagnostic microscopy (HISOP065, HISOP095)	A
FFPE slides Cytology fluid samples FFPE scrolls	<u>BRAF</u> <u>EGFR</u> <u>KRAS</u>	Biocartis Idylla HISOPPCR001, HISOPPCR003, HISOPPCR002	A
FFPE slides FFPE scrolls	<u>NRAS/BRAF</u> <u>Idylla Genefusion assay</u>		
END			