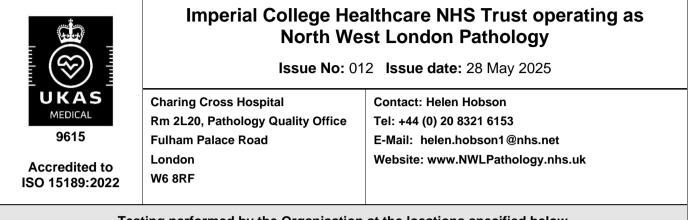
Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address	Local contact		
Charing Cross Hospital Fulham Palace Road Hammersmith London W6 8RF	Tyrone Dickson	Histopathology Electron Microscopy Diagnostic Cytology	X-Histo X-EM
Hammersmith Hospital Du Cane Road East Acton London W12 0HS	Tyrone Dickson	Frozen section histology Molecular Diagnostics/MRD Immunophenotyping Cytogenetics	H-Histo H-MOL H-Immunop H-CytoG

Site activities performed away from the locations listed above:

Location details	Activity	Location code
MOHS Chelsea and Westminster	MOHS, frozen section histology	C-MOHS
Endobronchial ultrasound (EBUS) Clinic SMH	FNA material/slide preparation & cellularity assessment	M-FNA



ISO 15189:2022

Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Imperial College Healthcare NHS Trust operating as North West London Pathology

Issue No: 012 Issue date: 28 May 2025

Testing performed by the Organisation at the locations specified

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	<u>Histopathological</u> examinations for the purpose of clinical diagnosis		
Tissues: biopsy, excision and resection.	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
		Tissue dissection:	
		Amputation - CEL-CP-033-NWL	X-Histo
		Bladder - CEL-CP-042-NWL	X-Histo
		Breast - CEL-CP-031-NWL	X-Histo
		Central and peripheral nervous system tumours - CEL-CP-040-NWL	X-Histo
		Head & Neck - CEL-CP-028-NWL	X-Histo
		Kidney - CEL-CP-043-NWL	X-Histo
		Osteoarticular - CEL-CP-034-NWL	X-Histo
		Penis - CEL-CP-044-NWL	X-Histo
		Prostate - CEL-CP-045-NWL	X-Histo
		Salivary gland - CEL-CP-029-NWL	X-Histo
		Skin - CEL-CP-027-NWL	X-Histo
		Testis - CEL-CP-046-NWL	X-Histo
		Gynaecological SOP - CEL-CP-035-NWL	X-Histo
		Respiratory Specimens cut-up SOP - CEL-CP-037-NWL	X-Histo

UKAS MEDICAL 9615	Schedule of Accreditation issued by United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK
	Imperial College Healthcare NHS Trust operating as North West London Pathology
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	Testing performed by the Organisation at the locations specified

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
Tissues: biopsy, excision and resection (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
		Haematopathology cut-up SOP - CEL- CP-047-NWL	X-Histo
		Hepatopancreaticobiliary SOP - CEL-CP- 051-NWL	X-Histo
		Kidney Transplant Resection - CEL-CP- 057-NWL	X-Histo
		Pancreas Transplant Resection - CEL- CP-058-NWL	X-Histo
		Thyroid and Parathyroid - CEL-CP-061- NWL	X-Histo
		Temporal Artery Samples - CEL-CP-063- NWL	X-Histo
		Upper G.I Cancer -CEL-CP-012-NWL	X-Histo
		Colorectal Specimens - CEL-CP-019- NWL	X-Histo
		Liver SOP - CEL-CP-020-NWL	X-Histo
		Placenta SOP - CEL-CP-022-NWL	X-Histo
		Bowel Cancer Screening Programme (BCSP) Specimen Handling - CEL-CP- 065-NWL	X-Histo
		Gallbladder and Appendices - CEL-CP- 066-NWL	X-Histo
		Specimen transfer SOP CEL-LP-303- NWL	X-Histo

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UKAS MEDICAL 9615 Accredited to	Imperial College Healthcare NHS Trust operating as North West London Pathology Issue No: 012 Issue date: 28 May 2025		
ISO 15189:2022			
	Testing performed by the Organi	sation at the locations specified	
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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
Tissues: biopsy, excision and resection (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection	

processing, embedding, staining and

Decalcification - CEL-LP-240-NWL

Leica cryostat CM1950 Preparing Tissue

Thermo Cryostar NX50 Preparing Tissue

for Frozen Section, Cryotomy and Diagnosis - CEL-LP-328-NWL

for Frozen Section, Cryotomy and Diagnosis - CEL-LP-328-NWL

Leica cryostat CM1950 CELP-LP-086-NWL

reporting:

Decalcification:

Frozen sections:

abnormalities for the

purpose of diagnosis

Examination of tissues in order to identify or exclude morphological

and cytological abnormalities for the purpose of diagnosis

(cont'd)

Fresh tissue

X-Histo

H-Histo

X-Histo

C-MOHS

UKAS MEDICAL 9615 Accredited to ISO 15189:2022	United King 2 Pine Trees, Chertse Imperial Colleg Nor	edule of Accreditation issued by gdom Accreditation Servic y Lane, Staines-upon-Thames, TW18 3 ge Healthcare NHS Trust operating a th West London Pathology p: 012 Issue date: 28 May 2025	3HR, UK
	Testing performed by the Organis	ation at the locations specified	
Materials/Products tested	Type of test/Properties measured/Range of	Standard specifications/ Equipment/Techniques used	Location Code

	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
Formalin fixed tissue processed to paraffin wax (FFPE), Fresh tissue, Frozen Tissue, Cell blocks	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	<u>Tissue processing</u> - Leica Peloris 3 CEL- LP-720-NWL	X-Histo
		Embedding -: HistoCore Arcadia	
		Embedding Protocol - CEL-LP-712-NWL	X-Histo
		<u>Microtomy</u> - Leica RM2255 Leica Histocore Autocut microtome	
		Microtomy Procedure - CEL-LP-718-NWL	X-Histo
		<u>Automated staining and coverslipping</u> - Leica ST5020 (autostainer), Leica CV5030 (coverslipper):, <u>Autostainer and Coverslipper (CEL-LP- 736-NWL)</u>	
		<u>Automated routine staining -</u> Ventana HE 600	
		Ventana HE 600 System - CEL-LP-732- NWL	X-Histo

	United Kir 2 Pine Trees, Cherts Imperial Colle	edule of Accreditation issued by agdom Accreditation Servic ey Lane, Staines-upon-Thames, TW18 ege Healthcare NHS Trust operating rth West London Pathology	3HR, UK
9615 Accredited to ISO 15189:2022	Issue No: 012 Issue date: 28 May 2025		
100 10100.2022	Testing performed by the Organi	sation at the locations specified	
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)	Histopathological examinations for the	In-house documented methods for macroscopic and microscopic	

HUMAN BODY TISSUE AND FLUIDS (cont'd) Histopathological examinations for the purpose of clinical diagnosis (cont'd) In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections. Special staining of Histopathology examinations to assist in detection of clinical abnormalities: In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections. Special staining of Histopathology examinations to assist in detection of clinical abnormalities: In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: In house preparations of to paraffin wax (FFPE) tissue sections. Special staining of Histopathology examinations to assist in detection of clinical abnormalities: In-house documented methods for macroscopic examination scientific Linistat Linear Stain - CEL- LP-064-NWL Acid mucins Acid and neutral mucins Acid and neutral mucins Alcian Blue - CEL-LP-064-NWL - CEL-LP-445-NWL Venost reporting - CEL- LP	Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections. Histopathology examinations to assist in abnormalities: Automated routine staining - Thermo Scientific Linistat Linear Stainer: Mohs - CEL-LP-459-C C-MOHS Manual techniques: X-Histo Acid mucins Alcian Blue - CEL-LP-064-NWL Acid and neutral mucins Alcian Blue Diastase Periodic Acid Schiff - CEL-LP-445-NWL Collagen/mallory bodies/giant mitochondria Chromotrope Aniline Blue Stain - CEL- LP-069-NWL Elastic fibres & connective tissue Elastic Picro Sirius - CEL-LP-378-NWL Haematopoietic cells Giernsa Stain - CEL-LP-383-NWL Fibrin/connective tissue/muscle Haematoxylin Van Gieson Stain - CEL- LP-082-NWL Haematoxylin Van Gieson Stain - CEL- LP-082-NWL Haematoxylin Van Gieson Stain - CEL- LP-082-NWL Helicobacter Pylori Modified Giernsa Stain - CEL-LP-206- NWL		examinations for the purpose of clinical	macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and	
Scientific Linistat Linear Stainer:C-MOHSMohs - CEL-LP-459-CC-MOHSManual techniques:X-HistoAcid mucinsAlcian Blue - CEL-LP-064-NWLAcid and neutral mucinsAlcian Blue Diastase Periodic Acid Schiff - CEL-LP-445-NWLCollagen/mallory bodies/giant mitochondriaChromotrope Aniline Blue Stain - CEL- LP-069-NWLElastic fibres & connective tissueElastic Picro Sirius - CEL-LP-378-NWLGram +/- organismsGram Stain - CEL-LP-383-NWLFibrin/connective tissue/muscleHaematoxylin Van Gieson Stain - CEL- LP-082-NWLArgentaffin/melaninMasson Fontana Stain - CEL-LP-206- NWLHelicobacter PyloriModified Giemsa Stain - CEL-LP-556-	10% Neutral Buffered Formalin fixed tissue processed to paraffin wax	Histopathology examinations to assist in detection of clinical		
Manual techniques:X-HistoAcid mucinsAlcian Blue - CEL-LP-064-NWLAcid and neutral mucinsAlcian Blue Diastase Periodic Acid Schiff - CEL-LP-445-NWLCollagen/mallory bodies/giant mitochondriaChromotrope Aniline Blue Stain - CEL- LP-069-NWLElastic fibres & connective tissueElastic Picro Sirius - CEL-LP-378-NWLHaematopoietic cellsGiemsa Stain CEL-LP-383-NWLGram +/- organismsGram Stain - CEL-LP-077-NWLFibrin/connective tissue/muscleHaematoxylin Van Gieson Stain - CEL- LP-082-NWLArgentaffin/melaninMasson Fontana Stain - CEL-LP-206- NWLHelicobacter PyloriModified Giemsa Stain - CEL-LP-556-				
Acid mucinsAlcian Blue - CEL-LP-064-NWLAcid and neutral mucinsAlcian Blue Diastase Periodic Acid Schiff - CEL-LP-445-NWLCollagen/mallory bodies/giant mitochondriaChromotrope Aniline Blue Stain - CEL- LP-069-NWLElastic fibres & connective tissueElastic Picro Sirius - CEL-LP-378-NWLHaematopoietic cellsGiemsa Stain CEL-LP-383-NWLGram +/- organismsGram Stain - CEL-LP-077-NWLFibrin/connective tissue/muscleHaematoxylin Van Gieson Stain - CEL- LP-082-NWLArgentaffin/melaninMasson Fontana Stain - CEL-LP-206- NWLHelicobacter PyloriModified Giemsa Stain - CEL-LP-556-			Mohs - CEL-LP-459-C	C-MOHS
Acid and neutral mucinsAlcian Blue Diastase Periodic Acid Schiff - CEL-LP-445-NWLCollagen/mallory bodies/giant mitochondriaChromotrope Aniline Blue Stain - CEL- LP-069-NWLElastic fibres & connective tissueElastic Picro Sirius - CEL-LP-378-NWLHaematopoietic cellsGiemsa Stain CEL-LP-383-NWLGram +/- organismsGram Stain - CEL-LP-077-NWLFibrin/connective tissue/muscleHaematoxylin Van Gieson Stain - CEL- LP-082-NWLArgentaffin/melaninMasson Fontana Stain - CEL-LP-206- NWLHelicobacter PyloriModified Giemsa Stain - CEL-LP-556-			Manual techniques:	X-Histo
Cellagen/mallory bodies/giant mitochondria- CEL-LP-445-NWLCollagen/mallory bodies/giant mitochondriaChromotrope Aniline Blue Stain - CEL- LP-069-NWLElastic fibres & connective tissueElastic Picro Sirius - CEL-LP-378-NWLHaematopoietic cellsGiemsa Stain CEL-LP-383-NWLGram +/- organismsGram Stain - CEL-LP-077-NWLFibrin/connective tissue/muscleHaematoxylin Van Gieson Stain - CEL- LP-082-NWLArgentaffin/melaninMasson Fontana Stain - CEL-LP-206- NWLHelicobacter PyloriModified Giemsa Stain - CEL-LP-556-		Acid mucins	Alcian Blue - CEL-LP-064-NWL	
bodies/giant mitochondriaLP-069-NWLElastic fibres & connective tissueElastic Picro Sirius - CEL-LP-378-NWLHaematopoietic cellsGiemsa Stain CEL-LP-383-NWLGram +/- organismsGram Stain - CEL-LP-077-NWLFibrin/connective tissue/muscleHaematoxylin Van Gieson Stain - CEL- LP-082-NWLArgentaffin/melaninMasson Fontana Stain - CEL-LP-206- NWLHelicobacter PyloriModified Giemsa Stain - CEL-LP-556-		Acid and neutral mucins		
connective tissueGiemsa Stain CEL-LP-383-NWLHaematopoietic cellsGiemsa Stain CEL-LP-077-NWLGram +/- organismsGram Stain - CEL-LP-077-NWLFibrin/connective tissue/muscleHaematoxylin Van Gieson Stain - CEL- LP-082-NWLArgentaffin/melaninMasson Fontana Stain - CEL-LP-206- NWLHelicobacter PyloriModified Giemsa Stain - CEL-LP-556-		bodies/giant		
Gram +/- organismsGram Stain - CEL-LP-077-NWLFibrin/connective tissue/muscleHaematoxylin Van Gieson Stain - CEL- LP-082-NWLArgentaffin/melaninMasson Fontana Stain - CEL-LP-206- NWLHelicobacter PyloriModified Giemsa Stain - CEL-LP-556-			Elastic Picro Sirius - CEL-LP-378-NWL	
Fibrin/connective Haematoxylin Van Gieson Stain - CEL- LP-082-NWL LP-082-NWL Argentaffin/melanin Masson Fontana Stain - CEL-LP-206- Helicobacter Pylori Modified Giemsa Stain - CEL-LP-556-		Haematopoietic cells	Giemsa Stain CEL-LP-383-NWL	
tissue/muscle LP-082-NWL Argentaffin/melanin Masson Fontana Stain - CEL-LP-206- Helicobacter Pylori Modified Giemsa Stain - CEL-LP-556-		Gram +/- organisms	Gram Stain - CEL-LP-077-NWL	
NWL Helicobacter Pylori Modified Giemsa Stain - CEL-LP-556-				
		Argentaffin/melanin		
		Helicobacter Pylori		

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections. Fresh tissue.	Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)	<u>Manual techniques (cont'd):</u>		
	Neutral mucins/polysaccharides/f ungi/basement membranes/glycogen	Periodic Acid Schiff +/- Diastase Stain - CEL-LP-377-NWL		
	Haemosiderin/Iron	Perls Stain - CEL-LP-053-NWL		
	Mast cell granules	Toluidine Blue - CEL-LP-409-NWL		
	Calcium salts	Von Kossa - CEL-LP-231-NWL		
	Mycobacterium leprae	Wade Fite - CEL-LP-230-NWL		

Mycobacterium spp. including tuberculosis

Ziehl Neelson - CEL-LP-413-NWL

X-Histo

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	Testing performed by the Organis	ation at the locations specified	
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)	Histopathological examinations for the		

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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosi	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
		Sakura Tissue-Tek Film Automated Coverslipper. SOP: use and maintenance of Sakura Automated Coverlipping Machine - CEL-LP-114-NWL	X-Histo
		Automated special staining – Dako Artisan Link Pro - Artisan Staining System SOP, CEL-LP-739-NWL:	X-Histo
	Amyloid	Congo Red	
	Basement Membranes	Jones Hexamine Silver	
	Fungi	Grocott Methanamine Silver	
	Fibrin / Connectie Tissue / Muscle	Masson Trichrome	
	Hepatitis B surface antigen/copper associated protein.	Orcein	
	Reticulin Fibres	Reticulin	
	Spirochetes / Helicobacter	Warthin and Starry	

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ISO 15189:2022	Tooting portormed by the Organi	·			
	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 TISSUE AND FLUIDS (cont'd)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)				
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Manual Direct Skin Immunofluorescence: CEL -LP-298-NWL - IF: Receipt, freezing and Slides preparation and CEL-LP-356- NWL - Immunofluorecence Staining Using antibodies for:	X-Histo		
Skin frozen sections	Bullous diseases, pemphigoid, LE - C3c complement	СЗс	X-Histo		
	Bullous diseases, pemphigoid, LE - Fibrinogen	Fibrinogen	X-Histo		
	Bullous diseases, pemphigoid, LE - IgA alpha chain	IgA	X-Histo		
	Bullous diseases, pemphigoid, LE - IgG gamma chain	IgG	X-Histo		
	Bullous diseases, pemphigoid, LE - IgM mu chain	IgM	X-Histo		

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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)	<u>Histopathological</u> <u>examinations for the</u> <u>purpose of clinical</u> <u>diagnosis (cont'd)</u>		
In house preparations of frozen tissue sections	Identification of antigens at a subcellular level by means of fluorescent antibodies	Manual immunofluorescence:	
		Renal IF Staining: CEL -LP-298-NWL - IF: Receipt, freezing and Slides preparation CEL-LP-356-NWL - Immunofluorecence Staining Using antibodies for:	X-Histo
	C1q complement	C1q	
	C3c complement	C3c	
	IgA alpha chain	IgA	
	IgG gamma chain	IgG	
	IgM mu chain	IgM	
	Light chain deposition	Карра	
	Light chain deposition	Lambda	
		Automated immunocytochemistry - Bond III:	X-Histo
		Automated Immunocytochemistry for the Bond - CEL-LP-357-H	
		Using antibodies for:	
	Fetal liver cells, liver disease	a-fetoprotein	
	Anaplastic large cell lymphoma	ALK-1	

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		

In-house documented methods for

examination incorporating manufacturer's

instructions where relevant for dissection,

Automated immunocytochemistry - Bond

Automated Immunocytochemistry for the

processing, embedding, staining and

macroscopic and microscopic

Bond - CEL-LP-357-H

Using antibodies for:

Androgen receptor

bcl-1/Cyclin D1

reporting:

Amyloid A

III:

	B and T cells in the mantle and marginal zone	bcl-2
	B and T cells in the mantle and marginal zone	bcl-2 alt
	Nuclei of germinal B cells	bcl-6
	Epithelial cells	BerEP4
Assessment Manager: JN		

Examination of tissues in

exclude morphological

abnormalities for the

purpose of diagnosis

order to identify or

and cytological

AA-amyloidosis

Androgen receptor

Mantle cell lymphoma

In house preparations of

processed to paraffin wax

(FFPE) tissue sections.

10% Neutral Buffered

Formalin fixed tissue

X-Histo

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)				
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections.	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and			

reporting:

Bond - CEL-LP-357-H

Using antibodies for:

beta-Catenin

BOB-1

C5b9

C4d

CA-IX

CA-125

III:

Automated immunocytochemistry - Bond

Automated Immunocytochemistry for the

purpose of diagnosis

Epithelial cells and

Complement activation

glomerular capillaries

Renal cell carcinomas

Tumour cells in GI and pancreas carcinomas

C-cells

Luminal surface of epithelial cells of the fallopian tube, endometrium and endocervix.

Peritubular and

fibroblasts

B cells

X-Histo

Calcitonin

Ca19.9

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections.	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis		
		Automated immunocytochemistry - Bond III:	X-Histo
		Automated Immunocytochemistry for the Bond - CEL-LP-357-H	
		Using antibodies for:	
	Smooth muscle	H-Caldesmon	
	Mesothelial cells	Calretinin	
	Epithelial cells (low molecular weight)	Cam5.2	
	Pre B and T cells, some T cells, germinal centre cells	CD10	
	Dendritic cells, monocytes, macrophages, neutrophils and some B cells	CD11c	
	Monocytes and dermal dendritic cells	CD14	
	B cells and follicular dendritic cells	CD19	

Langerhans cell, dendritic cells and thymocytes

CD1a

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax	Examination of tissues in order to identify or exclude morphological and cytological	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection,	

processing, embedding, staining and

Automated immunocytochemistry - Bond

Automated Immunocytochemistry for the

reporting:

Bond - CEL-LP-357-H

Using antibodies for:

III:

CD123

CD138

CD163

CD2

CD20

CD21

CD23

CD25

abnormalities for the

purpose of diagnosis

Plasmacytoid dendtritic

Follicular dendritic and

(cont'd)

cells

Plasma cells

Monocytes and

macrophages

Pan T cells

Pan B cells

mature B cells

B cells and EBV

Marker for hairy cell

leukemia and systemic

transformed B lymphoblasts

mastocytosis

(FFPE) tissue sections

(cont'd).

X-Histo

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9615 Accredited to			
ISO 15189:2022		,	
	Testing performed by the Organis	sation at the locations specified	
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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		

In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: <u>Automated immunocytochemistry - Bond</u> <u>III:</u> Automated Immunocytochemistry for the Bond - CEL-LP-357-H Using antibodies for:	X-Histo
	Pan T cells	CD3	
	Reed-Sternburg cells	CD30	
	Endothelial cells	CD31	
	Myelomonocytic lineage cells	CD33	
	Endothelial cells	CD34	
	Immature T and B cells, thymocytes, plasma cells	CD38	
	T helper cells, monocytes, macrophages and dendritic cells	CD4	
	Platelets, megakaryocytes, endothelial cells	CD42b	
	T cells, monocytes, granulocytes and some B cells	CD43 MT1	

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		

HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: <u>Automated immunocytochemistry - Bond</u> <u>III:</u> Automated Immunocytochemistry for the Bond - CEL-LP-357-H	X-Histo
		Using antibodies for:	
	T and B cells	CD45 (LCA)	
	T cells and some B cells	CD5	
	Neurons, glia, skeletal muscle and NK cells	CD56 (N-CAM)	
	NK cells	CD57 (Leu7)	
	Monocytes and macrophages	CD68 (PGM1)	
	T cells and NK cells	CD7	
	B cells	CD79a	
	Cytotoxic T cells	CD8	
	Intestinal epithelium	CDX2	
	Neuroendocrine cells	Chromogranin A	

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	Testing performed by the Organis	ation at the locations specified	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code

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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
		Automated immunocytochemistry - Bond III:	X-Histo
		Automated Immunocytochemistry for the Bond - CEL-LP-357-H	
		Using antibodies for:	
	Mast cells and GIST	C-kit CD117	
	Overexpression in hematopoitic tumours	С-Мус	
	Epithelial cells	Cytokeratin AE1/AE3	
	High molecular weight cytokeratin - basal cells	Cytokeratin 34BE12	
	Basal cells of squamous and glandular epithelium	Cytokeratin 5	
	Epithelial cells	Cytokeratin 8/18	
	Basal cells of squamous and some glandular epithelium	Cytokeratin 14	
	Basal cells of complex epithelia	Cytokeratin 17	
	Simple epithelium	Cytokeratin 18	

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	Testing performed by the Organis	sation at the locations specified	
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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological</u> <u>examinations for the</u> <u>purpose of clinical</u> <u>diagnosis (cont'd)</u>		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: <u>Automated immunocytochemistry - Bond</u> <u>III:</u> Automated Immunocytochemistry for the Bond - CEL-LP-357-H Using antibodies for:	X-Histo
	Epithelial cells	Cytokeratin 19	
	Gastric and intestinal epithelium, urothelium and Merkel cells	Cytokeratin 20	
	Glandular and transitional epithelium	Cytokeratin 7	
	Epithelial cells	Cytokeratin MNF116	
	Cytomegalovirus	Cytomegalovirus	
	Lymphatic endothelium	D2-40	
	Hairy cell Leukaemia	DBA 44	
	Smooth, skeletal and cardiac muscle	Desmin	
	GIST	DOG-1	
	Latent EBV RNA within B cells	EBER ISH	
	Epithelial tissue	E-cadherin	

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	Testing performed by the Organis	ation at the locations specified	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Histopothological		

	measurement		Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological</u> <u>examinations for the</u> <u>purpose of clinical</u> <u>diagnosis (cont'd)</u>		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: <u>Automated immunocytochemistry - Bond</u> <u>III:</u> Automated Immunocytochemistry for the Bond - CEL-LP-357-H Using antibodies for:	X-Histo
	Epithelial cells	EMA	
	Dermatofibroma	Factor XIIIa	
	T cells	Fox P3	
	Gastrin producing cells in the stomach	Gastrin	
	Bladder carcinoma	Gata-3	
	Apocrine epithelia of skin and breast	GCDFP-15 (BRST2)	
	Astrocytes, Schwann cells, glial cells, satellite cells	GFAP (GA5)	
	Glucagon secreting cells	Glucagon	
	Cytotoxic T cells and NK cells	Granzyme B	
L	1	1	L

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	Testing performed by the Organia	sation at the locations specified		
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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)			
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:		

III:

K light chain mRNA

Helicobacter pylori in

Adult and fetal liver

Latent nuclear antigen

Antigen presenting cells, B cells and some activated T cells

stomach

HSV I

HSV II

protein

Trophoblasts

X-Histo

HLA-DR

HHV8

Automated immunocytochemistry - Bond

Automated Immunocytochemistry for the

Bond - CEL-LP-357-H

Using antibodies for:

Hepatocyte/HepPar1

Herpes simplex I

Herpes simplex II

Kappa (ISH)

H. pylori

HCG

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	Testing performed by the Organia	sation at the locations specified	
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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue	Examination of tissues in order to identify or exclude morphological	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's	

	diagnosis (cont d)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: <u>Automated immunocytochemistry - , Bond</u> III:	X-Histo
		Automated Immunocytochemistry for the Bond - CEL-LP-357-H	
		Using antibodies for:	
	Surface IgA alpha - Myeloma	IgA (BMT)	
	Surface IgD delta chains	IgD	
	Surface IgG gamma	IgG (BMT)	
	lgG4 positive plasma cells	IgG4	
	Surface IgM mu chains	IgM (BMT)	
	Ovarian granulosa cells, testicular sertoli and leydig cells	Inhibin	
	Beta cells of the islets of Langerans in pancreas	Insulin	
	Surface immunoglobulin on B cells	Kappa (Lymphoma)	

	United Kin	edule of Accreditation issued by gdom Accreditation Service ay Lane, Staines-upon-Thames, TW18 31	
UKAS MEDICAL 9615 Accredited to ISO 15189:2022	Nor	ge Healthcare NHS Trust operating as rth West London Pathology lo: 012 Issue date: 28 May 2025	S
	Testing performed by the Organia	sation at the locations specified	
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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of	Examination of tissues in	In-house documented methods for	

AND FLUIDS (cont'd)	examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
	()	Automated immunocytochemistry - , Bond III:	X-Histo
		Automated Immunocytochemistry for the Bond - CEL-LP-357-H	
		Using antibodies for:	
	Proliferating cells	Ki67 (K2)	
	Lambda light chain mRNA	Lambda (ISH)	
	Surface immunoglobulin on B cells	Lambda (Lymphoma)	
	Langerhans cells	Langerin	
	Pre B and T cells	Lef-1	
	Detects circulating / met breast cancer cells	Mammaglobin	
	Mast cells	Mast Cell Tryptase	
	Melanocytes, junctional and blue nevus cells	Mel Sp Ag (HMB45)	
	Melanocytes/ melanomas	Melan A	

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	Testing performed by the Organis	ation at the locations specified	
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)	Histopathological examinations for the		

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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: <u>Automated immunocytochemistry - Bond</u> <u>III:</u> Automated Immunocytochemistry for the Bond - CEL-LP-357-H	X-Histo
		Using antibodies for:	
	Some lymphocytes, cortical thymocytes, granulosa cells of the ovary, Langerhans islet cells, sertoli cells	Mic-2	
	Apical surfaces of epithelial cells in breast, GI, respiratory and GU tracts	MUC-1	
	Goblet cells of the small intestine and colon, bronchus and salivary glands	MUC-2	
	Gastric and tracheo- bronchial mucosa, primary ovarian mucinous carcinoma	MUC-5AC	
	Antrum body and pyloric glands	MUC-6	

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	Testing performed by the Organis	sation at the locations specified	
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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		

AND FLUIDS (cont'd)	examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
		Automated immunocytochemistry - Bond III:	X-Histo
		Automated Immunocytochemistry for the Bond - CEL-LP-357-H	
		Using antibodies for:	
	Germinal centre B cells, plasma cells and activated T cells	MUM1	
	Precursors of granulocytes in BMT	Myeloperoxidase	
	Skeletal and cardiac muscle	Myoglobin	
	Rhabdomyosarcoma	Myo D1	
	Type II pneumocytes and lung adenocarcinoma	Napsin A	
	Neurones, Neuronal processes, peripheral nerves and ganglion cells	Neurofilaments	
	Neuroendocrine cells	NSE	
	B cells	OCT-2	
	Embryonic stem and germ cells	OCT 3/4	

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	Testing performed by the Organis	sation at the locations specified	
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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		

AND FLUIDS (cont'd)	examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	Y USAA
		Automated immunocytochemistry - , Bond III:	X-Histo
		Automated Immunocytochemistry for the Bond - CEL-LP-357-H	
		Using antibodies for:	
	HPV	P16 (RTU)	
	P40 protein in squamous cell carcinomas	p40	
	Tumour suppressor protein	P53 (D07)	
	Basal cells	P63	
	Prostate adenocarcinoma	P504S (AMACR)	
	Chief cells in the parathyroid gland	Parathyroid hormone	
	B cells	Pax-5	
	Thyroid, renal cell carcinomas	Pax-8	
	Activated T cells, B cells and myeloid cells	PD1	

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		

	measurement		
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: <u>Automated immunocytochemistry - , Bond</u> <u>III:</u> Automated Immunocytochemistry for the Bond - CEL-LP-357-H Using antibodies for:	X-Histo
	Cytotoxic T cells and NK cells	Perforin	
	Megakaryocytes	PGP3 (CD61)	
	Neuroendocrine cells	PGP9.5	
	Syncytiotrophoblasts	Plac. Lactogen (PL)	
	Germ cell tumours	PLAP	
	Glandular epithelium in prostate	Pros acid phos (PAP)	
	Glandular epithelium in prostate	Prostate specific antigen (PSA)	
	Tumour suppressor protein	PTEN	
	Red cells and their precursors	Ret40f/Glycophorin C	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code	

	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting: <u>Automated immunocytochemistry - , Bond</u> <u>III:</u> Automated Immunocytochemistry for the Bond - CEL-LP-357-H Using antibodies for:	X-Histo
	Melanocytes, Langerhans cells, histiocytes, Scwann cells, apidocytes	S-100	
	Enterochromaffin cells of the GI tract	Serotonin	
	Smooth muscle cells, myofibroblasts and myoepithelial cells	Smooth Muscle Actin	
	Pancreatic islets, delta cells in the antrum and duodenum	Somatostatin	
	Mantle cell lymphoma	SOX-11	
	SV-40	SV-40 (Bk virus)	
	Neuroendocrine cells	Synaptophysin	

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)		
In house preparations of	Examination of tissues in	In-house documented methods for	

	purpose of clinical diagnosis (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
		Automated immunocytochemistry - , Bond III:	X-Histo
		Automated Immunocytochemistry for the Bond - CEL-LP-357-H	
		Using antibodies for:	
	T cells	TCR-Beta F1	
	Primitive T and B cells, thymocytes	Tdt	
	Thyroid follicular cells	Thyroglobulin	
	Treponema Pallidum	Treponema Pallidum	
	Follicular epithelial cells of the thyroid, type II pneumocytes and Clara cells of the lung	TTF-1	
	Hairy cell Leukaemia	TRAP	
	Fibroblasts, endothelial cells, smooth muscle and melanocytes	Vimentin	

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd_	Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions:	Automated Immunocytochemistry Ventana. CEL-LP-647-NWL	X-Histo	

Alk-1 (Lung)

BRAF

ER

Detection anaplastic

lymphoma kinase (ALK) protein in NSCLC

Identification of mutant

protein BRAF V600E

Estrogen receptor

Heparan sulfate

proteoglycan

repair protein

repair protein

repair protein

repair protein

Identification of mismatch

Glypican 3

Cerb B2 in breast and GI HER2

Identification of mismatch MSH2 (25D12)

Identification of mismatch MSH6

Identification of mismatch MLH-1 (ES05)

PMS 2

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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)	Histopathological examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:		

	<u>purpose of clinical</u> <u>diagnosis</u> (cont'd)	examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections. (cont'd)	Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions (cont'd):	Automated Immunocytochemistry Ventana. CEL-LP-647-NWL:	X-Histo
	Trophoblastic disease	P57	
	Programme cell death ligand 1	PDL-1	
	Progesterone receptor	PR	
	Renal Cell Carcinoma	Renal Cell Carcinoma	
	Squamous cell carcinoma	SALL-4	
	Marker of embryonic stem cell pluripotency	SOX-2	

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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	Cytopathology (Non-	In-house documented methods for		

	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Cytopathology (Non- Gynae) examination</u> <u>activities for the purposes</u> of clinical diagnosis	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for preparation, staining and reporting	
Body fluids	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities		
	Demonstration of: Cells (nuclei and cytoplasm) and micro- organisms	Manual techniques:	
		Rapid Diff Quick - Staining Methods for Non-Gynae - CEL-LP-030-M Staining Methods – Cytology CEL-LP- 281-NWL	M-FNA
		Automated staining and coverslipping using Leica CV5030 (coverslipper) Leica ST5020 (autostainer) Autostainer and Coverslipper (CEL-LP- 736-NWL)	X-Histo
		MGG, Papanicolaou staining CEL-LP- 736-NWL	

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	Testing performed by the Organia	ation at the locations specified	
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code

Materials/Products tested	Type of test/Properties	Standard specifications/	Location
	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Cytopathology (Non- Gynae) examination</u> <u>activities for the purposes</u> <u>of clinical diagnosis</u> (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for preparation, staining and reporting:	
Body Fluids (cont'd)	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities (cont'd)		
	Demonstration of: Cells (nuclei and cytoplasm) and micro- organisms (cont'd)	Manual techniques:	
		Sample preparation - Hologic T2000:	X-Histo
		T2000 LBC Processor - Laboratory Equipment (General Use & Maintenance) - CEL-LP-419-NWL	
		In the preparation of:	
		Preparation of Anal & Vaginal LBC - CEL- LP-682-NWL	
		Sample preparation - Thermo Cytospin 2, Shandon Heraeus Megafuge 40R:	
		Cytospin - Laboratory Equipment (General Use & Maintenance) - CEL-LP- 365-NWL	
		Centrifuge - Laboratory Equipment (General Use & Maintenance) - CEL-LP- 415-NWL	
		Bronchoalveolar (BAL & Wash) - Specimen Preparation - CEL-LP-362- NWL	
		Cerebrospinal Fluid (CSF) - Specimen Preparation - CEL-LP-363-NWL	

E C	Schedule of Accreditation			
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	measured/Range of measurement	Equipment/Techniques used	Code	
	Cytopathology (Non-	In-house documented methods for		

HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Cytopathology (Non-Gynae) examination</u> <u>activities for the purposes</u> <u>of clinical diagnosis</u> (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for preparation, staining and reporting:	
Body Fluids (cont'd)	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities (cont'd)		
	Demonstration of: Cells (nuclei and cytoplasm) and micro- organisms (cont'd)	Manual techniques:	
		In the preparation of:	
		Serous & Miscellaneous Fluid - Specimen Preparation - CEL-LP-364-NWL	
		Urine - Specimen Preparation - CEL-LP- 367-NWL	
		Sputum - Specimen Preparation - CEL- LP-368-NWL	
		Synovial Fluid - Preparation - CEL-LP- 369-NWL	
		Fine Needle Aspiration Cytology - CEL- LP-282-NWL	
		Cell Block & Clot Processing of Cytology Specimens - CEL-LP-442-NWL	
		Papanicolaou & May Grünwald Giemsa Staining Methods - Cytology - CEL-LP- 281-NWL	
		Taking and Reporting Fine Needle Aspirate CEL-CP-003-NWL Microscopy Screening and Reporting CEL-LP-284-NWL	X-Histo M-FNA

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Cytopathology (Non- Gynae) examination</u> <u>activities for the purposes</u> <u>of clinical diagnosis</u> (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for preparation, staining and reporting: Interpretive/diagnostic microscopy - Olympus: BH2, BX41, BX45, BX50, BX51, BX40CY, BX 51XT, BX50F4 & BX51TF. Leitz: Laborlux K, Nikon: Eclipse 80i, Eclipse Ci-S, E600 & E400. Leica MZ8: Reporting - CEL-CP-032-IMP	X-Histo	

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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 AND TISSUES	Immunophenotyping examination procedures	Documented in house methods and manufacturer's instructions for flow	

AND TISE	0023	for the purposes of clinical diagnosis	cytometry using BD FacsCanto	
blood), bc (lithium he marrow (p heparin pl medium), effusions, needle as endobrom (EBUS), b lavage (B nodes/tiss	row, peripheral one marrow eparin), bone oreservative-free lus tissue culture CSF, pleural ascetic fluid, fine pirates (FNA), chial ultrasound oronchoalveolar AL), whole lymph sue samples, rare . vitreous fluids)	Examination of haematopoetic cells in order to identify the lineage and stage of maturation of the abnormal proliferating cells in the diagnosis and management of AML, ALL, LPD, MPD, CLL, MDS, MM, Non-Hodgkin lymphoma and PNH	<u>Manual sample preparation, sample set</u> <u>up, mixing of antibody cocktails</u>	
			Immunophenotyping for Haematological Malignancies - CELP-LP-107-HMS	H- Immunop
		Acute leukaemia screening	Using antibodies for: CYT MPO, CD79a, CD34, CD19, CD7, smCD3, CYCD3, CD45	H- Immunop
		Classification of acute leukaemia	CD117, CD58, CD66c, CD10, CD38, CD20, NUC TDT, CYT U, CD22, CD9, smlg LAMBDA, smLg KAPPA, CD1a, CD42a/CD61, CD64, CD99, CD8, CD11b, CD300e, HLA-DR, CD14, CD71, CD235a, CD36, CD105, CD56, CD123, CD64, CD3, CD4, CD5, CD15	H- Immunop
		Chronic lymphoproliferative screening	CD8, smlgIAMBDA, smlgKappa, CD56, CD5, CD19, TCRGammadelta, smCD3, CD38, CD20, CD4, CD45	H- Immunop
		Classification of chronic lymphoproliferative disorders	FMC7, CD10, CD23, CD79b, CD22, CD19, CD43, CD25, CD200, CD81, CD103, CD305, CD11c, CD27, CD49d, CD7, CD57, CD3, CD138, CD16, CYT Kappa, CYT Lambda, CD2, CD28, TCRAlphabeta, CD27, CD38	H- Immunop

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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 (cont'd)	Immunophenotyping examination procedures for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for flow cytometry using BD FacsCanto	
Bone marrow (EDTA),	Examination of	Manual sample preparation, sample set	

(cont'd)	examination procedures for the purposes of clinical diagnosis (cont'd)	manufacturer's instructions for flow cytometry using BD FacsCanto	
Bone marrow (EDTA), peripheral blood (EDTA), bone marrow (lithium heparin), bone marrow (preservative-free heparin plus tissue culture medium), CSF, pleural effusions, ascetic fluid, fine needle aspirates (FNA), endobronchial ultrasound (EBUS), bronchoalveolar lavage (BAL), whole lymph nodes/tissue samples, rare fluids (e.g. vitreous fluids) (cont'd)	Examination of haematopoetic cells in order to identify the lineage and stage of maturation of the abnormal proliferating cells in the diagnosis and management of AML, ALL, LPD, MPD, CLL, MDS, MM, Non-Hodgkin lymphoma and PNH (cont'd)	<u>Manual sample preparation, sample set</u> <u>up, mixing of antibody cocktails</u>	
		PNH Analysis:	
	Testing for the presence of PNH clones in Red blood cell and White blood cell populations:	Detection of Paroxysmal Nocturnal Haemoglobinuria by Flow Cytometry - CELP-LP-106-HMS	H- Immunop
	Red blood cells	Using antibodies for: CD59 and CD235a	H- Immunop
	White blood cells	FLAER, CD14, CD33, CD64, CD45, CD15, CD24	H- Immunop

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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 / TISSUES / CELLULAR MATERIAL	Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis	Documented in house methods and manufacturer's instructions for molecular diagnostics	
Whole blood (EDTA)	Sample processing for	QIAGEN Tissue Lyser	H-MOL

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL	Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis	Documented in house methods and manufacturer's instructions for molecular diagnostics	
Whole blood (EDTA) Bone Marrow (EDTA) Lyophilised cells	Sample processing for storage of cell lysate	QIAGEN Tissue Lyser CELP-LP-097-HMS	H-MOL
Whole blood (EDTA) Bone marrow (EDTA)	Mononuclear cell isolation	Lymphoprep cell isolation solution CELP-LP-090-HMS	H-MOL
Whole blood (EDTA) Bone marrow (EDTA)	CD3 T-cell separation	AutoMacs Pro CELP-LP-200-HMS	H-MOL
Whole blood (EDTA) Bone marrow (EDTA) Lymphoprep cell sample Cell lysate Lyophilised cells FFPE tissue CD3 T-cell separated sample	Extraction and storage of DNA and RNA	DNA & RNA Extraction - QIAsymphony, Eppendorf Micro-centrifuge - CELP-LP- 164-HMS	H-OL
		Manual DNA Extraction from FFPE Tissue using QIAGEN QIAmp DNA FFPE Tissue kit CELP-LP-120-HMS	H-MOL
		Manual DNA extraction using the QIAGEN QIAmp DNA mini kit CELP-LP- 093-HMS	H-MOL
		Manual RNA extraction using the QIAGEN RNeasy Mini kit CELP-LP-098-HMS	H-MOL
RNA extracted from sources as above	cDNA synthesis from RNA	cDNA synthesis using LunaScript Reverse Transcriptase CELP-LP-099-HMS	H-MOL

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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 / TISSUES / CELLULAR MATERIAL (cont'd)	Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for molecular diagnostics			
cDNA prepared from sources as above	BCR::ABL1 translocation identification	Multiplex PCR using the QIAxcel Advanced analyser for capillary electrophoresis CELP-LP-096-HMS CELP-LP-104-HMS	H-MOL		
	BCR::ABL1 TK Domain Mutation (TKD) Analysis – Sanger sequencing	In-house BCR::ABL1 TKD Sanger Sequencing using the Applied Biosystems 3500 XL DX analyser CELP-LP-103-HMS			
		Sanger Sequencing analysis using the Applied Biosystems SeqScape software CELP-LP-159-HMS			
cDNA prepared from peripheral blood or bone marrow	<i>BCR::ABL1</i> tyrosine kinase domain (TKD) analysis - NGS	In-house BCR::ABL1 TKD NGS using the Illumina MiSeq analyser CELP-LP-218-HMS CELP-LP-227-HMS	H-MOL		
cDNA prepared from peripheral blood or bone marrow	BCR::ABL1 e1a2 transcript quantitative monitoring (Minimal Residual Disease monitoring)	Thermofisher QuantStudio 5 RT-qPCR analyser using EAC modified e1a2 RT- qPCR assay and IDT synthetic dsDNA standards. CELP-LP-100-HMS CELP-LP-195-HMS	H-MOL		
cDNA prepared from peripheral blood or bone marrow	BCR::ABL1 e19a2 transcript quantitative monitoring (Minimal Residual Disease Monitoring)	Thermofisher QuantStudio 5 RT-qPCR analyser using EAC modified e19a2 RT- qPCR assay and IDT synthetic dsDNA standards. CELP-LP-100-HMS CELP-LP-195-HM	H-MOL		

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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 / TISSUES / CELLULAR MATERIAL (cont'd)	Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for molecular diagnostics	
	BCR::ABL1 reporting	Reporting and communicating MRD results CELP-LP-102-HMS CELP-LP-088-HMS	H-MOL
DNA as prepared from whole blood (EDTA), Bone Marrow (EDTA), lyophilised cells, FFPE and lymphoprep sample from whole blood (EDTA) and bone marrow (EDTA)	Clonality assessment of suspected T- or B-Cell lymphoproliferative disorders: IGH and IGK B-cell clonality TCR Gamma clonality	Commercial kits (InVivoScribe IdentiClone) fragment analysis CELP-LP-091-HMS <u>Applied Biosystems</u> 3500 XL DX analyser CELP-LP091-HMS CELP-LP-088-HMS	H-MOL

whole blood (EDTA) and bone marrow (EDTA)	clonality TCR Gamma clonality	CELP-LP091-HMS CELP-LP-088-HMS	
		Data analysis using GeneMapper	
DNA extracted from whole blood (EDTA) and bone marrow (ETA)	Assessment of AML prognostic markers FLT3 ITD FLT3 TKD NPM1 variant status		H-MOL
		FLT3 ITD and TKD variant analysis using LeukoStrat CDx FLT3 (Invivoscribe) Mutation Analysis kit Fragment analysis performed using Applied Biosystems 3500 XL DX analyser CELP-LP-163-HMS NPM1 variant analysis using in-house method and AllTaq Master Mix Kit for <i>NPM1</i> fragment analysis Fragment analysis performed using Applied Biosystems 3500 XL DX analyser CELP-LP-201-HMS Data analysis using GeneMapper CELP-LP-163-HMS CELP-LP-088-HMS	H-MOL

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HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)	Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for molecular diagnostics		
DNA from peripheral blood (EDTA), bone marrow (EDTA), lyophilised cells or CD3 T-cell separation	Chimerism Analysis		H-MOL	
		Powerplex 16HS Chimerism Assessment DNA Fragment Size Analysis using Capillary Electrophoresis Applied Biosystems 3500 XL DX analyser and PCR CELP-LP-158-HMS Chimerism analysis using ChimerMarker software CELP-LP-158-HMS CELP-LP-088-HMS		
DNA from peripheral blood (EDTA), bone marrow (EDTA) or lyophilised cells	MPN NGS Panel: Targeted capture of genes involved in Myeloproliferative Neoplasms: KRAS NRAS SRSF2 U2AF1	AmpliSeq for Illumina Library prep NGS sequencing using the Illumina MiSeq: CELP-LP-190-HMS MPN analysis using Illumina Connected Insights software CELP-LP-190-HMS CELP-LP-088-HMS	H-MOL	
DNA from peripheral blood (EDTA), bone marrow (EDTA) or lyophilised cells	Myeloid NGS Panel: Targeted capture of genes involved in Myeloid Leukaemias and Myelodyplasia - detection of small sequence variation by NGS panel	Targeted gene capture using the Thermofisher Oncomine Myeloid panel on the Ion Chef and S5 sequencer CELP-LP-203-HMS Myeloid NGS analysis using Ion reporter CELP-LP-208-HMS CELP-LP-088-HMS	H-MOL	

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HUMAN BODY TISSUES / CELLULAR MATERIAL (cont'd)	Electronmicroscopic examinations for the purpose of clinical diagnosis	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
Glutaraldehyde fixed nerve, Glutaraldehyde fixed renal biopsies, Glutaraldehyde fixed duodenal biopsies, Glutaraldehyde fixed muscle biopsies, wax re- processed blocks and slides	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Tissue dissection & Sample preparation:	
		Specimen dissection - CEL-LP-564-X	X-EM
		Processing paraffin wax blocks for TEM - CEL-LP-583-X	X-EM
		Reprocessing paraffin wax section for TEM - CEL-LP-584-X	X-EM
		Followed by either:	
		Manual sample processing:	
		Routine Processing to Spurr Epoxy Resin - CEL-LP-576-X	X-EM
		OR	
		Automated sample processing - Leica EM TP:	
		Automatic processing with two Leica processors - CEL-LP-587-X	X-EM

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HUMAN BODY TISSUES / CELLULAR MATERIAL (cont'd)	Electron microscopic examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
Resin embedded cells/tissue biopsies	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	<u>Section cutting</u> -	
		Preparation of resin embedded tissue blocks for ultramicrotomy - CEL-LP-589-X	X-EM
		Preparation of glass knives for ultramicrotomy - CEL-LP-590-X	X-EM
		Preparation of semi-thin (thick) survey sections for light microscopy - CEL-LP- 591-X	X-EM
		Preparation of ultra-thin (thin) sections for Transmission Electron Microscopy - CEL- LP-592-X	X-EM
		Manual staining:	
Semi-thin sections of resin embedded cells/tissue biopsies	Toluidine blue stain for overview staining	Staining semi-thin (thick) survey sections for examination by light microscopy - CEL-LP-593-X	X-EM
Ultra-thin sections of resin embedded cells/tissue biopsies		Staining ultra-thin (thin) sections with heavy metals for Transmission Electron Microscopy - CEL-LP-594-X	X-EM

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HUMAN BODY TISSUES / CELLULAR MATERIAL (cont'd)	Electronmicroscopic examinations for the purpose of clinical diagnosis (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
Ultra-thin sections of resin embedded cells/tissue biopsies		Electronmicroscopy & digital image capture - Hitachi HT7800 Transmission Electron Microscope Digital camera AMT XR80	
		Operation & Maintenance of the Hitachi H7800 Transmission Electron Microscope - CELP-LP-237-X	X-EM
		Digital Imaging on the Transmission Electron Microscope - CELP-LP-144-X	X-EM
		Interpretation/Reporting: Handling and reporting surgical tissues - CEL-LP-628-X	X-EM
	Cytogenetic examination for the purposes of clinical diagnosis		
Bone marrow, peripheral blood, CSF	Karyotyping analysis of G-banded chromosomes	Manual slide making for Zeiss Primo Star phase microscope: Cytogenetics sample set up CEL-LP-518-H Cytogenetics harvest CEL-LP-523-H Cytogenetics slide-making CEL-LP-525-H	H-CytoG
		Cytogenetics Banding - CEL-LP-463-H	H-CytoG
		Image capture for chromosome preparations using Leica GSL120 and Leica CytoVision karyotyping stations: Use of Cytogenetic Imaging Systems CEL-LP-714-H	H-CytoG

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HUMAN BODY TISSUES / CELLULAR MATERIAL (cont'd)	Cytogenetic examination for the purposes of clinical diagnosis	In-house documented methods for examination incorporating manufacturer's instructions where relevant:					
Fixed cells from bone marrow, peripheral blood and CSF/ Paraffin Embedded Tissue (FFPE)	FISH analysis for the detection of structural chromosome rearrangements and copy number changes	Manual FISH slide preparation, pre- treatment and probe hybridisation using commercial probes: Thermobrite Hybridisation systems. Commercial FISH Probes from Metasystems, Cytocell and Kreatech. Cytogenetics FISH set-up CEL-LP-521-H	H-CytoG				
		Cytogenetics Manual FFPE FISH - CEL- LP-529-H	H-CytoG				
		FISH analysis using Zeiss Axio Imager M2 and ISIS (Metasystems) software Use of Cytogenetic Imaging Systems - CEL-LP-714-H	H-CytoG				

 hybridisation (FISH) samples from patients with haematological neoplasms - CEL-LP-693-H

 END

Bone marrow, peripheral

blood

H-CytoG

H-CytoG

H-CytoG

CD138+ cell enrichment in plasma cell

Reporting and Authorisation of G-Banding

Guidelines for the Analysis of G-Banded chromosomes and fluorescence in situ

Automated cell separation using AutoMACS Pro Miltenyi Biotech

and FISH Reports in Cytogenetics

myeloma prior to FISH:

CEL-LP-703-H

CEL-LP-561-H