Schedule of Accreditation

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Poundbury Cancer Centre Limited trading as Poundbury Cancer Institute

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Histopathological examination activities for the purposes of clinical diagnosis	Macroscopic and Microscopic examination:
Fixed pre-excised neoplastic biopsies from • Breast • Urology • Gynaecology • Upper and Lower GI • Respiratory • Lymphoma • Dermatology • Head and neck • Endocrine • Soft tissue and bone		Tissue Processing, Embedding and Microtomy (PGM14) Thermo Excelsior processors Menarini Logos processor Lecia 2035 microtomes Tissue Tek TEC (PCI095) and Leica EG1160 SOP PGM15
FFPE Tissue Sections (prepared in house or received as referral)	Routine morphological staining for the detection of basophilic and eosinophilic structures	Haematoxylin and Eosin stain Manual staining Automated SOP PSM2 Sakura Tek DRS staining machine Dako CR100 Coverslipper
FFPE Tissue Sections (prepared in house or received as referral)		Special Stains Manual
	Acid mucins	Alcian Blue (PSM1B1)
	Glycogen, Neutral and Acid Mucins	Alcian Blue/ Periodic Acid Schiff (PSM1B38)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination:
FFPE Tissue Sections (prepared in house or received as referral) (cont'd)		Special Stains Manual (cont'd)
	Amyloid	Congo Red (PSM1B40)
	Elastic fibres, Collagen and Muscle	Elastic van Gieson (Miller's) (PSM1B20)
	Gram +ve&-ve bacteria	Gram (PSM1B9)
	Fungi	Grocott (PSM1B11)
	Connective tissue and fibrin	Martius Scarlet Blue (MSB) (PSM1B14), Van Gieson (PSM1B32)
	Melanin and argentaffin granules	Masson Fontana (PSM1B16)
	Melanin bleach	Melanin bleach (PSM1B53)
	HBV Ag	Orcein (PSM1B22)
	Glycogen, Fungi and Neutral Mucins	Periodic Acid (+/- diastase) (PSM1B23
	Ferric Iron	Perl's Prussian Blue (PSM1B24)
	Mast Cells	Toluidine Blue (PSM1)
	Mycobacterium tuberculosis	Ziehl Neelsen (PSM1B37)
	Calcium salts	Von Kossa

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Immunohistochemistry
FFPE Tissue Sections as above and within scope of probe requested		Ventana Benchmark XT and Ultra using the following probes: monoclonal, polyclonal and cocktail IVD or RTU antibodies: SOP (PIC31, PIC3)
	Lung – non- small cell carcinomas	ALK
	Basal Cell Carcinoma	BCC
	Adenocarcinoma vs malignant mesothelioma, epithelial cell types	BerEP4 (Ep-Cam)
	Mesothelioma	Calretinin
	Secretory granules of endocrine cells	Chromogranin
	Natural Killer cells, neuroendocrine tissue, macrophages, monocytes, myeloid cells	CD56
	CD117	CD117
	Adenocarcinoma	CDX2
	CEA glycoproteins	CEA
	Adenocarcinoma, stratified squamous epithelium, basal cells, mesotheliomas	CK5
	Squamous epithelium and Neoplasms of type	CK5/6
	Glandular/transitional epithelia and neoplasia of type	CK7
	Epithelial cells	CK8/18
	Normal GI epithelia/urothelium and neoplasia of type	CK20
	Nuclei of cells containing high levels of oestrogen	ER
	Breast epithelium	GATA 3

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Immunohistochemistry/ISH
	Her 2 amplification	Ventana Benchmark XT and UltraIn-situ hybridisation stained tissue to detect the presence or absence of targets listed: HER2 D DISH
FFPE Tissue Sections as above and within scope of probe requested		Ventana Benchmark XT and Ultra using the following probes: monoclonal, polyclonal and cocktail IVD or RTU antibodies: SOP (PIC31, PIC3)
	Proliferative cells	Ki67 (MIB1)
	Lung carcinoma	Napsin A
	NKX3.1 protein	NKX3.1
	mRNA/ p16 HPV biomarkers	P16 (Ventana ULTRA only)
	Tumour suppressor gene	P53
	Pax-8 expressing cells / ovarian tumours	PAX-8
	PD-L1	PD-L1 (SP142)
	Progesterone receptor	PR
	Melanoma	PRAME
	P504s protein	P504s
	Non small cell lung carcinoma	ROS-1
	Transcription factor SOX-10	SOX-10
	Neuroendocrine marke	Synaptophysin
	Wilm's tumour gene product	WT-1
	BCRA1 associated protein	BAP-1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Immunohistochemistry/ISH
FFPE Tissue Sections as above and within scope of probe requested		Ventana Benchmark XT and Ultra using the following probes: monoclonal, polyclonal and cocktail IVD or RTU antibodies: SOP (PIC31, PIC3)
	Normal and neoplastic lung and thyroid cells	TTF-1
	Basal epithelial cells	p63
	Squamous cells	p40
	Detection of Her-2 antigen	Her2
	V600E mutation in melanoma and colorectal carcinoma	BRAF V600E
	PD-L1	PD-L1 (SP263)
		Dako Autostainer Link 48
	PD-L1	PD-L1
	Androgen Receptor	AR
	Proliferative cells	Ki67
	Normal/neoplastic tissue epithelial in origin	AE1/AE3
	Follicular lymphomas, B cells lymphoproliferative diseases	Bcl-2 Bcl-6
	B cells pro, pre- and mature	PAX5
	T-cells and T-cell neoplasms	CD3/CD2
	T cells, macrophages	CD4
	Suppressor and cytotxic T-cells,	CD8
	S100 protein	S100

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Immunohistochemistry/ISH
FFPE Tissue Sections as above and within scope of probe requested (cont'd)		BOND III using the following probes, monoclonal, polyclonal and cocktail IVD or RTU antibodies: SOP (PIC1, PIC3)
	Mature B-cells, Burkitts lymphoma, Follicular lymphoma, renal Clear Cell carcinoma, myoepithelial cells, endometrial stroma	CD10
	B cells, and B cell neoplam, follicular dendritic cells	CD20
	Mature T-cells and T-cell lymphomas	CD5
	Mature B cells, FD cells	CD21
	B-cells, some T-cells	CD23
	ALCL, Reed Sternberg cells, Hodgkin's disease	CD30
	Beta-Catenin expressing cells	Beta Catenin
	CA 125 expressing cells	CA125
	CA1 expressing cells	CA1 (CA9)
	CD117 expressing cells	CD117
	Multiple myelome	CD138
	Cytokeratin 8/18 expressing cells	CK8-18
	Epithelial cells	E-Cadherin
	Smooth Muscle myosin	SMM
	Transcription factor SOX-10	SOX-10
	Prostate carcinoma	PSMA

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Immunohistochemistry
FFPE Tissue Sections as above and within scope of probe requested (cont'd)		BOND III using the following probes, monoclonal, polyclonal and cocktail IVD or RTU antibodies: SOP (PIC1, PIC3)
	Endothelial cells, vascular tumours	CD31
	Vascular and lymphatic tumours	CD34
	Neutral cell adhesion molecule	CD56
	T-cells, NK cells, Thymocytes	CD68
	Normal/neoplastic tissue epithelial in origin	MNF116
	Proliferative cells	Ki67 (MIB1)
	T cells	CD79a
	Cell cycle G1 phase	Cyclin D1
	Dendrocytes	Factor XIIIa
	Colorectal carcinoma	MLH-1
	Colorectal carcinoma	MSH-2
	Colorectal carcinoma	MSH-6
	GC cells	MUM-1
	Tumour suppressor gene	P53
	DNA mismatch repair	PMS-2
	Melanoma, neuroendocrine cells	S100 (polyclonal)
	Smooth muscle cells, myoepithelial cells	SMA

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Immunohistochemistry
FFPE Tissue Sections as above and within scope of probe requested (cont'd)		BOND III using the following probes, monoclonal, polyclonal and cocktail IVD or RTU antibodies: SOP (PIC1, PIC3)
	Normal and neoplastic neoplasia	EMA
	Melanocytes, Melanoma	HMB45, Melan A
	Leucocytes	LCA(CD45)
	Skeletal/cardiac muscle	Desmin
	Immunoglobulins	IgD
Stained FFPE Tissue Sections	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Interpretive Microscopy Digital Image Scanning: Sysmex 3D Histotech scanner (PGM31) and PGM 27 Diagnostic Microscopy: Digital reporting and Olympus microscopes
HUMAN BODY TISSUE (cont'd)	Molecular genetic examination activities for the purposes of clinical diagnosis	Molecular diagnostics
FFPE Embedded Tissue		Manual DNA extraction using Roche Cobas DNA extraction Kit (PML5)
DNA derived from FFPE Tissues	Detection and reporting of:	Real time PCR using Roche Cobas 480 and Roche COBAS Kits for detection of EGFR, BRAF, KRAS and NRAS mutations (PML5).
	EGFR mutations	
	BRAF mutations	
	KRAS/NRAS mutations	
END		