### **Schedule of Accreditation**

issued by

### **United Kingdom Accreditation Service**

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



ISO 15189:2022

#### **North Bristol NHS Trust**

Issue No: 005 Issue date: 04 September 2025

Cellular Pathology

Southmead Hospital

Westbury on Trym

Contact: Mr Mark Orrell

Tel: +44 (0) 117 414 49875

E-Mail: mark.orrell@nbt.nhs.uk

Bristol Website: www.nbt.nhs.uk/severn-pathology
BS10 5NB

Testing performed by the Organization at the locations specified below

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

#### **Laboratory locations:**

Location details		Activity	Location code
Address Cellular Pathology Southmead Hospital Westbury on Trym Bristol BS10 5NB	Local contact Mr Mark Orrell Tel: +44 (0) 117 414 49875 E-Mail: mark.orrell@nbt.nhs.uk	Histopathology Diagnostic Cytopathology Gynaecological Cytopathology Rapid frozen section for intra-operative diagnosis FNA material/slide preparation and cellularity assessment	A

#### Site activities performed away from the locations listed above:

Location details		Activity	Locatio n code
Address Cellular Pathology Bristol Royal Infirmary Marlborough Street Bristol BS2 8HW	Local contact Mr Mark Orrell Tel: +44 (0) 117 414 49875 E-Mail: mark.orrell@nbt.nhs.uk	Dissection and preparation and reporting of biopsies Diagnostic cytology, screening and reporting of urgent Head and Neck biopsies Rapid frozen section for intra-operative diagnosis	С

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#### **North Bristol NHS Trust**

#### 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 TISSUES AND FLUIDS	Histopathology	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
t	Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroanalysis and dissection Leica IPC Cassette writer and inhouse procedures: CP-HiCU-SOP-017 CP-HiCU-SOP-018  CP-HiCU-SOP-4 Bone Marrow trephine CP-HiCU-SOP-5 Thorasic CP-HiCU-SOP-6 Cystectomy and Cytoprostatectomy CP-HiCU-SOP-7 Testes CP-HiCU-SOP-8 Kidney CP-HiCU-SOP-9 Adrenal CP-HiCU-SOP-13 GI CP-HiCU-SOP-14 Skin CP-HiCU-SOP-16 Bone and soft tissue CP-HiCU-SOP-31 Prostate CP-HiCU-SOP-32 Penile  CP-HiCU-SOP-37 Placenta CP-HiCU-SOP-51 Gynae CP-HiCU-SOP-53 Thyroid CP-HiCU-SOP-54 Parathyroid CP-HiCU-SOP-55 Head and Neck CP-HiCU-SOP-77 Breast  Tissue processing Automated method using Leica Peloris tissue processors CP-HiML-SOP-57	A, C

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
		Embedding Manual method using Leica EG115H/E1150C, EG1160 and Histocare Arcadia embedding centres and in-house procedure: CP-HiML-SOP-19	
		Microtomy Automated method using Leica RM2135/2235/2245/2255 microtomes and in-house procedure: CP-HiML-SOP-20	
Formalin fixed, paraffin embedded (FFPE) tissue	Routine morphological staining	Routine Haematoxylin and Eosin staining and coverslipping using: Leica Autostainer CV5030 and XL ST5020/CV5030 stainer / cover slippers and in-house procedure: CP-HiML-SOP-21 CP-HiML-SOP-22	A
Fresh Tissue Frozen Tissue	Intra-operative diagnosis	Rapid Frozen Section Leica CM1950 Leica CM1850 UV using manual Haematoxylin and Eosin (H and E) stain with in-house procedure: CP-HiCU-SOP-20 CP-HiCU-SOP-12	A C

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
Formalin fixed, paraffin embedded (FFPE) tissue	Detection of:	Special Staining Manual Techniques using in-house procedures and the following stains:	
	Acid and neutral mucins	Alcian blue-PAS CP-HiSD-SOP-ABPASD	
	Amyloid	Congo red CP-HiSD-SOP-CR	
	Haematopoietic cells	Giemsa CP-HiSD-SOP-Giemsa	
	H. pylori	Giemsa modified CP-HiSD-SOP-ModifiedGiemsa	
	Reticulin fibres	Gordon and Sweets reticulin stain CP-HiSD-SOP-Retic	
	Gram positive and negative bacteria	Gram CP-HiSD-SOP-Gram	
	Basement membrane, Fungi	Grocott methenamine silver CP-HiSD-SOP-Grocott	
	General morphology nuclei, cytoplasm & connective tissue	Haematoxylin and eosin manual CP-HiSD-SOP-Manual	
	General morphology nuclei, cytoplasm & connective tissue	Haematoxylin and eosin rapid CP-HiSD-SOP-Rapid	
	Connective tissue collagen	Haematoxylin Van Gieson HVG CP-HiSD-SOP-HVG	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of: (cont'd)	Special Staining Manual (cont'd)	
	Fibrin & connective tissue	Martius scarlet blue MSB CP-HiSD-SOP-MSB	
	Melanin	Masson Fontana CP-HiSD-SOP-MassonFontana	
	Connective tissue	Masson Trichrome CP-HiSD-SOP-MBT	
	Removal of melanin pigment	Melanin Bleach CP-HiSD-SOP-MelaninBleach	
	Elastic fibres & connective tissue	Miller's elastic Van Gieson EVG CP-HiSD-SOP-EVG	
	Neutral mucins	Oil red O CP-HiSD-SOP-OilRedO	
	Hepatitis B surface antigen and copper associated protein	Orcein (Shikata) CP-HiSD-SOP-Orcein	
	Polysaccharides including glycogen	Periodic acid Schiff PAS CP-HiSD-SOP-PAS	
	Basement membrane	Periodic acid silver PAAg CP-HiSD-SOP-PAAG	
	Haemosiderin	Perl's Prussian blue CP-HiSD-SOP-Perls	
	Mast cells	Toluidine blue CP-SHIS-SOP-004 (no26)	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	А
FFPE Tissue (cont'd)	Detection of: (cont'd)	Special Staining Manual (cont'd):	
	Calcium salts	Von Kossa CP-SHIS-SOP-004 (no 28)	
	Atypical mycobacteria	Wade Fite CP-SHIS-SOP-004 (no29)	
	Acid fast bacilli	Ziehl-Neelsen ZN CP-HiSD-SOP-ZN	
FFPE Tissue	Detection of the following:	Immunohistochemistry Automated methods using Bond III IHC instruments using inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36	
		Incorporating the following antibodies:	
	High MW Cytokeratin	34BE12	
	Pan-cytokeratin CK1-8, 10, 14-16 and 19	AE1/3	
	Adenovirus	Adenovirus	
	Carcinoma marker liver, kidney, colon & prostate	AMACR P504s	
	Carcinoma marker prostate	AMACR/34BE12/P63 PIN cocktail	
	Amyloid	Amyloid A component	
	Germ Cell Tumours	Alpha Feto Protein (AFP)	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods using Bond III IHC instruments using inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36 Incorporating the following antibodies:	
	Human p80 protein	ALK-1 (Lymphoma)	
	T-cells, B-cells in the mantle zone	bcl-2	
	Follicular centre B-cells	bcl-6	
	B cells, plasma cells follicular lymphomas and lymphomas	BOB -1	
	Marker in renal glomerulopathy	C1q (renal)	
	Marker in renal glomerulopathy	C3c (renal)	
	Marker in renal glomerulopathy	C4d (renal)	
	Ovarian epithelial malignancies, seminal vesicle carcinoma, anaplastic lymphoma	Ca 125	
	Medullary Thyroid Tumours	Calcitonin	
	Mesothelial cell lining	Calretinin	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods (cont'd) Bond III IHC instruments and inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36	
	Epithelial cells, low molecular weight	CAM5.2	
	T-cell marker	CD2	
	T-cell marker	CD3	
	T-helper cells	CD4	
	T-cells, B-cells in the mantle zone	CD5	
	Cytotoxic T-cells	CD8	
	Mature B cells, follicular dendritic cells, CALLA	CD10	
	Dendritic cells	CD11c	
	Immature B lymphocytes	CD15	
	B-cell marker	CD20	
	Mature B-cells and FDC	CD21	
	FDC and EBV transformed blasts	CD23	
	Inflammatory and malignant conditions	CD25	
	RS cells	CD30	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods (cont'd) Bond III IHC instruments and inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36	
	Endothelial Cell Marker	CD31	
	Endothelial marker	CD34	
	T-cell and myeloid cells	CD43 (MT1)	
	Leukocyte common antigen	CD45 (LCA)	
	Neutral cell adhesion molecule	CD56	
	Platelet glycoprotein Illa	CD61	
	Macrophages	CD68 (KP1)	
	Monocytes & Macrophages	CD68 (PG-M1)	
	Mast cells and GIST	CD117	
	Plasma cells	CD138	
	B-cell marker	CD79a	
	Ewings sarcoma, T cell Lymphoma	CD99	
	Intestinal epithelial cells, colorectal + other adenocarcinomas	CDX2	
	Carcinoembryonic antigen	CEA	
	Neuroendocrine	Chromogranin A	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods (cont'd) Bond III IHC instruments and inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36	
	Gastrointestinal epithelia	CK20	
	Squamous and myoepithelial cells	CK5/6	
	Normal and neoplastic epithelia	CK7	
	Stratified epithelial cells	CK14	
	Epithelial cells, low molecular weight	CK8/18	
	Cytomegalovirus infected cells	CMV	
	Aggressive B cell lymphoma likely to harbour a c Myc rearrangement	С-Мус	
	Mantle cell lymphoma	Cyclin D1	
	Classification of lymphatic invasion of primary tumours	D2-40	
	Striated and smooth muscle cells	Desmin	
	Normal and neoplastic epithelium	ЕМА	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods (cont'd) Bond III IHC instruments and inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36	
	Lymphatic endothelium	Factor VIII	
	Fibrohistiocytic Tumour	Factor XIIIa	
	Erythroid cells, erythroleukemia	Glycophorin A	
	Hepatocellular carcinomas(HCC), yolk sac tumours	Glypican-3	
	Cytotoxic T cells granules	Granzyme B	
	Smooth muscle	h-Caldesmon	
	Trophoblasts	HCG	
	GVHD Skin	HLA-DP, DQ, DR	
	Melanosomes	HMB 45	
	Helicobacter pylori	H. pylori	
	Immunoglobulin G	IgG	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods (cont'd) Bond III IHC instruments and inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36	
	Sex chord stromal tumours	Inhibin	
	Islets of Langerhans tumours	Insulin	
	Cell proliferation marker	Ki 67	
	Breast cancer	Mammoglobin	
	Melanocytes (	MELAN-A/ MELAN-R	
	Broad range cytokeratin	MNF116	
	B-cells	MUM-1	
	Myeloid cells	Myeloperoxidase	
	Classification of rhabdomyosarcoma	Myo-D1	
	Classification of rhabdomyosarcoma and Wilms tumours	Myogenin	
	Skeletal and cardiac muscle	Myoglobin	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods (cont'd) Bond III IHC instruments and inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36	
	Seminoma	OCT-2	
	Germ Tumour cells	OCT3/4	
	Tumour suppressor gene	P53	
	mRNA/ p16 HPV biomarkers	P16	
	Basal cell marker	P63	
	ALL	Pax 5	
	Follicular helper T cells	PD-1	
	Placental alkaline phosphatase	PLAP	
	Prostatic intraepithelial neoplasia	PIN cocktail	
	Prostatic specific antigen	PSA	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	А
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated methods (cont'd) Bond III IHC instruments and inhouse procedures: CP-HiSD-SOP-ICC CP-HiSD-SOP-36	
	Melanoma, neuroendocrine cells	S100	
	Smooth muscle cells	Smooth muscle actin	
	SV40 infected cells	SV40	
	Neuroendocrine marker	Synaptophysin	
	Early B-Cell, thymocyte marker	TdT	
	Lumen of thyroid follicles	Thyroglobulin	
	Cytotoxic T cell granule. Anaplastic large cell lymphoma	TIA-1	
	Levels of Trypsin in pancreas	TRYPSIN	
	Thyroid transcription factor-1	TTF-1	
	Mesenchymal marker	Vimentin	
	Wilms Tumour gene product	Wilms Tumour	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated method using Roche Ventana Benchmark and in-house procedures:	
		Incorporating the following antibodies:	
	Cancer marker	Beta Catenin	
	Estrogen Receptor	ER	
	Malignant mesothelioma, colorectal cancer	Glut-1	
	Hepatocellular neoplasms	Glutamine synthetase	
	Breast carcinoma	Her2	
	Human Herpes virus 8 (Kaposi, AIDS)	HHV8	
	Hepatocytes	Hepatocyte Specific Antigen (HSA)	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry Automated method using Roche Ventana Benchmark and in-house procedures:	
		Incorporating the following antibodies:	
	Progesterone Receptor	PR	
	Smooth muscle cells	Smooth muscle myosin	
	Mantle Cell lymphoma transcription factor	SOX11	
FFPE tissue on glass slides	Preparation and examination to identify or exclude morphological and cytological abnormalities	In-Situ Hybridisation Bond III IHC instruments CP-HiSD-SOP-36 CP-HiSD-SOP-BOND	
	Detection and identification of:		
	Latent EBV infection	EBER-ISH	
	Kappa light chains, light chain restriction or monoclonality	Kappa-ISH	
	Lambda light chains, light chain restriction or monoclonality	Lambda-ISH	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	
Slides prepared in-house from sample types above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures:  CP-QMS-SOP-23 Report content	A, C
		CP-QMS-SOP-25 Double reporting using: Leica DM1000 Leica DM2500 Leica DM3000 Leica DM4000 Leica DMLB Leica DMLB Leica DMLB Leica DMRB Leica DMRB Leica DMR Laborlux S Nikon E600 Nikon Eclipse 400 Nikon Eclipse 50i Nikon Eclipse Ci-E Nikon Eclipse Ci-E Nikon Eclipse E400 Nikon Eclipse E600 Olympus BH2 Olympus BX40 Olympus BX40CY Olympus BX41 Olympus BX45 Olympus BX45 Olympus CX40RF200	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)  Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and microscopic examination using documented inhouse procedures in conjunction with manufacturer's instructions (where relevant)	A
Skin biopsies	Detection and identification of antigens and antibodies:	Using Leica CM1950 Microtome and Leica microscope with UV attachment and filters to enable viewing of fluorescein isothiocyanate (FITC) with in-house procedures: CP-HiSD-SOP-6 CP-HiSD-SOP-27	
	IgA	FITC conjugated anti Human IgA	
	IgG	FITC conjugated anti Human IgG	
	IgM	FITC conjugated anti Human IgM	
	C3 Complement	FITC conjugated anti Human C3	
	C1q Complement	FITC conjugated anti Human C1q	

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HUMAN TISSUES AND FLUIDS (cont'd)	Gynaecological Cytology		A
Cervical Cytology samples (Gynae)Cervical/Vaginal cells	Preparation and screening to identify or exclude morphological and cytological abnormalities (cont'd)	Liquid based Cytology processing Automated method using T5000 processor and in-house procedure: CP-CyCer-SOP-41 T2000 processor CP-CyCer-SOP-4 Leica ST5020/CV5030 stainer and coverslipper CP-CyCer-SOP-42 CP-CyCer-SOP-43  Papanicolaou staining CP-CyCER-SOP58	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy qualitative analysis In-house procedures: CP-CyCER-SOP-76 using microscopes listed above	
Cervical Cytology samples Vaginal/Cervical cells	Detection of high-risk HPV mRNA	Hologic Tomcat aliquotter and Hologic Panther Nucleic Acid Amplification Test (NAAT) using APTIMA HPV Assay and in-house procedure: CP-CyMol-SOP-14, CP-CyMOl-SOP-15	

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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Diagnostic Cytology</u>		А
Fluids Brushings Imprints, Fine-needle aspirations CSF Urine	Preparation and screening to identify or exclude morphological and cytological abnormalities (cont'd)	Preparation/Centrifugation Manual method using:  Hettich Rotina 46 centrifuge and inhouse procedure: CP-CyNG-SOP-4	
		Thermo Shandon Cytospin4 cytocentrifuge and in-house procedure: CP-CyNG-SOP-36	
Slides prepared from sample types listed above		Papanicolaou staining  Automated method using Leica ST5020/CV5030 Stainer and Coverslipper And in-house procedures: CP-CyNG-SOP-42 CP-CyNG-SOP-43	
Slides prepared from sample types listed above		Romanowsky Stains: Giemsa and May Grunwald Giemsa CP-CyNG-SOP-7	
Synovial fluid	Identification of crystals: Monosodium urate Calcium pyrophosphate Basic Calcium Phosphate Cholesterol	Polarising microscopy manual method using: Leica DMLB microscope with compensated polarised filter and in-house procedure: CP-CyNG-SOP-50	
Stained slides prepared in- house from sample types above	Morphological assessment and Interpretation/diagnosis	Microscopy (qualitative analysis) in house procedure CP-CyNG-SOP-50 and microscopes listed above	
END			

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