

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 8665 Accredited to ISO 15189:2012	<b>The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services</b>	
	Issue No: 004	Issue date: 16 November 2020
	Department of Cellular Pathology Pathology Centre C37 New Cross Hospital Wolverhampton Road Wolverhampton WV10 0QP United Kingdom	Contact: Katy New Tel: +44 (0)1902 07999 ext. 8247 E-Mail: <a href="mailto:katy.new@nhs.net">katy.new@nhs.net</a> Website: <a href="http://www.royalwolverhampton.nhs.uk">www.royalwolverhampton.nhs.uk</a>
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
<b>Address:</b> Department of Cellular Pathology Pathology Centre C37 New Cross Hospital Wolverhampton Road Wolverhampton WV10 0QP United Kingdom	<b>Local contact</b> Rita Mistry	Histopathology Cervical Cytology HPV testing Diagnostic Cytology Andrology for fertility and post vasectomy
		A

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

Location details	Activity	Location code
Department of Blood Sciences Walsall Manor Hospital Moat Road Walsall	Natalie Worton	Andrology investigations for fertility and post vasectomy
		B



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#### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND BODY FLUIDS  Fresh human tissue	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	Manufacturer's instructions and documented in house methods specified below:  <u>Decalcification</u> Manual method using SOP F2.H075P.HIS and chemical end point testing.	A  A



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN TISSUE AND BODY FLUIDS</p> <p>Fixed, paraffin-wax processed tissue</p>	<p><u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u></p>	<p>Specimen Dissection Manual method using documented in house procedure F2.H028P.CP Skin Punch Biopsy Dissection Protocol F2.H022P.CP Open Diagnostic Biopsies F2.H021P.CP Cystectomy F2.H018P.CP Ischaemic Bowel F2.H017P.CP Nephrectomy F2.H014P.CP Specimen Trimming Room - Specimen Dissection F2.H013P.CP Biomedical Scientist (BMS) Specimen Dissection F2.H010P.CP Specimen Dissection Procedure - Bowel Cancer Screening Polyps F2.H009P.CP Specimen Dissection Procedure - Larynx F2.H008P.CP Specimen Dissection Procedure - Salivary Gland F2.H007P.CP Specimen Dissection Procedure - Foreskin F2.H006P.CP Specimen Dissection Procedure - Vas Deferens F2.H005P.CP Specimen Dissection Procedure - Thyroid F2.H004P.CP Specimen Dissection Procedure - Appendix F2.H002P.CP Specimen Dissection Procedure - Gall Bladder</p>	<p>A</p>



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)		
Fixed, paraffin-wax processed tissue (cont'd)		Tissue processing Manufacturer's instructions using Leica Peloris, Sakura Finetek Tek and Thermo Fisher Excelsior tissue processors in conjunction with documented in house procedures F2.H099P.HIS Peloris Processing Machine F2.H098P.HIS Sakura VIP Tissue Processor. F2.H051P.CP Excelsior Processing Machines	A
		Tissue embedding Manufacturer's instructions for Sakura Finetek TEC in conjunction with documented in house procedure F2.H083P.HIS Embedding and Cerebro Actions	A
Fixed, paraffin-wax processed tissue		Tissue Microtomy Manual method using documented procedure - Rotary and sledge microtomes F2.H003P.CP Microtomy	A



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)		
	Fresh (unfixed and unprocessed tissue)	Manufacturer's instructions for Leica CM1900 Cryostat and documented in house method: C5.H004P.HIS Frozen Sections	A
	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	C5.H004P.HIS Frozen Sections	A
Fixed paraffin processed tissue on slides	Tissue architecture and nuclear detail (identification of basophilic and eosinophilic structures)	Haematoxylin & Eosin staining Documented procedure & manufacturer's instructions using Sakura Finetek Prisma and Sakura Finetek Glas F2.H097P.HIS Prisma Staining Machine, use and reagent maintenance	A



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)		
Fixed, paraffin processed tissue on slides (cont'd)	Special staining for the identification of:	In house documented manual staining technique: F2.H016P.CP Hand Staining SOP	A
	mast cells	Giemsa technique (manual)	
	Gram positive and Gram negative organisms	Gram	
	fibrin	Martius Yellow Brilliant Crystal Scarlet Soluble Blue (MSB)	
	melanin	Masson Fontana silver	
	Hepatitis B surface antigen, copper-associated protein and elastic connective tissue fibres	Orcein (Shikata) Mega blocks – Manual	
	collagen connective tissue fibres	van-Gieson	
	mast cells / metachromatic tissue components	Toluidine Blue technique	



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Manufacturer's instructions for Dako Artisan stainer and in house documented method F2.H011P.CP Dako Artisan Link Pro Special Stain Platform	A
Fixed, paraffin processed tissue on slides	Special staining for the identification of:		
	weakly sulphated and acidic mucins	Alcian Blue (AB)	
	acidic and neutral mucins	Alcian Blue Periodic Acid-Schiff (AB PAS) (With Haematoxylin)	
	acidic and neutral mucins	Alcian Blue Periodic Acid-Schiff (AB PAS)	
	amyloid	Congo Red	
	elastic connective tissue fibres	Elastic van-Gieson (EVG)	
	reticulin connective tissue fibres	Reticulin	
	fungi	Grocott	
	iron / haemosiderin	Perls Prussian Blue	
	connective tissue elements	Masson Trichrome	
	mucins	Mucicarmine	
	Hepatitis B surface antigen, copper-associated protein and elastic connective tissue fibres	Orcein (Shikata)	
	glycogen, mucopolysaccharide components, fungi and basement membranes	Periodic Acid-Schiff (PAS)	



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Manufacturer's instructions for Dako Artisan stainer and in house documented method F2.H011P.CP Dako Artisan Link Pro Special Stain Platform	A
Fixed, paraffin processed tissue on slides	Special staining for the identification of:  glycogen  basement membranes  Spirochaetes  acid and alcohol-fast bacilli	Diastase Periodic Acid-Schiff (D PAS)  P.A. Methenamine silver (PAS M, Jones Hexamine Silver)  Warthin Starry  Ziehl-Neelsen (ZN)	
Fixed, paraffin processed tissue on slides (cont'd)	Immunocytochemistry Identification of:  Prostate carcinoma Pan cytokeratin Non-small cell lung carcinoma Embryonic cell in normal cell and germ tumours Amyloid Diffuse lymph proliferative disease and neoplastic cells of follicular lymphoma Lymphoma Epithelial cell types	Automated Immunocytochemistry methods using manufacturer's instructions for Leica Bond III and Roche Ventana Benchmark Ultra Immunostaining Platforms F2.H012P.CP Leica Bond III F2.H050P.CP Roche Ventana Benchmark Ultra  Androgen Receptor (AR) AE1 / 3 Multicytokeratin ALK-1 Alpha Fetoprotein (AFP)  Amyloid A Bcl-2  Bcl-6 Ber-EP4	A





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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Automated Immunocytochemistry methods using manufacturer's instructions for Leica Bond III and Roche Ventana Benchmark Ultra Immunostaining Platforms F2.H012P.CP Leica Bond III F2.H050P.CP Roche Ventana Benchmark Ultra	A
Fixed, paraffin processed tissue on slides (cont'd)	Immunocytochemistry Identification of:  Carcinoma B cells, plasma cells follicular lymphoma and lymphomas Complement Complement Complement Ovarian epithelial malignancies, seminal vesical carcinoma, anaplastic lymphoma Pancreatic and GI tumours Parafollicular cells in thyroid and medullar thyroid carcinomas Mesothelioma Langerhans cells T cells T cell subsets T cells (helper and mature) T cells T cell lymphoma T ALL and lymphomas T cell subset Mature B cells, follicular dendritic cells, CALLA Granulocytes, Reed Sternberg cells B cells	Beta Catenin BOB-1  C9 C1q C3c CA125  CA19.9 Calcitonin  Calretinin CD1a CD2 CD3 CD4 CD5 CD7 CD8 CD10  CD15  CD20	



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Automated Immunocytochemistry methods using manufacturer's instructions for Leica Bond III and Roche Ventana Benchmark Ultra Immunostaining Platforms F2.H012P.CP Leica Bond III F2.H050P.CP Roche Ventana Benchmark Ultra	A
Fixed, paraffin processed tissue on slides (cont'd)	Immunocytochemistry Identification of: (cont'd)		
	Mature B cells Follicular dendritic cells	CD21	
	B cells	CD22	
	B cells	CD23	
	Reed Sternberg cells, plasma cells	CD30	
	Endothelial cells	CD31	
	Haematopoietic cells, vascular endothelium	CD34	
	T cells and myeloid lineage cells	CD43	
	Squamous epithelium	CD44	
	Natural Killer cells, neuroendocrine tissue, macrophages, monocytes, myeloid cells	CD56	
	NK Cells neuroendocrine tumours	CD57	
	B cells, macrophages, monocytes, myeloid cells	CD68	
	Mast cells	CD79a	
	Ewing's sarcoma, T cell marker	CD99	
	Differentiating B cells	CD117 (c-KIT)	
	Intestinal epithelial cells, colorectal and other	CD138	
	Endothelial cells	CD141 (Thrombomodulin)	
	Adenocarcinomas	CDX2	



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<p><u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)</p> <p>CEA glycoproteins Tissues of neuroendocrine origin Tumour expression Cytomegalovirus Normal and neoplastic epithelia Epithelial cells Epithelial cells CK for Carcinoma Adenocarcinomas, columnar epithelial cells Basal cells, filamentous keratin, prostate adenocarcinoma Lymphatic endothelium Striated and smooth muscle Gastro Intestinal Stromal tumours Normal duct epithelium, ductal carcinoma Normal and neoplastic epithelium Adenocarcinoma Nuclei of cells containing high levels of oestrogen VW factor in endothelial cells Fibrohistiocytic marker Thyroid, head and neck tumours Breast epithelium</p>	<p>Automated Immunocytochemistry methods using manufacturer's instructions for Leica Bond III and Roche Ventana Benchmark Ultra Immunostaining Platforms F2.H012P.CP Leica Bond III F2.H050P.CP Roche Ventana Benchmark Ultra</p> <p>CEA (Carcino Embryonic Antigen) Chromogranin A</p> <p>Cyclin D1 Cytomegalovirus (CMV) Cytokeratin 7(CK7)</p> <p>Cytokeratin 8/18 (CK8/18) Cytokeratin 14 (CK14) Cytokeratin 19 (CK19) Cytokeratin 20 (CK20)</p> <p>Cytokeratin (HMW)</p> <p>D240 Desmin DOG-1</p> <p>E-Cadherin</p> <p>Epithelial Membrane Antigen</p> <p>ESA/MOC31 Estrogen Receptor (ER)</p> <p>Factor VIII Factor XIIIa Galectin 3</p> <p>GATA 3</p>	A



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<p><u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)</p> <p>Schwann cells, enteric glial cells, astrocytomas, ependymomas T cells Placental trophoblasts Hepatocellular carcinoma Breast carcinoma typing Human Herpes Virus 8 Melanoma marker IgA IgD IgG IgM Sex cord stromal tumours Proliferating cells Leucocytes Melanoma marker Mesothelial cells Pan cytokeratin Colon carcinoma Lympho-haemopoietic tumours Colon carcinoma Colorectal carcinoma Neutrophil granulocytes, monocytes</p>	<p>Automated Immunocytochemistry methods using manufacturer's instructions for Leica Bond III and Roche Ventana Benchmark Ultra Immunostaining Platforms F2.H012P.CP Leica Bond III F2.H050P.CP Roche Ventana Benchmark Ultra</p> <p>GFAP</p> <p>Granzyme HCG Hep Par 1 (Hepatocyte) Herceptin (HER 2) C-ERB2 HHV8 HMB45 IgA IgD IgG IgM Inhibin Ki67 Leukocyte Common Antigen Melan-A Mesothelial Cell Marker MNF116 MLH1 MUM-1</p> <p>MSH2 MSH6 Myeloperoxidase</p>	A



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Automated Immunocytochemistry methods using manufacturer's instructions for Leica Bond III and Roche Ventana Benchmark Ultra Immunostaining Platforms F2.H012P.CP Leica Bond III F2.H050P.CP Roche Ventana Benchmark Ultra	A
Fixed, paraffin processed tissue on slides (cont'd)	Immunocytochemistry Identification of: (cont'd)		
	Rhabdomyoblastic differentiation	Myoglobin	
	Peripheral nerves, neuroendocrine tumours	Myosin	
	B cell germinal centre	OCT-2	
	Germ cell tumours	OCT-3/4	
	HPV	P16	
	Prostatic carcinoma	p504s	
	Cell proliferation	p53	
	Prostate basal cells, proliferative cells	p63	
	B cells	PAX-5	
	Nuclear staining	PAX-8	
	Neuronal marker	PGP 09.5	
	Prostate carcinoma	PIN-4	
	Germ cell tumours	PLAP	
	Nuclear expression	PMS2	
	Nuclei of cells expressing progesterone	Progesterone Receptor (PR)	
	Prostate secretory and ductal epithelium	Prostate Specific Antigen	
	Glandular Prostatic epithelium	PSAP	
	Renal neoplasm	RCC	
	Schwann cells, nerve processes, S100+ neoplasms	S100	
	Smooth muscle cell differentiation	Smoothelin	
	Smooth muscle cells, myoepithelium	Smooth Muscle Actin	



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Automated Immunocytochemistry methods using manufacturer's instructions for Leica Bond III and Roche Ventana Benchmark Ultra Immunostaining Platforms F2.H012P.CP Leica Bond III F2.H050P.CP Roche Ventana Benchmark Ultra	A
Fixed, paraffin processed tissue on slides (cont'd)	Immunocytochemistry Identification of: (cont'd)  Neuroendocrine cells Cytoplasmic staining Leukaemias, acute lymphocytic lymphomas Thyroglobulin containing cells Activated T cells Thyroid follicular cells Urothelial lesions Cells of mesenchymal origin Epithelial cells and smooth muscle of fallopian tube origin. Wilms tumour	Synaptophysin TAG-72 TdT  Thyroglobulin TIA-1 TTF-1 Uroplakin Vimentin WT-1	
Fixed, paraffin processed tissue on slides	Detection of diagnostically important tissue antigens: <ul style="list-style-type: none"> <li>• Kappa</li> <li>• Lambda</li> <li>• EBER</li> </ul>	In Situ Hybridisation Manufacturer's instructions for using Leica Bond III platform (hybridisation and visualisation in conjunction with in house documented method F2.H012P.CP Leica Immunostaining Platforms	



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Histopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)		
Paraffin processed tissue Fresh frozen tissue	Opinions and Interpretations Interpretation of histology and cytology staining	Microscopy using G1.S010P.CP Reporting Guidelines for Consultant and Trainee Clinical Staff F2.H204.HIS Summary of Biopsy/Cut Up and Reporting Guidelines – Processes to be followed by Trainee Medical Staff F2.H020P.CP Handling and Reporting of Specimens with Suspected Lymphoma	A
Bronchial brushings Sputum	<u>Cytopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>  Non-Gynae Cytology  Detection of Cytological abnormality to aid clinical diagnosis	Manufacturer's instructions for ThinPrep Liquid-Based Cytology (LBC) Hologic T5000 filtration processing platform, manual staining (Diff Quik Romanowsky stain variant) F2.C011B.CP Thin Prep 5000 Manual E3.C023P.CYT LBC Sample Processing (Cytology Specimen Handling & Processing)  E3.C024P.CYT Non-Gynae Cytology Specimen Preparation	A



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	Cytopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Manufacturer's instructions for Sakura Finetek DRS2000 platform (Papanicolaou) in conjunction with in house documented method: D1.H004N.CP Sakura Tissue-Tek DRS 2000 Automatic Slide Stainer Operating Manual E3.C024P.CYT Non-Gynae Cytology Specimen Preparation	A
Bronchial washings			
Cerebrospinal Fluid (CSF)			
Fine Needle Aspirates (Predominantly Head and Neck samples)			
Gastro-Intestinal (GI) and biliary brushings			
		Manufacturer's instructions for Hettich Rotina 380, manual staining (Diff Quik Romanowsky) in conjunction with in house documented method: H1.H006N.CP Hettich Rotina 380 Centrifuge User Manual E3.C024P.CYT Non-Gynae Cytology Specimen Preparation	A
		Manufacturer's instructions for Sakura Finetek DRS2000, manual staining (Diff Quik Romanowsky) in conjunction with in house documented method: E3.C024P.CYT Non-Gynae Cytology Specimen Preparation	A
		Manufacturer's instructions for Sakura Finetek DRS2000 platform (Papanicolaou) in conjunction with in house documented method: E3.C024P.CYT Non-Gynae Cytology Specimen Preparation	A





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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Cytopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)		
Joint fluids	Detection of monosodium urate and calcium pyrophosphate crystals	Manufacturer's instructions for Hettich Rotina 380, automated staining using Sakura Finetek DRS2000 platform (Papanicolaou) in conjunction with in house documented method: E3.C024P.CYT Non-Gynae Cytology Specimen Preparation	A
Nipple discharge specimens Serous Effusions Urine		Manufacturer's instructions for Sakura Finetek DRS2000 or manual staining (Diff Quik Romanowsky in conjunction with in house documented method: E3.C024P.CYT Non-Gynae Cytology Specimen Preparation	A
Cytology Fluids	Morphological assessment and interpretation/diagnosis	Microscopy using E3.C062P.CYT Cytology Synovial Fluids & Crystals (reporting) E3.C061P.CYT NON-GYNAE SCREENING & REPORTING	A



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Cytopathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)		A
ThinPrep Liquid Based Cytology samples	Cervical Cytology  Detection of DNA from high risk (HR) Human Papilloma Viruses (HPV): HPV 16 HPV 18 Other HR HPV genotypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) not individually identified.	In House methods : Procedure for testing High Risk HPV) and manufacturer's instructions using the Roche Cobas® HPV test with the Cobas® p480, 6800 and 8800 instruments.	A
ThinPrep Liquid Based Cytology samples	Cervical Cytology screening - detection of Cytological abnormality to aid clinical diagnosis	ThinPrep Liquid-Based Cytology (LBC) Manufacturer's instructions for Hologic T5000 filtration processing and Sakura Finetek DRS2000 (Papanicolaou) in conjunction with in house documented method: F2.C011B.CP Thin Prep 5000 Manual  E3.C060P.CYT Cytology Cervical Screening Procedure	A
ThinPrep Liquid Based Cytology samples prepared as above	Morphological assessment and interpretation/diagnosis Opinions and Interpretations	Microscopy & screening using E3.C102P.CYT Cervical Cytology - Reporting & Validating on TDHC E3.C060P.CYT Cytology Cervical Screening Procedure	A



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HUMAN TISSUE AND BODY FLUIDS (cont'd)	<u>Andrology examination activities to detect abnormalities in semen to aid clinical diagnosis</u>		A, B
Ejaculate	Andrology	In house documented manual method in conjunction with BAS guidelines for the assessment of post vasectomy semen samples (2002)	
Ejaculate	Post vasectomy examination (presence or absence of spermatozoa)	Manual preparatory technique and microscopy (reporting) F2.A002P.CP Andrology - Post Vasectomy SOP F2.H023P.CP Andrology Papanicolaou Staining Criteria	
Ejaculate	Infertility	In house documented manual technique in conjunction with WHO Examination and processing of human semen (2010) 5 <sup>th</sup> Ed  F2.A001P.CP Semen Analysis SOP (Andrology - Infertility)	
	Qualitative/quantitative assessment of: Volume Macroscopic appearance Sperm concentration Sperm motility Sperm morphology	F2.H023P.CP Andrology Papanicolaou Staining Criteria	
END			