


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 10259 Accredited to ISO 15189:2012	Birmingham Women's and Children's NHS Foundation Trust	
	Issue No: 006 Issue date: 29 September 2023	
	Birmingham Women's Hospital Mindelsohn Way Edgbaston Birmingham B15 2TG	Contact: Kerry Gawthorpe Tel: +44 (0) 121 333 9923 E-Mail: kerry.gawthorpe@nhs.net Website: www.bwc.nhs.uk
Testing performed at the above address only		

Site activities performed away from the locations listed above:

Location details		Activity
Address Lower Ground Floor Mindelsohn Way Edgbaston Birmingham B15 2TG	Local contact: Kerry Gawthorpe	Mortuary



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
EDTA Plasma / Red Blood Cells. Neonatal EDTA Red Blood Cells	Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh D Negative AB Rh D Negative B RhD Negative O Rh D Negative	IBG Immucor NEO Iris Analyser SOP1527: ABO/D group, antibody screen and DAT using the NEO Iris analyser IBG Immucor ECHO Lumena Analyser SOP1565: ABO/ D group antibody screen and DAT using the ECHO Lumena analyser Manual test using Grifols DG Therm incubator and DG Spin centrifuge using Grifols DG Gel ABO/Rh (2D) + Kell card and Grifols DG Gel Newborn Card SOP40: Manual methods for ABO/D Group Antibody Screen and DAT
EDTA Plasma	Antibody Screen by detection of antibodies to - Rh (C, D, E, c, e Cw); - Kell (K k Kpa Kpb Jsa Jsb); - Duffy (Fya Fyb); - Kidd (Jka Jkb); - P1; - MNS (M N S s); - Lutheran (Lua and Lub) - Lea and Leb	IBG Immucor NEO Iris Analyser SOP1527: ABO/D group, antibody screen and DAT using the NEO Iris analyser IBG Immucor ECHO Lumena Analyser SOP1565: ABO/ D group antibody screen and DAT using the ECHO Lumena analyser



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EDTA Plasma	Antibody Screen by detection of antibodies to - Rh (C, D, E,c, e Cw); - Kell (K k Kpa Kpb Jsa Jsb); - Duffy (Fya Fyb); - Kidd (Jka Jkb); - P1; - MNS (M N S s); - Lutheran (Lua and Lub) - Lea and Leb	Indirect Antiglobulin Test: column agglutination technology using Grifols DG Gel Coombs card and Serascan 4 red cells. SOP40: Manual methods for ABO/D Group Antibody Screen and DAT Manual: Indirect Antiglobulin Test using NHSBT 4 Cell rr r'r and r''r cells, Indirect Antiglobulin test using DG Coombs card and Column Agglutination Technology SOP 1410: 4 Cell D negative Antibody Screen



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:
EDTA Plasma	Identification of antibodies to: - Rh (C, D, E, c, e Cw); - Kell (K k Kpa Kpb Jsa Jsb); - Duffy (Fya Fyb); - Kidd (Jka Jkb); - P1; - MNS (M N S s); - Lutheran (Lua and Lub) - Lea and Leb	IBG Immucor NEO Iris Analyser SOP 41: Antibody Identification by automated and manual Techniques IBG Immucor ECHO Lumena Analyser SOP 41: Antibody Identification by automated and manual techniques Manual Indirect Antiglobulin Test: column agglutination technology using Grifols DG Gel Coombs card and Identisera DIANA red cell panel. SOP 41: Antibody Identification by automated and manual techniques SOP 41: Antibody Identification by automated and Manual Techniques
EDTA Plasma	Compatibility testing of patients' plasma with donor cells	Manual test using Grifols DG Therm incubator and DG Spin Centrifuge SOP 28: Compatibility Testing Using Grifols System



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:
EDTA Red Cells	Direct Antiglobulin Test (DAT): Detection of antibodies adsorbed on the red cell membrane	IBG Immucor NEO Iris Analyser SOP1527: ABO/ D group antibody screen and DAT using NEO Iris Analyser. IBG Immucor ECHO Lumena Analyser SOP 1565: ABO/ D group antibody screen and DAT using ECHO Lumena Analyser. Manual Indirect Antiglobulin test on DG Coombs card or DAT columns on DG Gel Newborn card. SOP40: Manual methods for ABO/D Group Antibody Screen and DAT
EDTA Red Cells	Antigen Phenotyping: - Rh and K C E c e K	IBG Immucor NEO Iris Analyser SOP 1279: Red Cell Phenotyping IBG Immucor ECHO Lumena Analyser SOP 1279: Red Cell Phenotyping
EDTA Whole Blood	Kleihauer test for estimation of foeto-maternal haemorrhage: Qualitative screen for the presence of foetal cells. Quantitative assessment of volume by calculation from cell count.	Microscopic analysis of blood film. Manual staining using Guest Fetal Red cell detection kit SOP 24: The Kleihauer Test



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:
Blood	Full Blood Count (FBC) analysis of the following parameters: WBC RBC HGB HCT MCV MCH MCHC RDW-CV PLT NEUT LYMPH MONO EOS BASO Reticulocyte count	Sysmex XN-2000 SOP: Haematology 2222 – FBC and Retic processing using Sysmex XN-2000 analysers
Blood	Glucose 6 Phosphate Dehydrogenase (G6PD) screen	Commercial kit - Trinity Biotech G6PDH Deficiency SOP: 59 G6PD screening test
Blood	Reporting of normal and abnormal morphologies Nucleated red blood cell (NRBC) count	Hematek stain machine, Hematek commercial stain pack SOP: 64 Blood film preparation, examination and reporting



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: Documented -in-house methods to meet the requirements of the SCT screening programme as defined in the July 2018 NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements
Blood	Detection of haemoglobin S (Hb-S)	Commercial kit Microgen Bioproducts S-Test Kit SOP: 83 - Sickle Solubility Test
Blood	Haemoglobinopathy screening for: - α and β thalassemia and abnormal haemoglobins - Determination of HbA2, HbF and HbS levels.	SEBIA Capillars 2 Flex Piercing analyser SOP: 79A Capillary Iso-electric focusing (CIEF) on Sebia Capillars2 Flex piercing
Citrated plasma	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> - PT, INR - APTT 1. Fibrinogen Lupus anticoagulant screen and confirmation LMWH Anti Xa assay	Werfen ACL TOP 350 SOP: 85 Routine use of TOP 500 Werfen ACL TOP 350 SOP: 82 Lupus anticoagulant screening on TOP 500 Werfen ACL TOP 350 SOP: 87 LMW Heparin anti Xa assay on TOP 500



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Documented -in-house methods to meet the requirements of the FASP screening programme as defined in the April 2019 'FASP screening: laboratory QA evidence requirements'
Serum	Alpha-fetoprotein (AFP)	Roche cobas e601 electrochemiluminescence immunoassay:
	Free B human Chorionic Gonadotrophin (B-hCG)	Clinical Chemistry 3188
	Pregnancy Associated Plasma Protein A (PAPP-A)	Clinical Chemistry 54662
	Total human Chorionic Gonadotrophin (hCG+B)	Clinical Chemistry 54661
	Inhibin A	Clinical Chemistry 3180
	unconjugated Oestriol (uE3)	Beckman Access 2 electrochemiluminescence immunoassay:
		Clinical Chemistry 54663
		Chem/MsuE3AD



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<p>HUMAN BODY TISSUE</p> <p>Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue Frozen Tissue</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u></p> <p>Routine diagnostic examination of Histological specimens using the following:</p>	<p>Using in house methods: Dissection: Routine Surgical Trimming Procedures for Technical Staff – SOP 68386.</p> <p>Tissue Pathways for Gynaecological Pathology - External Document 1191.</p> <p>Embedding: using the Leica Arcadia Embedding Station & Coldplate & Leica EG 1150 Embedder.</p> <p>Specimen Embedding – SOP 68306.</p> <p>Microtomy: using the PFM 3004 / 3003, Anglia Scientific AS300 and Slee Cut 4060 Microtomes.</p> <p>Section Cutting – SOP 68294.</p> <p>Staining / Coverslipping: using the HistoCore Spectra Workstation (integrated stainer & coverslipper).</p> <p>Routine H&E Staining Using the Leica HistoCore Spectra Stainer – SOP 68295.</p> <p>Using the Leica HistoCore Spectra Workstation – SOP 2220.</p> <p>Cryomicrotomy: using the Leica CM1950 Cryostat.</p> <p>Urgent Specimens (Rapid Frozen Sections) – SOP 68274.</p> <p>Frozen Sections Using The Leica CM1950 Cryostat – SOP 68296.</p>



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<p>HUMAN BODY TISSUE</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u></p>	
	Identification of nuclei, cell cytoplasm and most connective tissues in cells and tissues.	Documented In-house Methods and Manufacturer's instructions for Haematoxylin & Eosin stain: Routine H&E Staining Using the Leica HistoCore Spectra Stainer – SOP 68295
	Special staining of Histopathology examinations to assist in detection of clinical abnormalities.	Documented In-house Methods for special stains
	Acid mucins	Alcian Blue Method (pH2.5) for Acid Mucin - SOP 68352
	Neutral & acid mucins / glycogen	Combined Periodic Acid Schiff (PAS) Reaction with Alcian Blue for the Demonstration of Acidic & Neutral Mucins, + Diastase (PASD) for the Demonstration of Glycogen – SOP 1188
	Fungi, neutral mucins /glycogen	Periodic Acid Schiff (PAS) + Diastase (PASD) Reaction for the Demonstration of Glycogen & Neutral Mucins - SOP 68355
	Reticulin fibres	Gordon and Sweet's Method for Reticulin Fibres - SOP 68358
	Gram positive & negative bacteria	Gram Twort Method for Gram Positive & Gram Negative Micro-organisms - SOP 68359
	Fungi	Grocott's Method for Fungi (Sliver Hexamine) - SOP 68360
	Collagen, fibrin & muscle	Masson Trichrome - SOP – 68365
	Elastic fibres, collagen & muscle	Verhoeff's Elastic Van Gieson - SOP 68372
	Ferric iron	Prussian Blue (Perl's) Method for Iron III Compounds – SOP 68371



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HUMAN BODY TISSUE	<u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u>	
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.	Identification of nuclei, cell cytoplasm and most connective tissues in cells and tissues.	
	Mycobacterium tuberculosis	Ziehl-Neelsen Stain for Tubercle Bacilli - SOP 68374
Frozen Tissue	Lipids	Oil Red O Method for Lipids in Frozen Sections - SOP 68369
10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue	Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.	Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry: Leica Bond Autostainer - SOP 924
	Ready to Use Antibodies:	
	Tissue epithelial in origin	AE1/AE3
	Adenocarcinoma vs malignant mesothelioma	βerEP4
	Smooth muscle tumours	Caldesmon
	Tumour cells in GIT carcinomas	CA19.9
	Adenocarcinoma – ovarian vs colorectal	CA125
	Gastric neoplasms	CDX2
	Non-neoplastic endometrial stroma. Neoplastic endometrial stromal tumours, Differentiation of primary clear cell gynaecological tumours from clear cell tumours metastatic to the gynaecological tract	CD10
	Stem cells, melanocytes, mast cells, germ cells	CD117



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<p>HUMAN BODY TISSUE</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Endothelial tumours</p> <p>Vascular & lymphatic tumours</p> <p>Leucocytes</p> <p>Neuroendocrine cells, NK cells</p> <p>T-cells, NK cells, Thymocytes</p> <p>Surface of GI cells, colon carcinoma</p> <p>Secretory granules of endocrine cells</p> <p>Mesothelioma, adenocarcinoma, ovarian sex chord stromal tumours</p> <p>Squamous epithelium and neoplasms of type</p> <p>Identifying mantle cell lymphomas (cyclin D1 positive) from CLL/SLL and follicular lymphomas (cyclin D1 negative)</p> <p>Glandular and transitional epithelia and neoplasia of type</p> <p>Normal GI epithelia and urothelium and neoplasia of type</p> <p>Rhabdomyosarcomas, leiomyomas, mesotheliomas</p> <p>Normal and neoplastic epithelial neoplasia</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry: Leica Bond Autostainer - SOP 924</p> <p>CD31</p> <p>CD34</p> <p>CD45 (LCA)</p> <p>CD56</p> <p>CD68</p> <p>CEA (Mono)</p> <p>Chromogranin</p> <p>Calretinin</p> <p>Cytokeratin 5</p> <p>Cyclin D1</p> <p>CK7</p> <p>CK20</p> <p>Desmin</p> <p>EMA</p>



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<p>HUMAN BODY TISSUE</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Expression of ER containing cells</p> <p>Breast carcinoma (primary & metastatic)</p> <p>Breast carcinoma and metastatic tumours</p> <p>Normal, reactive and neoplastic astrocytes</p> <p>Differentiation between benign and malignant liver diseases</p> <p>Melanocytes and melanomas</p> <p>Granulosa cell tumours</p> <p>Proliferative cells</p> <p>Melanocytes, melanomas</p> <p>Mismatch repair gene hMLH1 is a ubiquitous gene encoding the mismatch repair protein (MMR) known as MutL protein homolog 1 (MLH1). MLH1 is utilized by normal proliferating cells to repair point mutations that may occur during DNA replication. Antibody used to detect normal or loss of MLH1 expression.</p> <p>MutS protein homolog 2 (MSH2) is part of the mismatch repair (MMR) pathway which is utilized by normal proliferating cells to repair mutations that may occur during DNA replication. Antibody used to detect normal or loss of MSH2 expression.</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry: Leica Bond Autostainer - SOP 924</p> <p>Estrogen</p> <p>GATA3</p> <p>GCDFP-15</p> <p>GFAP</p> <p>Glypican 3</p> <p>HMB45</p> <p>Inhibin</p> <p>Ki67</p> <p>Melan A</p> <p>MLH1</p> <p>MSH2</p>



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<p>HUMAN BODY TISSUE</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>MutS protein homolog 6 (MSH6) is part of the mismatch repair (MMR) pathway which is utilized by normal proliferating cells to repair mutations that may occur during DNA replication. Antibody used to detect normal or loss of MSH6 expression.</p> <p>Tumor cell nuclei of rhabdomyosarcomas</p> <p>Clear cell carcinoma</p> <p>HPV related high grade cervical intraepithelial squamous neoplasia and glandular neoplasia</p> <p>High grade serous carcinomas of the ovary</p> <p>Molar pregnancy</p> <p>Squamous differentiation in poorly differentiated carcinoma</p> <p>Cases of secretory carcinoma and congenital fibrosarcoma. Pan-TRK IHC can help determine whether translation occurs for novel NTRK rearrangements</p> <p>Parvovirus infected cells</p> <p>Renal cell carcinoma. Can also be used in distinguishing ovarian serous papillary carcinoma (PAX-2 positive) from primary breast carcinoma (PAX-2 negative)</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry: Leica Bond Autostainer - SOP 924</p> <p>MSH6</p> <p>Myo D1</p> <p>Napsin</p> <p>P16</p> <p>P53</p> <p>P57</p> <p>P63</p> <p>Pan-TRK</p> <p>Parvovirus</p> <p>PAX 2</p>



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<p>HUMAN BODY TISSUE</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Expressed in the female genital tract and in epithelial cells of endo cervix and endometrium</p> <p>To demonstrate Placental Alkaline phosphatase in the cells</p> <p>Postmeiotic segregation increased 2 (PMS2) is part of the DNA mismatch repair (MMR) pathway, which is utilized by normal proliferating cells to repair mutations that may occur during DNA replication. Antibody used to detect normal or loss of MSH2 expression.</p> <p>Expression of PGR containing cells</p> <p>SARS-CoV spike and SARS-CoV-2 spike proteins</p> <p>Cancer cells (including neuroendocrine tumor) of colorectal origin</p> <p>Smooth muscle cells, myoepithelial cells, leiomyosarcomas</p> <p>Malignant melanoma</p> <p>Malignant melanocytic tumours, Schwannoma</p> <p>Neuroendocrine cells and neoplasms</p> <p>Normal and neoplastic lung and thyroid cells</p> <p>Primary cells of mesenchymal origin in normal and neoplastic cells</p>	<p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry: Leica Bond Autostainer - SOP 924</p> <p>PAX 8</p> <p>PLAP</p> <p>PMS2</p> <p>Progesterone</p> <p>SARS-CoV-2</p> <p>SATB2</p> <p>SMA</p> <p>SOX-10</p> <p>S100</p> <p>Synaptophysin</p> <p>TTF-1</p> <p>Vimentin</p>



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<p>HUMAN BODY TISSUE</p> <p>10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE). Fresh tissue.</p> <p>Gynae and non-gynae cytology cellular slide preparations provided by associated laboratory</p>	<p><u>Cellular Pathology examination activities for the purposes of clinical diagnosis:</u></p> <p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions.</p> <p>Primary F/Tube high grade serous Ca, Wilm's tumour, malignant mesotheliomas</p> <p>Concentrated Antibodies:</p> <p>Germ cell / Yolk sack tumours</p> <p>Beta Amyloid in brain tissue</p> <p>Adenocarcinoma, squamous cell carcinoma</p> <p>Normal/neoplastic tissue epithelial in origin</p> <p>Basement membrane protein in muscle</p> <p>Skeletal muscle – Slow type</p> <p>Skeletal muscle – Fast type</p> <p>Cytological assessment and interpretation/diagnosis</p>	<p>Documented In-house Methods:</p> <p>Documented In-house Methods and Manufacturer's instructions for Immunohistochemistry: Leica Bond Autostainer - SOP 924</p> <p>WT1</p> <p>AFP</p> <p>βAPP</p> <p>CAM5.2</p> <p>Pan CK</p> <p>α Laminin</p> <p>HC Myosin (S)</p> <p>HC Myosin (F)</p> <p>Cellular Pathology 1264 - Dissecting and Reporting Histology Cases</p>



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy:</u> Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy and documented in-house procedure SOP Post Vasectomy Semen Analysis CP68300
Semen	<u>Fertility testing:</u> Volume pH Sperm morphology including TZI scoring and round cell count	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedure SOPs: Initial macroscopic evaluation of the semen sample. CP 68235 Instructions for the use of pH strips. CP 1075 Evaluation of sperm concentration. CP 68241 Evaluation of sperm morphology. CP 68234 Procedure for Romanowsky stain for morphology assessment CP 68234 Evaluation of sperm motility. CP 68239 Evaluation of sperm vitality CP 68224. Volume/weight Colorimetric strips Stained slides (Papanicolaou) microscopy (Bright field)



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HUMAN BODY FLUIDS (cont'd) Semen (cont'd)	<u>Andrological examination activities for the purposes of clinical diagnosis</u> (cont'd) <u>Fertility testing</u> (cont'd): Sperm concentration Sperm motility Sperm vitality	Improved Neubauer counting chambers and Microscopy (Phase contrast) Microscopy (Phase contrast) Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)
END		