Schedule of Accreditation

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Birmingham Women's and Children's NHS Foundation Trust

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Testing performed at the above address only

Site activities performed away from the locations listed above:

Location details		Activity
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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

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	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Blood Transfusion examinations to assist in clinical investigations (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

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

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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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)	**Sickledex** SOP: 83 - Sickle Solubility Test
Blood	Haemoglobinopathy screening for: - α and β thalassemia and abnormal haemoglobins - Determination of HbA2, HbF and HbS levels.	**SEBIA Capillarys 2 Flex** Piercing analyser SOP: 79A Capilliary Iso-electric focusing (CIEF) on Sebia Capilliarys2 Flex piercing
	<u>Coagulation examination activities for the purpose of clinical diagnosis</u>	
Citrated plasma	- PT, INR - APTT 1. Fibrinogen	**Werfen ACL TOP 350** SOP: 85 Routine use of TOP 500
	Lupus anticoagulant screen and confirmation	**Werfen ACL TOP 350** SOP: 82 Lupus anticoagulant screening on TOP 500
	LMWH Anti Xa assay	**Werfen ACL TOP 350** SOP: 87 LMW Heparin anti Xa assay on TOP 500

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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Cellular Pathology examination activities for the purposes of clinical diagnosis:	
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.	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	Cellular Pathology examination activities for the purposes of clinical diagnosis:	
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	ßerEP4
	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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HUMAN BODY TISSUE	Cellular Pathology examination activities for the purposes of clinical diagnosis:	
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
	Endothelial tumours	CD31
	Vascular & lymphatic tumours	CD34
	Leucocytes	CD45 (LCA)
	Neuroendocrine cells, NK cells	CD56
	T-cells, NK cells, Thymocytes	CD68
	Surface of GI cells, colon carcinoma	CEA (Mono)
	Secretory granules of endocrine cells	Chromogranin
	Mesothelioma, adenocarcinoma, ovarian sex chord stromal tumours	Calretinin
	Squamous epithelium and neoplasms of type	Cytokeratin 5
	Identifying mantle cell lymphomas (cyclin D1 positive) from CLL/SLL and follicular lymphomas (cyclin D1 negative)	Cyclin D1
	Glandular and transitional epithelia and neoplasia of type	CK7
	Normal GI epithelia and urothelium and neoplasia of type	CK20
	Rhabdomyosarcomas, leiomyomas, mesotheliomas	Desmin
	Normal and neoplastic epithelial neoplasia	EMA

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HUMAN BODY TISSUE	Cellular Pathology examination activities for the purposes of clinical diagnosis:	
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
	Expression of ER containing cells	Estrogen
	Breast carcinoma (prinary & metastatic)	GATA3
	Breast carcinoma and metastatic tumours	GCDFP-15
	Normal, reactive and neoplastic astrocytes	GFAP
	Differentiation between benign and malignant liver diseases	Glypican 3
	Melanocytes and melanomas	HMB45
	Granulosa cell tumours	Inhibin
	Proliferative cells	Ki67
	Melanocytes, melanomas	Melan A
	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.	MLH1
	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.	MSH2

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Cellular Pathology examination activities for the purposes of clinical diagnosis:	
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
	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.	MSH6
	Tumor cell nuclei of rhabdomyosarcomas	Myo D1
	Clear cell carcinoma	Napsin
	HPV related high grade cervical intraepithelial squamous neoplasia and glandular neoplasia	P16
	High grade serous carcinomas of the ovary	P53
	Molar pregnancy	P57
	Squamous differentiation in poorly differentiated carcinoma	P63
	Cases of secretory carcinoma and congenital fibrosarcoma. Pan-TRK IHC can help determine whether translation occurs for novel NTRK rearrangements	Pan-TRK
	Parvovirus infected cells	Parvovirus
	Renal cell carcinoma. Can also be used in distinguishing ovarian serous papillary carcinoma (PAX-2 positive) from primary breast carcinoma (PAX-2 negative)	PAX 2

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Cellular Pathology examination activities for the purposes of clinical diagnosis:	
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
	Expressed in the female genital tract and in epithelial cells of endo cervix and endometrium	PAX 8
	To demonstrate Placental Alkaline phosphatase in the cells	PLAP
	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.	PMS2
	Expression of PGR containing cells	Progesterone
	SARS-CoV spike and SARS-CoV-2 spike proteins	SARS-CoV-2
	Cancer cells (including neuroendocrine tumor) of colorectal origin	SATB2
	Smooth muscle cells, myoepithelial cells, leiomyosarcomas	SMA
	Malignant melanoma	SOX-10
	Malignant melanocytic tumours, Schwannoma	S100
	Neuroendocrine cells and neoplasms	Synaptophysin
	Normal and neoplastic lung and thyroid cells	TTF-1
	Primary cells of mesenchymal origin in normal and neoplastic cells	Vimentin

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Cellular Pathology examination activities for the purposes of clinical diagnosis:	Documented In-house Methods:
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
	Primary F/Tube high grade serous Ca, Wilm's tumour, malignant mesotheliomas	WT1
	Concentrated Antibodies:	
	Germ cell / Yolk sack tumours	AFP
	Beta Amyloid in brain tissue	ßAPP
	Adenocarcinoma, squamous cell carcinoma	CAM5.2
	Normal/neoplastic tissue epithelial in origin	Pan CK
	Basement membrane protein in muscle	α Laminin
	Skeletal muscle – Slow type	HC Myosin (S)
	Skeletal muscle – Fast type	HC Myosin (F)
Gynae and non-gynae cytology cellular slide preparations provided by associated laboratory	Cytological assessment and interpretation/diagnosis	Cellular Pathology 1264 - Dissecting and Reporting Histology Cases

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Andrological examination activities for the purposes of clinical diagnosis	
Semen	Post vasectomy:	
	Detection of sperm	Manual method using large volume chambers/ manual microscopy Post Vasectomy Semen Analysis (Andrology 2276)
Semen	Fertility testing:	
	Volume	Volume/weight using EK-200i balance SOP CP68235 - Initial MACROSCOPIC Evaluation of a Semen Sample
	pH	Colorimetric strips SOP CP68235 - Initial MACROSCOPIC Evaluation of a Semen Sample
	Sperm concentration	Manual method using Improved Neubauer counting chambers and phase contrast microscopy SOP 2403 - Evaluation of Sperm and Round Cell Concentration
	Sperm motility	Manual method using phase contrast microscopy SOP 2402 - Evaluation of Sperm Motility
	Sperm vitality	Manual method using Eosin/Nigrosin dye exclusion test and brightfield microscopy SOP 2404 - Evaluation of Sperm Vitality
	Sperm morphology including TZI scoring and round cell count	Manual method using Papanicolaou staining and brightfield microscopy SOP 2307 - Sperm Morphology
END		