


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8846</p> <p>Accredited to ISO 15189:2012</p>	<h3>East and North Hertfordshire NHS Trust</h3> <p>Issue No: 007 Issue date: 09 September 2021</p>	
	<p>Lister Hospital Coreys Mill Lane Stevenage Hertfordshire SG1 4AB</p>	<p>Contact: Laarni Calonzo Tel: +44 (0)1438 285225 E-Mail: l.calonzo@nhs.net Website: www.enher-ts-tr.nhs.uk</p>
<p>Testing performed at the above address only</p>		

Site activities performed away from the locations listed above:

Location details	Activity
<p>Ambulatory Care QE2 Hospital Howlands Welwyn Garden City Hertfordshire AL7 4HQ</p>	<p>Blood storage & issue Fridge managed by Haematology</p>
<p>Blood Transfusion Department Lister Hospital Coreys Mill Lane Stevenage Hertfordshire SG1 4AB</p>	<p>Blood storage & issue Fridge managed by Haematology</p>
<p>Hertford Hospital North Road Hertford SG14 1LP</p>	<p>Local contact Elaine Stokes Phlebotomy services</p>
<p>Lister Hospital Coreys Mill Lane Stevenage Hertfordshire SG1 4AB</p>	<p>Local contact Elaine Stokes Phlebotomy services</p>
<p>QE2 Hospital Howlands Welwyn Garden City Hertfordshire AL7 4HQ</p>	<p>Local contact Elaine Stokes Phlebotomy services</p>



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

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:
Blood Plasma	Antibody Identification by detection of antibodies to: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	Automated using Grifols Gel Column Technology DG Gel Coombs Cards, SOP BTSOP1822 (The use of Grifols Erytra [manual interpretation of results] SOP BTSOP1827 (Antibody Identification [manual interpretation of results
Blood Plasma	Antibody Identification by detection of antibodies to: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	Manual using Grifols DG Gel Coombs Cards SOP BTSOP1829 (Grifols Manual Techniques
Blood	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 Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens	Automated using Grifols Gel Column Technology SOP BTSOP 1822 (The use of the Grifols Erytra



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

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 (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	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 Negative AB Rh D Negative B RhD Negative O Rh D Negative Including the presence of A2 antigens	Manual using Grifols DG Gel ABO/Rh (2D + Kell Cards) SOP BTSOP 1829 (Grifols Manual Techniques) Manual tube techniques using Lorne Antisera for possible subgroups of A using SOP BTSOP1708 (Sub groups of A with anti-A1)
Blood Plasma	Antibody Screen by detection of antibodies to: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	Automated using Grifols Gel Column Technology SOP BTSOP 1822
Blood Plasma	Antibody Screen by detection of antibodies to: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb	Manual using Grifols DG Gel Coombs Cards SOP BTSOP1829 (Grifols Manual Techniques)
Blood Plasma	Compatibility testing of patients plasma with donor cells	Cross matching using manual indirect anti globulin test using Grifols Gel column technology and SOP BTSOP 1830
Blood Plasma	Compatibility testing of patients plasma with donor cells	Cross matching using Grifols serological testing using SOP BTSOP1822



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

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 (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood Plasma	Compatibility testing of patients plasma with donor cells	Electronic cross match using BTSOP 1510
Blood Plasma	Direct Antiglobulin Test (DAT)	Automated using Grifols Gel Column technology SOP BTSOP 1822 (The use of the Grifols Erytra)
Blood Plasma	Foetal Maternal Haemorrhage	Manual Kleihauer Acid Elution Technique using SOP BTSOP 1707
Blood Plasma	Red cell phenotyping for Rh and Kell antigens	Automated using Grifols Gel Column Technology SOP BTSOP 1822 (The use of Grifols Erytra) SOP BTSOP 1825 (Red Cell Phenotyping)
Blood Plasma	Red Cell phenotyping for RBC antigens other than Rh and Kell	Manual using Grifols DG Gel Coombs Cards and manual tube methods using Lorne Antisera; SOP BTSOP 1825 (Red Cell Phenotyping)
	<u>Haematological examinations for the purpose of clinical diagnosis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: HbA1c Hb A2 Hb F	Documented In-House Methods to meet the requirements of the SCT screening programme as defined in the July 2018 sickle cell and thalassaemia screening: laboratory QA evidence requirements Menarini HA8180 HPLC using SOP BLSOPHAEM24 (Procedure on the Use of Menarini HA-8180) BLSOPHAEM25 (Haemoglobinopathy Screening (ANEP))



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East and North Hertfordshire NHS Trust
Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Erythrocyte Sedimentation Rate (ESR)	Red blood cell sedimentation rate using sediplus s2000 analyser and M2000 mixer and SOP BSL SOP HAEM7
Blood Bone marrow	Blood / Bone marrow film analysis in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis	Manual Romanowsky stain using SOP BSLSOPHAEM 4 Perl's Prussian blue reaction using SOP BSLSOPHAEM6
Blood	Blood film analysis, Detection of normal and abnormal blood cell morphology and manual differential	Automated slide and stain maker (Sysmex SP-10) which methanol fixes and stains films by Romanowsky method SOP BSLSOPHAEM 33, 3, 4 and 5.
Blood	FBC and reticulocyte count: WB Differential Hb Platelets RBC MCV MCH MCHC Hct nRBC	Sysmex XN cytometry and spectrophotometry using SOP BSLSOPHAEM31 and BSLSOPHAEM32
Blood	G6PD qualitative screen	Manual fluorescence technique using the Trinity Biotech Kit 203-A BSLSOPHAEM18
Blood	Detection of IM Hetrophile antibodies-Glandular Fever Screen	Manual antibody-antigen latex agglutination using the Monogen Biokit, for IM Hetrophile antibodies. BSLSOPHAEM17



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East and North Hertfordshire NHS Trust
Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Partial detection & speciation of malaria parasites:	Preparation of thin films, manual Giemsa staining and light microscopy using SOP BLSOPHAEM8
Blood	Malarial antigens of: <i>Plasmodium falciparum</i> and pan-detection for: <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> & <i>Plasmodium vivax</i>	Optimal IT rapid malaria screen Immunochromatographic test using SOP BLSOPHAEM9
Blood	Insolubility of HbS Sickle cell screen	Qualitative solubility using the TCS Biosciences Sickle-Check screening kit. SOP BLSOPHAEM14
Urine	Haemosiderin	Perl's Prussian blue reaction using SOP BLSOPHAEM10
Blood	Coagulation testing PT INR Fibrinogen APTT/APTT ratio DDimer Clauss Fibrinogen (QFA Quantitated fibrinogen assay)	Symex CS-2500 using SOP BLSOPHAEM37, BLSOPHAEM38 & BLSOPHAEM39



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East and North Hertfordshire NHS Trust
Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Quantitative determination of: Beta HcG	Roche Cobas e601 Module
Serum	Cortisol	Electrochemiluminescence-immunoassay sandwich assay BSLSOPBIO21
Blood	Digoxin	Competitive Chemiluminescence Immunoassay using BSLSOPBIO72
Blood	Ferritin	ECL Competitive immunoassay, using BSLSOPBIO38 –
Serum	Folate	Sandwich assay using BSLSOPBIO64
Blood	FSH	Competition assay using BSLSOPBIO63 serum folate
Blood	FT3	Sandwich immunoassay BSLSOPBIO66
Blood	FT4	Competition principle BSLSOPBIO62
Blood	LH	Competition principle BSLSOPBIO59
Serum	Oestradiol	Sandwich immunoassay BSLSOPBIO67
Serum	PIGF – Placental Growth Factor	Competitive Chemiluminescence Immunoassay using BSLSOPBIO70
Serum	Procalcitonin	ECLIA using BSLSOPBIO084
Serum	Progesterone	BRAHMS Sandwich Assay using BSLSOPBIO083
Blood	PRL	Competitive Chemiluminescence Immunoassay using BSLSOPBIO71
Serum	PSA	Sandwich immunoassay BSLSOPBIO68
		Competitive Chemiluminescence Immunoassay using BSLSOPBIO73



8846
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East and North Hertfordshire NHS Trust
Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Serum	Quantitative determination of: Free PSA	Roche Cobas e601 Module Competitive Chemiluminescence Immunoassay using BLSOPBIO74
Serum	sFlt-1 - Soluble fms-Like Tyrosine Kinase-1	ECLIA using BLSOPBIO84
Serum	Testosterone	Competitive Chemiluminescence Immunoassay using BLSOPBIO69
Blood	Troponin T	Electrochemiluminescence immunoassay sandwich assay BLSOPBIO27
Blood	TSH	Sandwich Immunoassay BLSOPBIO
Blood	Vitamin B12	Competition assay BLSOPBIO
Blood	Quantitative determination of: Albumin	Roche Cobas c501 module BCG method using SOP BLSOPBIO15 Cobas Albumin
Urine	Albumin	Immunoturbidimetric using BLSOPBIO79
Blood	ALP	Amp buffer (IFCC) BLSOPBIO7 Cobas Alkaline Phosphatase (ALP)
Blood	ALT	Tris buffer without PLP (IFCC) BLSOPBIO8 Cobas Alanine Aminotransferase (ALT)
Blood	AST	ASAT/GOT UV without P5P, using BLSOPBIO6 – Cobas Aspartate Aminotransferase (AST).
Blood	Ammonia	Glutamate Dehydrogenase Infinity direct enzymatic method BLSOPBIO4



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East and North Hertfordshire NHS Trust
Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Quantitative determination of: Amylase	Roche c501 Kinetic G7PNP Substrate (IFCC) BSLSOPBIO5
Blood	Bicarbonate (CO2)	PEP Carboxylase method BSLSOPBIO9
Blood	Bilirubin (Direct)	3 rd Party Wako Vanadate Oxidation method, using BSLSOPBIO31-WAKO Conjugated Bilirubin on Coba
Blood	Bilirubin (Total)	Diazo method BSLSOPBIO35
Blood	Calcium	NM-BAPTA Method BSLSOPBIO10
Blood	Carbamazapine	Immunoassay/turbidimetry BSLSOPBIO12
Urine	Creatinine	Spectrophotometric Enzymatic using BSLSOPBIO17
Blood	CRP	Immunoturbidimetry using BSLSOPBIO18
Blood	Phenytoin	KIMS method BSLSOPBIO46
Blood	Theophylline	KIMS method BSLSOPBIO25
Blood	Chloride	Indirect ISE BSLSOPBIO22
Blood	Potassium	Indirect ISE BSLSOPBIO22
Blood	Sodium	Indirect ISE BSLSOPBIO22
Blood	Cholesterol	Enzymatic Cholesterol Oxidase BSLSOPBIO13
Blood	HDL Cholesterol	Enzymatic Cholesterol Esterase BSLSOPBIO13
Blood	CK	Enzymatic UV Test NAC (IFCC), using BSLSOPBIO14
Blood	Creatinine	Enzymatic method BSLSOPBIO17



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East and North Hertfordshire NHS Trust
Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturers instructions for
	Quantitative determination of:	Roche C501
Blood	Ethanol	Enzymatic UV BLSOPBIO16
Blood	Salicylate	Enzymatic method BLSOPBIO24
CSF	CSF Protein	Turbidimetry BLSOPBIO19
Blood	Gentamicin	CEDIA Method, using BLSOPBIO48
Blood	GGT	Carboxynitroanilide (IFCC) BLSOPBIO39
Blood/CSF	Glucose	Hexokinase + G6PD BLSOPBIO40
Blood	Iron	Ferrozine/Ferene BLSOPBIO41
Blood/CSF	Lactate	Enzymatic colourimetric BLSOPBIO43
Blood	LDH	L to P Glucamine (IFCC) BLSOPBIO42
Blood	Lithium	Colourimetric method BLSOPBIO32
Blood	Paracetamol	Colourimetric method, using BLSOPBIO45
Blood	Magnesium	Xylidyl Blue (M&Y) BLSOPBIO44
Blood	Phosphate	Phosphomolybdate UV BLSOPBIO47
Blood	Protein (Total)	Biuret method BLSOPBIO32
Urine	Protein	Spectrometric using BLSOPBIO19
Blood	Triglyceride	Total glycerol GPO BLSOPBIO26
Blood	Urea	Kinetic Urease BLSOPBIO28



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturers instructions for
Urine	Quantitative determination of: Urea	Roche c501 Spectrophotometric Enzymatic using BLSOPBIO28
Blood	Uric Acid (Urate)	Enzymatic Uricase BLSOPBIO29
Blood	Valproic Acid	Enzyme immunoassay BLSOPBIO30
Blood	Vancomycin	Two point end assay using BLSOPBIO60
Fluid/Urine	Urine pH	Ph/Mv/Temperature meter model 3510 BLSOPBIO37
Whole Blood	Blood Gas Analysis pH pCO ₂ pO ₂ tHb & derivatives	Siemens RapidPoint 500e Series Blood gas analyser (Potentiometry, amperometry and conductance) BLSOPBIO87
Serum Urine	Osmolality	Advanced Micro Monometer 3300 Freezing point depression BLSOPBIO1
Sweat	Sweat Test Chloride	Sweat collection - Macroduct® Sweat Collection system which includes Webster Sweat Inducer and Macroduct sweat collector. Sweat Analyser Equipment - Sherwood MK2 Chloride analyser model 926S, Ion exchange method, using BLSOPBIO36 - Sweat Chloride SOP
Faeces	Faecal Haemoglobin	Quantitive faecal immunoturbidmetry (FIT) using Eiken OC-Sensor IO BLSOPBIO76



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East and North Hertfordshire NHS Trust
Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturers instructions for
Blood	Calculated determination of: eGFR	Calculated in Winpath
Blood	Adjusted Calcium	Adjusted in Winpath
Serum	sFlt1 / PIGF Ratio	Calculated from Roche Cobas e601 Using BLSOPBIO084
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Tissue: biopsy, excision, resection, and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	HISSOP111 – receipt and processing of post mortem specimens HISSOP112 – receipt of POC samples Specimen Dissection using: HISSOP81 – Cut up set up HISSOP78 – BMS cut up HISSOP64 – Assigning BMS cut up HISSOP41 – Cut up of large specimens by the pathologist – Bladder HISSOP51 – Cut up of large specimens by the pathologist – Prostate HISSOP60 – Cut up of large specimens by the pathologist – Penis



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, resection, and post-mortem specimens</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>HISSOP37 – Cut up of large specimens by the pathologist – Gall bladder</p> <p>HISSOP39 – Cut up of large specimens by the pathologist – Parathyroid</p> <p>HISSOP38 – Cut up of large specimens by the pathologist – Thyroid</p> <p>HISSOP40 – Cut up of large specimens by the pathologist – Small bowel</p> <p>HISSOP54 – Cut up of large specimens by the pathologist – Uterus and cervix</p> <p>HISSOP42 – Cut up of large specimens by the pathologist – Salivary gland</p> <p>HISSOP45 – Cut up of large specimens by the pathologist – Ovary</p> <p>HISSOP46 – Cut up of large specimens by the pathologist – Fallopian tube</p> <p>HISSOP44 – Cut up of large specimens by the pathologist – Placenta</p> <p>HISSOP43 – Cut up of large specimens by the pathologist – Lymph node</p>



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

East and North Hertfordshire NHS Trust
Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, resection, and post-mortem specimens</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>HISSOP57 – Cut up of large specimens by the pathologist – Vulva</p> <p>HISSOP55 – Cut up of large specimens by the pathologist – Colon</p> <p>HISSOP49 – Cut up of large specimens by the pathologist – laparotomy for lymphoma</p> <p>HISSOP56 – Cut up of large specimens by the pathologists – Skin</p> <p>HISSOP59 – Cut up of large specimens by the pathologist – Breast</p> <p>HISSOP52 – Cut up of large specimens by the pathologist – Spleen</p> <p>HISSOP47 – Cut up of large specimens by the pathologist – Bone</p> <p>HISSOP48 – Cut up of large specimens by the pathologist – Kidney</p> <p>HISSOP53 – Cut up of large specimens by the pathologist – Appendix</p>



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
Tissue: biopsy, excision, resection, and post-mortem specimens. Cytology clots	Tissue processing	Tissue Processing using Sakura VIP and HISSOP69 – Processing VIP1&2 HISSOP85 – VIP 1&2 maintenance HISSOP66 – Processing VIP3 HISSOP88 – VIP3 maintenance CPF80 – VIP usage maintenance log HISSOP65 – Removal of blocks from VIPs HISSOP84 – VIP failure
Tissue: biopsy, excision, resection, and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	
	De-calcification	De-calcification using HISSOP70 – De-calcification CPF69 – Decal end point test
	Tissue embedding	Tissue Tek 5EC and HISSOP10 – Embedding procedure
Formalin Fixed Paraffin wax blocks of processed tissue	Microtomy	Tissue sectioning using Tissue Tek and Leica microtomes and HISSOP9 – The sectioning procedure CPF18 – Histology cutting list
Tissue for frozen sections	Cryotomy	Cryotomy Intra-operative frozen sections using Bright Cryostat and HISSOP1 – Frozen section procedure HISSOP50 – Cut up of large specimens by the pathologist - Neurosafe



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Routine morphological staining For the detection of: Basophilic and eosinophilic structures	Routine morphological staining using Sakura Tissue Tek Prisma and HISSOP64 – Operation of the Prisma stainer and cover slipper HISSOP1 – Frozen section procedure
FFPE slides	Special stains for the detection of: Acid mucopolysaccharides Acid and Neutral Mucopolysaccharides Helicobacter Pylori Neutral Mucopolysaccharides, glycogen and fungus Elastic fibres and connective tissue Helicobacter/Microorganisms Gram positive and negative micro-organisms Fungi (Aspergillus) and Pneumocystis Elastic fibres and connective tissue	Documented in-house procedures for manual special stains Alcian Blue/PAS using HISSOP14 – Alcian Blue PAS Alcian Blue using HISSOP17 – Alcian Blue Cresyl Violet Acetate using HISSOP16 – Cresyl Violet Acetate Diastase PAS using HISSOP19 – Diastase PAS Elastic van Gieson using HISSOP 11 – Elastic Van Gieson Giemsa using HISSOP30 – Giemsa Gram using HISSOP20 – Gram Grocott using HISSOP13 – Grocott Haematoxylin Van Gieson using HISSOP12 – Haematoxylin Van Gieson



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides	Special stains for the detection of:	Documented in-house procedures for manual special stains
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana using HISSOP21 – Masson Fontana
	Melanin	Melanin Bleach using HISSOP113 – Melanin bleach
	Connective tissue and fibrin	Martius Scarlett Blue using HISSOP25 – MSB
	Copper assoc. Protein and Hepatitis B	Orcein using HISSOP26 – Orcein
	Neutral Mucopolysaccharides, glycogen and fungus	PAS using HISSOP18 – PAS
	Reticulin fibres	Reticulin using HISSOP28 – Reticulin
	Mast cells	Toluidine Blue using HISSOP114 – Toluidine blue
	Calcium	Von Kossa using HISSOP29 – Von Kossa
	Tubercle bacilli	Ziehl Neelson using HISSOP23 – Ziehl Neelson
	Tubercle bacilli	HISSOP24 – Modified Ziehl Neelson



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides	Immunohistochemistry to detect the following: Smooth muscle cells, myofibroblasts, myoepithelial cells, Diagnosis of leiomyomas, leiomyosarcomas Broad band cytokeratin marker, epithelial cell carcinomas HGPIN, prostate adenocarcinoma BCL-2 oncoprotein BCL-6 gene Epithelial cell types Ovarian cancer Carcinomas, RCC Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas T cells Mature T cells, T cell lymphomas Granulocytes Reed-Sternberg cells Mature B cells, Follicular dendritic cells B cells, some T cells	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation Incorporating the following antibodies Actin AE1/3 AMACR/P63 BCL-2 BCL-6 BerEP4 CA125 CA-IX Calretinin CD3 CD5 CD10 CD20 CD21



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides	Immunohistochemistry to detect the following:	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation Incorporating the following antibodies
	B Cells, Reed-Sternberg cells	CD23
	Reed-Sternberg cells and ALCL	CD30
	Haematopoietic cells, vascular endothelium	CD31
	T cells and some soft tissue	CD34
	Leukocyte common antigen	CD45
	Neuroendocrine cells	CD56
	Macrophages	CD68
	B lymphocytes	CD79
	GIST	CD117
	Plasma cells	CD138
	Adenocarcinoma and carcinoid (intestinal epithelium)	CDX-2
	CEA glycoproteins in adenocarcinoma	CEA
	Neuroendocrine tumours	Chromogranin
	Stratified squamous epithelium, basal cells, mesotheliomas	CK5
	Normal and neoplastic epithelia	CK7



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides	Immunohistochemistry to detect the following:	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation
	Incorporating the following antibodies	
	Glandular and transitional epithelium	CK8/18
	Basal cell carcinoma, squamous cell carcinoma	CK14
	Adenocarcinomas	CK19
	Adenocarcinomas, columnar epithelial cells	CK20
	Striated and smooth muscle cells	Desmin
	GIST	DOG-1
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin
	Normal and neoplastic epithelium	EMA
	Nuclei of cells containing a high level of oestrogen	ER
	V.W factor in endothelial cells	Factor VIII
	Mesothelial Cells Thyroid carcinomas	HBME-1
	Melanoma, melanocyte differentiation	HMB45
	Proliferating Cells	Ki67



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides	Immunohistochemistry to detect the following:	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation
	Incorporating the following antibodies	
	B cells and plasma cells	Kappa
	B cells and plasma cells	Lambda
	Melanoma marker	Melan A
	Epithelial tissue from glandular to stratified squamous	MNF116
	Peripheral nerves, neuroendocrine tumours	NSE
	Seminomas	Oct3/4
	HPV driven tumour eg Squamous cell carcinoma	P16
	Neoplastic cells in epithelium	P53
	Squamous epithelium	P63
	Nuclei of cells showing expression of Progesterone	PR
	Prostate secretory and ductal epithelium	PSA
	Prostate secretory and ductal epithelium	PSAP
	Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma	S100



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified
FFPE slides	Immunohistochemistry to detect the following: Smooth muscle cells, myoepithelial cells Neuroendocrine cells TTF-1 found in lung and thyroid (thyroid follicular cells) Cells of mesenchymal origin Plasma cells Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	Leica Bond III using HISSOP97 – Bond III staining machine procedure HISSOP106 – Antibody optimisation and validation Incorporating the following antibodies SMM Synaptophysin TTF1 Vimentin VS38c WT1
FFPE slides – Breast tissue only	Human Epidermal Growth Factor Receptor 2 (HER 2) oncoprotein expression in breast cancer	Her2 testing and reporting on Breast tissue using the Bond Oracle Her2 IHC system Using the following HISSOP136 Bond Oracle Her2 IHC system HISSOP137 Reporting of Her2 specimens Interpretive/diagnostic microscopy Using HISSOP95 – Reporting of Cellular Pathology requests CPM24 – Procedure for issuing an amended report HISSOP100 – Giving results over the telephone CPM23 – Authorisation of cellular Pathology results



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Fine needle aspirates –Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of : Cells (nuclei and cytoplasm) and micro organisms</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Diagnostic cytology (Non-gynae) in house documented manual procedures for preparation and screening and reporting using Hologic-T2000, Sakura DRS 2000</p> <p>CYTSOP5 – General procedure for the receipt and processing of non-gynaecological specimens</p> <p>CYTSOP15 – Preparation of breast samples</p> <p>CYTSOP16 – Preparation of Bronchoscopy specimens</p> <p>CYTSOP17 – Preparation of cerebrospinal fluid (CSF)</p> <p>CYTSOP18 – Preparation of EBUS samples</p> <p>CYTSOP19 – Preparation of Head and Neck samples</p> <p>CYTSOP20 –Preparation of Lymph node aspirates</p> <p>CYTSOP21 – Preparation of natural and induced clots</p> <p>CYTSOP22 – Preparation of Serous fluids</p> <p>CYTSOP23 – Preparation of Sputum samples</p> <p>CYTSOP24 – Preparation of Urine samples</p>



8846

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

East and North Hertfordshire NHS Trust

Issue No: 007 Issue date: 09 September 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Fine needle aspirates –Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples</p>	<p>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro organisms</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Diagnostic cytology (Non-gynae) in house documented manual procedures for preparation and screening and reporting using Hologic-T2000, Sakura DRS 2000</p> <p>CYTSOP5 – General procedure for the receipt and processing of non-gynaecological specimens</p> <p>CYTSOP11 – Operation of the centrifuge</p> <p>CYTSOP12 – Operation of the safety cabinet</p> <p>CYTSOP13 – Operation of the Thin Prep 2000 processor</p> <p>CYTSOP30 –Screening of non-gynaecological preparations</p> <p>CYTSOP14 – Operation of the tissue tek DRS staining machine</p> <p>Papanicalou stain for non-gynae specimens and CYTSOP33 – Papanicolaou staining method</p> <p>May-Grunwald Giemsa staining for air dried slides using CYTSOP7 – May Grunwald Giemsa staining method</p> <p>Diff Quick staining technique using CYTSOP2 – Diff - quick staining procedure for FNA's</p>
END		