


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	The Christie Pathology Partnership LLP Issue No: 009 Issue date: 06 September 2021	
	Christie Hospital Manchester M20 4BX	Contact: Neil Wrathall Tel: +44 (0) 161 918 7264 Fax: +44 (0) 161 446 8549 E-Mail: neil.wrathall1@nhs.net Website: www.christie.nhs.uk
Testing performed at the above address only		

Site activities performed away from the locations listed above:

Location details	Activity	
Address Haematology & Blood Transfusion The Christie Wilmslow Road Manchester M20 4BX	Local contact Contact: Dr. Neil Wrathall Tel: +44 (0)0161-918-7264 Fax: +44 (0)161-446-8549 E-Mail: neil.wrathall1@nhs.net	Theatre Blood Issue Fridge



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Serum, plasma</p> <p>Additionally CSF[^]</p> <p>Additionally urine[*]</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u></p> <p>Quantification of the following:</p> <p>Sodium[*]</p> <p>Potassium[*]</p> <p>Chloride[*]</p> <p>Urea[*]</p> <p>Albumin</p> <p>Alkaline phosphatase</p> <p>ALT</p> <p>Ammonia</p> <p>Amylase</p> <p>AST</p> <p>Bicarbonate</p> <p>Calcium[*]</p> <p>CPK</p> <p>Total Bilirubin</p> <p>Direct Bilirubin</p> <p>Cholesterol</p> <p>HDL Cholesterol</p> <p>Creatinine[*] (kinetic Jaffe method)</p> <p>Gamma Glutamyl Transferase</p> <p>Glucose[^]</p> <p>Total Iron</p> <p>LDH</p> <p>Magnesium[*]</p> <p>C reactive protein</p> <p>Phosphate[*]</p> <p>Total Protein</p> <p>Triglyceride</p> <p>Uric acid[*]</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Siemens Advia 1800 using spectrophotometry, chemiluminescence and ion selective electrodes.</p> <p>LI-BIO-Christie Advia 1800 daily operation</p> <p>LI-BIO-Christie Advia 1800 assay summary</p>



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<p>HUMAN BODY FLUIDS</p> <p>Serum, plasma</p> <p>Urine, CSF</p> <p>Serum</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u></p> <p>Quantification of the following: (cont'd)</p> <p>Transferrin Lipase Immunoglobulins (IgG, IgM, IgA) Protein Beta2 microglobulin Methotrexate</p> <p>Creatinine</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Siemens Advia 1800 using spectrophotometry, turbidometric, and homogeneous enzyme immunoassay. LI-BIO-Christie Advia 1800 daily operation</p> <p>ARK Diagnostics kit</p> <p>LI-BIO-CPP-Advia 1800 MTX</p> <p>Enzymatic</p>



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<p>HUMAN BODY FLUIDS</p> <p>Serum</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u></p> <p>Quantification of the following:</p> <p>Free T3 Free T4 TSH LH/FSH Prolactin Testosterone Cortisol Oestradiol Progesterone CA125 CA 19-9 CA 15-3 AFP HCG CEA PSA PTH Troponin I High sensitivity Troponin 1 (TNIH) Cyclosporin Gentamicin Vancomycin Testosterone TSTII Macroprolactin</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Siemens Centaur XP by chemiluminescence LI-BIO-Christie Centaur XP daily operation LI-BIO-Christie Centaur assay summary</p> <p>LI-BIO-CPP-Centaur macroprolactin (Polyethylene glycol pre-treatment)</p>



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HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant
Serum	PTH	Siemens Centaur CP by chemiluminescence LI-BIO-Christie Centaur CP daily operation
Serum	Quantification of Chromogranin A	Brahms Kryptor using time resolved amplified Cryptate emission. LI-BIO-CPP-Kryptor Chromogranin A
Serum	Quantification of: IGF-1 and growth hormone Vitamin D	IDS i-sys analyser using chemiluminescence LI-BIO-CPP-IDS i-sys
Serum	Quantification of the following: Calcitonin Thyroglobulin Thyroglobulin antibodies	Siemens Immulite 2000 immunoassay analyser LI-BIO-CPP- Immulite daily operation LI-BIO-CPP-Immulite assay summary
Plasma	ACTH	
Serum, urine	Osmolality (detection of total solute concentration)	Vitech Osmometer 3320 LI-BIO-CPP Osmometer Operation



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<p>HUMAN BODY FLUIDS</p> <p>Serum, urine</p> <p>Serum, urine</p> <p>Serum (ETDA)</p> <p>Serum</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u></p> <p>Qualitative detection of monoclonal proteins in serum and urine, Quantitation of paraprotein</p> <p>Detection and quantitation of serum and urine proteins</p> <p>Measurement of HbA1c</p> <p>Quantitation of Serum free light chains kappa and lambda</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Electrophoresis using Sebia Hydrasys 2 system. LI-BIO-CPP-Sebia serum electrophoresis LI-BIO-CPP-Sebia Urine Electrophoresis</p> <p>Immunofixation using Sebia Hydrasys 2 system LI-BIO-CPP-Sebia Serum Immunofixation LI-BIO-CPP-Sebia Urine Immunofixation</p> <p>Ion-exchange HPLC using BioRad D10 analyser LI-BIO-CPP-Biorad D-10HbA1c</p> <p>Latex enhanced Immunoassay Binding site SPA Plus</p>



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<p>HUMAN BODY FLUIDS</p> <p>Venous whole blood: EDTA</p> <p>Bone marrow aspirate</p> <p>Ascitic/pleural fluid</p> <p>Venous blood: citrated</p> <p>Venous whole blood: EDTA</p> <p>Urine</p>	<p><u>Haematological examination activities for the purpose of clinical diagnosis</u></p> <p>Blood film assessment (peripheral) for detection of abnormalities and cell differential.</p> <p>Bone marrow film for the detection of normal and abnormal morphology by microscopic examination</p> <p>Fluid cytospin for the detection of normal and abnormal morphology by microscopic examination</p> <p>Erythrocyte sedimentation Rate (ESR)</p> <p>Sickle cell solubility</p> <p>Detection of Urinary Haemosiderin</p>	<p>Documented in-house procedures with manufacturer's instructions</p> <p>Hematek 2000 stainer modified Wright stain and Nikon microscope. Manual assessment with ref to: LI-Haem-Christie-Bloodfilm exam</p> <p>LI-Haem-Christie-BMSmears LI-Haem-Christie-BMReports</p> <p>,Modified Wright stain with ref to: LI-Haem-CPP CSF</p> <p>Manual method - Sedimentation with reference to : LI-Haem Christie -ESR</p> <p>Solubility screening test, Clintech screening kit with reference to : LI-Haem Christie-sicklestest</p> <p>LI-Haem-Christie-haemosiderin using Perls Prussian blue (iron) stain with ref to : LI-Haem-Christie-perls</p>



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HUMAN BODY FLUIDS	<u>Haematological examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions
Citrated plasma	Coagulation Screen: Prothrombin time (PT) Activated partial thromboplastin time (APTT) Derived Fibrinogen Clauss Fib Thrombin time Reptilase time D-Dimer 50/50 Basic correction test FX assay	Werfen ACL TOP (50 series) with reference to: LI-Haem-Christie-ACL TOP 350 Analyser Routine Operation
Venous whole blood: EDTA, cerebrospinal fluid and bone marrow aspirate.	<u>Diagnosis and Monitoring of Haematological malignancies-differential assessment of surface antigens and cytoplasmic antigens using flow cytometry</u>	Navios/FC500 (fluorochrome labelled antibody expression) with reference to :
Venous whole blood: EDTA or peripheral stem cells in EDTA	Predictive CD34 count and CD 34 count on harvested cells	CD34 LI-Haem-CPP-NAVIOS CD34 Counting



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<p>HUMAN BODY TISSUE</p> <p>Tissues: biopsy, excision and resection from anatomical sites as listed below:</p> <p>Urology Skin, lung , GI, Plastics, Thyroid Head & Neck Haematolymphoid, Gynae Sarcomas</p> <p>Formalin Fixed Paraffin wax blocks of processed tissue. (FFPE slides)</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>Macroscopic and Microscopic examination:</p> <p>In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant:</p> <p>Specimen dissection: Steelline downdraft benches</p> <p>Tissue processing Peloris and Pathcentre tissue processors, LI-Hist-CPP-SOP-02001</p> <p>Tissue Embedding Using Leica Embedding Centre, LI-Hist-CPP-SOP-03001</p> <p>Tissue sectioning: LI-Hist-CPP-Microtomy</p>



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<p>HUMAN BODY TISSUE</p> <p>Frozen sections</p> <p>FFPE slides and frozen sections (Formalin fixed paraffin embedded)</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Routine morphological staining For the detection of:</p> <p>Basophilic and eosinophilic structures</p> <p>Special stains for the detection of:</p> <p>Acid mucins</p> <p>Acid and neutral mucins</p> <p>Amyloid</p> <p>Glycogen</p>	<p>Macroscopic and Microscopic examination:</p> <p>In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant:</p> <p>Cryotomy Frozen sections Using Leica CM 3050S cryostat. LI-Hist-CPP-Frozen sections Manual Haematoxylin and eosin (H&E) staining LI-HIST-CPP frozen sections</p> <p>Routine morphological staining Leica XP stainer, Leica CV5030 coverslipper and LI-Hist-CPP-SOP-05001 Haematoxylin and eosin (H&E) staining LI-Hist-Christie-SOP-05001</p> <p>Documented in-house procedures for manual special stains</p> <p>Alcain Blue (AB) LI-Hist-Christie-SOP-05008</p> <p>AB/Periodic Acid Schiff (PAS)</p> <p>Congo Red LI-Hist-Christie-SOP-05010</p> <p>Diastase Digestion / PAS LI-Hist-Christie-SOP-05011</p>



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<p>HUMAN BODY TISSUE</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Special stains for the detection of:</p> <p>Helicobacter</p> <p>Haematopoietic cells</p> <p>Bacteria</p> <p>Fungi</p> <p>Hyaluronic acid</p> <p>Fibrin</p> <p>Melanin</p> <p>Connective tissue</p> <p>Elastic fibres</p> <p>Glycogen</p> <p>Reticulin fibres</p>	<p>Macroscopic and Microscopic examination:</p> <p>In house documented procedures using manual methods :in conjunction with manufacturers' instructions where relevant:</p> <p>Giemsa - Modified LI-Hist-Christie-SOP-05024</p> <p>Giemsa LI-Hist-Christie-SOP-05040</p> <p>Gram Stain LI-Hist-Christie-SOP-05017</p> <p>Grocott LI-Hist-Christie-SOP-05018</p> <p>Hyaluronidase / AB LI-Hist-Christie-SOP-05016</p> <p>Martius Scarlet Blue LI-Hist-Christie-SOP-05021</p> <p>Masson Fontana LI-Hist-Christie-SOP-05021</p> <p>Masson's Trichrome LI-Hist-Christie-SOP-05014</p> <p>Miller's Elastic Stain (EVG) LI-Hist-Christie-SOP-05022</p> <p>Periodic Acid Schiff (PAS)LI-Hist-Christie-SOP-05022</p> <p>Reticulin LI-Hist-Christie-SOP-05006</p>



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<p>HUMAN BODY TISSUE</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Special stains for the detection of:</p> <p>Neutral mucin</p> <p>Mast cells</p> <p>Connective tissue</p> <p>Calcium</p> <p>Mycobacterium leprae</p> <p>Acid fast bacilli</p> <p><u>Immunohistochemistry to detect the following:</u></p> <p>Cytokeratin</p> <p>Cytokeratin</p> <p>AFP glycoprotein</p> <p>Anaplastic lymphoma kinase</p>	<p>Macroscopic and Microscopic examination:</p> <p>In house documented procedures using manual methods :in conjunction with manufacturers' instructions where relevant:</p> <p>Southgate's Mucicarmin LI-Hist-Christie-SOP-05030</p> <p>Toluidine Blue LI-Hist-Christie-SOP-05030</p> <p>Van Gieson Stain LI-Hist-Christie-SOP-05039</p> <p>Von Kossa Stain LI-Hist-Christie-SOP-05047</p> <p>Wade Fite LI-Hist-Christie-SOP-05033</p> <p>Ziehl - Neelsen LI-Hist-Christie-SOP-05034</p> <p>Using Ventana Ultra LI-Hist-CPP-IHC-Running IHC slides on Ventana Ultras.</p> <p>34BE12</p> <p>AE1/AE3</p> <p>AFP</p> <p>Alk-1</p>



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FFPE slides	<p>HUMAN BODY TISSUE</p> <p><u>Immunohistochemistry to detect the following:</u></p> <p>Prostate adenocarcinoma</p> <p>Associated with cell adhesion</p> <p>Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.</p> <p>Classification of lymphomas</p> <p>Adenoca/mesothelioma</p> <p>Reed-sternberg cells</p> <p>Tumour marker</p> <p>Mesotheliomas</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Using Ventana Ultra LI-Hist-CPP-IHC-Running IHC slides on Ventana Ultras.</p> <p>AMACR</p> <p>B Catenin</p> <p>BCL-2</p> <p>BCL-6</p> <p>BER EP4</p> <p>Ber H2</p> <p>Calcitonin</p> <p>Calretinin</p>



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HUMAN BODY TISSUE FFPE slides	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> <u>Immunohistochemistry to detect the following:</u> Carcinoid tumours Stratified squamous epithelium, basal cells, mesotheliomas Normal and neoplastic epithelia Squamous cell tumours Epithelial tumours GI carcinomas AML/GISTS/small cell lung ca Cytomegalovirus Basement membranes Classification of lymphomas	Macroscopic and Microscopic examination: In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant: Using Ventana Ultra LI-Hist-CPP-IHC-Running IHC slides on Ventana Ultras. Chromogranin CK5/6 CK7 CK14 CK19 CK20 CKit CMV Collagen Type IV c-myc



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination:
FFPE slides	<u>Immunohistochemistry to detect the following:</u> Expressed in variety tumours e.g. Mantle cell lymphoma Mesothelioma/rhabdomyosarcoma Hairy cell leukaemia GIST E-cadherin positive cells Neoplastic epithelia Breast carcinomas Gastrin producing cells Bladder cancers, breast cancer Breast/prostate carcinomas	In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant: Using Ventana Ultra LI-Hist-CPP-IHC-Running IHC slides on Ventana Ultras. Cyclin D1 D33 DBA-44 DOG-1 E-Cadherin EMA ERG Gastrin GATA-3 GCDF-15



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<p>HUMAN BODY TISSUE</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p><u>Immunohistochemistry to detect the following:</u></p> <p>Salivary gland neoplasms</p> <p>Pancreatic cells, intestine, stomach</p> <p>Classification of lymphomas</p> <p>Hepatocellular carcinomas</p> <p>Leukaemia's</p> <p>Classification of lymphomas</p> <p>Mesothelioma</p> <p>Germ cell tumours</p> <p>Hepatocellular tumours</p> <p>Kaposi's sarcoma</p> <p>Melanomas</p>	<p>Macroscopic and Microscopic examination:</p> <p>In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant:</p> <p>Using Ventana Ultra LI-Hist-CPP-IHC-Running IHC slides on Ventana Ultras.</p> <p>GFAP</p> <p>Glucagon</p> <p>Glycophorin A</p> <p>Glypican-3</p> <p>GP11a</p> <p>Granzyme</p> <p>HBME-1</p> <p>hCG</p> <p>Hepa</p> <p>HHV8</p> <p>HMB45</p>



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FFPE slides	<u>Immunohistochemistry to detect the following:</u>	In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant: Using Ventana Ultra LI-Hist-CPP-IHC-Running IHC slides on Ventana Ultras.
	Classification of lymphomas	IgA
	Classification of lymphomas	IgD
	Classification of lymphomas	IgM
	Rhabdoid tumours	INI-1
	Adrenalcortical v renal cell tumours	Inhibin
	Insulin producing cells	Insulin
	Malignant vascular disorders	JC70A
	B cells and plasma cells	Kappa
	Classification of lymphomas	L26
	B cells and plasma cells	Lambda
	Dendritic cells	Langerin



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<p>HUMAN BODY TISSUE</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p><u>Immunohistochemistry to detect the following:</u></p> <p>B cells, T cells, monocytes, macrophages</p> <p>Reed-sternberg cells</p> <p>Classification of lymphomas</p> <p>Mast cells</p> <p>Melanomas</p> <p>Soft tissue sarcomas</p> <p>Neoplasms of epithelial origin</p> <p>Classification of lymphomas</p>	<p>Macroscopic and Microscopic examination:</p> <p>In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant:</p> <p>Using Ventana Ultra LI-Hist-CPP-IHC-Running IHC slides on Ventana Ultras.</p> <p>LCA</p> <p>Leu M1</p> <p>LMP(EBV)</p> <p>Mast Cell Tryptase</p> <p>Melan A</p> <p>MIB-1</p> <p>MNF116</p> <p>MUM 1</p>



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<p>HUMAN BODY TISSUE</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p><u>Immunohistochemistry to detect the following:</u></p> <p>Lymphoid v myeloid disorders</p> <p>myoD1 positive cells</p> <p>rhabdomyosarcomas</p> <p>neuronal differentiation</p> <p>testicular germ cell tumours</p> <p>Marker for Pulmonary Carcinoids</p> <p>Cervical intraepithelial neoplasia</p>	<p>Macroscopic and Microscopic examination:</p> <p>In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant:</p> <p>Using Ventana Ultra LI-Hist-CPP-IHC-Running IHC slides on Ventana Ultras.</p> <p>Myeloperoxidase</p> <p>Myo D1</p> <p>Myogenin</p> <p>Neurofilament</p> <p>OCT 3/4</p> <p>OTP</p> <p>p16</p>



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<p>HUMAN TISSUE AND FLUIDS</p> <p>Blood Bone Marrow Other Tissues</p>	<p><u>Cytogenetics examination procedures for the purposes of clinical diagnosis</u></p>	<p>In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions where relevant:</p> <p><u>Pre-analysis preparation</u> Chromosome culture by in-house procedures using commercial medium and Setting Up Bone Marrow and Blood Cultures (LI-CG-CPP-BMSetup) Setting Up Cultures with B and T cell mitogens (LI-CG-Christie-T&BSetup)</p> <p>Preparation of material for chromosome analysis by manual harvesting using in-house methods and Harvesting Cells from Tissue Cultures (LI-CG-CPP-Harvest). Preparation and staining of slides using Slide Making (LI-CG-CPP-Slide Make) and G-Banding (LI-CG-CPP-Gband).</p>



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Bone marrow	CD138+cell enrichment prior to FISH in plasma cell myeloma and related disorders	Isolation of CD 138 plasma cells using Easy Sep kit prior to FISH analysis in plasma cell myeloma and related disorders (LI-CG-Christie-CD138) and Multistand [LI-CG-CPP-CD138 and Multistand].
Bone marrow	<p align="center"><u>Molecular Cytogenetics (FISH) examination procedures for the purposes of clinical diagnosis</u></p>	Fluorescence in situ Hybridisation (FISH)
Solid Tumours – formalin-fixed paraffin embedded tissue (FFPE) and other fixed cells	FISH analysis using fluorescent labelled gene probes and fluorescence microscopy to detect chromosome structural rearrangements and copy number of specific regions of the genome	Microscopic analysis of FISH preparations using FISH Analysis and Quality Assurance (LP-CG-CPP-FISH Anal) Use of FISH image capture hardware and software- Metasystems (LI-CG-CPP-Meta)
	FISH analysis by use of fluorescent labelled gene probes and fluorescence microscopy to detect chromosome structural rearrangements and copy number of specific regions of the genome	As FISH protocols above <u>plus</u> FISH on Paraffin Sections; Invitrogen Pre-treatment (LI-CG-Christie-ParaFISH Invitrogen)
END		