


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9878</p> <p>Accredited to ISO 15189:2012</p>	<h3>Royal Free London NHS Foundation Trust</h3> <p>Issue No: 005 Issue date: 25 September 2025</p>	
	<p>Jack O'Neill Amyloidosis Laboratories National Amyloidosis Centre Royal Free London NHS Foundation Trust Rowland Hill Street London NW3 2PF</p>	<p>Contact: Anna Baginska Tel: +44 (0) 20 7433 2761 Fax: +44 (0) 20 7433 2817 E-Mail: anna.baginska@nhs.net Website: https://www.ucl.ac.uk/amyloidosis/centre-amyloidosis-and-acute-phase-proteins</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE</p> <p>Tissue biopsies</p> <p>Formalin Fixed Paraffin Embedded (FFPE) blocks of processed tissue</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>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Specimen Dissection Fat Aspirate - LP-LINST-Fat Aspirates Cardiac Biopsy - LP-LINST-Histo-Cardiac Biopsy Other tissues: LP-HISTO-Histology Manual SOP</p> <p>Tissue Processing using Leica ASP300 and Peloris tissue processors</p> <p>LP-HISTO-Histology Manual SOP</p> <p>Embedding using the Tissue TEK 2 embedding Centre LP-HISTO-Histology Manual SOP</p> <p>Microtomy using the Leica RM2135 and Leica HistoCore Biocut Microtomes LP-HISTO-Histology Manual SOP Automated Coverslipping using ClearVue coverslipper LP-22INST-HISTO-ClearVue LP-HISTO-Histology Manual SOP Manual Coverslipping LP-HISTO-Histology Manual SOP</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
FFPE slides prepared as above	Routine morphological staining for the detection of basophilic and eosinophilic structures	Manual Haematoxylin and Eosin (H&E) Haematoxylin and Eosin - LP-HIST-H&E SOP
FFPE slides prepared as above	Special stains for the detection of:	Documented in-house procedures for manual special stains using the following SOPs:
	Amyloid	Congo red - LP-HISTO-Congo Red SOP
FFPE slides prepared as above	Immunohistochemistry to detect the following:	Automated IHC using documented in-house methods for the Leica Bond Max with Bond polymer define detection LP-HIST-IMMUNO SOP LP-LINST-HIST-Bond Max
	Insulin	Insulin
FFPE slides prepared as above, unstained resin sections, and cytopreparations	Immunohistochemistry to detect the following:	Automated IHC using documented in-house methods for the Leica Bond Max with Bond Polymer Refine detection LP-HISTO-IMMUNO SOP LP-LINST-HISTO-Bond Max
	<u>Serum Amyloid A (Reu86.1)</u>	Serum Amyloid A (Reu86.1) antibody
FFPE slides prepared as above	Immunohistochemistry to detect the following:	Manual IHC using documented in-house methods for the Sequenza system and Vector Immpress Kit LP-HIST-IMMUNO SOP
	Serum Amyloid A Kappa light chain Lambda light chain Tranthyretin Apolipoprotein A1	Serum Amyloid A Kappa light chain Lambda light chain Tranthyretin Apolipoprotein A1



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Slides prepared as above</p> <p>Formalin fixed tissue and fat biopsies</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Morphological assessment and Interpretation/diagnosis</p> <p>Amyloid Protein typing</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Interpretive/diagnostic reporting LP-Histo-Reporting SOP LP-INST-HISTO-Leica DM4000</p> <p>Proteomic analysis and Laser Capture Dissection Mass Spectrometry (LCDMS), using the Leica LMD7 laser microdissection microscope for dissection and specimen collection, trypsin digestion, and liquid chromatography-mass spectrometry using the Thermo Scientific Q-Exactive Plus (QEX+) Mass Spectrometer coupled with a Dionex UltiMate 3000 nano liquid chromatography system.</p> <p>Analysis and protein identification by interrogation of the Swissprot database using the MASCOT search engine. LP-HISTO-LCMD SOP LP-HISTO-LC-MS SOP LP-HISTO-Reporting SOP</p>



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<p>HUMAN BODY FLUIDS</p> <p>EDTA Whole Blood Saliva (collected in Oragene kit)</p>	<p><u>Molecular Genetics Examination procedures for the purpose of clinical diagnosis.</u></p> <p>DNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage</p>	<p>Documented methods for DNA extraction</p> <p>Automated DNA Extraction</p> <p>Using:</p> <p>Qiagen Qiacube and QIAGEN QIAamp DNA Mini and Blood Mini protocol. Quantification using nanodrop ND 1000.</p> <p>SOPs: LP-GENE-DNA-EXTRACTION Qiacube SOP</p> <p>Manual DNA Extraction</p>
<p>EDTA Whole Blood Saliva (collected in Oragene kit)</p>		<p>Using:</p> <p>QIAGEN QIAamp DNA Mini and Blood Mini protocol</p> <p>Quantification using nanodrop ND 1000</p> <p>SOPs: LP-LINST-GENE-QIAGEN Manual DNA Extraction Protocol</p>



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<p>HUMAN BODY FLUIDS</p> <p>Genomic DNA extracted in-house from the specimen samples listed above or pre-extracted genomic DNA received as primary type from external source</p>	<p><u>Molecular Genetics Examination procedures for the purpose of clinical diagnosis.</u></p> <p>Detection of genetic variants (SNVs and indels) in genes associated with hereditary amyloidosis and systemic autoinflammatory diseases.</p>	<p>Documented methods for DNA extraction</p> <p>Amplification of genomic DNA using Polymerase Chain Reaction (PCR) and DNA Sanger sequencing using commercially available kits and in-house SOPs.</p> <p>Key SOPs: LP-GENE-PCR Set Up SOP LP-GENE-Setting up Sequencing SOP</p> <p>Thermal cyclers and upgraded ABI3500xl genetic analyser.</p> <p>Analysis of PCR products for QC purpose is performed on Agarose Gel Electrophoresis.</p> <p>Key SOP: LP-GENE-Review-Genetics Reporting SOP</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from the sample types listed and samples received as primary samples and DNA from external sources (cont'd)</p>	<p><u>Molecular Genetics Examination procedures for the purpose of clinical diagnosis (cont'd)</u></p> <p>Targeted detection of genetic variants (SNVs and indels) in genes associated with hereditary amyloidosis and systemic autoinflammatory diseases</p>	<p>Next Generation Sequencing</p> <p>Using Ampliseq NGS Library Preparation kit and sequencing using Illumina MiSeq.</p> <p>And</p> <p>Targeted Illumina Custom Panels :</p> <p>SAID/autoinflammatory (24 genes) Hereditary Amyloidosis (22 gene)</p> <p>SOPs: LP-GENE-Ampliseq NGS Library Prep SOP</p> <p>Analysis of Next Generation Sequencing (NGS) data for genes associated with hereditary amyloidosis and systemic autoinflammatory diseases.</p> <p>SOPs: LP-GENE-NGS Data Analysis SOP</p> <p>LP-GENE-NGS Reporting SOP</p>

END