

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: 002 Issue date: 16 November 2021</p>	
	<p>Jack O'Neill Amyloidosis Laboratories National Amyloidosis Centre UCL Division of Medicine Royal Free Hospital Rowland Hill Street London NW3 2PF</p>	<p>Contact: Hadija Trojer Tel: +44 (0) 20 7433 2761 Fax: +44 (0) 20 7433 2817 E-Mail: hadija.trojer@nhs.net / h.trojer@ucl.ac.uk 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	Immunohistochemistry to detect the following:	Manual IHC using documented in-house methods for the Sequenza system and Vector Impress Kit LP-HIST-IMMUNO SOP
	Serum Amyloid A Kappa light chain Lambda light chain Transthyretin Apolipoprotein A1	Serum Amyloid A Kappa light chain Lambda light chain Transthyretin Apolipoprotein A1



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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:
Slides prepared as above	Morphological assessment and Interpretation/diagnosis	Interpretive/diagnostic reporting LP-Histo-Reporting SOP LP-INST-HISTO-Leica DM4000
Formalin fixed tissue and fat biopsies	Amyloid Protein typing	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. 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



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<p>HUMAN BODY FLUIDS</p> <p>EDTA whole blood and Saliva</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>Extraction of DNA</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 using one or combination of the techniques including QIAGEN QIAcube automated method, in-house extraction and commercial kit.</p> <p>Key SOPs: Automated DNA extraction: LP-GENE-DNA-Extraction QIAcube SOP LP-GENE-DNA Extraction DNA quantification method: Nanodrop ND1000</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 ABI3500 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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HUMAN BODY FLUIDS (cont'd) NGS data generated on the Illumina MiSeq Platform by an ISO15189:2012 accredited laboratory	<u>Molecular Genetics Examination procedures for the purpose of clinical diagnosis (cont'd)</u> Detection of genetic variants (SNVs and indels) in genes associated with hereditary amyloidosis and systemic autoinflammatory diseases.	Analysis of Next Generation Sequencing (NGS) data for genes associated with hereditary amyloidosis and systemic autoinflammatory diseases. LP-GENE-NGS Data Analysis SOP LP-GENE-NGS Reporting SOP
END		