


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 15189:2022</p>	<h3>Royal Free London NHS Foundation Trust</h3> <p>Issue No: 009 Issue date: 10 June 2026</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: Ania 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
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:
Tissue biopsies	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen Dissection Fat Aspirate - LP-LINST-Fat Aspirates Cardiac Biopsy - LP-LINST-Histo-Cardiac Biopsy Other tissues: LP-HISTO-Histology Manual SOP
Formalin Fixed Paraffin Embedded (FFPE) blocks of processed tissue		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
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 Amyloid	Documented in-house procedures for manual special stains using Congo red - LP-HISTO-Congo Red SOP



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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:
	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
FFPE slides prepared as above	Insulin	Insulin
FFPE slides prepared as above, unstained resin sections, and cytopreparations	Serum Amyloid A (Reu86.1)	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 detection system LP-HIST-IMMUNO SOP
	Serum Amyloid A	Serum Amyloid A
	Kappa light chain	Kappa light chain
	Lambda light chain	Lambda light chain
	Tranthyretin	Tranthyretin
	Apolipoprotein A1	Apolipoprotein A1
Slides prepared as above	Morphological assessment and Interpretation/diagnosis	Interpretive/diagnostic reporting LP-Histo-Reporting SOP LP-INST-HISTO-Leica DM4000



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<p>HUMAN BODY TISSUE (cont'd)</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>Amyloid Protein typing using proteomic analysis</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</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 and Thermo-Scientific Orbitrap Exploris 240 Mass spectrometer and Vanquish Neo UHPLC</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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HUMAN BODY FLUIDS	<u>Molecular Genetics Examination procedures for the purpose of clinical diagnosis.</u>	Documented methods for DNA extraction
EDTA Whole Blood Saliva (collected in Oragene kit)	DNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Automated DNA Extraction Qiagen Qiacube and QIAGEN QIAamp DNA Mini and Blood Mini protocol. Quantification using nanodrop ND 1000. LP-GENE-DNA-EXTRACTION Qiacube SOP Manual DNA Extraction
EDTA Whole Blood Saliva (collected in Oragene kit)		QIAGEN QIAamp DNA Mini and Blood Mini protocol Quantification using nanodrop ND 1000 LP-LINST-GENE-QIAGEN Manual DNA Extraction Protocol
Genomic DNA extracted in-house from the specimen samples listed above or pre-extracted genomic DNA received as primary type from external source	Measuring DNA concentration prior to Sanger sequencing and Next Generation Sequencing tests	ThermoScientific NanoDrop Eight Spectrophotometer LP-GENE-NanoDrop Eight SOP
Genomic DNA extracted in-house from the specimen samples listed above or pre-extracted genomic DNA received as primary type from external source	Measuring DNA concentration prior to Sanger sequencing and Next Generation Sequencing tests	Invitrogen Qubit 4 Fluorometer LP-GENE-Qubit Quantification SOP
Genomic DNA extracted in-house from the specimen samples listed above or pre-extracted genomic DNA received as primary type from external source	Purification of samples post-PCR prior to Sanger sequencing and Next Generation Sequencing	ExoSAP-IT LP-GENE-PCR Cleanup SOP
Genomic DNA extracted in-house from the specimen samples listed above or pre-extracted genomic DNA received as primary type from external source	Purification of samples post-PCR prior to Sanger sequencing and Next Generation Sequencing	Thermo Fisher Scientific BigDye XTerminator Purification Kit LP-LF-GENE-Setting up Sequencing SOP



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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. LP-GENE-PCR Set Up SOP LP-GENE-Setting up Sequencing SOP</p> <p>Thermal cyclers and upgraded ABI3500xl genetic analyser. Analysis of PCR products for QC purpose is performed on Agarose Gel Electrophoresis. Key SOP: LP-GENE-Review-Genetics Reporting SOP</p>
END		