Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

9878

Accredited to ISO 15189:2022

Royal Free London NHS Foundation Trust

Issue No: 006 **Issue date:** 09 June 2025

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Histopathological examination activities for the purposes of clinical diagnosis	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 Tissue Processing using Leica ASP300 and Peloris tissue processors LP-HISTO-Histology Manual SOP Embedding using the Tissue TEK 2 embedding Centre 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (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: Amyloid	Documented in-house procedures for manual special stains using the following SOPs: Congo red - LP-HISTO-Congo Red SOP
FFPE slides prepared as above	Immunohistochemistry to detect the following: Insulin	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
FFPE slides prepared as above, unstained resin sections, and cytopreparations	Immunohistochemistry to detect the following: Serum Amyloid A (Reu86.1)	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 Serum Amyloid A (Reu86.1) antibody
FFPE slides prepared as above	Immunohistochemistry to detect the following: Serum Amyloid A Kappa light chain Lambda light chain Transthyretin Apolipoprotein A1	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (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

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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Molecular Genetics Examination procedures for the purpose of clinical diagnosis.	Documented methods for DNA extraction
Genomic DNA extracted in-house from the specimen samples listed above or pre-extracted genomic DNA received as primary type from external source	Detection of genetic variants (SNVs and indels) in genes associated with hereditary amyloidosis and systemic autoinflammatory diseases.	Amplification of genomic DNA using Polymerase Chain Reaction (PCR) and DNA Sanger sequencing using commercially available kits and in-house SOPs. Key SOPs: LP-GENE-PCR Set Up SOP LP-GENE-Setting up Sequencing SOP 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

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