Schedule of Accreditation

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Royal Free London NHS Foundation Trust

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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
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	Histopathological examination activities for the purposes of clinical diagnosis	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
	Transthyretin	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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HUMAN BODY TISSUE	Histopathological examination activities for the purposes of clinical diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant:
Formalin fixed tissue and fat biopsies	Amyloid Protein typing using proteomic analysis	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 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	Genomics analysis for the purpose of clinical diagnosis of rare disease	Documented in house methods incorporating manufacturers' instructions where relevant
	DNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	**Automated DNA Extraction**
EDTA Whole Blood Saliva (collected in Oragene kit)		(1) Qiagen Qiacube and QIAGEN QIAamp DNA Mini and Blood Mini protocol. Quantification using nanodrop ND 1000. LP-GENE-DNA-EXTRACTION Qiacube SOP
EDTA Whole Blood Saliva (collected in Oragene kit)		(2) QIAGEN QIAamp DNA Mini and Blood Mini protocol Quantification using SOP: LP-LINST-GENE-QIAGEN Manual DNA Extraction Protocol
EDTA Whole Blood Saliva (collected in Oragene kit)		(3) Manual DNA Extraction QIAamp DNA Blood Mini Kit (250 SOP: LP-LINST-GENE-QIAGEN Manual DNA Extraction Protocol
		DNA quantification for QC purposes
Genomic DNA extracted in-house using methods 1 to 3 from the specimen samples listed above or genomic DNA received as a primary sample from an external source		(4) TapeStation SOP: LP-GENE-4200 TapeStationSystem SOP
Genomic DNA extracted in-house using methods 1 to 3 from the specimen samples listed above or genomic DNA received as a primary sample from an external source	Measuring DNA concentration prior to Sanger sequencing and Next Generation Sequencing tests	(5) ThermoScientific NanoDrop Eight Spectrophotometer SOP: LP-GENE-NanoDrop Eight SOP

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease	Documented in house methods incorporating manufacturers' instructions where relevant **DNA quantification for QC purposes**
Genomic DNA extracted in-house using methods 1 to 3 from the specimen samples listed above or genomic DNA received as a primary sample from an external source	Measuring DNA concentration prior to Sanger sequencing and Next Generation Sequencing tests	(6) Invitrogen Qubit 4 Fluorometer SOP: LP-GENE-Qubit Quantification SOP
		Purification of samples post-PCR prior to Sanger sequencing
Genomic DNA extracted in-house using methods 1 to 6 from the specimen samples listed above or genomic DNA received as a primary sample from an external source		(7) ExoSAP-IT SOP: LP-GENE-PCR Cleanup SOP
Genomic DNA extracted in-house using methods 1 to 6 from the specimen samples listed above or genomic DNA received as a primary sample from an external source		(8) Thermo Fisher Scientific BigDye XTerminator Purification Kit SOP: LP-LF-GENE-Setting up Sequencing SOP

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease	Documented in house methods incorporating manufacturers' instructions where relevant **Sanger Sequencing**
Genomic DNA extracted in-house using methods 1 to 8 from the specimen samples listed above or genomic DNA received as a primary sample from an external source	Detection of genetic variants (SNVs and indels) in genes associated with hereditary amyloidosis and systemic autoinflammatory diseases APOA1 NLRP3/ NALP3 APOA2 MEFV B2M MVK FGA TNFRSF1A GSN NLRP12 LYZ IL-36RN TTR NOD2 SAA1 MYD88 APOC3 APOA4 ADA2	Amplification of genomic DNA using Polymerase Chain Reaction (PCR) and DNA Sanger sequencing using commercially available kits and in-house SOPs HotstarTaq DNA Polymerase Invitrogen 2.5mM dNTPs Advantage GC Genomic LA Polymerase mix kit PureTaq RTG PCR beads Thermal cyclers ABI3500xl genetic analyser Analysis Agarose Gel Electrophoresis. SOPs: LP-GENE-Review-Genetics Reporting SOP, LP-GENE-PCR Set Up SOP, LP-GENE-Setting up Sequencing SOP

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease	Documented in house methods incorporating manufacturers' instructions where relevant **Next Generation Sequencing**
Genomic DNA extracted in-house using methods 1 to 6 from the specimen samples listed above or genomic DNA received as a primary sample from an external source	Next generation sequencing for hereditary amyloidosis gene panel (R204 on national genomic test directory) for the detection of: APOA1 APOA2 APOA4 APOC2 APOC3 APOE B2M CST3 EFEMP1 FGA GSN LGAL27 IGKC LECT2 LyZS MYD88 OSMR TGFBI TTR Next generation sequencing for Autoinflammatory Disorders gene panel (R413 national genomic test directory) for the detection of: ADA2 ALPK1 CARD14 COPA ELF4 IKBKG ILRN IL36RN LPIN2 MEFV MVK MYD8	Hamilton STARLet – liquid handling for automated Illumina DNA Prep with enrichment (IDPE) library preparation method Manual library preparation Illumima DNA Prep with enrichment method Sequencing Illumina NextSeq 2000 Variant annotation and interpretation Illumina Emedgene for SOPs: LP_GENE_Manual_IDPE_NGS_Library Prep SOP LP_NAC_Automated_IDPE_NGS library Prep SOP LP_GENE_NextSeq 2000_Sequencing SOP LP_GENE_NGS_Data_Emedgene_analysis_SOP LP_GENE_NGS_Reporting_SOP

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Genomics analysis for the purpose of clinical diagnosis of rare disease	Documented in house methods incorporating manufacturers' instructions where relevant **Next Generation Sequencing**
Genomic DNA extracted in-house using methods 1 to 6 from the specimen samples listed above or genomic DNA received as a primary sample from an external source	Next generation sequencing for Autoinflammatory Disorders gene panel (R413 national genomic test directory) for the detection of: NLRC4 NLRP3 NOD2 OTULIN PLCG2 POMP PSMA3 PSMB10 PSMB4 PSMB8 PSMB9 PSMG2 PSTPIP1 RBCK1 RELA RIPK1 STING1 TBK1 TNFAIP3 TNFRSF1A UBA1	Hamilton STARLet – liquid handling for automated Illumina DNA Prep with enrichment (IDPE) library preparation method Manual library preparation Illumima DNA Prep with enrichment method Sequencing Illumina NextSeq 2000 Illumina Emedgene for reads alignment, variant calling, annotation, visualization and interpretation SOPs: LP_GENE_Manual_IDPE_NGS_Library Prep SOP LP_NAC_Automated_IDPE_NGS library Prep SOP LP_GENE_NextSeq 2000_Sequencing SOP LP_GENE_NGS_Data_Emedgene_analysis_SOP LP_GENE_NGS_Reporting_SOP
END		