Schedule of Accreditation

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Royal Brompton and Harefield 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 TISSUES AND FLUIDS	Molecular genetic examinations for the purpose of clinical diagnosis	In house documented methods incorporating manufacturer's instructions where relevant
Blood		DNA extraction from blood using Qiagen EZ1 Advanced XL robot with EZ1 Blood DNA kit 350ul kit CLINGEN.INS.1
		DNA extraction from blood using Qiagen QIAsymphony SP robot CLINGEN.INS.80
Blood		DNA extraction from blood using Nucleon BACC2 kit CLINGEN.INS.54
Saliva		DNA extraction from saliva using Norgen DNA Extraction Kit CLINGEN.INS.64

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular genetic examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant
DNA	Inherited Cardiac Conditions gene panel for detection of clinically relevant nucleic acid sequence variants (including SNVs, CNVs indels, down to single exon level):	NGS library preperation using the Agilent SureSelect QXT custom kit CLINGEN.INS.63 DNA sequencing on Illumina MiSeq / NextSeq550 automated benchtop sequencers. CLINGEN.INS.63 Bioinformatic data analysis using commercial software and databases, and in-house bioinformatics pipeline. CLINGEN.SOP.40 Variant interpretation and reporting CLINGEN.SOP.37
	Inherited Respiratory Conditions gene panel for detection of clinically relevant nucleic acid sequence variants (including SNVs, indels and CNVs down to single exon level):	NGS library preparation using Agilent SureSelect QXT custom library prep kit CLINGEN.INS.63 DNA sequencing on Illumina MiSeq / /NextSeq550 automated benchtop sequencers. CLINGEN.INS.63 Bioinformatic data analysis using commercial software and databases, and in-house bioinformatics pipeline. CLINGEN.SOP.40 Variant interpretation and reporting CLINGEN.SOP.37

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular genetic examinations for the purpose of clinical diagnosis</u> (cont'd) Aortopathy and Vasculopathy gene panel for detection of clinically relevant nucleic acid sequence variants (including SNVs, indels and CNVs down to single exon level):	In house documented methods incorporating manufacturer's instructions where relevant NGS library preparation using Agilent SureSelect QXT custom library prep kit CLINGEN.INS.63 DNA sequencing on Illumina MiSeq / /NextSeq550 automated benchtop sequencers. CLINGEN.INS.63 Bioinformatic data analysis using commercial software and databases, and in-house bioinformatics pipeline. CLINGEN.SOP.40 Variant interprétation and reporting CLINGEN.SOP.37
DNA	Detection of clinically relevant nucleic acid sequence variants (including SNVs, indels and CNVs down to single exon level) in genes associated with inherited respiratory and cardiac conditions, for variant screening confirmation of NGS findings (including GEL WGS), and cascade testing	PCR and Sanger sequencing using AB Veriti thermal cycler and AB3500 genetic analyser, including primer design and validation Sequencing results analysed using JSI Medical SeqPilot software. CLINGEN.SOP.36 CLINGEN.INS.3 Multiplex Ligation-dependant Probe Amplification (MLPA) using AB Veriti thermal cycler and AB3500 genetic analyser. Results analysed using Coffalyser software CLINGEN.INS.55 Digital droplet PCR using Biorad ddPCR platform Results analysed using Quantasoft software CLINGEN.INS.69

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturer's instructions where relevant
DNA	Determination of genotype for sample identification in cases of potential sample swap or contamination	DNA fragment analysis at specific loci using PowerPlex HS kit (co-amplification and three-color detection of sixteen loci in a multiplex STR system) using AB Veriti thermal cycler and AB3500 genetic analyser. CLINGEN.INS.31 Results analysed using GeneMapper software CLINGEN.INS.51
DNA	CFTR common variant screening using the Devyser *CFTR* Core kit	Multiplex ARMS PCR with the Devyser *CFTR* Core Kit using AB Veriti thermal cycler and AB3500 genetic analyser. Analysis with GeneMapper software CLINGEN.INS.60
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