Schedule of Accreditation

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Guy's and St. Thomas' 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 Saliva		DNA extraction using Qiagen QIAsymphony SP robot from blood CLINGEN.INS.80 from saliva CLINGEN.INS.89
FFPE tissues Fresh frozen tissue (FF) Blood		DNA extraction using Promega Maxwell RSC CLIN-GEN.INS.91

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 , respiratory conditions, Aortopathy and Vasculopathy gene panels for detection of clinically relevant nucleic acid sequence variants (including SNVs, CNVs indels, down to single exon level):	NGS library preparation using the Twist Biosciences library prep kits and automation on the Hamilton liquid handling robot CLINGEN.INS.95 CLINGEN.SOP.35 DNA sequencing on Illumina MiSeq / NextSeq550 and NextSeq2000 automated benchtop sequencers. CLINGEN.INS.95 CLINGEN.INS.88 Bioinformatic data analysis using commercial software and databases, and in-house bioinformatics pipeline (Bromptome). CLINGEN.SOP.40 Variant interpretation 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
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