Schedule of Accreditation

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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS	<u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis:</u> <u>Cytogenetics</u>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
Blood (includes fetal) Bone marrow Other tissues Fixed, cultured cells Other fluids		Preparation of material for chromosome analysis: Using Robo-Sep S cell separator and Blood culture & Harvesting DOC5182, Haematological Oncology Culture & Harvesting DOC5173
Blood (includes fetal) Bone marrow Other tissues Fixed, cultured cells Other fluids	Chromosome analysis for: Developmental disorders Reproductive medicine disorders Haematological/Oncology disorders	G-banding Macroscopic and microscopic examination, detection, analysis and reporting of G banding and karyotyping against considered normal G banding pattern. Cytovision image analysis system SOPs DOC5004, DOC5642, DOC5003
Blood (including fetal) Bone marrow Lymph nodes Solid Tissues Solid Tumours Formalin fixed paraffin embedded tissue (FFPE) Fixed culture cells Other fluids	Macroscopic and microscopic detection and analysis of genetic rearrangements and/or genomic imbalance for haematological/oncology, developmental and reproductive medicine disorders including confirmation and inheritance testing following proband microarray findings	Fluorescent in situ hybridisation (FISH) using in-house procedures and manufacturers instructions for Hybrite and in conjuction with SOP DOC5094

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis: (cont'd)</u> <u>Molecular Genetics</u>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
Blood, Blood spot, Fetal blood, buccal/saliva samples, urine, cultured cells, amniocytes, chorionic villi, solid tissues, tissue sections, products of conception, fetal tissue, embryo tissue, formalin fixed paraffin embedded tissue, Bone Marrow	DNA extraction for detection of abnormal sequences for common and rare genetic disease conditions	DNA extraction using Janus Robot (MSM1 module), BioRobot EZ1 Advanced Nanodrop Spectrophotometer, Chemagen extractor and SOP's DOC5464, DOC5418, DOC5583
DNA	Mutation detection of sequence variants for the purpose of clinical diagnosis and quality assessment of PCR products GJB6 (Connexin 30) Spinal Cerebellar Ataxia 1 (SCAR 1)	Thermal Cyclers, Biomek Robot Nx, PCR & Agarose Gel electrophoresis in conjunction with SOP's DOC5387 PCR Procedure, DOC5148 Beckman Biomek NX, DOC5409, SOP Polyacrylamide Gel Electrophoresis, DOC5439 Protocol for BioSpectrum AC imaging system

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis: (cont'd)</u> <u>Molecular Genetics (cont'd)</u>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
DNA	Mutation detection, confirmation and carrier/ predictive testing for the purpose of clinical diagnosis in genes: Detection of clinical relevant nucleic acid sequence for confirmation/cascade testing of NGS results or family studies related to validated methods ABCD1 (Adrenoleukodystrophy) Notch3 (Cadasil) LDLR/ APOB ex27/ PCSK9 ex7 (Familial Hypercholesterolaemia) FXN (Friedreich Ataxia) GJB2 (Hearing Loss) PMP22/MPZ/GJB1/MFN2 (HMSN/HNPP) PLA2G6 (Infantile Neuroaxonal Dystrophy) SGCE (Myoclonic Dystonia) MTM1 (Myotubular Myopathy) PANK2 (Pantothenate kinase-associated neurodegeneration) MECP2 (Rett Syndrome) FGFR3 exon 9 and 12 (Achondroplasia and Hypochondroplasia)	PCR amplification and Sanger Sequencing of DNA using Thermal Cyclers, Biomek Robot Nx Bravo automated Liquid handler, ABI 3730 in conjunction with SOP's DOC5387 PCR Procedure, DOC5148 Beckman Biomek NX, DOC5388 Operation of Applied Biosystems Genetic Analysers, DOC5397 Fluorescent DNA Sequencing Protocol

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis: (cont'd)</u> <u>Molecular Genetics (cont'd)</u>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
DNA	Mutation detection for the purpose of clinical diagnosis, carrier detection and predictive testing in disorders: Huntington Disease, Myotonic Dystrophy1, Myotonic Dystrophy2, Friedreich Ataxia, Oculopharyngeal Muscular Dystrophy, Spinal Bulbar Muscular Atrophy, Spinal Cerebellar Ataxia 1, 2, 3, 6, 7 & 17, Dentatorubral-pallidoluysian atrophy, Maternal Cell Contamination	DNA PCR and fluorescent fragment size analysis (F-PCR), including PCR amplification of DNA using thermocyclers ABI 3730 ABI 3500 In conjunction with SOP's DOC5387 PCR Procedure, DOC5388 Operation of Applied Biosystems Genetic Analysers,
DNA	Mutation detection for the purpose of clinical diagnosis, carrier detection and predictive testing in genes: Friedreich Ataxia, Myotonic Dystrophy1, Myotonic Dystrophy2	DNA PCR, triplet-primed PCR (TP-PCR) and fluorescent fragment size analysis And QP-PCR

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis: (cont'd) Molecular Genetics (cont'd)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
DNA	Mutation detection, confirmation and carrier testing in disorders/ genes: Allele Specific PCR: Cystic Fibrosis	Allele-specific PCR amplification of DNA and Fluorescent fragment size analysis using SOP: DOC5387 PCR Procedure, DOC5388 Operation of Applied Biosystems Genetic analysers. Using Elucigene (Yourgene) diagnostic Kits, ABI 3730/ ABI 3500
DNA	Detection of DPYD variants: c.1905+1G> A c.1679T>G c.2846A>T HapB3	AS-PCR and fluorescent fragment size analysis using Elucigene (Yourgene) diagnostic Kits PCR, allele-specific,Thermal Cyclers, ABI 3130/ ABI 3500
DNA	Analysis of copy number changes for the purpose of clinical diagnosis and carrier/predictive testing in genes: ABCD1, Dystrophin, GJB1/PMP22/MPZ, MECP2, LDLR, SGCE, PANK2/PLA2G6	DNA PCR and dosage analysis by Multiplex ligation probe – dependant amplification (MLPA) using DOC5150 MLPA Protocol

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis: (cont'd) Molecular Genetics (cont'd)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
DNA	Dosage Analysis by quantitative fluorescent PCR: Rapid Aneuploidy Screening, Spinal Muscular Atrophy	DNA PCR and dosage analysis by quantitative fluorescent PCR (QF-PCR) amplification of DNA
DNA	Mutation detection of sequence variants for the purpose of clinical diagnosis and carrier testing in genes: LHON, HFE	DNA PCR and Pyrosequencing using Thermal Cyclers, PyroMark PSQ-96 ID in conjunction with SOP's DOC 5387 PCR Procedure, DOC 5435 Pyrosequencing
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