Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

9322

Accredited to ISO 15189:2012

Manchester University NHS Foundation Trust

Issue No: 003 **Issue date:** 04 May 2021

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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 AND FLUIDS Blood Amniotic Fluid Chorionic Villus Bone marrow Lymph nodes Solid Tissues Solid Tumours Formalin fixed paraffin embedded tissue (FFPE) Fixed culture cells	Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis: Cytogenetics Chromosome analysis for: Prenatal Diagnosis Developmental disorders Reproductive medicine disorders Chromosome Breakage disorders Haematological/Oncology disorders	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to: Preparation of material for chromosome analysis: Multiprep genie 205 (automated harvester) in conjunction with SOP's: Blood culture & Harvesting CY 32293, Haematological Oncology Culture & Harvesting CY 32299 Amniotic Fluid Culturing and Harvest CY 32294, Chorionic Villus Culture & Harvest, CY 32295 Solid Tissues Culture & Harvesting CY 32306, Solid Tumour Culture & Harvest CY 32325 Fluorescent in situ hybridisation (FISH) using in-house procedures and manufacturers instructions for Hybrite and in conjuction with SOP CY 32323

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) Cytogenetics (cont'd)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
Blood Amniotic Fluid Chorionic Villus Bone marrow DNA Solid tissues Other tissues Formalin fixed paraffin embedded tissue (FFPE) Fixed, cultured cells Other fluids	Chromosome analysis for: Prenatal Diagnosis Developmental disorders Reproductive medicine disorders Chromosome Breakage 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 CY 32311, CY 32303, CY 32288
	Microarray profiling using Agilent technology for macroscopic detection, analysis and reporting of genomic imbalance against a reference	In house documented procedures and commercial kits for macroscopic detection, analysis and reporting of genomic imbalance against a reference, Agilent microarray scanner Hybridisation oven, Nextseq 550, Nextseq 550 in conjuction with SOP's Oligonucleotide Microarray Protocol: CY 32310 Microarray Infinium CytoSNP-850K Assay Protocol CY 641

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	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
Blood, buccal/saliva samples, urine, cultured cells, amniocytes, chorionic villi, solid tissues, tissue sections, formalin fixed paraffin embedded tissue	DNA profiling for detection of abnormal sequences for common and rare genetic disease conditions	DNA extraction using Janus Robot (MSM1 module), BioRobot EZ1 Advanced Nanodrop Spectrophotometer, Chemigen extractor and SOP's MG0043, MG0100, MG0148

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
DNA	Mutation detection of sequence variants for the purpose of clinical diagnosis	Thermal Cyclers, Biomek Robot Nx, PCR & Agarose Gel electrophoresis, GJB6 (Connexin 30) in conjunction with SOP's MG0101 PCR Procedure, MG0147 Beckman Biomek NX, MG0105 SOP Polyacrylamide Gel Electrophoresis, MG0153 Protocol for BioSpectrum AC imaging system
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:

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
DNA	Mutation confirmation and carier/predictive testing and Mutation detection of sequence variants for the purpose of clinical diagnosis in genes: ABCD1 (Adrenoleukodystrophy) BRCA1/BRCA2 (Familial breast cancer) Notch3 (Cadasil) LDLR/ APOB ex27 / PSK9 ex7 (Familial Hypercholesterolaemia) FXN (Friedreich Ataxia) GJB2 (Hearing Loss) PMP22/MPZ/GJB1/MFN2 (HMSN/HNPP) MLH1/MSH2/MSH6 (Lynch Syndrome) PLA2G6 (Infantile Neuroaxonal Dystrophy) SGCE (Myoclonic Dystonia) MTM1 (Myotubular Myopathy) LMX1B (Nail Patella Syndrome) PRSS1 (Pancreatitis) STK11 (Peutz-Jegher Syndrome) PANK2 (Pantothenate kinase-associated neurodegeneration) MECP2 (Rett Syndrome) JAK2 exon 12 (MPN / PRV)	PCR amplification and Sanger Sequencing of DNA using Thermal Cyclers, Biomek Robot Nx, ABI 3730 in conjunction with SOP's MG0101 PCR Procedure, MG0147 Beckman Biomek NX, MG0109 Operation of Applied Biosystems Genetic Analysers, MG0110 Fluorescent DNA Sequencing Protocol
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:

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
DNA	Mutation detection of expansions for the purpose of clinical diagnosis, carrier detection and predictive testing in genes: Huntington Disease , Myotonic Dystrophy1, Myotonic Dystrophy2, FragileX, Friedreich Ataxia, Gilbert Syndrome, Oculopharyngeal Muscular Dystrophy, Spinal Bulbar Muscular Atrophy, Spinal Cerebellar Ataxia 1, 2, 3, 6, 7 & 17, Dentatorubral-pallidoluysian atrophy, Torsion Dystonia, Maternal Cell Contamination, Calreticulin	DNA PCR and fluorescent fragment size analysis, including PCR amplification of DNA using thermocyclers ABI 3130 ABI 3500 In conjunction with SOP'sMG0101 PCR Procedure, MG0109 Operation of Applied Biosystems Genetic Analysers, MG0108 MLPA protocol, MG0111 Dosage Analysis, MG0113 Microsatellite Analysis
DNA	Mutation detection of expansions for the purpose of clinical diagnosis, carrier detection and predictive testing in genes: Friedreich Ataxia, Myotonic Dystrophy1, Myotonic Dystrophy2 Allele Specific PCR: Cystic Fibrosis, JAK2 Rapid aneuploidy screening for: ABCD1, Dystrophin, GJB1/PMP22/MPZ, MLH1/MSH2, MSH6, MECP2, LDLR, STK11, SGCE, PANK2/PLA2G6, LMX1B, PRSS1.	DNA PCR, triplet-primed PCR (TP-PCR) and fluorescent fragment size analysis Allele-specific PCR amplification of DNA
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:

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
DNA	Dosage Analysis by quantitative fluorescent PCR: Rapid Aneuploidy Screening, Spinal Muscular Atrophy DNA Methylation Analysis: Prader Willi/Angelmann Syndrome.	DNA dosage analysis by quantitative fluorescent PCR (QF-PCR) amplification of DNA, MLPA
DNA	Mutation detection of sequence variants for the purpose of clinical diagnosis in gene panels: Quantitative: MELAS, MERRF, NARP, LHON, NRAS, KRAS, BRAF, MGMT	PCR and Pyrosequencing using Thermal Cyclers, PyroMark PSQ-96 ID, HFE, SPINK1 in conjunction with SOP's MG0101 PCR Procedure, MG0119 Pyrosequencing
DNA	Mutation detection of sequence variants for the purpose of clinical diagnosis in gene panels: Haloplex Custom Target Enrichment: Neuropathy Epilepsy and Spastic Paraplegia Panel Orofacial Clefting Panel	Next-generation sequencing with Long-range PCR using Agilent NGS Bravo A, Agilent Bioanalyser, MiSeq in conjunction with SOP's MG 393 Agilent High Sensitivity DNA Kit MG 423 Haloplex Library Preparation MG 470 Haloplex Library Preparation using the Bravo platform, MG 422 Operation of the MiSeq
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