Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

9322
Accredited to
ISO 15189:2022

Manchester University NHS Foundation Trust

Issue No: 012 **Issue date:** 09 March 2026

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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	Molecular and Cytogenetics examination activities for the purposes of clinical diagnosis: Cytogenetics	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 specified material for chromosome analysis using Robo-Sep S cell separator DOC5182 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 Using Metasystems Image Analysis System and Dako automated coverslipper DOC5004 DOC5642 DOC5003 MP000018
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 manufacturer's instructions for Hybrite and Metasystems Image Analysis System 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:</u> (cont'd)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:
SNP array data received from external source	Chromosome profile analysis for detection of chromosomal imbalance as copy number gains or losses, and copy neutral changes. For diagnosis in Haematological/ Oncology disorders	Analysis and interpretation of Illumina GSA-Cyto+ SNP array data using Bionano VIA software DOC5967 DOC5988 DOC5989
	<u>Molecular Genetics</u>	
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 and quantification	DNA extraction using Chemagic PRIME extractor and BioRobot EZ1 DOC5418 DOC5406 DOC5407 DOC5867 DNA quantification for QC purposes using DropSense 16 and Advanced Nanodrop Spectrophotometer DOC5583 DOC5405
DNA	Mutation detection of sequence variants for the purpose of clinical diagnosis and quality assessment of PCR products: GJB6 (Connexin 30)	Thermal Cyclers, PCR & Agarose Gel electrophoresis DOC5387 DOC5148 DOC5409 DOC5439

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/ 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) CFTR (Cystic fibrosis transmembrane conductance regulator)	PCR amplification and Sanger Sequencing of DNA using Thermal Cyclers, Bravo automated Liquid handler, ABI 3730 DOC5387 DOC5388 DOC5397 DOC5415

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 for the purpose of clinical diagnosis, confirmation, carrier detection and predictive testing in disorders: Huntington Disease, Huntington Disease-like 2 Myotonic Dystrophy1, Myotonic Dystrophy2, Friedreich Ataxia, Oculopharyngeal Muscular Dystrophy, Spinal Bulbar Muscular Atrophy, Spinal Cerebellar Ataxia 1, 2, 3, 6, 7, 12 & 17, Dentatorubral-pallidoluysian atrophy, Maternal Cell Contamination	DNA PCR and fluorescent fragment size analysis (F-PCR), including PCR amplification of DNA using thermocyclers ABI 3500 and Genemapper software. DOC5387 DOC5388
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
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 Elucigene (Yourgene) diagnostic Kits, ABI 3500 DOC5387 DOC5388

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 for the purpose of clinical diagnosis, confirmation, carrier detection and predictive testing in C9orf72-related disorders	DNA PCR, repeat primed PCR and fluorescent fragment size analysis using thermocyclers, ABI3500XL, Genemapper software and Asuragen AmplideX PCR/CE C9orf72 kit in conjunction with: DOC5808 AmplideX PCR/CE C9orf72 Kit (Asuragen) protocol
DNA	Analysis of copy number changes for the purpose of clinical diagnosis and carrier/predictive testing in genes: Dystrophin, GJB1/PMP22/MPZ, LDLR CFTR SMN1/2	DNA PCR and dosage analysis by Multiplex ligation probe – dependant amplification (MLPA) using ABI3500 and Genemapper and Mutation Surveyor software. DOC5150
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 DOC5198 DOC5395

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:
Whole Blood DNA from blood	Detection of clinically relevant pharmacogenetic sequence variants in genes: • DPYD • CYP2C19	Loop-mediated Isothermal Amplification (LAMP) with melt curve analysis using in-house software, manual or automated PCR set up using: BioMek i5 liquid handler, Quantstudio 3 Real-Time PCR and LaCar LAMP kits (DPYD, CYP2C19) DOC6092 DOC6086 DOC6685
Whole Blood DNA from blood	Detection of sequence variants for the purpose of clinical diagnosis and predictive testing in gene: • HFE (haemochromatosis)	Loop-mediated Isothermal Amplification (LAMP) with melt curve analysis using in-house software, manual or automated PCR set up using: BioMek i5 liquid handler, Quantstudio 3 Real-Time PCR and LaCar LAMP kits (DPYD, CYP2C19) DOC6092 DOC6086 DOC6685
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