

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9865</p> <p>Accredited to ISO 15189:2012</p>	<h3>Manchester University NHS Foundation Trust</h3> <p>Issue No: 005 Issue date: 09 September 2021</p>	
	<p>North West Genomic Laboratory Hub (Manchester)</p> <p>Manchester Centre for Genomic Medicine</p> <p>St Mary's Hospital</p> <p>Oxford Road</p> <p>Manchester</p> <p>M13 9WL</p>	<p>Contact: Emma Howard</p> <p>Tel: +44 (0) 151 702 4228</p> <p>E-Mail: emma.howard@mft.nhs.uk</p> <p>Website: www.mft.nhs.uk/nwglh</p>

**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
<p>HUMAN BODY FLUIDS/TISSUE</p> <p>Blood, amniotic fluid (AF), chorionic villus samples (CVS)</p> <p>DNA from blood, mouthwashes, AF, CVS, foetal tissue</p> <p>DNA from blood, mouthwashes, AF, CVS, foetal tissue</p>	<p><u>Cytogenetics examination for the purposes of clinical diagnosis</u></p> <p>Chromosome analysis for: Prenatal diagnosis Reproductive medicine disorders Disorders of sexual development Developmental disorders</p> <p>Chromosome profile analysis for: Prenatal diagnosis Developmental disorders (including 22q11, Williams syndrome, Angelman syndrome, Prader-Willi syndrome, etc.) Inheritance testing following proband microarray findings (targeted) Pregnancy loss</p> <p>Prenatal/Postnatal diagnosis of aneuploidy (chromosomes 13, 18, 21 or sex chromosomes) Maternal contamination testing</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Metaphase preparation, microscopic examination and analysis of <u>G-banded karyotypes</u> using light microscopy or Metasystems image analysis system. Cell culture LP200 003, 011, LP110 015, 003, 012, LP120 012, 014, 015. G-banding analysis LP000 017, 008, 024, DOC2630</p> <p><u>Microarray</u> process using Beckman Coulter NX Span 8, Agilent microarray technology, OGT Constitutional V3 array, Agilent Microarray Scanner, Cytosure analysis software. DOC3097, 3236, LP130 011, LP430 004</p> <p><u>QF-PCR (Polymerase chain reaction)</u> analysis using automated or manual DNA extraction (Instagene), in-house primer preparation, PCR (ABI9700), Genetic analyser (Applied Biosystems 3500XL), analysis (Genemapper software). LP500 001, 003, 005, 008, DOC868</p>



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Cytogenetics examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
DNA from blood	Identity testing	LP500 001, 003, 005, 008
DNA from blood	Graft v Host determination following bone marrow transplant	LP500 001, 003, 005, 008
Blood, AF, CVS, buccal swabs, tissue touch preparation slides	Macroscopic and microscopic detection and analysis of genetic rearrangements and/or genomic imbalance including confirmation and inheritance testing following proband microarray findings.	<u>FISH</u> using in-house procedures and commercial probes - including Kreatech (Leica), Abbott Molecular (Vysis), Cytocell (OGT), TCAG (Toronto, Canada), BlueGnome (Illumina), Pisces Scientific FISH probes (Empire Genomics). Thermobrite hybridisation station, fluorescence microscopes (Olympus), Metasystems Isis software. DOC3033, LP300 024
FFPE tissue slide	Detection of ALK and ROS1 gene rearrangements in non-small cell carcinoma of the lung.  Detection of 1p/19q codeletions in Glioma.	DOC1411
Blood, AF, CVS, fresh tissue (including fibroblasts)	Cell culture for cryogenic storage, DNA/RNA extraction, export or immortalisation (lymphoblastoid cell lines)	DOC2285, LP160 015, 018, 022, 033, 041, 050, 043, 012, 015



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>Blood, mouthwashes, AF, CVS, solid tissues (products of conception, skin, placenta, umbilical cord, liver etc.), blood spots, FFPE tissue</p>	<p><u>Molecular genetics examination for the purposes of clinical diagnosis</u></p> <p>Extraction and storage of DNA</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Automated JANUS Chemagic Prime system for DNA extraction (Perkin Elmer). DOC4355 Automated Chemagen DNA extraction (Chemagen 360). DOC2000 EZ1 DNA extraction kits. DOC905, 906, 907, 908, 913 COBAS FFPE extraction. DOC1300 iGENatal extraction. DOC2354 Cleaning DNA samples. DOC2047, DOC2347, LP400 002 Quality assessment. LP 000 239, Nanodrop LP 000 230, Qubit 2.0 DOC2356, DropSense DOC2828. DNA dilutions DOC752</p>
<p>Plasma</p>	<p>Extraction and storage of DNA</p>	<p>Plasma preparation from blood using DOC2893, ctDNA and cfDNA extraction from plasma using DOC3183</p>
<p>PHA stimulated short term lymphocyte cultures; melanocyte cultures</p>	<p>Extraction and storage of RNA</p>	<p>ENZ1 RNA extraction kit DOC992</p>
<p>DNA from primary samples</p>	<p>Mutation detection of sequence variants causing genetic diseases and disorder: Single Nucleotide Variants (SNVs) Indels Copy Number Variations (CNVs)</p>	<p><u>Next Generation Sequencing</u> using: NextSeq 500 or MiSeq and SureSelect XT, Nextera XT or GeneRead/ TruSeq gene panels. Data Analysis using: BWA bioinformatics pipelines DOC2258, 2047, 2146, 3234, 1146, 2176, 2204, 2175, 2608, 3087, 4056, DOC1146</p>
<p>DNA from blood</p>	<p>Breast and Ovarian Cancer familial (BRCA1 and 2)</p>	<p>MiSeq, LP 000 284, DOC2816</p>



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular genetics examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
DNA from primary samples	<p>Mutation detection of sequence variants causing genetic diseases and disorder: Single Nucleotide Variants (SNVs) Indels Copy Number Variations (CNVs)</p> <p>Cardiac disorders:</p> <ul style="list-style-type: none"> <li>• Arrhythmia/ Cardiac Arrest</li> <li>• Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)</li> <li>• Brugada Syndrome</li> <li>• Cardiomyopathies</li> <li>• Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT)</li> <li>• Familial Dilated Cardiomyopathy</li> <li>• Familial Hypertrophic Cardiomyopathy</li> <li>• Familial Thoracic Aortic Aneurysm</li> <li>• Long QT Syndrome</li> <li>• Molecular Autopsy</li> </ul> <p>Cystic fibrosis (CFTR; extended mutation testing)</p> <p>Familial Adenomatous Polyposis (APC) (FAP) and MUTYH-Associated Polyposis (MUTYH) (MAP)</p> <p>Lynch Syndrome (HNPCC, familial colorectal cancer) (MLH1, MSH2, MSH6)</p> <p>Fabry disease (GLA)</p>	<p>Next Generation Sequencing using: NextSeq 500 or MiSeq and SureSelect XT, Nextera XT or GeneRead/ TruSeq gene panels. Data Analysis using: BWA bioinformatics pipelines. DOC2258, 2047, 2146, 3234, 1146, 2176, 2204, 2175, 2608, 3087, 4056, DOC1146</p> <p>NextSeq, DOC2273</p> <p>MiSeq, DOC4032</p> <p>MiSeq, LP 000 062</p> <p>MiSeq, LP 000 050</p> <p>MiSeq, DOC761</p>



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>DNA from primary samples</p>	<p><u>Molecular genetics examination for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Mutation detection of sequence variants causing genetic diseases and disorder: Single Nucleotide Variants (SNVs) Indels Copy Number Variations (CNVs)</p> <p>Metabolic Disorders:</p> <ul style="list-style-type: none"> <li>• Amino acid metabolism and neurotransmission disorders (AA&amp;NT)</li> <li>• Carbohydrate metabolism disorders (CHO)</li> <li>• Disorders associated with hyperammonaemia, fatty acid oxidation defects and disorders of ketogenesis and ketolysis (AMN&amp;FAOD&amp;KET)</li> <li>• Lysosomal Storage Diseases and neuronal ceroid lipofuscinoses (LSD&amp;NCL)</li> <li>• Niemann Pick C (NPC1, NPC2)</li> <li>• Organic acidaemias and vitamin cofactor disorders (OA&amp;VIT)</li> <li>• Peroxisomal disorders (PER)</li> </ul>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p><u>Next Generation Sequencing</u> using: NextSeq 500 or MiSeq and SureSelect XT, Nextera XT or GeneRead/ TruSeq gene panels. Data Analysis using: BWA bioinformatics pipelines. DOC2258, 2047, 2146, 3234, 1146, 2176, 2204, 2175, 2608, 3087, 4056, DOC1146</p> <p>NextSeq, DOC2658</p>



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>DNA from primary samples</p>	<p><u>Molecular genetics examination for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Mutation detection of sequence variants causing genetic diseases and disorder: Single Nucleotide Variants (SNVs) Indels Copy Number Variations (CNVs)</p> <p>Inherited Cancer</p> <ul style="list-style-type: none"> <li>• Breast</li> <li>• Carney complex</li> <li>• Colorectal cancer and polyps</li> <li>• Cutaneous melanoma</li> <li>• CyldromatosisFanconi anemia</li> <li>• Gastric cancer</li> <li>• Hereditary diffuse gastric cancer</li> <li>• Hyperparathyroidism</li> <li>• Leukaemia</li> <li>• Melanoma</li> <li>• Neuroendocrine</li> <li>• Nevoid Basal Cell Carcinoma</li> <li>• Ovarian</li> <li>• Pancreatic</li> <li>• Paraganglioma / pheochromocytoma</li> <li>• Renal cell carcinoma</li> <li>• Schwannomatosis / meningioma</li> </ul>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p><u>Next Generation Sequencing</u> using: NextSeq 500 or MiSeq and SureSelect XT, Nextera XT or GeneRead/ TruSeq gene panels. Data Analysis using: BWA bioinformatics pipelines. DOC2258, 2047, 2146, 3234, 1146, 2176, 2204, 2175, 2608, 3087, 4056, DOC1146</p> <p>NextSeq, DOC4335</p>



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular genetics examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
DNA from primary samples	Mutation detection of sequence variants causing genetic diseases and disorder: Single Nucleotide Variants (SNVs) Indels Copy Number Variations (CNVs)	<u>Next Generation Sequencing</u> using: NextSeq 500 or MiSeq and SureSelect XT, Nextera XT or GeneRead/ TruSeq gene panels. Data Analysis using: BWA bioinformatics pipelines. DOC2258, 2047, 2146, 3234, 1146, 2176, 2204, 2175, 2608, 3087, 4056, DOC1146
	Ophthalmic disorders: <ul style="list-style-type: none"> <li>• Anterior segment dysgenesis and glaucoma</li> <li>• Brittle cornea syndrome</li> <li>• Corneal abnormalities (including corneal dystrophy, BSC and other corneal genes)</li> <li>• Corneal dystrophy</li> <li>• Foveal hypoplasia &amp; nystagmus</li> <li>• Lens abnormalities, including congenital cataracts</li> <li>• Lens abnormalities, non-cataract</li> <li>• Microphthalmia/ Coloboma</li> <li>• Ocular/ oculocutaneous albinism</li> <li>• Optic nerve disorders (including ocular/ oculocutaneous albinism, foveal hypoplasia &amp; nystagmus, and optical atrophy)</li> <li>• Stickler syndrome</li> </ul>	NextSeq, DOC3110
	Retinal Degeneration Conditions: Full gene panel Retinitis Pigmentosa, X-Linked (RPGR/ RP2) Macular Dystrophy (PRPH2/BEST1)	NextSeq, DOC1139
	Retinoblastoma (RB1)	MiSeq, LP 000 075
DNA from blood or fresh tissue	Overgrowth syndromes (PIK3CA/ PIK3R2/ AKT1/ AKT3 /mTOR/ CCND2/ PTEN)	MiSeq, DOC2671



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DNA from primary samples	Mutation detection of sequence variants causing genetic diseases and disorder: Single Nucleotide Variants (SNVs) Indels Copy Number Variations (CNVs)	<u>Next Generation Sequencing</u> using: NextSeq 500 or MiSeq and SureSelect XT, Nextera XT or GeneRead/ TruSeq gene panels. Data Analysis using: BWA bioinformatics pipelines. DOC2258, 2047, 2146, 3234, 1146, 2176, 2204, 2175, 2608, 3087, 4056, DOC1146
DNA/RNA from blood/melanocytes	Neurofibromatosis type 1 (NF1)	MiSeq, LP 000 250
DNA from FFPE tissue sections, slides or shavings	Breast and Ovarian Cancer treatment focussed (BRCA1 and 2) and germline mutations	DOC3340
DNA from FFPE tissue sections, slides or shavings	Cancer screening for somatic mutations (including malignant melanoma, non-small cell lung cancer, colorectal cancer and GIST)	MiSeq, DOC3338
	Glioma / CNS cancer panel screening for somatic mutations	MiSeq, DOC4253
	Glioma / CNS cancer panel screening for somatic mutations - Meningioma/schwannoma subpanel (NF2, SMARCB1, SMARCE1, SMARCA4, LZTR1)	MiSeq, DOC4763
	Colorectal cancer - tumour samples for somatic mutations (KRAS, NRAS, BRAF, PIK3CA)	MiSeq, DOC3338
	Colorectal cancer - tissue samples for somatic and germline mutations (APC, BMPR1A, CDH1, CTNNB1, MSH6, SMAD4, MLH1, MSH2, MUTYH, POLD1, POLE, PTEN and STK11)	MiSeq, DOC3339
RNA from FFPE samples	Lung cancer fusion gene panel (ALK, ROS1, NTRK3, RET)	QIAseq Targeted RNAScan Panel, MiSeq, DOC4764





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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular genetics examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
DNA from primary samples	Mutation detection of sequence variants causing genetic diseases and disorder: Single Nucleotide Variants (SNVs) Indels Copy Number Variations (CNVs)	<u>Next Generation Sequencing</u> using: NextSeq 500 or MiSeq and SureSelect XT, Nextera XT or GeneRead/ TruSeq gene panels. Data Analysis using: BWA bioinformatics pipelines. DOC2258, 2047, 2146, 3234, 1146, 2176, 2204, 2175, 2608, 3087, 4056, DOC1146
DNA from FFPE tissue sections, slides or shavings	Schwannomatosis in tumour samples (NF2, LZTR1, SMARCB1, SMARCE1, SMARCA4)	MiSeq LP 000 249, LP 000 069
DNA from blood, fresh tissue, AF, CVS	Schwannomatosis; Atypical Familial Rhabdoid Tumour (SMARCB1/ LZTR1)	MiSeq, LP 000 249
DNA from blood or FFPE tissue sections, slides, shavings, fresh tissue, AF, CVS	Neurofibromatosis type 2 (NF2)	MiSeq, LP 000 069
DNA from blood	Mutation detection of sequence variants causing genetic diseases and disorder: Single Nucleotide Variants (SNVs) Indels  Exomes Panel (Clinical)  Exomes Panel (Learning Difficulties)	<u>Next Generation Sequencing</u> using:  NextSeq, DOC3256  NextSeq, DOC3196
DNA from blood or FFPE tissue sections, slides, shavings, fresh tissue, AF, CVS	Detection of clinical relevant nucleic acid sequence and copy number variants for confirmation of NGS results or family studies related to validated methods	Sanger sequencing using Thermo Thermal Cyclers and ABI3730XL sequencers, DOC1585, LP 000 236  Multiplex Ligation-dependant Probe Amplification (MLPA) or MS-MLPA using ABI3500XL analyser and DOC955, DOC1030, LP 000 162



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DNA from primary samples	Mutation detection for the purpose of clinical diagnosis, carrier detection and predictive testing in the following:	PCR amplification and <u>Sanger sequencing</u> using Thermo Thermal Cyclers and ABI3730XL sequencers, DOC1585, LP 000 236
DNA from blood	Rare disease mutation confirmation on request	DOC1284
	Angelman Syndrome/ Prader-Willi Syndrome (UBE3A, SNRPN)	LP 000 054
	Doyne Honeycombe Retinal Dystrophy (DHRD; EFEMP1)	LP 000 246
	Late onset retinal dystrophy (LORD; C1QTNF5)	LP 000 247
	Legius Syndrome (SPRED1)	LP 000 251
	LCHAD common mutation (HADHA)	LP 000 264
	Macular Dystrophy (PROM1 c.1117C>T p.(Arg373Cys))	DOC1426
	Malignant melanoma tumour (KIT)	LP 000 232
	Schwannomatosis 1 (SMARCE1)	DOC1590
	Sorsby Fundus Dystrophy (SFD) (TIMP3)	LP 000 222
DNA from blood, AF, CVS	Congenital adrenal hyperplasia due to 21 hydroxylase deficiency (CYP21A2)	LP 000 082
	Retinitis Pigmentosa, X-Linked (RPGR, exon ORF15 only)	DOC2245
DNA from blood, AF, CVS, blood spots	MCADD common mutation (ACADM)	LP 000 268



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RNA from lymphocyte culture	Retinoblastoma (RB1)	LP 000 075
DNA from primary samples	Mutation detection for the purpose of clinical diagnosis, carrier detection and predictive testing in the following cont'd:	PCR amplification and <u>Sanger sequencing</u> using Thermo Thermal Cyclers and ABI3730XL sequencers, DOC1585, LP 000 236
DNA from FFPE tissue sections, slides or shavings	Non-Small Cell Lung Cancer (somatic mutations, - tumour samples) (EGFR)	LP 000 257
	Gastro intestinal Stromal tumours for familial GIST (KIT, PDGFRA)	LP 000 232
	Glioma- hTERT promoter	DOC4161
	Melanoma (KIT)	DOC3104 and LP 000 232
DNA from primary samples	Mutation detection for the purpose of clinical diagnosis, carrier detection and predictive testing in the following:	PCR using Thermo Thermal Cycler and Pyromark PQQ 96MA <u>pyrosequencing</u> , DOC887 and:
DNA from blood, AF, CVS	Congenital Adrenal Hyperplasia due to 21 hydroxylase deficiency (CYP21A2)	LP 000 082
DNA from FFPE tissue sections, slides or shavings	Colorectal cancer (MLH1 hypermethylation and BRAF codon 600)	DOC3389, DOC869, DOC3104
	Malignant melanoma (BRAF, NRAS)	DOC3104
	MGMT methylation analysis (Glioma)	DOC3349
	Glioma (MGMT hypermethylation and BRAF codon 600)	DOC3349, DOC869



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DNA from primary samples	Detection of whole or partial gene deletions and duplications and probe specific mutations of the following genes/disease regions:	<u>Multiplex Ligation-dependant Probe Amplification</u> (MLPA) or MS-MLPA using ABI3500XL analyser and DOC955, DOC1030, LP 000 162 and:
DNA from blood	Angelman syndrome/ Prader-Willi Syndrome (UBE3A, SNRPN)	LP 000 054
	Breast and Ovarian cancer (BRCA1 and 2)	LP 000 284
DNA from primary samples	Familial Adenomatous Polyposis (APC) (FAP) and MUTYH-Associated Polyposis (MUTYH) (MAP)	LP 000 062
	Lynch Syndrome (HNPCC, familial colorectal cancer) (MLH1, MSH2, MSH6)	LP 000 050
	Niemann Pick C (NPC1, NPC2)	DOC4020
DNA from blood, AF, CVS	Cystic fibrosis (CFTR)	DOC4032
	Duchenne and Becker Muscular Dystrophy (DMD)	LP 000 063
DNA/RNA from blood, lymphocyte culture, melanocyte culture	Neurofibromatosis type 1 (NF1)	LP 000 250
DNA from whole blood, FFPE tissue sections, slides or shavings, fresh tissue, AF, CVS	Neurofibromatosis type 2 (NF2)	LP 000 069
	Retinoblastoma (RB1)	LP 000 075
DNA from whole blood, FFPE tissue sections, slides or shavings, fresh tissue	Schwannomatosis; Atypical Familial Rhabdoid Tumour (SMARCB1/LZTR1)	LP 000 249
	Schwannomatosis 1 (SMARCE1)	DOC1590



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DNA from FFPE tissue sections, slides or shavings	Quantitative detection of clinically relevant nucleic acid sequence variants for the following:  Colorectal cancer - tumour samples for sporadic mutations (BRAF, KRAS)  Malignant Melanoma - tumour samples (BRAF)	<u>Real time PCR</u> using Cobas Z 480* analyser DOC1185 or Digital Droplet PCR using Biorad QX200 Droplet Digital System^and:  DOC1186*  DOC1184*
DNA from: FFPE tissue sections, slides or shavings, and circulating tumour DNA (ctDNA)	Non-Small Cell Lung Cancer (somatic mutations, - tumour samples) (EGFR)	LP 000 257, DOC3065, DOC3312*^
RNA from FFPE samples	Glioma (KIAA1549: BRAF fusion, C11orf95: RELA fusion, EGFRvIII transcript)	DOC4206
DNA extracted from plasma	Non-Invasive Foetal Sex Determination (cffDNA)	<u>Real time PCR</u> using ABI Prism 7900 analyser and LP 000 253
DNA from primary samples	Mutation detection for the purpose of clinical diagnosis, carrier detection and predictive testing in the following:	<u>PCR methods</u> using Thermo Thermal Cycler and either: CE- Capillary electrophoresis using ABI3500XL genetic analyser, DOC955 or GE- Gel electrophoresis, LP 000 017 including:
Blood	Angelman/ Prader-Willi Syndrome (incl. UDP/parent of origin studies)  Breast and Ovarian cancer (BRCA1 and 2)  Huntington Disease (HTT)	Methylation sensitive PCR, LP 000 054 using EZ DNA methylation kit, Zymo Research, LP 000 087 and GE Microsatellite analysis using CE, LP 000 054  ARMS PCR and GE, LP 000 284 Microsatellite analysis using CE, LP 000 284  Fragment analysis using CE, LP 000 060



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Blood, AF, CVS	Mutation detection for the purpose of clinical diagnosis, carrier detection and predictive testing in the following:	<u>PCR methods</u> using Thermo Thermal Cycler and either: CE- Capillary electrophoresis using ABI3500XL genetic analyser, DOC955 or GE- Gel electrophoresis, LP 000 017 including:
Blood, AF, CVS	Congenital Adrenal Hyperplasia due to 21 hydroxylase deficiency (CYP21A2)	Fragment analysis or Fluorescence PCR using CE, LP 000 082
Blood, AF, CVS	Fragile X Syndrome and associated disorders (FXTAS and FXPOI) (FMR1)	Fragment analysis (in-house or Asuragen Amplidex) using CE, LP 000 061, DOC1174
Blood, AF, CVS, blood spots	Cystic Fibrosis (CFTR)	ARMS PCR, DOC4032 or Fluorescence PCR, DOC850 using CE
FFPE tissue sections, slides or shavings	Microsatellite Instability (MSI) Testing	Fluorescence PCR using CE, DOC1332
	MLH1 promoter hypermethylation (MLH1)	Methylation using Qiagen Epitect Plus FFPE Bisulphite kit, DOC869 and pyrosequencing, DOC887
DNA from blood, FFPE tissue sections, slides or shavings, fresh tissue, AF, CVS	Neurofibromatosis type 2 (NF2; incl. LOH)	Microsatellite analysis for LOH or linkage using CE, LP 000 069 Mosaicism detection using ARMS PCR and GE, LP 000 069
	Retinoblastoma (RB1)	Microsatellite analysis for LOH or linkage using CE, LP 000 075
	<u>Schwannomatosis (LZTR1, SMARCB1)</u>	LP 000 249



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular Haematology examinations for the purposes of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
DNA from blood, AF, CVS	Detection of F8 intron 22 gene inversion mutation	Long PCR. DOC4392
	Detection of F8 intron 1 gene inversion mutation	PCR, DOC4393
	Detection of single nucleotide polymorphism of: Prothrombin G20210A FV Leiden HFE C282Y/H63D TPMT	<u>PCR methods</u> using Thermo thermal cyclers and mass spectrometry using Agena MassArray DOC4434
	<u>Detection of the following gene mutations:</u>	<u>PCR methods</u> using Thermo thermal cyclers and Sanger sequencing using Applied Biosystems 3730XL sequencer and Alamut mutation surveyor software.
	F2	DOC4441
	F5	DOC4446
	F7	DOC4425
	F8	DOC4448
	F9	DOC4401
	F10	DOC4449
	F11	DOC4415
	F13A1, F13B	DOC4445
	GGCX, VKORC1	DOC4444
	TPMT	DOC4428
	Beta thalassemia (HBB and HBG2 promoter region)	DOC4409
	Alpha thalassemia (HBA1 and HBA2)	DOC4414
	Von Willebrand factor (VWF)	DOC4405
	Combined FVIII and FV deficiency analysis (LMAN1 and MCFD2)	DOC4450



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular Haematology examinations for the purposes of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
DNA from blood	<u>Detection of whole or partial gene deletions and duplications:</u> F7 F8 F9 F10 F11 Alpha globin gene cluster deletions Beta globin gene cluster deletions	MLPA analysis using Applied Biosystems and Thermo thermal cyclers and Applied Biosystems AB 3500XL genetic analyser DOC4407
DNA or RNA from blood or bone marrow	<u>Quantitative monitoring of gene expression for:</u> BCR-ABL (t9;22) AML-MTG8 (t8;21) PML-RARA (t15;17) CBFB-MYH11 (Inv16 and t16;16) NPM1	Real time PCR using Applied Biosystems QuantStudio6 and DOC4453, DOC4454
DNA from blood or bone marrow	<u>Detection of mutations in the following genes:</u>  CEBPA BCR-ABL TKD	PCR and Sanger sequencing using Thermo thermal cyclers and Applied Biosystems 3730XL genetic analysers DOC4439 DOC4443
DNA from blood or bone marrow	<u>Detection of mutations in the following genes:</u>  CALR exon 9 FLT3-ITD JAK 2 (Exon 12) MPL (Exon 10) NPM1 (Exon 12) JAK2 V617F	PCR fragment analysis using Thermo thermal cyclers and Applied Biosystems AB 3500XL genetic analyser DOC4436 DOC4429 DOC4442 DOC4438 DOC4440 DOC4411





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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular Oncology examinations for the purposes of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
DNA from blood or bone marrow	Targeted detection of specific variants associated with acute myeloid leukaemia	Agena SNP panel PCR using Thermo thermal cyclers, iPLEX single base extension and Agena MassArray system DOC4447
Blood and bone marrow	DNA extraction	Maxwell DNA extraction system DOC4410
	RNA extraction	Qiagen Qiacube RNA extraction system and cDNA synthesis using Superscript DOC4422, DOC4413



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Biochemical genetics examination for the purposes of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
Leucocytes, CVS, cultured cells	<u>Detection of plasma and white cell lysosomal storage enzymes:</u>  Acid esterase (liposomal acid lipase) Wolman Disease/ CESD/ LAL-D  a-fucosidase (Fucosidosis)  b-galactosidase (GM 1 gangliosidosis/ MPS IV B/ Morquio B/ Galactosialidosis)  b-glucosidase (Gaucher disease)  b-glucuronidase (MPS VII, Sly disease)  a-iduronidase (Hurler disease / MPS I/ Scheie disease)	Enzyme assay using Perkin Elmer fluorescent spectrophotometer LS55 and LS30, DOC 578 and:  DOC630  DOC559  DOC570  DOC591, DOC571, DOC602  DOC572  DOC554
Lymphocytes, CVS, cultured cells	a-glucosidase (Pompe) confirmatory	DOC560, DOC563
Leucocytes, cultured cells	Galactocerebrosidase (screen) Krabbe leukodystrophy	DOC579
Leucocytes	N-acetyl-a-galactosaminidase (Schindler disease)  NCL screen (neuronal ceroid lipofuscinosis/ Batten's)	DOC566  DOC2688, DOC2864
Plasma, leucocytes, CVS, cultured cells	b-hexosaminidase A (Tay-Sachs disease)  b-hexosaminidase A & B (Sandhoff's disease)  a-mannosidase (alpha Mannosidosis)	DOC573  DOC574  DOC565



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Biochemical genetics examination for the purposes of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant
Plasma, leucocytes, CVS, cultured cells	<u>Detection of plasma and white cell lysosomal storage enzymes cont'd:</u>  b-mannosidase (beta Mannosidosis)	Enzyme assay using Perkin Elmer fluorescent spectrophotometer LS55 and LS30, DOC 578 and:  DCO575, 603
Plasma, leucocytes	a-N-acetylglucosaminidase (MPS III B/ Sanfilippo III B disease)	DOC633, DOC588
Plasma, cultured cells	a-galactosidase (Fabry disease) confirmatory	DOC562
Plasma, leucocytes	Multiple hydrolases (I-cell disease/ mucopolipidosis II/III) screen. [battery composition depends on sample type]	DOC574
Plasma	Aspartylglucosaminidase (Aspartylglucosaminuria)	DOC634
Plasma	Chitotriosidase	DOC576
Leucocytes, cultured cells	Arylsulphatase A (Metachromatic leukodystrophy)	Enzyme assay with colorimetric detection using CECIL CE1011 spectrophotometer and DOC567
Leucocytes, CVS, cultured cells	Arylsulphatase B (MPS VI, Maroteaux-Lamy)	Enzyme assay with fluorescence detection using Perkin Elmer LS 30. DOC948, DOC600
Leucocytes, CVS, cultured cells	Detection of the following:  Galactose-6-sulphatase (MPS IV A, Morquio A)	Enzyme assay with fluorescent detection using Biotech Synergy Microplate reader and:  DOC2760
Leucocytes, CVS, cultured cells	Heparan sulphamidase (MPS III A, Sanfilippo A)	DOC577



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Biochemical genetics examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Leucocytes	Detection of the following:  NCL screen (neuronal ceroid lipofuscinosis/ Batten's)	Enzyme assay with fluorescent detection using Biotech Synergy Microplate reader and:  DOC2688, DOC2864
Plasma, leucocytes, CVS, cultured cells	Iduronate sulphatase (Hunter disease/ MPS II)	DOC564
Dry blood spot	a-galactosidase (Fabry disease) screen	DOC594
	a-glucosidase (Pompe) screen	DOC595
Leucocytes, CVS, cultured cells	Detection of the following:  Galactocerebrosidase (confirmatory)	Scintillation counting using Canberra Packard scintillation counter and DOC631
	Sphingomyelinase (Niemann Pick type A/B, acid sphingomyelinase deficiency, ASMD)	DOC596
Plasma, leucocytes, cultured cells	Multiple sulphatases (multiple sulphatase deficiency) [composition can comprise any of several sulphatases]	Enzyme assay using Perkin Elmer fluorescent spectrophotometer LS55 (or LS30), Biotech Synergy Microplate reader, CECIL CE1011 spectrophotometer and/or Lambda 25 and DOC564, 567, 580, 948, 2760
Cultured cells	Detection of stored cholesterol(Niemann-Pick Type C)	Fluorescent Filipin staining and microscopy using DOC673
Lymphocytes, cultured cells	a-glucosidase CRIM (Pompe)	Western blot using manual method and DOC2686



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Biochemical genetics examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Urine, amniotic fluid	Mucopolysaccharide urine screen	A manual method of different analyses (DOC643) including isolation (DOC555), colorimetric quantitation (DOC553), 2D electrophoresis (DOC552) and thin layer chromatography of oligosaccharides and sialic acid (DOC558).
Urine	Oligosaccharide/ sialic acid screen	Manual method of thin layer chromatography using DOC558
Urine	<u>Detection of other Metabolic disorders:</u> Amino acid screen	Derivatisation, Waters Acuity Ultra performance liquid chromatography (UPLC) and DOC696
Blood spot	Amino acid quantitation	DOC4348
Plasma, urine, CSF	Amino acid quantitation	Derivatisation, ion exchange chromatography using Biochrom 30 and DOC1195
Blood, bile, plasma, serum, urine	Acyl carnitines and free carnitine	Derivatisation, MS/MS using Waters Quattro LC TMS and DOC666
	Detection of the following:	Liquid Chromatography-Mass Spectrometry LC-MS/MS using Waters Quattro LC and
Plasma, serum	Biotinidase	DOC2365
Plasma, serum, urine	Methylmalonic acid	DOC698
Urine	Orotic acid	DOC705
Urine	Quantitative detection of Creatinine	Isotope dilution TMS using Waters TQD and Waters Quattro-LC and DOC4132
Plasma	Oxysterol	LC-MS/MS using Waters TQD and DOC2378



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Biochemical genetics examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Plasma	Detection of the following:  Cholestanol	Gas chromatography-Mass Spectrometry, GC-MS using Agilent 6890N and: DOC647
Plasma, serum, liver, spleen, amniotic fluid, CVS	7-dehydrocholesterol	DOC647
Plasma, serum	Phytanic acid and Pristanic acid	DOC644
	Very long chain fatty acids	DOC646
Erythrocytes	Plasmalogens	DOC645
Urine	Detection of the following:  Organic acids	GC-MS using Shimadzu QP2010 SE and: DOC688.
Urine	Succinylacetone (to investigate tyrosinemia type 1)	DOC688
Plasma	Total homocysteine	HPLC using JASCO LC2000 and DOC652
Urine	Sugar chromatography	Manual method using thin layer chromatography and DOC4368
Urine	Sulphite	Colorimetric assay using Mquant sulphite stick and DOC2277
Blood	Beutler screening test for classical galactosaemia (galactose-1-phosphate uridylyl transferase)	Enzyme assay with fluorescence detection using CAMAG spectrophotometer and DOC653
Blood spot	PKU monitoring	TMS using Waters TQD or Quattro Micro and DOC1123



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HUMAN BODY FLUIDS/TISSUE (cont'd)  Blood spot	<u>Biochemical genetics examination for the purposes of clinical diagnosis</u> (cont'd)  <u>Newborn Screening:</u>  Of IMD disorders: PKU, MCADD, MSUD, IVA, GA1, HCU	In house documented methods incorporating manufacturers' instructions where relevant  TMS using Waters TQD or Quattro Micro and DOC1410
END		