Schedule of Accreditation

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Leeds Teaching Hospitals NHS Trust

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Testing performed by the Organisation at the locations specified below

Laboratory locations:

Location details	Activity	Location code
Address Yorkshire and North East Genomic Laboratory Hub, Central Lab Ashley Wing St James's University Hospital Leeds LS9 7TF United Kingdom	Molecular and Cytogenetics testing	A
Address Clinical Sciences Building St James's University Hospital Leeds LS9 7TF United Kingdom	NGS sequencing	B
Address Bexley Wing St James's University Hospital Leeds LS9 7TF United Kingdom	FISH testing, DNA extraction and quantification, NGS library preparation	C

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS	Molecular genetic examinations for the purpose of clinical diagnosis (including predictive and prenatal) for a range of disorders:	In house documented methods incorporating manufacturers' instructions where relevant	
Human DNA / RNA Blood, saliva, tissue, paraffin embedded tissue amniotic fluid, chorionic villus sampling (CVS)Extracted DNA from external sources	DNA/RNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage	Using a combination of the methods listed below, supported by: DNA Extraction by: Automated EZ1 robot: (LGSR004 Automated Chemagic and Chemagic 360i: (DN312) Manual extraction of cfDNA from plasma with Qiagen QIAamp kit: (LGTPM001) DNA Quantification by Nanodrop spectrophotometer or Qubit: LGGLM003 Amplification by Polymerase Chain Reaction/PCR (Thermocyclers: DN110, Tecan Robot: DN330) 1. Sanger DNA sequencing (Applied Biosystems (AB) Analysers 3730, 3130XL: DN122) 2. Multiplex Ligation-dependent Probe Amplification, (AB, Thermocyclers: DN073) 3. Gel Electrophoresis (DN085) 4. Fragment analysis (AB) : DN136) 5. Next Generation Sequencing: sequencing and dosage analysis (Sureselect – custom targeting and clinical exomeIllumina NextSeq 500 NextSeq 550DX: DN331, Sureselect Library Prep: DN258 (manual contingency) Agilent Bravo: LGTPM002 Sciclone SureSelect Library Preparation: DN327 Tecan Liquid Handling Protocols: DN330) Agilent Bioanalyser: DN219 Covaris S2 Episonic 1100: DN217 Illumina Miseq: DN256 Quantitative DNA analysis (PicoGreen): DN214 Qiagen DNA clean up: DN216)	A, C C A A A,C A C A,B A A A B C C C B B B B B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (including predictive and prenatal) for a range of disorders (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
		6. CFEU2 (Elucigene) (Thermocyclers, AB : DN006)	A
		7. MFI-Y Plus (Elucigene) (Thermocyclers, AB: DN038)	A
Human DNA obtained from: A. blood, saliva, tissue, paraffin embedded tissue B. amniotic fluid, chorionic villus sampling (CVS)			A or A & B, or A, B & C (see techniques 1-7 above)
A, B	Breast Cancer (BRCA1, BRCA2)	DN194 – 1, 2, 3, 5	
A	Cancer Gene panel (Agilent Custom Design) including:	DN260, DN275 –	
	Adenomatous Polyposis of the Colon Breast Cancer	DN012 – 1, 2, 3, 5	
	Colorectal Cancer, Hereditary Nonpolyposis	DN194 - 1, 2, 3, 5 DN020 – 1, 2, 3, 5	
	Li-Fraumeni syndrome Lynch syndrome; Turcot syndrome, Colorectal cancer-PMS2	DN039 - 1, 2, 3, 5 DN167, DN260 - 1, 2, 3, 5	
	Melanoma, Cutaneous Malignant		
	Multiple Endocrine Neoplasia, TypeI	DN011 – 1, 2, 3, 5	
	Multiple Endocrine Neoplasia, TypeII	DN023 – 1, 3, 5	
	Pheochromocytoma and Paraganglioma, Von Hippel-Lindau syndrome	DN237 – 1, 2, 3, 5	
A	Clinical Exome (Agilent All Exon V5)	DN311 - 1, 3, 5	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd) Human DNA obtained from: A. blood, saliva, tissue, paraffin embedded tissue B. amniotic fluid, chorionic villus sampling (CVS)	<u>Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal) (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	A or A & B or A, B & C (see techniques 1-7 above)
A, B	Cystic Fibrosis	DN006 – 1, 3, 4, 6	
A	Deafness, Autosomal Recessive 1	DN005 – 1, 3, 4	
A, B	DNA Profiling	DN009 – 4	
A	Dystonia 1, Torsion, Autosomal Dominant	DN034 – 4	
A, B	Huntington disease	DN021 – 4	
A, B	Li-Fraumeni syndrome	DN039 - 1, 2, 3, 5	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal) (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	A or A & B (see techniques 1-7 above)
A	Selected Gene Panel (Agilent Custom Design) including: Aicardi-Goutieres syndrome Cerebral malformation panel Central Core Disease Familial Exudative Vitreoretinopathy Hypertrophic Cardiomyopathy Loeys-Dietz syndrome Malignant Hyperthermia Marfan syndrome Meckel-Gruber syndrome Optic Atrophy 1 Primary Ciliary Dyskinesia Primary Hypertrophic Osteoarthropathy	DN258, DN275 - DN001 - 1, 2, 3, 5 DN263 - 1, 2, 3, 5 DN022 - 1, 3, 5 DN215 - 1, 3, 5 DN215 - 1, 3, 5 DN326 - 1, 3, 5 DN022 - 1, 3, 5 DN022 - 1, 3, 5 DN229 - 1, 3, 6 DN102 - 1, 3, 5 DN235 - 1, 3, 5 DN326 - 1, 3, 5	
A, B	Variant Confirmation	DN295 - 1, 2, 3, 4	
A (Blood only)	Y Chromosome Microdeletions	DN038 – 4, 7	
Tumour material	Mutation detection in non-small cell lung cancer, colorectal cancer, melanoma – mutations in EGFR, KRAS, NRAS and BRAF genes and detection of mutations in IDH1, IDH2, BRAF & TERT, H3F3A and HIST1H3B genes in brain tumours	Next Generation Sequencing involving DNA extraction followed by molecular analysis of mutations in non-small cell lung cancer (CYMCM068), and colorectal cancer (CYMCM071), gliomas (CYMCM070) and melanoma (CYMCM082) using Illumina MiSeq & FLUOstargalaxy., LGONM004, CYMCM072, CYMCM063, CYMCM069	A & C
Blood (EDTA anticoagulant), amniotic fluid, chorionic villus or solid tissue	Detection of aneupoidy of chromosomes 13, 18, 21 or sex chromosomes	QF-PCR analysis involving DNA extraction followed by molecular analysis of DNA dosage for rapid aneuploidy using ABI 3130 gene scanner CYMCM016, CYMCM018, CYMCM017	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal) (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	A
Blood (EDTA anticoagulant)	Assessment of DNA dosage for confirmation of abnormalities detected by array CGH & NGS dosage that cannot be confirmed using FISH	Q-PCR test involving DNA extraction followed by molecular analysis of DNA dosage changes using real time PCR for array CGH follow up using Qiagen rotor gene CYMCM052, CYMCM054, CYMCM051, CYMCM053	A
FFPE Tumour	Detection of BRAF gene fusions in pilocytic astrocytomas	RT-PCR and detection of fluorescence if BRAF gene fusion present using Rotorgene, Nanodrop, EZ1 extractor. CYMCM074, CYMCM075	A & C
Blood, paraffin embedded tumour material	Human identity testing for detection of specimen mix up	Microsatellite PCR test to identify DNA variation at multiple genomic loci known to be unique to individuals using Thermal cycler, ABI 3130 genetic analyser, Nanodrop CYMCM079, CYMCM080	
Gastro intestinal stromal tumours (GIST's) & melanomas	Detection of KIT and PDGFRA mutations in GISTs and KIT mutations in melanomas (by DNA sequencing test)	Sanger sequencing involving manual DNA extraction [CYMCM069] followed by molecular analysis of KIT and PDGFRA mutations in GISTs using ABI 3130, and Nanodrop LGGLM003, DN249, DN341	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal) (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	A
Brain tumours	Detection of methylation of the MGMT gene (by DNA sequencing test)	Pyrosequencing involving DNA extraction followed by MGMT methylation in gliomas using Pyromark Q48 or ID equipment CYMCM060, LGONM008, LGGLM003	
Blood plasma	Mutation testing of circulating tumour DNA - targeted mutation testing of the EGFR gene	Separation of blood plasma from whole blood, DNA extraction from blood plasma, and targeted EGFR mutation detection by real-time PCR using the Qiagen Rotagene Q and Therascreen Plasma RGQ PCR kit (LGONM002)	
Bone marrow, Blood	DNA extraction for the purposes of external Whole Genome Sequencing	Automated Chemagic and Chemagic 360i: (DN312)	C

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS/TISSUE	Cytogenetics examination activities for the purpose of clinical diagnosis	In house documented methods incorporating manufacturers' instructions where relevant	A
Amniotic fluid, chorionic villus, solid tissue, blood (lithium heparin), bone marrow	Karyotype	Culture and karyotype analysis using G-banding CYLGM016 and light microscope using SOPs: CYPNM013, CYLGM025, CYPNM017 (amniotic fluid) CYPNM011, CYLGM025, CYPNM017 (chorionic villus) Culture and karyotype analysis using G-banding CYLGM016 and image analysis via automatic slide scanner /Cytovision using SOPs: CYPNM012, CYLGM015, CYLGM035, CYPNM017 (solid tissue) CYBLM009, CYBLM014, CYLGM015, CYLGM035, CYBLM002 (blood) CYHMM007, CYLGM015, CYLGM035, CYHMM002 (bone marrow)	
Blood (lithium heparin anticoagulant)	Karyotype	Culture and karyotype analysis using G-banding and image analysis via automatic slide scanner /Cytovision CYBLM009, CYLGM016, CYBLM014, CYLGM015, CYLGM035, CYBLM002	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS/TISSUE (cont'd)	Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	A
Bone marrow	Karyotype	Culture and karyotype analysis using G-banding and image analysis via automatic slide scanner /Cytovision CYHMM007, CYLGM016, CYLGM015, CYLGM035, CYHMM002	
Blood (EDTA anticoagulant), saliva and solid tissue	Genome wide screen for copy number gain or loss of DNA at a resolution of 60kb	CNV sequencing involving molecular analysis of DNA dosage changes by next generation sequencing using Illumina HiSeq, Qubit and Covaris CYMCM059, CYMCM058, CYMCM044, CYMCM088	A, B & C
Illumina Bead Array GTC Files received from ISO 15189 accredited laboratory 9028	Interpretation of data to detect microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number in: Postnatal disorders, prenatal diagnosis, neoplastic genetics	SNP array analysis using Illumina BlueFuse Multi software and SOP LGPPM001	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Fixed cells/Formalin Fixed Paraffin Embedded tissue (FFPE) from: Peripheral Blood Bone Marrow Amniotic fluid CVS- Chronic villus samples Solid tissues Solid tumours Buccal smears	Detection of chromosomal aberrations loci changes including confirmation of array CGH findings and rearrangements in the diagnosis of haematological malignancy, bone marrow failure syndromes, constitutional disorders, solid tumours	Pre analytical preparation of tissues for Fluorescent in situ hybridisation procedures (FISH) using Hybrite, Water bath, hot-plate and SOPs: CYMCM 006 (FFPE slides) CYMCM 007 (fixed suspension samples) followed by:	C
	Break-apart probes Fusion product probes Single copy probes to detect gain or loss of a specific locus	Fluorescent in situ hybridization (FISH) analysis of metaphase and interphase cells using commercial (and including probe validation/verification) using Cyto-vision analysis system and Fluorescent microscopy as defined in SOP CYMCM004 v1.16 in conjunction with SOPs CYMCM009, CYMCM007, CYMCM022, CYMCM006, CYMCM026, CYMCM013	C

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