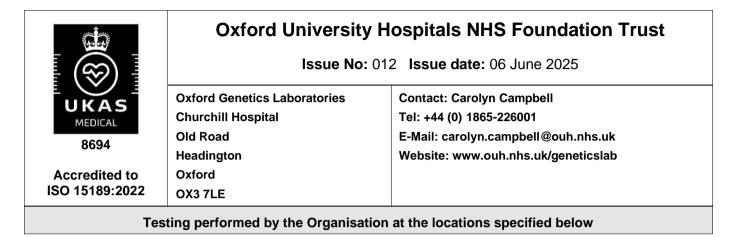
Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | | Activity | Location code |
|--|--|------------------------------------|---------------|
| Oxford Regional Genetics Laboratories Churchill Hospital Old Road Headington Oxford OX3 7LE | Carolyn Campbell (contact details above) | Molecular Genetics CytoGenetics | СН |
| Level 4 John Radcliffe University Hospital Headley Way Headington Oxford OX3 9DU | Carolyn Campbell (contact details above) | Molecular Haematology | JRH |

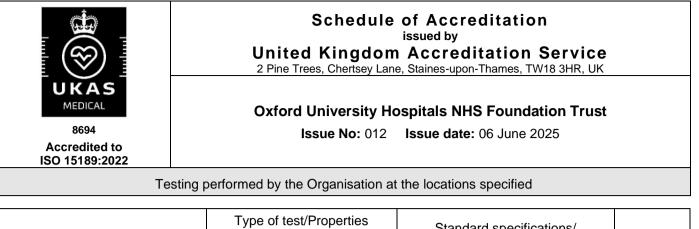
| | Schedule of Accreditation issued by United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK |
|---------------------------------|--|
| UKAS MEDICAL 8694 | Oxford University Hospitals NHS Foundation Trust Issue No: 012 Issue date: 06 June 2025 |
| Accredited to ISO 15189:2022 | |
| Testi | ng performed by the Organisation at the locations specified |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location |
|---|---|---|----------|
| HUMAN TISSUES AND BODY FLUIDS | Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer | Documented in house procedures incorporating manufacturer's instructions (where relevant) | СН |
| | DNA extraction, quantification and quality check for subsequent in- house analysis (see below), referral to specialist centres and long term storage | Manual and automated DNA extraction and quantification using: | |
| | and long term storage | Automated or semi automated extraction: | СН |
| Blood | | Tecan Evo-HSM Robot with ReliaPrep™ Large Volume HT gDNA Isolation kit | |
| | | DNA SOP 2011 62, 440, 2005- 0159 | |
| Blood Bone Marrow | | Promega Maxwell RSC platfrom with Maxwell RSC Blood DNA Kit | |
| Fresh Tissue Cultured Cells Saliva/Buccal (Oragene collections) Urine | | DNA SOP 2011 62, 2005-0159, 607 | |
| FFPE fixed tissue Blood Spots | | Promega Maxwell RSC platfrom with Maxwell RSC FFPE DNA Kit | |
| | | DNA SOP 2005-0159, DNA SOP 2019 609, DNA SOP 2019 608 | |
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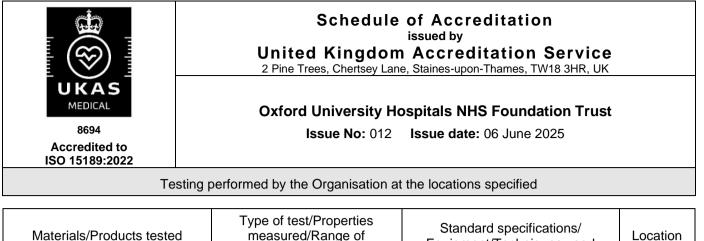
DETAIL OF ACCREDITATION

| | United Kingdom | of Accreditation issued by Accreditation Service e, Staines-upon-Thames, TW18 3HR, UK | |
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| NEDICAL 8694 Accredited to ISO 15189:2022 | • | ospitals NHS Foundation Trust Issue date: 06 June 2025 | : |
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| | Type of test/Properties | Standard specifications/ | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location |
|---|---|---|----------|
| HUMAN TISSUES AND BODY FLUIDS | Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer | Documented in house procedures incorporating manufacturer's instructions (where relevant) | СН |
| Bloods Pleural Effusions Urine | | Manual DNA extraction InstaGENE Matrix CYTO SOP 376, DNA SOP 2011 | |
| Genomic DNA extracted in- house from the sample types | | 62, 2005-0159 DNA Quantification for QC purposes: | СН |
| listed above or received as primary sample type from an external source | | Qubit fluorometer, Nanodrop (ND- 2000) and Glomax | |
| | | SOPs: CYTO SOP 456, DNA SOP 038, 040, 083. | |
| Genomic DNA extracted in- house from the sample types listed above or received as | Detection of specific SNVs and indels (including confirmatory testing) | Fragment Analysis Non-fluorescent PCR amplification followed by restriction enzyme digest using: | |
| primary sample type from an external source | [Definitive list as per GEN DOC 926] | Thermal cycler and gel electrophoresis equipment | |
| | | SOPs | |
| | | DNA SOP 002, 049 090, 107 | |
| Genomic DNA extracted in- house from the sample types listed above or received as | Presence/absence of DNA regions (including confirmatory testing) | Non-fluorescent PCR amplification followed by agarose gel electrophoresis using: | |
| primary sample type from an external source | [Definitive list: GEN DOC 926] | Thermal cyclers and gel electrophoresis equipment | |
| | | SOPs | |
| | | DNA SOP 002. 049, 062, 090, 184 | |
| | | | |
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| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location |
|---|--|--|----------|
| HUMAN TISSUES AND BODY FLUIDS | Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer | Documented in house procedures incorporating manufacturer's instructions (where relevant) | |
| Genomic DNA extracted in- house from the sample types listed above | Detection of specific SNVs and smallindels (including confirmatory testing) | Fluorescent PCR amplification followed by Restriction enzyme digest using fluorescently tagged primers | СН |
| or received as primary sample type from external source | [Definitive list as per GEN DOC 926] | using: | |
| nom external source | | thermal cyclers ABI 3730 Analysis using Gene Mapper software | |
| | | SOPs | |
| | | DNA SOP 002, 049 | |
| Genomic DNA extracted in- house from the sample types listed above or received as primary sample type from an external source | Detection of expansions including triplet repeats, microsatellite marker analysis, detection of specific SNVs and indels | Fluorescent PCR amplification (including repeat primed PCR and, Devyser) and fragment analysis using commercially available kits or in-house designed assays | |
| | [Definitive list :GEN DOC 926] | using: | |
| | 520] | thermal cyclers ABI 3730 | |
| | | Analysis using Gene Mapper software | |
| | | SOPs | |
| | | CYTO SOP 376, DNA SOP 079, 081, 090, 126, 184, 2006-0014, 2010 34, 049, 225 | |
| | | | |
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| | measurement | Equipment/Techniques used | Location |
|--|---|---|----------|
| HUMAN TISSUES AND BODY FLUIDS | Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer | Documented in house procedures incorporating manufacturer's instructions (where relevant) | СН |
| Genomic DNA extracted in- house from the sample types listed above or received as primary sample type from external source | Quantification of mtDNA copy number [Definitive list as per GEN DOC 926] | Real-time PCR using commercially available kits or in- house designed assays Using: ABI 7500 Analysis using 7500 software | СН |
| | | | |
| | | SOPs | |
| | | DNA SOP 052, 013, 002, GEN SOP 014, 2008 4 | |
| Genomic DNA extracted in- house from the sample types | Detection and quantification of specific SNVs and indels [Definitive list: GEN DOC 926] | Pyrosequencing | |
| listed above or received as | | using: | |
| primary sample type from external source | | Standard primer design methodology SOP: DNA SOP 731 | |
| | | in-house methods and Qiagen PyroMark ID System | |
| | | SOPs DNA SOP 002, 026, 101, 2010 34 | |
| Genomic DNA extracted in- house from the sample types listed above or received as primary sample type from external source | Targeted detection and quantification of known germline and somatic variants; SNVs, CNVs [Definitive list: DOC 926] | Digital Droplet PCR Reaction setup using in-house or commercial primer/probe mixes using: Techne PCR Machines, Biorad AutoDG for droplet generation and Biorad QX200 Droplet Reader. Analysis using QX Manager Software. | СН |
| | | SOP 665, 666, 667, 941, 944 | |

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| HUMAN TISSUES AND BOD FLUIDS | OY Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer | Documented in house procedures incorporating manufacturer's instructions (where relevant) | СН |
| Genomic DNA extracted in- house from the sample types listed above or received as primary sample type from | and small indels | Sanger sequencing using: | |
| external source | [Definitive list:GEN DOC 926] | Standard Primer Design methodology: | |

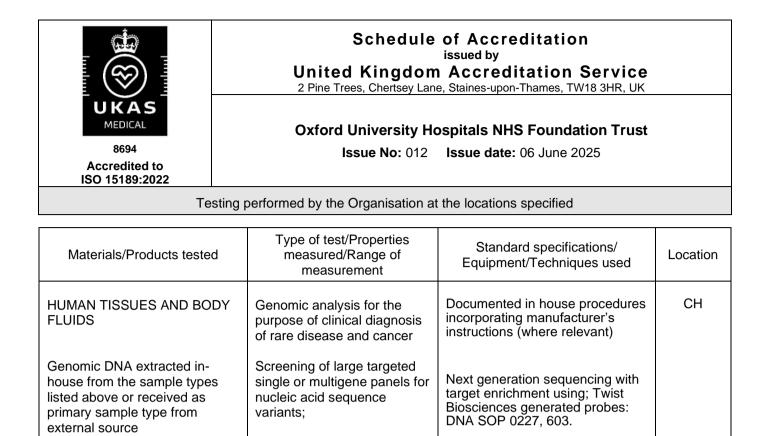
Robot: Biomek NX-MC(96)

with analysis using Mutation surveyor software and Alamut

DNA SOP 023, 049, 140, 731, GEN SOP 156

ABI 3730

SOPs



SNVs. indels

926]

[Definitive list: GEN DOC

SNVs, indels and CNVs

[Definitive list:GEN DOC 926]

Genomic DNA extracted in-

primary sample type from

external source

house from the sample types listed above or received as

validated bioinformatics pipeline

DNA SOP 0227, 421, 2015 327, 2019 592 and 2019 593.

Using: Veriti PCR Machines,

MiSeq.

GloMax®-Multi+' Fluorometer, Agilent 2200 Tape Station,

Illumina NovoSeq (located within the West Midlands Regional Genetics Laboratory) or Illumina

Analysis of DNA sequence data generated internally or externally using an in-house validated bioinformatics pipeline. Variant interpretation using Alamut

SOPs: DNA SOP 2019 602, 2019 606, 2020 621, 2020 622,

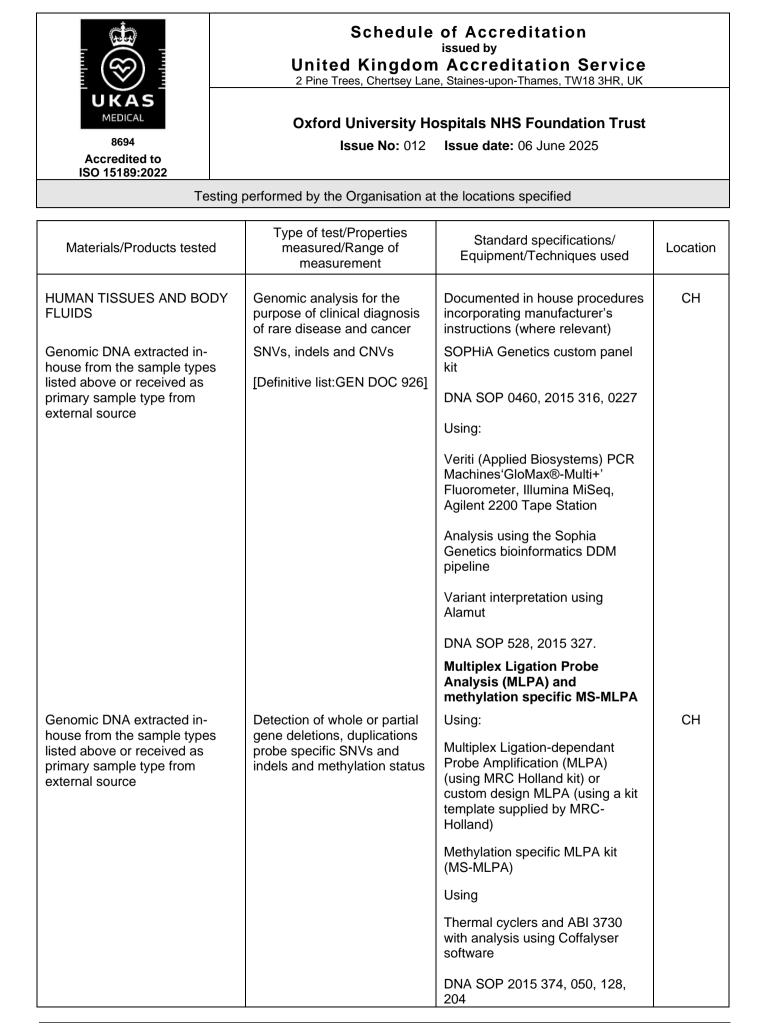
Dyad PCR Machines Glomax Multi+ Fluorometer, Illumina MiSeq, Agilent 2200 Tape Station

Analysis of DNA sequence data generated either internally or externally using an in-house

2020 628, 712

Using:

Illumina NexteraXT



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| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location |
|--|---|---|----------|
| HUMAN TISSUES AND BODY FLUIDS | Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer | Documented in house procedures incorporating manufacturer's instructions (where relevant) | |
| Products of conception Biopsies (includes skin) Tissues CSF Pleural Fluid, Ascites Whole Blood Bone Marrow | G-Banding/Karyotyping Detection of chromosomal rearrangements or aberrations arising from: <i>(e.g)</i> Developmental disorders Reproductive medicine disorders Haematological/Oncology disorders (Preparative Pre- examination steps listed first) | <u>G-Banding/Karyotyping</u> Manual culturing using commercial media, processing (cell harvesting and slide preparation and banding) of human tissue to provide metaphase cells Using: Safety cabinets, incubators, centrifuges, hotplate, SOPs: CYTO SOP 67, 111, 185, 271, 414 Analysis: Karyotype analysis of metaphase chromosomes light microscopy using: | СН |
| Products of conception Biopsies (includes skin) Tissues CSF Pleural Fluid, Ascites Whole Blood Bone Marrow Urine Buccal swabs | (Preparative Pre-examination steps for FISH) | Microscopes, Cytovision Image Capture System Direct preparation (without culture) to provide fixed interphase cells and Processing of FFPE sections for material suitable for FISH Using: Hotplate, fume hood, water bath, and Hybrite/Thermobrite SOPs 67, 132, 271, 340, 352 | |



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| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location |
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| HUMAN TISSUES AND BODY FLUIDS | Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer | Documented in house procedures incorporating manufacturer's instructions (where relevant) | СН |
| Fixed cultured cells as prepared as detailed in G- banding/Karyotyping section Fixed uncultured cells FFPE sections | Targeted analysis of the genome for copy number alterations, balanced chromosome rearrangements, mosaicism and formation of gene fusions. Using locus specific probes for: Translocations and/or inversion Deletions Fusions Copy Number [Definitive list:GEN DOC 926] | Fluorescence in situ hybridisation (FISH) using: Hybrite/Thermobrite, UV light box, microfuge fume hood and waterbath. FISH analysis by use of fluorescently tagged probes and fluorescence microscopy to detect copy number and spatial location of specific regions of the genome using: SOPs CYTO SOP 67, 132, 271, 340, 352, 364, 412, 414 FISH analysis by use of fluorescently tagged probes and fluorescence microscopy to detect copy number and spatial location of specific regions of the genome using: Cytovision Image Capture System | |

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| HUMAN TISSUES AND FLUIDS | Molecular genetic analysis for genetic mutations and variants | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | JRH |
| Blood Bone Marrow CVS Amniotic Fluid FFPE tissue | | Automated DNA extraction and quantification using the QIAGEN Symphony and in-house procedures: Haem SOP 940 HC 2531 HC 2271 HC 2315 | JRH |
| Blood Bone Marrow | | Semi-automated RNA extraction and cDNA preparation using the QIAGEN Qiacube and in house procedures HC 2302 | |
| Blood Bone Marrow FFPE | | Automated Paramegnetic particle nucleic acid extraction and purification using the Promega Maxwell system; Haem SOP 2599: DNA using AS1321 kit Haem SOP 2608: RNA using AS410 kit Haem SOP 2611: FFPE using RSC FFPE DNA plus kit | |



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| HUMAN TISSUES AND FLUIDS (cont'd) | Molecular genetic analysis for genetic mutations and variants (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | JRH |
| Blood DNA | Somatic myeloid disorder diagnostic gene panel. Mutations in: | NextSeq 550 Next Generation Sequencing and custom designed commercial panel (SeqCap EZ HyperCap (Roche) | |
| | ASXL1 (NM_015338.5), ATRX (NM_000489.3), CBL (NM_005188), CBLB (NM_170662.3), CBLC (NM_012116.3), CSF3R (NM_156039.3), DNMT3A (NM_022552), ETV6 (NM_001987.4), EZH2 (NM_004456.4), HRAS (NM_005343.2), IDH1 (NM_005896.2), IDH2 (NM_002168.2), FLT3 (NM_004119), JAK2 (NM_004972.3), KIT (NM_004972.3), KIT (NM_000222.2), KRAS (NM_033360.2), MPL (NM_005373), NPM1 (NM_002520.6), NRAS (NM_002524.4), PDGFRA (NM_006206.4), PHF6 (NM_032458.2), PTEN (NM_000314), RUNX1 (NM_001754.4), SETBP1 (NM_015338.5), SF3B1 (NM_012433.2), SRSF2 (NM_001195427.1), TET2 (NM_001127208.2), TP53 (NM_000546.5), U2AF1 (NM_005089.3) | Haem SOP 2623 Haem SOP 2618 Haem SOP 2619 | JRH |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Molecular genetic analysis for genetic mutations and variants (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | JRH |
| Next Generation Sequencing Data in the form of BAM files, variant lists, and gene- level coverage data received from Oxford Regional Genetics (UKAS 8694) | Rare anaemia diagnostic gene panel. Mutations in: ABCB7 (NM_004299.3), ALAS2 (NM_000032.4), ALDOA (NM_000034.3), ANK1 (NM_000037.3), C15orf41 (NM_001130010.1), CDAN1 (NM_138477.2), ENO1 (NM_001428.3), EPB41 (NM_004437.3), EPB42 (NM_00119.2), G6PD (NM_001042351.2), GATA1 (NM_002049.3), GATA2 (NM_032638.4), GCLC (NM_00175.3), GPX1 (NM_000581.2), GSR (NM_000175.3), GPX1 (NM_000581.2), GSS (NM_000178.2), HK1 (NM_000637.3), GSS (NM_00178.2), HK1 (NM_000178.2), HK1 (NM_000178.2), KIF23 (NM_138555.2), KLF1 (NM_006563.3), LPIN2 (NM_014646.2), NT5C3A (NM_016489.12), PFKM (NM_000289.5), PGK1 (NM_001142864.2), PKLR (NM_000281.3), PIEZO1 (NM_001142864.2), PKLR (NM_000987), RPL26 (NM_000987), RPL26 (NM_000987.3), RPL26 (NM_000987.3), RPL26 (NM_000987.3), RPL27 (NM_000987.3), RPL26 (NM_000987.3), RPL27 (NM_000987.3), RPL35A (NM_0000987.3), RPL35A (NM_000987.3), RPL35A (NM_000987.3), RPL35A (NM_000987.3), RPL35A (NM_000987.3), RPL35A (NM_000987.3), RPL35A (NM_0000987.3), RPL35A (NM_0000987.3), RPL35A (NM_0000987.3), RPL35A (NM_0000987.3), RPL35A (NM_0000987.3), RPL35A (NM_0000987.3), RPL35A (NM_0000987.3), RPL35A (NM_000987.3), RPL35A (NM_00 | Analysis and reporting of data only using Alamut Visual and IGV software HC 2154 HC 2152 Haem SOP 2457 | JRH |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Molecular genetic analysis for genetic mutations and variants (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | JRH |
| Next Generation Sequencing Data in the form of BAM files, variant lists, and gene- level coverage data received from | Rare anaemia diagnostic gene panel (cont). Mutations in: | Analysis and reporting of data only using Alamut Visual and IGV software | JRH |
| Oxford Regional Genetics (UKAS 8694) | RPS19 (NM_001022.3), RPS24 (NM_033022.3), RPS26 (NM_001029.3), RPS27 (NM_001030.4), RPS29 (NM_001032.4), RPS7 (NM_001011.3), SBDS (NM_016038.2), SEC23B (NM_006363.4), SLC11A2 (NM_000617.2), SLC25A38 (NM_017875.2), SLC2A1(NM_006516.2), SLC4A1 (NM_000342.3), SPTA1 (NM_000342.3), SPTA1 (NM_000347.5), TMPRSS6(NM_153609.2), TPI1(NM_000365.5). | HC 2154 HC 2152 Haem SOP 2457 | |
| Blood Bone Marrow | BCR-ABL analysis (ALL, CML) Diagnosis and monitoring of MRD (p210, p190 only) | Published Multiplex RT-PCR method using Qiagen, Rotorgene, Commercial QPCR (Qiagen) kit for MRD, Pyrosequencing using QIAGEN Pyromark Q24 HC 2301 HC 2302 HC 2303 HC 2304 HC 2306 | JRH |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Molecular genetic analysis for genetic mutations and variants (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods: | |
| | Acute Leukaemia Diagnosis: | RE-PCR using Biometra Thermocycler | |
| Blood | FLT-3 D835 | HC 2118 | JRH |
| Bone Marrow | NPM1 | In house fragment analysis method using ABI instrumentation HC 2119 | |
| Blood Bone Marrow | Acute Leukaemia MRD monitoring (PML-RARA, Inv16, AML-ETO) | Commercial QPCR (Qiagen) kit for MRD using QIAGEN Rotorgene, HC 2304 | |
| Blood Bone Marrow Tissue | Lymphoma B Clonality (IgH rearrangements) | Commercial (Invivoscribe) fragment analysis using ABI instrumentation Haem SOP 1163 | |
| | Lymphoma T Clonality (TCR re-arrangements) | HC 2268 HC 2267 Haem SOP 1163 | |
| Blood Bone Marrow | Jak-2 mutation screen (V617F) | In house ARMS-PCR using Biometra thermocycler, Pyrosequencing using the QIAGEN Rotorgene HC 2261 | JRH |
| Blood Bone Marrow | Chimerism STR pattern analysis (Chimerism) to detect mxed samples (e.g. Maternal contamination / Chimerism | Promega Powerplex Fusion commercial kit, and fragment analysis using ABI instrumentation HC 2381 HC 2141 | |
| Blood Bone Marrow FFPE | Detecting L265P point mutation of the MYD88 gene | Allelic specific real-time PCR assay using hydrolysis probes ABI Real Time 7500 Haem SOP 2468. | |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Molecular genetic analysis for genetic mutations and variants (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following: | |
| FFPE DNA | EGFR common mutation screen | COBAS 4800 system, RT-PCR and commercial (COBAS) kits Haem SOP 578 | JRH |
| FFPE DNA | BRAF mutation screen (V600E) | COBAS 4800 system, RT-PCR and commercial (COBAS) kits Haem SOP 579 | |
| FFPE DNA | Somatic Cancer 50 gene diagnostic panel. Mutations in: TP53 NM_000546.5, PTEN NM_000314.4, PIK3CA NM_006218.2, PDGFRA NM_006206.4, KRAS NM_006206.4, KRAS NM_002524.4, KIT NM_000222.2, EGFR NM_002528.3, BRAF NM_004333.4. ERBB4, FGFR1, ERBB2, MET, FLT3, FGFR3, GNAS, SMARCB1, CTNNB1, CDKN2A, ABL1, NOTCH1, ATM, PTPN11, SMO, SMAD4, VHL, NPM1, MPL, CSF1R, HRAS, JAK3, AKT1, IDH1, CDH1, FGFR2, SRC, KDR, ALK, JAK2, RB1, MLH1, HNF1A, APC, RET, STK11, FBXW7, EZH2, GNA11, GNAQ and IDH2 Acquired NGS panel using custom AmpliSeq primer pools and S5 Ion Torrent Sequencing DNA -AmpliSeq panel on S5 Ion Torrent | Thermofisher Ampliqseq Next Generation Sequencing commercial panel and Ion Torrent next generation sequencing. Haem SOP 624 Haem SOP 625 HC 2411 HC 2408 | JRH |
| | END | 1 | 1 |