Schedule of Accreditation

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8031 **Accredited to ISO 15189:2022**	**Nottingham University Hospitals NHS Trust** **Issue No:** 006 **Issue date:** 22 July 2025
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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 FLUIDS/TISSUE	<u>Cytogenetics examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant
Blood Amniotic Fluid Chorionic Villus Bone marrow Solid tissues Effusion/ascitic fluid /CSF	Chromosome analysis for disorders listed below	<u>Preparation of material for chromosome analysis:</u> Cell culture by in-house procedures using commercial media and equipment: • Biological safety cabinets; Class 1 and 2 • Centrifuges • Incubators • Optichrome controlled environment stations. • Inverted microscope • Dissection microscope • Light microscopes Prenatal culture and harvest SOPs CYG SOP PND1 CYG SOP PND6 Postnatal culture and harvest SOPs CYG SOP CONST1 CYG SOP CONST2 CYG SOP CONST7 CYG SOP CONST8 Haematology/solid tumour culture and harvest CYG SOP MAL1 CYG SOP MAL3

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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
See page 1	Chromosome analysis for disorders listed below	Solid Tissue – Fibroblast - culture CYG SOP PND1 CYG SOP CONST10 Slide Making CYG SOP GEN32 CYG SOP GEN20 (optichrome)
Blood Amniotic Fluid Chorionic Villus Solid tissues Effusion/ascitic fluid /CSF	Developmental Disorder and reproductive medicine disorders Prenatal Diagnosis Reproductive medicine disorders Developmental disorders	Chromosome analysis: Microscopic examination, detection, analysis and reporting of G band karyotypes using either direct microscope analysis using brightfield microscopes or analysis of microscopic images using the Metasystem image analysis system. CYG SOP PND5 CYG SOP GEN33 CYG SOP GEN22 Reporting CYG SOP GEN42
Bone marrow / blood	Haematological/Oncological disorders	Chromosome analysis: Microscopic examination, detection, analysis and reporting of G band karyotypes using either direct microscope analysis using brightfield microscopes or analysis of microscopic images using the Metasystem image analysis system. CYG SOP MAL2 CYG SOP GEN22 Reporting CYG SOP GEN42

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd) Buccal smear FFPE preparations – various tissue types Cytogenetic preparations from Blood Amniotic Fluid Chorionic Villus Bone marrow Solid tissues Effusion/ascitic fluid /CSF	<u>Cytogenetics examination activities for the purpose of clinical diagnosis</u> (cont'd) Microscopic detection and analysis of genetic rearrangements and/or genomic imbalance. Detecting aneuploidies, deletion/duplications associated with clinical syndromes, confirmation of rearrangements, detection of recurrent rearrangements resulting in the juxtaposition of specific genes or parts of genes.	In house documented methods incorporating manufacturers' instructions where relevant <u>Fluorescence in situ hybridisation (FISH):</u> In-house procedures and commercial kits (including probe kits supplied by Abbott Vysis; Kreatech; Cytocell; Zytovision; DAKO; Metasystem whole chromosome paints; Empire Genomics) using Thermobrite hybridisation stations. CYG SOP FISH1 CYG SOP FISH5 CYG SOP FISH6 CYG SOP FISH7 CYG SOP FISH8 CYG SOP FISH9 CYG SOP ARRAY3 CYG SOP CONST11 CYG SOP CONST14 CYG SOP PND7 FISH Administration CYG SOP FISH3 CYG SOP FISH4

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Cytogenetics examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Blood, Amniotic Fluid, Chorionic Villus, Bone marrow, Solid tumour, Lymph Node, Solid tissues, Effusion/ascitic fluid /CSF, Culture Cells, Fixed Cell Preparations	DNA extraction, quantification and quality check for subsequent in-house analysis and long term storage	<u>DNA extraction:</u> Semi –automated/automated extraction using Maxwell RSC CYG SOP CONST13 CYG SOP ARRAY10 CYG SOP PND3
DNA (Received in lab as DNA, extracted from various human tissues as per this schedule)	Analysis for clinically significant genomic imbalance (and Loss of heterozygosity) for the purpose of clinical diagnosis.	Microarray process using Affymetrix Cytoscan 750k and HD arrays and GeneChip System 3000 platform including DNA cleaning, labelling, hybridisation to microarray chip and scanning Equipment: • GeneChip 3000 Scanner • Spectrophotometer (Nanodrop) • Thermal Cycler • Fluidics stations CYG SOP ARRAY1 CYG SOP ARRAY2 CYG SOP ARRAY5 CYG SOP CONST13 CYG SOP PND3 CYG SOP PND6 CYG SOP PND8 Analysis and Reporting CYG SOP ARRAY6 CYG SOP ARRAY7 CYG SOP ARRAY8 CYG SOP ARRAY9 CYG SOP ARRAY11 CYG SOP MAL8

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS	Molecular Diagnostic examinations for the purpose of haematological malignancy diagnosis	In house documented methods incorporating manufacturers' instructions where relevant:
Human blood, bone marrow films, fluid aspirates, tissue samples, FFPE sections		Automated extraction of DNA and RNA using Promega Maxwell System RSC 16 and 48 systems– CYG SOP MD37 CYG SOP MD25 CYG SOP MD7
DNA extracted in-house from sample types above	CALR exon 9 indels Chimerism FLT3 (TKD & ITD) NPM1	Fluorescent PCR, Fragment analysis using endpoint on the ABI3500XL X2 CYG SOP MD36 NUH Cancer Genomics CALR Assay CYG SOP MD30 NUH Cancer Genomics Use of Microsatellite Analysis to Assess Chimerism CYG SOP MD35 NUH Cancer Genomics NPM1 Assay CYG SOP MD43 FLT-3 ITD AND D835 TKD ASSAY CYG SOP MD33 NUH Cancer Genomics Fragment Analysis on the 3500
DNA extracted in-house from sample types above	JAK2	Allele Specific PCR and electrophoresis using Thermal Cyclers CYG SOP MD32 CYG SOP MD27
RNA extracted in-house from sample types above	Reverse transcription of RNA to cDNA	Reverse transcriptase for the preparation of cDNA using CYG SOP MD26

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Molecular Diagnostic examinations for the purpose of haematological malignancy diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant:
cDNA prepared in-house from sample types above	Quantification of SNVs, fusions and translocations BCR-ABL1 p210 major (e13a2 and e14a2) and p190 minor (e1a2) transcripts BCR::ABL1 p210 major (e13a2 and e14a2) and p190 minor (e1a2) transcripts	Semi-quantitative /Quantitative reverse transcription PCR using Applied Biosystems 7500 Fast Real-Time qPCR system reporting BCRQ results according to the International Standard CYG SOP MD42 CYG SOP MD41
	Detection of BCR::ABL1 p210 major (e13a2 and e14a2) transcripts for monitoring	
	Detection of PML:: RARA t(15;17) fusion	Qualitative reverse transcription qPCR using Applied Biosystems 7500 Fast Real-Time PCR system CYG SOP MD42
FFPE tissue sections	Detection of biomarkers in solid tumours: BRAF	Idylla Integrated genetic testing platform incorporating sample preparation, PCR amplification and fluorescence detection CYG SOP MD45
FFPE tissue, DNA and RNA extracted in house from FFPE tissue	SNV's and fusion detection: Oncomine Precision Panel for Colorectal, Lung cancer, Melanoma, GI stromal tumour, Thyroid cancers, Cholangiocarcinoma	Next Generation Sequencing Panel using the Genexus sequencer on Genexus Oncomine CYG SOP MD55, CYG SOP MD56

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HUMAN TISSUE AND FLUIDS	Molecular Genetics examinations for the purpose of clinical diagnosis	Documented in-house methods incorporating manufacturers' instructions where relevant:
Whole Blood, Amniocytes Chorionic villi Buccal/saliva samples Cultured cells Urine Formalin fixed paraffin embedded tumour sections] Soft Tissue	DNA extraction, quantification and quality check for subsequent in-house analysis (detailed on this schedule), referral to specialist centres and for long-term storage	Manual and automated DNA extraction and quantification Using:
Amniocytes Chorionic villi Cultured cells Soft Tissue		Phenol Chloroform GEN SOP-1 CVS extraction GEN SOP-2 Clotted Blood
Peripheral Blood Soft Tissue		BACC2/3 Nucleon Kit GEN SOP-14/29 (nucleon) GEN SOP-3 Soft tissue
FFPE		Cell lysis followed by Proteinase K digestion method GEN SOP 87 (paraffin –embedded tissue)
Saliva		Oragene GEN SOP-81 Saliva (Oragene)
Peripheral Blood		Perkin Elmer Chemagic 360-D automated DNA extractor GEN SOP-109-Chemagic DNA Extraction
Peripheral Blood		Promega Maxwell RSC DNA Extractor and Maxwell DNA whole blood kit and Maxwell DNA blood kit GEN SOP-120 GEN SOP-130
Uncultured amniocytes and chorionic villus samples		RSC Cell DNA Purification Kit and Promega Maxwell RSC DNA Extractor GEN SOP-121 Maxwell amnio CVS

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular Genetics examinations for the purpose of clinical diagnosis (cont'd)	Documented in-house methods incorporating manufacturers' instructions where relevant:
Uncultured amniocytes and chorionic villus samples (cont'd)	DNA extraction, quantification and quality check for subsequent in-house analysis (detailed on this schedule), referral to specialist centres and for long-term storage (cont'd)	Quantification for QC purposes using NanoDrop 1000 Spectrophotometer and Qubit 3.0 Fluorometer) GEN SOP-79
Genomic DNA extracted in house from sample types listed above and received as primary samples from external sources	Determination of copy number and methylation abnormalities	**Multiplex Ligation Probe Amplification (MLPA)** Using: MLPA and methylation-specific MLPA using MRC Holland Kits, thermal cyclers Capillary electrophoresis using Applied Biosystems 3500XL capillary sequencers X2 Analysis using Genemapper and custom designed Excel spreadsheets for dosage analysis SOPs: GEN SOP-101/106 (MLPA SOP), PWAS SOP-15 (PWS/AS MS-MLPA SOP), HNPCC SOP-10 (MLH1 MS-MLPA SOP), GEN SOP-128 ABI3500XL operation
Genomic DNA extracted in house from sample types listed above and received as primary samples from external sources	Detection of known sequence variants [definitive list to be held by this laboratory]	**Gel Electrophoresis** Using: Allele specific PCR SOPs: HAEM POL-1, HAEM SOP-1 (HFE ARMS PCR), BRCA SOP-13 (BRCA1 exon 13 duplication PCR, GEN SOP-12, GEN SOP-67 (agarose gel electrophoresis) PCR followed by restriction enzyme digestion SOPs: SMA POL-1, SMA SOP-1, HAEM POL-1, HAEM SOP-1 GEN SOP-67 (agarose gel electrophoresis) Using: DNA using thermal cyclers –using in house methods, agarose gel electrophoresis

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd) Genomic DNA extracted in house from sample types listed above and received as primary samples from external sources DNA from the above	<u>Molecular Genetics examinations for the purpose of clinical diagnosis</u> (cont'd) Detection of fragment length size, deletions, known mutations, repeat expansions and linkage markers (including microsatellite)	Documented in-house methods incorporating manufacturers' instructions where relevant: **Fragment Analysis** CF base kit for PCR amplification SOPs: CF POL-1, CF SOP-18 (CF KIT SOP), CF SOP-19 (CF Kit analysis SOP), GEN SOP-128 ABI3500xl operation Amplidex Asuragen FMR1 kit for PCR amplification FRAX SOP-18 In-house PCR using Capillary electrophoresis/fluorescent electrophoresis using thermal cyclers, Applied Biosystems ABI3500xl capillary sequencer x2 HD SOP-9, DM SOP-2, FRAX SOP-19, DMD SOP-26; SMA SOP-4; CF SOP-13; UPD7 SOP-7, UPD14 SOP-17, PWAS SOP-16, MAT CON SOP-1 Triplet repeat PCR using thermal cyclers Capillary electrophoresis/fluorescent electrophoresis using Applied Biosystems ABI3500xl capillary sequencerX2 HD POL-1, HD SOP-2, HD SOP-7, DM POL-1, DM SOP-3, DM SOP-10, FRAX SOP-20

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd) Genomic DNA extracted in house from sample types listed above and received as primary samples from external sources DNA from the above	Molecular Genetics examinations for the purpose of clinical diagnosis (cont'd) Chromosomal aneuploidy	Documented in-house methods incorporating manufacturers' instructions where relevant: **DNA dosage analysis** Using: Quantitative fluorescent PCR (QF-PCR) amplification and DNA using thermal cyclers –using In house methods Capillary electrophoresis using Applied Biosystems 3500xl capillary sequencers X2 SOPs: QF-PCR POL-1, QF-PCR SOP-3 (QF-PCR preparation and set-up), QF-PCR SOP-4 (QF-PCR Analysis), GEN SOP-128 ABI3500xl operation
END		