Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8031

Accredited to ISO 15189:2012

Nottingham University Hospitals NHS Trust

Issue No: 002 **Issue date:** 20 July 2020

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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	Cytogenetics examination activities for the purpose of clinical diagnosis	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	Chromosome analysis for disorders listed below	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 Preparation of material for chromosome analysis: Prenatal culture and harvest SOPs CYG SOP PND1 CYG SOP PND6 Postnatal culture and harvest SOPs CYG SOP CONST1 CYG SOP CONST2 CYG SOP CONST4 CYG SOP CONST7 CYG SOP CONST8 Haematology/solid tumour culture and harvest CYG SOP MAL1 CYG SOP MAL3 CYG SOP MAL5 CYG SOP MAL6

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 (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant
Continued from above	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) CYG SOP CONST5
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 Metatsystem image analysis system. CYG SOP PND5 CYG SOP GEN33 CYG SOP GEN22 Reporting CYG SOP W13
Bone marrow Solid tumour Lymph Node	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 Metatsystem image analysis system. CYG SOP MAL2 CYG SOP GEN22 Reporting CYG SOP W13

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
Blood	Chromosome Breakage (Fanconi Anaemia)	Microscope analysis of block stained chromosome preparations for detection of chromosome breakage – Fanconi Anaemia CYG SOP CONST6 CYG SOP GEN22 Reporting CYG SOP W13
Buccal smear FFPE preparations – various tissue types Cytogenetic preparations from the tissues listed above	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.	Fluorescence in situ hybridisation (FISH) using 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

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd) Malignancy samples DNA (Received in lab as DNA, extracted from various human tissues, or extracted as above)	<u>Cytogenetics examination activities for the purpose of clinical diagnosis</u> (cont'd) Analysis for clinically significant genomic imbalance (and Loss of heterozygosity) for the purpose of clinical diagnosis.	In house documented methods incorporating manufacturers' instructions where relevant DNA extraction using Maxwell RSC (Promega) 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: • Vortex • Microcentrifuges • Plate Centrifuges • GeneChip 3000 Scanner • Spectrophotometer (Nanodrop) • Thermal Cycler • Hybridisation oven • 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
END		