


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2022	University Hospitals of Leicester NHS Trust	
	Issue No: 012 Issue date: 21 May 2024	
	Cytogenetics Department Leicestershire Genetics Department Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW United Kingdom	Contact: Lara Cresswell Tel: +44 (0)1162585637 E-Mail: lara.cresswell@uhl-tr.nhs.uk Website: www.leicestershospitals.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address: Cytogenetics Department Leicestershire Genetics Department Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW Local contact: Lara Cresswell Tel: 44(0)1162585637	Cytogenetics	A
Address: University of Leicester Leicester Molecular Diagnostics Leicester Cancer Research Centre 3 rd Floor Lab 341 Robert Kilpatrick Clinical Sciences Building Leicester Royal Infirmary Leicester LE1 5WW Local contacts: Caroline Cowley	Molecular	B



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES	<u>Cytogenetics examination activities for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Blood	Chromosome analysis for:	Chromosome culture by in-house procedures using commercial medias	A
Amniotic Fluid	Prenatal Diagnosis	Preparation of material for chromosome analysis:	A
Chorionic Villus	Developmental disorders	Prenatal culture and harvest	
Bone marrow	Reproductive medicine disorders	SOPs NC-006/007/008/043/078	
DNA	Haematological/Oncology disorders	Postnatal culture and harvest	
Solid tissues		SOPs NC-001/010/170	
Other tissues		Haematology culture and harvest	
Formalin fixed paraffin embedded tissue (FFPE)		SOPs NC-004/171	
Other fluids		Plasma cell purification SOP NC177	
		Fluorescent in situ hybridisation (FISH) using in-house procedures and commercial kits (including Kreatech, Abbott-Vysis, Cytocell, Metasystems and Illumina) and Thermobrite hybridisation station or PCT-200 tower hybridisation station. SOPs NC-066/092	A
		Macroscopic and microscopic detection and analysis of genetic rearrangements and/or genomic imbalance	
		SOPs NC-037/067/070/071/143/150/173/212	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Blood Amniotic Fluid Chorionic Villus Bone marrow DNA Solid tissues Other tissues Formalin fixed paraffin embedded tissue (FFPE) Other fluids	Chromosome analysis for: Prenatal Diagnosis Developmental disorders Reproductive medicine disorders Haematological/Oncology disorders	G-banding SOP NC038 Macroscopic and microscopic examination, detection, analysis and reporting of G banding and karyotyping against considered normal G banding pattern. SOPs NC-009/040/041/042/083 Cytovision image analysis system SOPs NC-087/211	A
Blood Amniotic Fluid Chorionic villus Tissue samples		DNA extraction using Qiagen EZ1 Advanced XL SOP NC246	A
Post-natal and pre-natal DNA samples	Microarray profiling using Agilent technology for macroscopic detection, analysis and reporting of genomic imbalance against a reference	In house documented procedures and commercial kits for macroscopic detection, analysis and reporting of genomic imbalance against a reference NC188/190/191/194/209/221/225/226/ 229/232/233/234 Agilent microarray scanner NC222 Hybridisation oven NC192 DeNovix spectrophotometer NC236 Supported by: Extraction SOP NC221	A



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HUMAN BODY FLUIDS AND TISSUES	<u>Molecular Genetics examinations for the purpose of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Formalin Fixed Paraffin Embedded Tissue (FFPE)		Manual and automated DNA extraction and quantification using KingFisher Flex and MagMax purification kit, Qubit 4 Fluorometer SOP NC 313/315/316/317/318	B
DNA extracted as above	Mutation detection of the following – EGFR BRAF JAK 2 KRAS	Automated Realtime PCR using Qiagen Rotogene Q MDx platform and Qiagen Therascreen kit SOP NC 239/240/241/242/244/245/ 247/ 331	B
END			