Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8069

Accredited to ISO 15189

University Hospitals of Leicester NHS Trust

Issue No: 009 **Issue date:** 23 April 2021

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 3rd Floor Lab 341 Robert Kilpatrick Clinical Sciences Building Leicester Royal Infirmary Leciester LE1 5WW	**Local contacts:** Caroline Cowley	Molecular	B

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	Cytogenetics examination activities for the purpose of clinical diagnosis	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	Chromosome culture by in-house procedures using commercial medias	A
		Preparation of material for chromosome analysis: Prenatal culture and harvest SOPs NC-006/007/008/043/078 Postnatal culture and harvest SOPs NC-001/010/170 Haematology culture and harvest SOPs NC-004/171 Plasma cell purification SOP NC177	A
		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 Macroscopic and microscopic detection and analysis of genetic rearrangements and/or genomic imbalance SOPs NC-037/067/070/071/143/150/173/212	A

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)	Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES	Molecular Genetics examinations for the purpose of clinical diagnosis	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	Automated Realtime PCR using Qiagen Rotogene Q MDx platform SOP NC 239/240/241/242/244/245	B
Oropharyngeal / nasopharyngeal swabs in VTM (nose and throat swabs, NTS), nasal swabs		Automated RNA extraction using KingFisher Flex and MagMax viral pathogen kit and automated liquid handling using Integra Assit Plus, Assit and Via Flow. Extracted material to be tested for SARS-CoV-2 at separate laboratory (8605) SOP NC 251/252/317	B
END			