Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8652

Accredited to ISO 15189:2022

Sheffield Children's Hospital NHS Foundation Trust

Issue No: 012 **Issue date:** 14 October 2026

Sheffield Diagnostic Genetics Service
Sheffield Children's Hospital
Western Bank
Sheffield
S10 2TH
United Kingdom

Contact: Rebecca Pollitt
Tel: +44 (0)114 271 7014
E-Mail: scn-tr.sheffield.diagnosticgenetics@nhs.net
Website: www.sheffieldchildrens.nhs.uk/sdgs

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 TISSUE and FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	
Whole Blood, Bone Marrow, FFPE, Slide sections, Sperm, Saliva, Buccal swabs, Fetal Blood, Products of conception, Tissue, Fibroblasts, Lyophilised Cells, Amniocytes, Dried bloodspots, Buccal Swabs, Foetal Blood	Forwarding of human tissue and fluids to partner laboratories in the NEYGLH or other specialist centres, receipt of test results data for in-house analysis and reporting.	
		Multiplex Ligation Probe Amplification (MLPA
MLPA data files received from an external source	Analysis, interpretation and reporting of copy number variants and specific pathogenic single nucleotide variants (SNV)	Flexible scope limited to analysis, interpretation and reporting of copy number variants and specific pathogenic single nucleotide variants (SNVs) for Rare Disease as defined in Definitive List 407.103 MLPA Analysis using MRC Holland Coffalyser data analysis software SOP: 401.071

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	**Sanger Sequencing**
Sanger sequencing data files received from an external source	Analysis, interpretation and reporting of known and unknown nucleic acid sequence variants and confirmation of sequence variants including SNVs, insertions, deletions, structural variant breakpoints and fusion genes	Flexible scope limited to analysis, interpretation and reporting of nucleic acid variants, SNVs, insertions, deletions, structural variant breakpoints and fusion genes in Rare Disease as defined in Definitive List 401.336 Analysis Alamut Visual Plus Mutation Surveyor Variant interpretation and reporting using variant classification procedure SOPs: 601.235, 601.314 402.005
		Real Time PCR
Real time PCR data files received from an external source	Interpretation and reporting of known gene fusions events	Flexible scope limited to the interpretation and reporting of known gene fusion events for Oncology in accordance with Definitive List 407.102 SOPs: 601.037

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	**Fragment length analysis**
Fragment length data files received from an external source	Analysis, interpretation and reporting of fragment length size, deletions, known mutations, and repeat expansions	Flexible scope limited to analysis, interpretation and reporting of fragment length size, deletions, known mutations, and repeat expansions as defined in Definitive List 407.100 and 407.101 Analysis, interpretation and reporting GeneMapper software Analysis, interpretation and reporting of Agarose Gel Electrophoresis images SOPs: 401.026, 401.347, 601.014

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	**Next Generation Sequencing**
Next Generation Sequence data files received from an external source	Analysis, interpretation and reporting of single- gene or multigene panels for genetic variants (SNVs/indels/CNVs/gene fusions)	Flexible scope limited to analysis, interpretation and reporting of single- gene or multigene panels for genetic variants in Rare Disease and Oncology as defined in Definitive list 413.004 Analysis variant interpretation and reporting including variant classification procedures Qiagen Clinical Insight (QCI) Classic Integrative Genomics Viewer (IGV) Alamut VarDB HaemOncDB RNA Seek Alignment SOPs: 401.047, 402,005, 401.341, 401.398, 401.380

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	**SNP Array**
SNP array data files received from an external source	Analysis, interpretation and reporting of microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number and CN-LOH (copy neutral loss of heterozygosity) **Rare Disease** Congenital heart disease Congenital malformation and dysmorphism syndromes Differences in sex development Recurrent miscarriage with products of conception available for testing Fetus with a likely chromosomal abnormality Chromosomal mosaicism Diagnostic testing for known variants Predictive testing for known familial variants Carrier testing for known familial variants Validation of unaccredited findings Confirmation test Variant re-interpretation Family follow-up testing to aid variant interpretation Validation of WGS diagnostic discovery findings Prenatal testing	Analysis, interpretation and reporting Analysis and interpretation of genetic imbalances using BlueFuse Multiand web-based UCSC genome browser SOPs: 401.340, 401.346, 401.427

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and FLUIDS	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer	**SNP Array**
SNP array data files received from an external source	Analysis, interpretation and reporting of microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number and CN-LOH (copy neutral loss of heterozygosity) **Oncology** Acute Myeloid Leukaemia Myelodysplastic Syndromes Myeloproliferative Neoplasm Chronic Myeloid Leukaemia Acute Lymphoblastic Leukaemia - B cell Acute Lymphoblastic Leukaemia - T cell Chronic Lymphocytic Leukaemia Myeloma Mature B Cell Neoplasms Mature T Cell Neoplasms	Analysis, interpretation and reporting Analysis and interpretation of genetic imbalances using BlueFuse Multiand web-based UCSC genome browser SOPs: 401.340, 401.346, 401.427
		Quantitative Fluorescent PCR (QF-PCR)
QF-PCR data files received from an external source	Analysis, interpretation and reporting of aneuploidies	Flexible scope limited to analysis, interpretation and reporting of aneuploidies using the GeneMapper Software as defined in Definitive List 407.452 Analysis Genemapper Software SOPs: 401.006, 401.026

8652
Accredited to ISO 15189:2022

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Sheffield Children's Hospital NHS Foundation Trust

Issue No: 012 **Issue date:** 14 October 2026

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE and FLUIDS	Cytogenetic analysis for the purpose of clinical diagnosis of rare disease and cancer	**Karyotyping**
Karyotyping image files received from an external source	Analysis, interpretation and reporting of chromosomal rearrangements or aberrations arising from: Prenatally detected Disorders Developmental disorders Reproductive medicine disorders Haematological/Oncology disorders Chromosomal breakage disorders	Analysis, interpretation and reporting of chromosomal rearrangements or aberrations. Analysis Leica Cytovision software SOPs: 501.010, 401.356, 501.032, 501.044, 501.028 501.051, 401.075, 611.021
		Fluorescence in situ hybridisation (FISH)
FISH result files received from an external source	Interpretation and reporting of chromosomal aberrations in the diagnosis of: Haematological malignancy Bone marrow failure syndromes, Solid tumours and companion testing	Interpretation and reporting SOPs: 401.075, 501.028

END