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: 010 Issue date: 16 October 2025

Sheffield Diagnostic Genetics Service

OCI VICE

Sheffield Children's Hospital

Western Bank

Sheffield

S10 2TH

United Kingdom

Contact: Richard Kirk Tel: +44 (0)114 271 7014

E-Mail: sheffield.diagnosticgenetics@nhs.net Website: www.sheffieldchildrens.nhs.uk/our-

services/laboratory-medicine/

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.	
MLPA data files received from an external source within the NEYGLH	Analysis, interpretation and reporting of copy number variants and specific pathogenic single nucleotide variants (SNV)	Multiplex Ligation Probe Amplification (MLPA) – Analysis, interpretation and reporting :
	[Definitive list in 407.103]	MLPA Analysis using MRC Holland Coffalyser data analysis software
		SOP 401.071, 401.446b

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HUMAN TISSUE and FLUIDS (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	
Sanger sequencing data files received from an external source within the NEYGLH	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 [Definitive list of known targets listed in 401.336]	Sanger Sequencing – Analysis, interpretation and reporting: Analysis using Alamut Visual Plus Mutation Surveyor and variant interpretation and reporting using variant classification procedure SOPs, 601.235, 601.314 402.005
Real time PCR data files received from an external source within the NEYGLH	Interpretation and reporting of known gene fusions events for BCR-ABL [Definitive list in 407.102]	Real Time PCR – Interpretation and reporting: SOPs: 601.037,
ddPCR technical report received from an external source within the NEYGLH	Interpretation and reporting of nucleic acid sequence variants - CNVs [Definitive list in 407.446]	ddPCR - Interpretation and reporting: SOPs: 401.411
Fragment length data files received from an external source within the NEYGLH	Analysis, interpretation and reporting of fragment length size, deletions, known mutations, and repeat expansions [Definitive list in 407.100, 407.101]	Fragment length analysis – Analysis, interpretation and reporting: GeneMapper software SOPs 401.026, 401.347 Or Agarose Gel Electrophoresis 601.014

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	measured/Range of measurement	Equipment/Techniques used
HUMAN TISSUE and FLUIDS (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	
Next Generation Sequence data files received from an external source within the NEYGLH	Analysis, interpretation and reportingof single- gene or multigene panels for genetic variants (SNVs/indels/CNVs/gene fusions)	Next Generation Sequencing – Analysis, interpretation and reporting:
	[Definitive list in 413.004]	Analysis using NEYGLH VarDB and variant interpretation and reporting including variant classification procedures
		SOPs 401.047, 402,005, 401.341,401.387, 401.398, 401.380
SNP array data files received from an external source within the NEYGLH	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).	SNP Array – Analysis, interpretation and reporting: Analysis and interpretation of genetic imbalances using BlueFuse Multiand web-based UCSC genome browser SOPs 401.340, 401.346, 401.388, 401.427
Karyotyping image files received from an external source within the NEYGLH	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	Microscopic analysis chromosomes – Analysis, interpretation and reporting: Analysis using Leica Cytovision software SOPs 501.010, 401.356, 501.032, 501.044, 501.028 501.051, 401.075, 611.021

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HUMAN TISSUE and FLUIDS (cont'd)	Genomic analysis for the purpose of clinical diagnosis of rare disease and cancer (cont'd)	
FISH result files received from an external source within the NEYGLH	Interpretation and reportingof chromosomal aberrations in the diagnosis of:	Fluorescence in situ hybridisation (FISH) – Interpretation and reporting:
	Haematological malignancy Bone marrow failure syndromes, Non haematological malignancies and constitutional disorders, Solid tumours and companion testing	SOPs 401.075, 501.028, 501.052
QF-PCR data files received from an external source within the NEYGLH	Analysis, interpretation and reporting of common trisomy's: [Definitive list in 401.006].	QF-PCR – Analysis, interpretation and reporting:
		Analysis by Genemapper Software
		SOPs 401.006, 401.026
END		

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