Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8290

Accredited to ISO 15189:2022

NHS Greater Glasgow and Clyde

Issue No: 012 **Issue date:** 27 February 2025

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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 TISSUE AND FLUIDS A. Whole blood, mouth wash/ buccal cells, fresh tissue B. Amniotic fluid, chorionic villus C. Malignant tissue (tumour, FFPE, lymph node etc) D. Malignant fluid (bone marrow, CSF etc) E. Neonatal blood spots A, B, C, D, E	Cytogenetic and Molecular Genetic examination activities for the purpose of genetic investigations	Documented in-house methods and commercial kits for automated and manual processing: Using a combination of examination processes supported by the **pre-examination techniques** listed below 1. Process for the automated or manual extraction of DNA and RNA using Precellys, Leica microtomes, EZ1, QIAcube, QIAsymphony, Chemagic STAR, Maxwell 48 or Manual DNA extraction: EXAM-425, EXAM-468 2. Automated and manual cDNA preparation using commercial assay and Microlab STAR/STARlet automated platforms: EXAM-425 3. Automated cell separation and cell counts using AutoMACS, MultiMACS and Sysmex XP-300: EXAM-425 4. Quantitation by Nanodrop, Qubit, or 2100 Bioanalyser: EXAM-425

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd) A, B, C, D, E	<u>Cytogenetic and Molecular Genetic examination activities for the purpose of genetic investigations:</u> (cont'd)	Documented in-house methods and commercial kits for automated and manual processing: 5. PCR amplification of DNA and cDNA with commercial kits and in-house assays using Veriti and Proflex thermocyclers, ABI7500and COBAS z480 realtime instruments and Quant Studio digital PCR: EXAM-427 6. Robotic automation for pre and post PCR processing using Microlab STAR/STARlet: EXAM-427, EXAM-428 7. Gel electrophoresis to separate DNA fragments, manual imaged using Syngene GeneFlash/ Ingenius3 and automated using 2100 Bioanalyzer: EXAM-427 8. Cell culture and harvesting of preparations for chromosome analysis, manual and automated (Hanabi harvester): EXAM-426 9. Slide staining for chromosome preparation and H&E, manual and automated (Varistain Gemini, ClearVue coverslipper): EXAM-426 10. FISH slide preparation, pre-treatment manual and automated (VIP2000) and probe hybridisation using commercial probes: EXAM-431 11. Image capture for chromosome preparations and FISH (automated and manual) using Bioview image analysis system: EXAM- 426, EXAM-497

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd) A, B, C, D, E	<u>Cytogenetic and Molecular Genetic examination activities for the purpose of genetic investigations</u> (cont'd)	Documented in-house methods and commercial kits for automated and manual processing: Using the following **examination processes** (pre-examination techniques shown in bold square brackets): 12. Sanger sequencing by capillary electrophoresis (ABI3730XL, Mutation Surveyor, Sequence Scanner, Alamut): EXAM-428 **[1,4,5,6,7]** 13. Fragment analysis using PCR (AS-PCR, ARMS, TP-PCR, RT-PCR etc) and quantitative PCR (Q-PCR, QF-PCR, MLPA, D-PCR) techniques by PyroMarkQ48, ABI35003730/7500/7900, COBAS 4800, QuantStudio, GeneMarker, 7500 System Software, ABI SDS software: EXAM-427 **[1,2,3,4,5,6,7]** 14. Next Generation sequencing using various commercial kits for library generation (MiSeq, NextSeq500/550, Biomedical Genomics Workbench, Congenica, Alamut): EXAM-429 **[1,4,5,6]** 15. Genomic profiling using 180kb Illumina Global Screening Array:EXAM-430 **[1,4,6]** 16. G banded bright field analysis and karyotyping (Bioview Duet System: EXAM-426 **[3,8,9,10,13]** 17. Fluorescence in situ hybridisation (FISH) microscopy for signal detection and analysis (Bioview Duet System): EXAM-497, EXAM-507, EXAM-524 **[3,8,9,11,12,13]**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Cytogenetic and Molecular Genetic investigations for the detection of germline mutations and genomic imbalance related to the following:	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
A, B	Aneuploidy testing for common trisomies (T13, T18, T21, X and Y)	EXAM-448, EXAM-453, **[13, 16]**
A	Angelman Syndrome	EXAM-145, **[12,13]**
A, B	Becker Muscular Dystrophy	EXAM-115, **[12,13]**
A	Beckwith-Weidemann Syndrome	EXAM-140, **[13]**
A	Neurodegeneration with Brain Iron accumulation (CE subpanel)	EXAM-491 **[12,14]**
A	Breast Cancer (hereditary) (NGS, 8 gene panel)	EXAM-147, **[12,13,14]**
A	Breast and Ovarian cancer (hereditary) (NGS, 14 gene panel)	EXAM-147 **[12,13,14]**
A	Breast, ovarian and colorectal cancer (hereditary) (NGS, 22 gene panel)	EXAM-147 **[12,13,14]**
A	CADASIL	EXAM-153, **[12]**
A, B	CHARGE Syndrome	EXAM-161, **[12,13]**
A	Chondrodysplasia Punctata (CE subpanel)	EXAM-491 **[12,14]**
A, B	Chromosome investigation for inherited and congenital abnormalities	EXAM- 448, EXAM-453 **[13, 15, 16 17]**
A	Cowden Syndrome	EXAM-147, **[12,13]**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Cytogenetic and Molecular Genetic investigations for the detection of germline mutations and genomic imbalance related to the following: (cont'd)	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
A, B, E	Cystic Fibrosis, including; • CFTR-related disorders using Devyser CFTR68 kit	EXAM-449, EXAM-527 **[13]**
A	Developmental delay, including; • Fragile X syndrome	EXAM-451, **[13,15,16]**
A	DICER1 syndrome (CE)	EXAM-298 **[12]**
A, B	DiGeorge Syndrome	EXAM-372, **[13]**
A	Dilated Cardiomyopathy	EXAM-455**, [12,13]**
A	Disorders of Sexual Development (NGS, 56 gene panel)	EXAM-402, **[12,14]**
A	Dihydropyrimidine Dehydrogenase (DPYD)	EXAM – 495 **[13]**
A, B	Duchenne Muscular Dystrophy	EXAM-115, **[12,13]**
A, B	Epilepsy (NGS, 104 gene panel)	EXAM-126, EXAM-296 **[12,13,14]**
A	Episodic ataxia type 1 & type 2 (KCNA1 and CACNA1A)	EXAM-337, **[12]**
A	Familial Hemiplegic Migraine (FHM) (NGS, 5 gene panel)	EXAM-296 **[12,14]**
A	Fertility investigations, including; • Y deletions	EXAM-450, **[13,16]**
A, B	Fibrodysplasia Ossificans Progressiva	EXAM-141, **[12]**
A	Rhabdomyolysis (CE Subpanel) Arthrogryposis	EXAM-491 **[12,14]**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Cytogenetic and Molecular Genetic investigations for the detection of germline mutations and genomic imbalance related to the following: (cont'd)	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
A	Peripheral neuropathy (CE Subpanel)	EXAM-491 **[12,14]**
A	SMA/dHMN (CE Subpanel)	EXAM-491 **[12,14]**
A	Rhabdoid tumour	EXAM-491 **[12,14]**
A	Osteopetrosis	EXAM-491 **[12,14]**
A	Osteochondromas	EXAM-491 **[12,14]**
A, B	Fragile X syndrome, including; • FMR1-related disorders • FXTAS • POF	EXAM-102, **[13]**
A	Gorlin Syndrome (CE subpanel)	EXAM-491 **[12,14]**
A	Hereditary Ataxia (CE subpanel)	EXAM-491 **[12,14]**
A	Hereditary Haemochromatosis (HFE related)	EXAM-46, **[13]**
A	Hereditary Spastic Paraplegia (CE subpanel)	EXAM-154, **[12,13, 14]**
A, B	Lesch Nyhan Syndrome	EXAM-160, **[12,13]**
A	Li-Fraumeni Syndrome	EXAM-147, **[12,13]**
A, B	Limb Girdle Muscular Dystrophy type 2I FKRP and 2R	EXAM-455, **[12]**
A, B	Limb Girdle Muscular Dystrophy 1B laminopathy	EXAM-455, **[12,13]**
A	Malignant Melanoma (hereditary) (NGS, 5 gene panel)	EXAM-147, **[12, 14]**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Cytogenetic and Molecular Genetic investigations for the detection of germline mutations and genomic imbalance related to the following: (cont'd)	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
A	Medium-chain acyl-coenzyme A dehydrogenase deficiency (MCADD)	EXAM-477 **[12]**
A, B	Microdeletion/Microduplication syndromes	EXAM-451, **[13]**
A, B	Myotonic Dystrophy (type 1)	EXAM-103, **[13]**
A	Ovarian Cancer (hereditary) (NGS, 8 gene panel)	EXAM-147, **[12, 13, 14]**
A	Pancreatic Cancer (hereditary) 9 gene panel	EXAM-147 **[12,13,14]**
A	Phenylketonuria	EXAM-168, **[12,13]**
A	Prader Willi Syndrome	EXAM-145, **[12]**
A	Respiratory Disease (CE subpanel)	EXAM-491 **[12,14]**
A	Pregnancy loss	EXAM-452, **[15, 16, 17]**
A, B	Prenatal diagnosis	EXAM-453, **[15, 16, 17]**
A, B	Rett and Rett-like Syndrome	EXAM-126, **[12,13]**
A	Sex determination	EXAM-448, **[13,16]**
A	Short Stature, including: • Turner syndrome • SHOX related	EXAM-448, **[12,13,16,17]**
A, B, E	Sickle Cell Anaemia	EXAM-44, **[13]**
A	Silver Russell Syndrome	EXAM-140, **[13]**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Cytogenetic and Molecular Genetic investigations for the detection of somatic mutations and genomic imbalance related to the following: (cont'd)	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
A, B	Smith-Lemli-Opitz Syndrome	EXAM-172, **[12]**
A	Thiopurine methyltransferase (TPMT)	EXAM-506, **[12]**
A	X-inactivation Studies	EXAM-406, **[13]**
A, C, D	Acute Lymphoblastic Leukaemia (ALL), including: ▪ Minimal residual disease (MRD) ▪ Paediatric ALL (including. SNP microarray)	EXAM-433, **[12,13, 15, 16,17]**
A, C, D	Acute Myeloid Leukaemia (AML)/ Myelodysplastic Syndrome (MDS)	EXAM-434, **[12, 13, 14,16,17]** EXAM-443, **[12, 13, 14, 16,17]**
C	Breast Cancer (acquired)	EXAM-349, **[17]**
A	Chimerism analysis	EXAM-435, **[6,13]**
C	Colorectal Cancer (acquired) including; ▪ MLH1 promoter methylation analysis	EXAM-436, **[12,13, 14]** EXAM-530 **[13]**
C	Brain and CNS Cancer (including Glioma) including; 1p36/1q25 and 19q13/19p13 IDH1/IDH2 and BRAF MGMT promoter methylation in Glioma	EXAM-437, **[12,13, 14, 17]** EXAM-529 **[13]**
C	Gastro-oesophageal cancer • Gastric Her-2	EXAM-534 **[17]**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Cytogenetic and Molecular Genetic investigations for the detection of somatic mutations and genomic imbalance related to the following: (cont'd)	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
C	FOXL2 for adult granulosa cell tumours	EXAM-528 [12]
A, C, D	Haematological Malignancy, not otherwise specified	EXAM-438, **[12, 14, 16,17]**
A, C, D	Lung Cancer, Non-Small Cell (acquired) including; ▪ ALK1 ▪ ROS1	EXAM-439, **[12,13, 14, 17]**
A, C, D	Lymphoproliferative Neoplasms (LPN), including: ▪ Chronic Lymphocytic Leukaemia (CLL) ▪ Lymphoma ▪ Myeloma ▪ Waldenströms macroglobulinaemia	EXAM-440, **[12,13,16,17]**
	Malignant Melanoma (acquired), including; ▪ Uveal Melanoma	EXAM-441, **[12, 14, 17]**
A, C, D	Mesothelioma	EXAM-442, **[17]**
A, D	Myeloproliferative Disorders (MPD), including; ▪ Chronic Myeloid Leukaemia (CML) ▪ Polycythaemia Vera ▪ Essential Thrombocythaemia ▪ Myelofibrosis	EXAM-444, **[12,13, 14, 16,17]**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Cytogenetic and Molecular Genetic investigations for the detection of somatic mutations and genomic imbalance related to the following: (cont'd)	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
C	Ovarian cancer; • Somatic NGS, 2 gene panel (BRCA1, BRCA2) using QIAseq kit	EXAM-414 **[14]**
C	Prostate cancer; ▪ Somatic NGS, 2 gene panel (BRCA1, BRCA2) using QIAseq kit	EXAM-414 **[14]**
C	Sarcoma	EXAM-446, **[13,16,17]**
C	Solid Tumours, not otherwise specified	EXAM-445, **[14, 16,17]**
END		