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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 F. Embryo biopsy A, B, C, D, E, F	<u>Cytogenetic and Molecular Genetic examination activities for the purpose of genetic investigations</u>	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: 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, F	<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, ABI9700/9750 and COBAS 4800 realtime instruments and Quant Studio digital PCR: EXAM-427 6. Robotic automation for pre and post PCR processing using Microlab STAR/STARlet and Biomek NXp: 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-426 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, F	<u>Cytogenetic and Molecular Genetic examination activities for the purpose of genetic investigations</u>	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, ABI3130XL/ 3730XL/ 3730/7500/ 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, Biomedical Genomics Workbench, Congenica, Alamut): EXAM-429 **[1,4,5,6]** 15. Genomic profiling using 180kb SNP microarray (NextSeq 550, BlueFuse Multi): EXAM-430 **[1,4,6]** 16. G banded bright field analysis and karyotyping (Leica, GSL120 & CytoVision): 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]**
	Angelman Syndrome	EXAM-145, **[12,13]**
	Bardet-Biedl Syndrome	EXAM-152, **[12]**
	Becker Muscular Dystrophy	EXAM-115, **[12,13]**
	Beckwith-Weidemann Syndrome	EXAM-140, **[13]**
	Neurodegeneration with Brain Iron accumulation (CE subpanel)	EXAM-491 **[14]**
	Breast Cancer (hereditary) (NGS, 8 gene panel)	EXAM-147, **[12,13,14]**
	Breast and Ovarian cancer (hereditary) (NGS, 14 gene panel)	EXAM-147 **[14]**
	Breast, ovarian and colorectal cancer (hereditary) (NGS, 22 gene panel)	EXAM-147 **[14]**
	CADASIL	EXAM-153, **[12]**
	CHARGE Syndrome	EXAM-161, **[12,13]**
	Chondrodysplasia Punctata (CE subpanel)	EXAM-491 **[14]**
	Congenital Hypothyroidism	EXAM-113, **[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)
	Chromosome investigation for inherited and congenital abnormalities	EXAM- 448, EXAM-453 **[13, 15, 16 17]**
	Cowden Syndrome	EXAM-147, **[12,13]**
A, B, E	Cystic Fibrosis, including; • CFTR-related disorders using Devyser CFTR68 kit	EXAM-449, EXAM-527 **[13]**
	Developmental delay, including; • Fragile X syndrome	EXAM-451, **[13,15,16]**
	DICER1 syndrome (CE)	EXAM-298 **[12]**
	DiGeorge Syndrome	EXAM-372, **[13]**
	Dilated Cardiomyopathy	EXAM-455**, [12,13]**
	Disorders of Sexual Development (NGS, 56 gene panel)	EXAM-402, **[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	DPYD	EXAM – 495 **[13]**
	Duchenne Muscular Dystrophy	EXAM-115, **[12,13]**
	Epilepsy (NGS, 104 gene panel)	EXAM-126, EXAM-296 **[12,13,14]**
	Episodic ataxia type 1 & type 2 (KCNA1 and CACNA1A)	EXAM-337, **[12]**
	Familial Hemiplegic Migraine (FHM) (NGS, 5 gene panel)	EXAM-296 **[14]**
	Fertility investigations, including; • Y deletions	EXAM-450, **[13,16]**
	Fibrodysplasia Ossificans Progressiva	EXAM-141, **[12]**

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)
	FOXL2 for adult granulosa cell tumours	EXAM-528
	Fragile X syndrome, including; • FMR1-related disorders • FXTAS • POF	EXAM-102, **[13]**
	Gorlin Syndrome (CE subpanel)	EXAM-491 **[14]**
	Hereditary Ataxia (CE subpanel)	EXAM-491 **[14]**
A, B	Hereditary Haemochromatosis (HFE related)	EXAM-46, **[13]**
	Hereditary Spastic Paraplegia (CE subpanel)	EXAM-154, **[12,13, 14]**
	Lesch Nyhan Syndrome	EXAM-160, **[12,13]**
	Li-Fraumeni Syndrome	EXAM-147, **[12,13]**
	Limb Girdle Muscular Dystrophy type 2I FKRP and 2R	EXAM-455, **[12]**
	Limb Girdle Muscular Dystrophy 1B laminopathy	EXAM-455, **[12,13]**
	Malignant Melanoma (hereditary) (NGS, 5 gene panel)	EXAM-441, **[13, 14]**
	Medium-chain acyl-coenzyme A dehydrogenase deficiency (MCADD)	EXAM-477 **[12]**

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	Microdeletion/Microduplication syndromes	EXAM-451, **[13]**
	Myotonic Dystrophy (type 1)	EXAM-103, **[13]**
	Ovarian Cancer (hereditary) (NGS, 8 gene panel)	EXAM-147, **[12, 13, 14]**
	Pancreatic Cancer (hereditary) 9 gene panel	EXAM-491 **[14]**
	Phenylketonuria	EXAM-168, **[12,13]**
	Prader Willi Syndrome	EXAM-145, **[12]**
	Respiratory Disease (CE subpanel)	EXAM-491 **[14]**
F	Pregnancy loss	EXAM-452, **[15, 16, 17]**
	Prenatal diagnosis	EXAM-453, **[15, 16, 17]**
	Pre-implantation Genetics Diagnosis	EXAM-453, **[15, 16, 17]**
A, B	Rett and Rett-like Syndrome	EXAM-126, **[12,13]**
	Sex determination	EXAM-448, **[13,16]**
	Short Stature, including: • Turner syndrome SHOX related	EXAM-448, **[12,13,16,17]**
	Sickle Cell Anaemia	EXAM-44, **[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:	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
F	Silver Russell Syndrome	EXAM-140, **[13]**
	Smith-Lemli-Opitz Syndrome	EXAM-172, **[12]**
A	Thiopurine methyltransferase (TPMT)	EXAM-506, **[12]**
	X-inactivation Studies	EXAM-406, **[13]**
A, C, D	Acute Lymphoblastic Leukaemia (ALL), including; ▪ Minimal residual disease (MRD)	EXAM-433, **[12,13, 15, 16,17]**
	Acute Myeloid Leukaemia (AML)/ Myelodysplastic Syndrome (MDS)	EXAM-434, **[12, 13, 14,16,17]** EXAM-443, **[12, 13, 14, 16,17]**
	Breast Cancer (acquired)	EXAM-349, **[17]**
	Chimerism analysis	EXAM-435, **[6,13]**
	Colorectal Cancer (acquired) including; ▪ MLH1 promoter methylation analysis	EXAM-436, **[12,13, 14]** EXAM-530 **[13]**
	Brain and CNS Cancer (including Glioma) including; CNS tumour 1p36/1q25 and 19q13/19p13 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:	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
	Haematological Malignancy, not otherwise specified	EXAM-438, **[12, 14, 16,17]**
	Head and Neck cancer	EXAM-209, **[12, 13, 14]**
A, C, D	Lung Cancer, Non-Small Cell (acquired) including; ▪ ALK1 ▪ ROS1	EXAM-439, **[12,13, 14, 17]**
A, C, D, F	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]**

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:	Documented in-house methods and commercial kits for automated and manual processing (examination processes shown in bold square brackets)
A,C,D	Mesothelioma	EXAM-442, **[17]**
A	Musculoskeletal Disorders CE subpanel including; ▪ Rhabdomyolysis ▪ Peripheral neuropathy, ▪ SMA/dHMN ▪ Rhabdoid tumour ▪ Osteopetrosis ▪ Osteochondromas ▪ Arthrogryposis	EXAM-491 **[14]**
	Myeloproliferative Disorders (MPD), including; ▪ Chronic Myeloid Leukaemia (CML) ▪ Polycythaemia Vera ▪ Essential Thrombocythaemia ▪ Myelofibrosis	EXAM-444, **[12,13, 14, 16,17]**
	Ovarian cancer; ▪ Somatic NGS, 2 gene panel (BRCA1, BRCA2) using QIAseq kit	EXAM-414 **[14]**
	Sarcoma	EXAM-446, **[13,16,17]**
	Somatic arrays	EXAM-430 **[15]**
	Solid Tumours, not otherwise specified	EXAM-445, **[14, 16,17]**

END