Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8220

Accredited to ISO 15189:2012

NewGene Ltd

Issue No: 003 **Issue date:** 31 October 2017

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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
	<u>Molecular pathology</u>	
Formalin fixed paraffin-embedded tissue Slide sections Fixed cells DNA	Targeted mutation detection in specific genes, listed below, using DNA	DNA extraction and quantification using in-house procedures or commercial kits (Promega Maxwell or Qiagen) according to the following procedures: NG-PREEXAM-26 NG-PREEXAM-30 NG-EQUIP-07
	BRAF targeted mutation detection (colorectal cancer, hairy cell leukaemia and melanoma) EGFR targeted mutation detection (non-small-cell lung cancer) RAS targeted mutation detection in colorectal tumours including KRAS and NRAS genes	PCR amplification of DNA and mutation detection by MALDI-TOF mass spectrometry using a Sequenom MA4 system according to the following procedures: NG-EXAM-SEQ-01 NG-EXAM-SEQ-02 NG-EXAM-SEQ-03 NG-EXAM-SEQ-05 NG-EXAM-SEQ-18 NG-POST-SEQ-01 Fragment analysis (EGFR deletions and insertions) using PCR amplification, detection on an ABI 3139xl calillary analyser and data analysis using GeneMarker software according to the following procedureS: NG-EXAM-SEQ-04 NG-IT-07 NG-POST-03

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Molecular haematology	
Whole Blood	Analysis of DNA and RNA	DNA and RNA extraction and quantification using in-house procedures or commercial kits (Promega Maxwell or Qiagen) according to the following procedures: NG-PREEXAM-07 NG-PREEXAM-10 NG-PREEXAM-34 NG-PREEXAM-35 NG-PREEXAM-36 NG-EQUIP-07
	BCR-ABL monitoring in chronic myeloid leukaemia	Amplification of RNA by real time PCR on a Roche LC480 light cycler using a commercial kit (Ipsogen) and data analysis using Roche software according to procedures: NG-EXAM-BCR-01 NG-EXAM-BCR-01 NG-EXAM-BCR-01
	JAK2, MPL and calreticulin targeted mutation detection in myeloproliferative neoplasms	PCR amplification of DNA. Mutation detection by MALDI-TOF mass spectrometry using a Sequenom MA4 system NG-EXAM-SEQ-01 NG-EXAM-SEQ-02
	TPMT genotyping	NG-EXAM-FLX-14 NG-EXAM-SEQ-13 NG-POST-08 NG-POST-SEQ-01
		Fragment analysis (calreticulin) using PCR amplification and detection on an ABI 3130xl calillary analyser according to the following procedures: NG-EXAM-SEQ-16

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	<u>Molecular Genetics</u>	
Whole Blood Mouth washes DNA	Analysis of DNA and RNA for mutations in genes underlying hereditary diseases listed below.	DNA and RNA extraction and quantification using in-house procedures or commercial kits (Promega Maxwell or Qiagen) according to the following procedures: NG-PREEXAM-07 NG-PREEXAM-10 NG-PREEXAM-18 NG-PREEXAM-34 NG-PREEXAM-35 NG-PREEXAM-36 NG-EQUIP-04 NG-EQUIP-07
	Breast cancer: Full gene sequencing of the BRCA1 and BRCA2 genes	PCR amplification using a Multiplicom system (breast cancer) or sequence capture using Haloplex (Noonans) and next generation sequencing using an Illumina MiSeq. Data analysis using commercial softwares (NextGENe) and in-house methods. Procedures: NG-EXAM-MISEQ-01 NG-EXAM-MISEQ-05 NG-EXAM-MISEQ-06 NG-EXAM-MISEQ-09 NG-EXAM-FLX-14 NG-POST-05 NG-POST-MISEQ-01 NG-POST-MISEQ-05 NG-POST-MISEQ-06
	Noonan spectrum disorders: Full gene sequencing for the following genes - PTPN11, SPRED1, KRAS, SOS1, RAF1, NRAS, BRAF, SHOC2 (exon 1 only), MAP2K1, MAP2K2, HRAS, CBL , NF1, RIT1 and A2ML1	
	Familial hypercholesterolaemia targeted mutation detection in genes APOB, PCSK9 and LDLR	PCR amplification of DNA and mutation detection by MALDI-TOF mass spectrometry using a Sequenom MA4 system according to the following procedures: NG-EXAM-SEQ-01 NG-EXAM-SEQ-02 NG-EXAM-SEQ-14
END		