

# Schedule of Accreditation



Organisation Name	Genseq Diagnostics Limited
Trading As	Genseq Diagnostics Ltd
INAB Reg No	421MT
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Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	04/09/2024
Scope Classification	Genetics
Services available to the public <sup>1</sup>	No

<sup>1</sup> Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	Head Office	Building 4, Cherrywood Business Park, Dublin 18, Co. Dublin, D18 K7W4

# Scope of Accreditation

## Head Office

## Genetics

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1075 Molecular genetics - .06 Assay for identified pathogenic variant(s)	Cytochrom P450 Family Subfamily C Member 19 (CYP2C19 gene mutations CYP2C19*2, CYP2C19*3, CYP2C19*17)	Whole Blood	Reverse transcription polymerase chain reaction (RT-PCR)	Biorad CFX 96 DX Thermal Cycler	Non CE-Marked	LP-SEQ-0032
			Reverse transcription polymerase chain reaction (RT-PCR)	Roche Light Cycler 480II	Non CE-Marked	LP-SEQ-0032
	Dihydropyrimidine Dehydrogenase Genetic Screen (DPYD gene mutations DPYD*2A, DPYD*13, DPYD HapB3, DPYD c.2846A>T)		Reverse transcription polymerase chain reaction (RT-PCR)	Biorad CFX 96 DX Thermal Cycler	CE Marked	LP-SEQ-0032

			Reverse transcription polymerase chain reaction (RT-PCR)	Roche Light Cyclers 480II	Non CE-Marked	LP-SEQ-0032
	Haemochromatosis Genetic Screen (Hereditary Haemochromatosis HFE gene mutations) (C282Y, H63D, S65C)		Reverse transcription polymerase chain reaction (RT-PCR)	Biorad CFX 96 DX Thermal Cycler	CE Marked	LP-SEQ-0032
			Reverse transcription polymerase chain reaction (RT-PCR)	Roche Light Cyclers 480II	Non CE-Marked	LP-SEQ-0032
	Thiopurine S-Methyltransferase Genetic Screen (TPMT gene mutations TPMT*2, TPMT*3B, TPMT*3C)		Reverse transcription polymerase chain reaction (RT-PCR)	Biorad CFX 96 DX Thermal Cycler	CE Marked	LP-SEQ-0032
			Reverse transcription polymerase chain reaction (RT-PCR)	Roche Light Cyclers 480II	Non CE-Marked	LP-SEQ-0032
1075 Molecular genetics - .07 Prenatal testing	Non-Invasive Prenatal Screening	Whole Blood in Cell-Free DNA Blood Collection Tube	Illumina/VeriSeq NIPS Solution	NextSeq 550 DX	CE Marked	LP-SEQ-0028
1075 Molecular genetics - .10 DNA sequencing	Comprehensive Next Generation Sequencing (NGS) Cancer Panel (134 targets)	Whole Blood	Next Generation Sequencing (NGS) - screening for clinically significant germline SNPs, small (<10) indels and CNVs associated with rare/inherited disorders	NextSeq 550 DX	CE Marked	
			Next Generation Sequencing (NGS) - screening for clinically significant germline SNPs, small (<10) indels and	NovaSeq 6000	CE Marked	

			CNVs associated with rare/inherited disorders			
	Next Generation Sequencing (NGS) Panels Long QT syndrome Core Long QT syndrome Expanded Short QT syndrome Brugada syndrome Core Brugada syndrome Expanded Catecholaminergic polymorphic VT Arrhythmogenic right ventricular cardiomyopathy Comprehensive cardiac arrhythmias Comprehensive Cardiomyopathy Left Ventricular Noncompaction Cardiomyopathy Hypertrophic Cardiomyopathy Core Hypertrophic Cardiomyopathy Expanded Dilated cardiomyopathy and conduction defects Core Dilated cardiomyopathy and conduction defects Expanded Dyslipidaemia panel Aorthopathy panel Hereditary Breast	Whole Blood DNA Extracted from Whole Blood	Next Generation Sequencing (NGS) - screening for clinically significant germline SNPs, small (<10) indels and CNVs associated with rare/inherited disorders	NovaSeq 6000	CE Marked	LP-SEQ-0026

	Cancer Hereditary Breast and Gynaecological Cancer Colorectal Cancer and Polyposis Panel					
	Sanger Sequencing		Sanger Sequencing - screening for clinically significant germline SNPs and small (<10) indels and CNVs for the purposes of confirmatory testing, cascade testing & targeted genes	SeqStudio Genetic Analyser	CE Marked	LP-SEQ-0010
1075 Molecular genetics - .11 DNA extraction	Deoxyribonucleic acid (DNA) Extraction	Whole Blood	Whole blood	Flexstar Plus	CE Marked	LP-DNA-0001