

# 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, D18 K7W4, Cherrywood Business Park, Dublin 18, Dublin

# 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	CE Marked	LP-SEQ-0032
			Reverse transcription polymerase chain reaction (RT-PCR)	Roche Light Cycler 480II	CE Marked	LP-SEQ-0032
	Dihydropyrimidine Dehydrogenase Genetic Screen (DPYD gene mutations DPYD*2A,		Reverse transcription polymerase chain reaction (RT-PCR)	Biorad CFX 96 DX Thermal Cycler	CE Marked	LP-SEQ-0032

	DPYD*13, DPYD HapB3, DPYD c.2846A>T)					
	Haemochromatosis Genetic Screen (Hereditary Haemochromatosis HFE gene mutations) (C282Y, H63D, S65C)		Reverse transcription polymerase chain reaction (RT-PCR)	Roche Light Cyclers 480II	CE Marked	LP-SEQ-0032
	Thiopurine S-Methyltransferase Genetic Screen (TPMT gene mutations TPMT*2, TMPT*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	CE Marked	LP-SEQ-0032
			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	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 -	Next Generation	DNA Extracted from	Next Generation	NovaSeq 6000	Non CE-Marked	LP-SEQ-0026

.10 DNA sequencing	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 Cancer Comprehensive Nephrology Comprehensive Neurology Comprehensive Ophthalmology Comprehensive cardiac arrhythmias Comprehensive Cardiomyopathy Left Ventricular Noncompaction Cardiomyopathy Hypertrophic Cardiomyopathy Core Hypertrophic Cardiomyopathy Expanded Dilated cardiomyopathy and	Whole Blood DNA Extracted from Saliva DNA Extracted from Buccal Swab	Sequencing (NGS) - screening for clinically significant germline SNPs, small (<10) indels and CNVs associated with rare/inherited disorders			
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	<p>conduction defects Core Dilated cardiomyopathy and conduction defects Expanded Dyslipidaemia Aortopathy Hereditary Breast Cancer Hereditary Breast and Gynaecological Cancer Colorectal Cancer and Polyposis</p>					
	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	Non-CE, Based on Standard Method	LP-SEQ-0010
1075 Molecular genetics - .11 DNA extraction	Deoxyribonucleic acid (DNA) Extraction	Buccal Swab	Deoxyribonucleic acid (DNA) Isolation	Promega Maxwell	Non-CE, Based on Standard Method	LP-DNA-0018
		Formalin Fixed Paraffin Embedded (FFPE) Tissue	Deoxyribonucleic acid (DNA) Isolation	Promega Maxwell	Non-CE, Based on Standard Method	LP-DNA-0007
		Saliva	Deoxyribonucleic acid (DNA) Isolation	Flexstar Plus	Non-CE, Based on Standard Method	LP-DNA-0026

		Whole Blood	Deoxyribonucleic acid (DNA) Extraction	Flexstar Plus	Non-CE, Based on Standard Method	LP-DNA-0001
			Deoxyribonucleic acid (DNA) Isolation	Promega Maxwell	Non-CE, Based on Standard Method	LP-DNA-0012
1076 Molecular pathology - .04 Assay for somatic variants in gene structure	Roche Avenio Tumour Tissue Targeted CGP Kit V2	DNA Extracted from Formalin Fixed Paraffin Embedded (FFPE) Tissue	Automated using Hamilton Robot	NextSeq 550 DX	Non-CE, Based on Standard Method	LP-SEQ-0033
			Manual using Test Kit	NextSeq 550 DX	Non-CE, Based on Standard Method	LP-SEQ-0034