

Schedule of Accreditation



Organisation Name	Children's Health Ireland
Trading As	CHI at Crumlin: Department of Clinical Genetics Laboratory
INAB Reg No	417MT
Contact Name	Julie Egan
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Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	17/04/2024
Scope Classification	Genetics
Services available to the public ¹	No

¹ 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	Department of Clinical Genetics, Crumlin, Dublin, 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
1071 Cytogenetics - .25 Fluorescent in situ hybridisation	BCR/ABL1 Plus, dual fusion	Blood, Bone marrow, Human tissue, Slides (unstained)	Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	CBFA2T3/GLIS2, dual fusion		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	CBFB, break apart		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	CBFB/MYH11, dual fusion		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	CHD5/160H23		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	Chromosome 10 enumerator probes		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting

Chromosome 11 enumerator probes
Chromosome 12 enumerator probes
Chromosome 15 enumerator probes
Chromosome 16 enumerator probes
Chromosome 17 enumerator probes
Chromosome 18 enumerator probes
Chromosome 19 enumerator probes
Chromosome 2 enumerator probes
Chromosome 20 enumerator probes
Chromosome 3 enumerator probes
Chromosome 4 enumerator probes
Chromosome 5 enumerator probes
Chromosome 6 enumerator probes

Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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Chromosome 7 enumerator probes
Chromosome 8 enumerator probes
Chromosome 9 enumerator probes
Chromosome X enumerator probes
Chromosome Y enumerator probes
CKS1B/CDKN2C
CRLF2, break apart
D13S319/D13S1825/D12Z3
D15S10/D15Z1/PML Angelman
D22S75
D22S75/SHANK3
DEK/NUP214, dual fusion
del(13q)

Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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del(5q)/monosomy 5
del(7q)/monosomy 7
ELN/D7S486/D7S552
ERG/EWSR1, dual fusion
ETV6, break apart
ETV6/RUNX1, dual fusion
EWSR1, break apart
FGFR1, break apart
FIP1L1-CHIC2-PDGFR, DeIF
FLI1/EWSR1, dual fusion
FOXO1, break apart
FUS, break apart
IGH, break apart

Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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IGH/BCL2, dual fusion
IGH/CCND1, dual fusion
IGH/FGFR3, dual fusion
IGH/MAF, dual fusion
IGH/MYC, dual fusion
KMT2A, break apart
MECOM, break apart
MLL/MLLT10, dual fusion
MPO/TP53
MYC
MYC, break apart
MYCN
NUP214/DEK, break apart

Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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NUP98, break apart
NUP98/NSD1, dual fusion
PAX3, break apart
PAX7, break apart
PBX1/HLF/TCF3, dual fusion
PDGFRB, break apart
PML/RARA, dual fusion
RUNX1/RUNX1T1, dual fusion
SHOX/DYZ1
SNRPN
SRY
SS18, break apart
STS (Xp22)

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Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
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	Subtelomere probes (locus specific)		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	TCF3, break apart		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	TERT		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	TLX3, break apart		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	TP53		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
	XIST		Manual/microscope	Thermobrite, Zeiss microscope, Metasystems	Based on standard method	LP-CYT-FISHAnalysis, LI-CYT-Reporting
1071 Cytogenetics - .99 Miscellaneous tests	Chromosome analysis by G-band staining	Blood, Bone marrow, Human tissue	Manual/microscope	Zeiss microscope, Metasystems	Based on standard method	LP-CYT-HONCAAnalGuide, LP-CYT-ConstGbandAnal, LI-CYT-Reporting
1075 Molecular genetics - .05 Screening for unidentified pathogenic variant(s)	Detection of whole genome genetic imbalance using Array Comparative Genomic Hybridisation (aCGH)	DNA	Microarray based Comparative Genomic Hybridisation (aCGH)	Agilent SureScan Microarray Scanner	Non-CE, Based on standard method	LP-CYT-CGHAnal, LI-CYT-Reporting, LP-CYT-CGHNeoAna
1075 Molecular genetics - .06 Assay for identified pathogenic variant(s)	Angelman/Prader Willi syndrome (AS/PWS)		MS-MLPA assay kits by MRC-Holland- Kit ME028-C1	ABI 3500xl Genetic Analysers	MLPA Kits: Version C1 Non -CE, Version D1 CE marked ABI 3130xl/3500: Non-CE	LI-MOL-MS-MLPA, LI-MOL-MLPAGeneMarker
	Cystic Fibrosis (CF)		Multiplex PCR by X-Tag method (Luminex) Cystic Fibrosis 39 Kit v2	Luminex 200 System	Non-CE	LI-MOL-Luminex xTag CF39Kit, LP-MOL-LumxTagCF39dataCheck
	Fragile X		Expansion PCR and sizing , Amplidex PCR CE kit	Bioer thermocycler, Biorad tetrad thermocycler,	Expansion PCR and sizing: Based on standard method	LP-MOL-FRAXPCR&sizing LI-MOL-FRAXAsuragen

			(Asuragen)	MiniAmp thermocyclers, ABI 3500xl Genetic Analyser	Amplidex PCR kit (Asuragen): CE ABI 3130xl/3500: Non-CE	
	Spinal Muscular Atrophy (SMA)		PCR Testing (via MLPA). MLPA assay kits by MRC-Holland-Kit P021-B1	ABI 3500xl Genetic Analyser	MLPA kit: Non -CE (as do not use Coffalyser) ABI 3130xl/3500: Non-CE	LI-MOL-MLPA, LI-MOL-MLPAGeneMarker
1075 Molecular genetics - .10 DNA sequencing	Breast Cancer - hereditary BRCA1 & BRCA2		Sanger sequencing	ABI 3500xl Genetic Analyser	Sanger sequencing: Based on standard method ABI 3500: Non-CE	LI-MOL-SangSeqGen, LI-MOL-BRCAAnalysis
1075 Molecular genetics - .11 DNA extraction	DNA extraction (Cytogenetics & Molecular Genetics)	Whole blood	Magnetic bead technology	Chemagic 360	Non-CE	LI-LAB-ChemDNAextract
	DNA extraction (Cytogenetics)	Blood, Bone marrow, Human tissue	Qiagen Midi kit technique	Manual process N/A	Non-CE, Based on standard method	LP-CYT-CghDNAExtract, LP-CYT-NeoplasticDNAExtract
	DNA extraction (Molecular Genetics)	Whole blood, Dried Blood Spot	Magcore tissue extraction (Magnetic particle technology)	Magcore Plus II Instrument	CE marked	LI-MOL-MagcoreExtract
		Whole blood, Dried Blood Spot, Human tissue	EZ1 DNA extraction (Magnetic bead technology)	EZ1 Advanced, EZ1 Advanced XL	Non-CE (EZ1 Advanced) CE marked (EZ1 Advanced XL)	LI-MOL-EZ1SolidTissue; LI-MOL-DNAExtCFDBS, LI-MOL-EZ1DNAExtract
		Whole blood, Human tissue	Phenol/ Chloroform	N/A Manual Technique	Based on standard method	LI-MOL-PhenolExtraction
1075 Molecular genetics - .99 Miscellaneous tests	Linked STR Markers for Uniparental Disomy (UPD), for Chromosomes 15	DNA	Linked marker PCR	ABI 3500xl Genetic Analyser	Linked marker PCR: Based on standard method ABI 3130xl/3500: Non-CE	LI-MOL-LinkedMarkerPCR