

Schedule of Accreditation



Organisation Name	The Coombe Hospital National Cervical Screening Laboratory
Trading As	
INAB Reg No	420MT
Contact Name	Tomasz Tomczyk
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Website	https://www.coombe.ie/
Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	04/09/2024
Scope Classification	Histopathology and cytopathology
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	National Cervical Screening Laboratory, The Coombe Hospital, Cork Street, Dublin 8, Dublin
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Scope of Accreditation

Head Office

Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1052 Cytopathology - .01 Gynaecological (cervical)	Cytology sample receipt, preparation and description	Thin Prep Cervical Liquid Based Cytology samples, unstained liquid based cytology, cell blocks	N/A	N/A	N/A	NCSL/SR/SOP/1, NCSL/DE/SOP/1
	HPV DNA HR Genotyping	Thin Prep Cervical Liquid Based Cytology samples	HPV Test using COBAS 6800, HPV Test and Cobas Prime, HPV Test using COBAS 8800	CE	HR HPV 16 Detected, HR HPV 18 Detected, HR HPV Other Detected, HR HPV 16 Not Detected, HR HPV 18 Not Detected, HR HPV Other Not Detected, HR HPV Indeterminant	NCSL/HPV/SOP/1, NCSL/HPV/SOP/7

	HPV DNA HR testing		HPV Test using COBAS 6800, HPV Test and Cobas Prime, HPV Test using COBAS 8800	CE	HR HPV Detected, HR HPV Not Detected, HR HPV Indeterminate	NCSL/HPV/SOP/1, NCSL/HPV/SOP/7
	Papanicolaou Staining and Slide Coverslipping	Unstained Liquid Based Cytology slide	Tissue-Tek Prisma® Plus series, Tissue-Tek® Glas™	CE	N/A	NCSL/CYTO/SOP/5
	Screening of stained slides	Stained slides from Liquid Based Cytology Samples	Microscopy	Based on standard method	N/A	NCSL/CYTO/II/1, NCSL/CYTO/SOP/21, NCSL/CYTO/SOP/23
	Slide Preparation		Hologic ThinPrep 5000 with Autoloader - automated, Hologic ThinPrep Genesis with/without associated slide printer - semiautomated	CE	N/A	NCSL/CYTO/SOP/4, NCSL/CYTO/SOP/6, NCSL/CYTO/SOP/7
1052 Cytopathology - .04 Cytopathological interpretation	Diagnostic interpretation and reporting of cervical samples		Microscopy	Based on standard method	N/A	NCSL/CYTO/SOP/21, NCSL/CYTO/SOP/24, NCSL/CYTO/SOP/26