

# Schedule of Accreditation



Organisation Name	Synergy Health Ireland Ltd
Trading As	
INAB Reg No	164T
Contact Name	Panagiota Loule
Address	IDA Business & Technology Park, Tullamore, Offaly, R35 X865
Contact Phone No	
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Website	
Accreditation Standard	EN ISO/IEC 17025 T
Standard Version	2017
Date of award of accreditation	23/05/2005
Scope Classification	Biological and Veterinary Testing
Services available to the public <sup>1</sup>	Yes

<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)

	<b>Name</b>	<b>Address</b>
1	Business Office	IDA Business & Technology Park, Tullamore, Offaly, R35 X865

# Scope of Accreditation

## Business Office

### Biological and Veterinary Testing

Category: A

Biology/veterinary field - Tests	Test name	Technique	Matrix	Equipment	Std. reference	
803 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of bacteria	Microbial counts	Q04-WI-002075 Bioburden (Pour plate and membrane filtration)	Medical devices	Q04-WI-002075 Bioburden	Q04-WI-002075 based on ISO 11737-1:2018	
	Sterility Tests	Q04-WI-002097 - Sterility test using TSB incubated at 20°C - 25°C or FTM incubated at 30°C - 35°C Sterility Test using TSB incubated at 28°C - 32°C Q04-WI-002096 Bacteriostatis and Fungistatsis Test	Medical Devices	Q04-WI-002097 Sterility, Q04-WI-002096 Bacteriostatis and Fungistatsis Test	Q04-WI-002097 based on US and European Pharmacopeia (Current Revision) Q04-WI-002097 based on EN ISO 11137-2:2013 and ISO 11737-2:2019 Q04-WI-002096 based on US and European Pharmacopeia (Current Revision)	

803 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Microbial counts	Q04-WI-002075 Bioburden (Pour plate and membrane filtration)	Medical devices	Q04-WI-002075 Bioburden	Q04-WI-002075 based on ISO 11737-1:2018	
	Sterility Tests	Q04-WI-002097- Sterility test using TSB incubated at 20°C - 25°C or FTM incubated at 30°C - 35°C Sterility Test using TSB incubated at 28°C - 32°C Q04-WI-002096- Bacteriostatis and Fungistatsis Test	Medical Devices	Q04-WI-002097 Sterility, Q04-WI-002096 Bacteriostatis and Fungistatsis Test	Q04-WI-002097 based on US and European Pharmacopeia (Current Revision) Q04-WI-002097 based on EN ISO 11137-2:2015 and ISO 11737-2:2019 Q04-WI-002096 based on US and European Pharmacopeia (Current Revision). Plus based on EN ID ISO 11137-2:2015 and ISO 11737-2:2019	
822 Detection of Bacterial Endotoxins - .01 Kinetic Turbidimetric, CE marked commercial systems	Endotoxin tests	Q04-WI-002091-LAL	Medical devices	Q04-WI-002091 - LAL	Method based on ISO 11737-3:2023, US and European Pharmacopeia (Current revision)	
		Turbidimetric method 0.01 to 10 EU/mL	Medical devices	Q04-WI-002091 LAL Tube Reader	Method based on ISO 11737-3:2023, US and European Pharmacopeia (Current Revision).	
822 Detection of Bacterial Endotoxins - .03 Gel-clot test, CE marked commercial systems		Gel Clot method: 0.007 to 0.25 EU/mL	Medical devices	Q04-WI-002091 - LAL	Method based on ISO 11737-3:2023, US and European Pharmacopeia (Current revision)	

