

# Schedule of Accreditation



Organisation Name	Synergy Health Ireland Ltd
Trading As	
INAB Reg No	164T
Contact Name	Stephanie Parsons
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Accreditation Standard	ISO 17025 T
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)		
	Name	Address
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	WI-LAB-015 Bioburden (Pour plate and membrane filtration)	Medical devices	WI-LAB-15 Bioburden	WI-LAB-015 based on ISO 11737-1:2018
	Sterility Tests	WI-LAB-042- 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 WI-LAB-041 Bacteriostatis and Fungistatsis Test	Medical Devices	WI-LAB-042 Sterility, WI-LAB-041 Bacteriostatis and Fungistatsis Test	WI-LAB-042 based on US and European Pharmacopeia (Current Revision) WI-LAB-042 based on EN ISO 11137-2:2013 and ISO 11737-2:2019 WI-LAB-041 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	WI-LAB-015 Bioburden (Pour plate and membrane filtration)	Medical devices	WI-LAB-15 Bioburden	WI-LAB-015 based on ISO 11737-1:2018
	Sterility Tests	WI-LAB-042- Sterility test using TSB incubated at 20°C - 25°C or FTM incubated at 30°C - 35°C	Medical Devices	WI-LAB-042 Sterility, WI-LAB-041 Bacteriostatis and Fungistatsis Test	WI-LAB-042 based on US and European Pharmacopeia (Current Revision)

		Sterility Test using TSB incubated at 28°C - 32°C WI-LAB-041 Bacteriostatis and Fungistatis Test			WI-LAB-042 based on EN ISO 11137-2:2015 and ISO 11737-2:2019 WI-LAB-041 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	Turbidimetric method: 0.01 to 10 EU/mL	Medical devices	WI-LAB-027-LAL	Method based on 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	WI-LAB-027-LAL	Method based on US and European Pharmacopeia (Current revision)