

LABORATORY SERVICES



TEST PORTFOLIO OF MICROBIOLOGICAL LABORATORY TESTING SERVICES 2012

VERSION 2012-2

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INTRODUCTION

All Synergy Health sterilisation and contamination control operations are supported by state of the art microbiology laboratories. With a primary focus on healthcare and related industries, Synergy Health facilities are able to provide a range of regulatory compliant tests required within ISO 11135 and ISO 11137, including microbiological validations and determination of contamination levels. In addition to the medical device market, other industries such as cosmetics & toiletries, packaging and labware can also benefit from the range of tests, training and consultation provided by Synergy Health.

BENEFITS

The benefits to our customers

One stop shop

- “You give us the samples, we give the validated dose”
- No requirement for the customer to be involved in setting dose or organising samples to be transported between the irradiation provider and the laboratory services provider
- No requirement for the customer to deal with a number of different companies and contacts

Full technical support

- All validation work and ancillary tests will be undertaken by our laboratory specialists trained in all of the sterilisation techniques
- The laboratories will work closely together with our inhouse sterilisation experts to establish the dose
- Global network of connected laboratories and dedicated specialists
- Global network of connected sterilisation companies

Savings

- Significant savings in both lead time and cost because of the close relationship with our sterilisation company
- Facilitating cost reductions and improved turnaround times for product release
- Suggesting alternatives in reducing lead times
- We will offer you a free quote to show the advantages

“Why don’t you work with the sterilisation experts and allow them to take care of all your associated validation and laboratory requirements in a timely and cost efficient manner”

ACCREDITATIONS

Microbiology testing by SynergyHealth in Europe is implemented in our custom built facility in the Netherlands where the laboratories are fully accredited for ISO 9001, ISO 13485 and GMP.

GENERAL INFORMATION

This document is a guide that provides information of the standard test portfolio. For custom testing an individual test protocol and price quotation may be made based on the complexity of the product and the level of testing required.

Typical time frame for a complete Validation, ISO 11137-2:2006 (Method 1 and VDmax)

Item Description	Week Number									
	--	--	1	2	3	4	5	6	7	8
Protocol Definition	■	■								
Quotation		■								
Samples at lab			■							
Samples 25 kGy				■						
Pre-Bioburden				■						
Bioburden Validation				■						
Bioburden Assay					■					
Verification Dose						■				
Sterility Test							■			
Completion Report										■

■	Typical time frame
■	Fixed testing times

Report and standard lead time Validation Packages

Reports will be in English. Standard lead time is:

- Initial Validation : 8 weeks
- Periodic Dose Audit(s): 4 - 6 weeks

Chapter 1

Validations according to ISO 11137-2:2006 Method 1

145 samples – 8 weeks validated dose

Initial Validation:

Test description	Required number of samples
Sample examination / Backup	10
Validation of the Bioburden technique	5
Bioburden Assay* (Aerobes, Yeasts and Moulds)	10
	10
	10
Verification Experiment** (Verification Dose and Sterility Test)	100
Total number of samples	145

* For the Bioburden Assay 3 different batch numbers are required

** E-beam verification experiment 3 extra samples required

Periodic Dose Audit:

Test description	Required number of samples
Bioburden Assay (Aerobes, Yeasts and Moulds)	10
Verification Experiment (Verification Dose and Sterility Test)	100
Total number of samples	110

Chapter 2

Validations according to ISO 11137-2:2006 Method VDmax25 Multiple production batches

55 samples – 8 weeks 25 kGy verified dose

Initial Validation:

Test description	Required number of samples
Sample examination / Backup	10
Validation of the Bioburden technique	5
Bioburden Assay* (Aerobes, Yeasts and Moulds)	10
	10
	10
Verification Experiment** (Verification Dose and Sterility Test)	10
Total number of samples	55

* For the Bioburden Assay 3 different batch numbers are required

** E-beam verification experiment 3 extra samples required

Periodic Dose Audit:

Test description	Required number of samples
Bioburden Assay (Aerobes, Yeasts and Moulds)	10
Verification Experiment (Verification Dose and Sterility Test)	10
Total number of samples	20

Remarks:

- Bioburden Assay may not exceed 1,000 cfu/unit
- Routine irradiation at minimal 25 kGy
- Other VDmax methods can be performed, including methods according to AAMI TIR33. Please contact us for further information

Chapter 3

Validations according to ISO 11137-2:2006 Method VDmax25 Single production batch

35 samples – 8 weeks 25 kGy verified dose

Test description	Required number of samples
Sample examination / Backup	10
Validation of the Bioburden technique	5
Bioburden Assay (Aerobes, Yeasts and Moulds)	10
Verification Experiment* (Verification Dose and Sterility Test)	10
Total number of samples	35

* E-beam verification experiment 3 extra samples required

Remarks:

- Bioburden Assay may not exceed 1,000 cfu/unit
- Irradiation of that batch at minimal 25 kGy
- Other VDmax methods can be performed, including methods according to AAMI TIR33. Please contact us for further information

Chapter 4

Accelerated Aging Tests According to ASTM F1980-07

Accelerated Aging Tests protocols designed to the requirements of the customer in accordance with **ASTM F1980-07 “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”**.

Price proposal generated based on the product, incubation temperature and time. The price contains the standard incubation period in the oven, (optional) Sterility Tests and the report.

Because accelerated aging is performed at relative high temperatures, the samples will be stored at room temperature for 2 weeks after the aging period, before starting sterility testing.

Typical time frame and conditions for accelerated aging tests, including 10 Sterility Tests per aging period and report:

Aging Period	Oven use at 55 °C (period)	Sterility Test (period)	Report (period)
1 year	6 weeks	4 weeks	within 1 week
2 years	11 weeks	4 weeks	within 1 week
3 years	16 weeks	4 weeks	within 1 week
4 years	22 weeks	4 weeks	within 1 week
5 years	27 weeks	4 weeks	within 1 week

Often used package is a total of 20 samples:
10 samples return to the customer for Functionality Tests and 10 samples are tested on Sterility.

Remarks:

- Next to Accelerated Aging a real time aging study is required. Results of the accelerated study can be used awaiting the real time study
- Sterility testing is optional but is often used for additional information about the microbiological status of the product after accelerated aging

Chapter 5

Routine Laboratory Tests

Bioburden Test according to ISO 11737-1
Bioburden, Total Aerobes
Bioburden, Total Aerobes, Yeasts and Moulds
Bioburden, Total Aerobes, Spores, Yeasts and Moulds
Bioburden Validation according to ISO 11737-1
Bioburden Validation, Inoculative Method
Bioburden Validation, Repetitive Recovery Method, 5 washes
Bioburden Validation, Repetitive Recovery Method, 10 washes
B&F Test according to ISO 11737-1 and EP/USP (= suitability of the method in the presence of the product Ph.Eur 2.6.12)
Sterility Test according to ISO 11737-2
Direct Transfer Method-per product (TSB & FTM) 100 ml media 14 days
Direct Transfer Method-per product (TSB & FTM) 400 ml media 14 days
Direct Transfer Method-per product (TSB & FTM) 1,000 ml media 14 days
B&F test according to ISO 11737-2 Tested in samples of sterility test (Ph.Eur micro organisms)
B&F test according to ISO 11737-2 and EP/USP (= Ph.Eur 2.6.1 Method suitability test)
Micro Organism Identification
Organism Characterisation using Gram Reaction and Colony Morphology
Gram Reaction, Colony Morphology and Organism Identification using BBL Crystal Identification system
Bacterial Endotoxin Test (LAL test): Gel-Clot or Kinetic/Turbidimetric according to EP/USP
Validation of the method (once per product) From 3 batches, each 3 -10 items are required
Routine test based on validation report. Per batch 3 -10 items are required

Remarks:

- Standard lead times:
 - Bioburden Test: 1 week
 - Bioburden Validation: 2 weeks
 - Sterility Test: 2 weeks
 - Micro Organism Identification: 1 week
 - Bacterial Endotoxin Test: 1 week

Chapter 6

Environmental Monitoring of production location, cleanroom etc.

Contact plates, Rodac, 6 cm, cleanroom quality
Settle plates, (= passive air sample) TSA plate 9 cm
Finger prints, TSA plate 9 cm
Active air sample (for example Mas100)
Monitoring on location, per hour

Remarks:

- Prevent shipment of samples during the weekend
- Standard lead time: 1 week

Synergy Health Laboratory Services Contact Information

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