



Certificate of Analysis-CRY-120

PRODUCT batch number: P734604
BASE batch number: P734602
ACTIVATOR batch number: P734601

Product Name:	Cry-Spore (Sterile 5L)	
Product batch number:	P734604	
Reference:	CRY/SPO/023	
This is to certify that Cry-Spore (Sterile 5L) Working Solution bearing the batch no's: P734602 and P734601 were tested on 2017-12-07 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear pale yellow liquid free of matter	Conforms
SPECIFIC GRAVITY	0.995 – 1.005	1.002
pH	2.5 – 5.5	3.0
ClO ₂ concentration – after 10 minutes (ppm)	230 – 280	250

Product Name:	Cry-Spore (Sterile 5L) Base Solution	
Reference:	CRY/SPO/022	
Date of Manufacture:	2017-12-06	
Date of Expiry:	2019-12	
This is to certify that Cry-Spore (Sterile 5L) Base Solution was tested on 2017-12-06 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear, blue liquid free of matter	Conforms
SPECIFIC GRAVITY	0.995 – 1.005	1.002
pH	2.5 – 3.5	2.8
STERILITY	No growth	Conforms





Product Name:	Cry-Spore (Sterile 5L) Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	2017-11-06	
Date of Expiry:	2019-11	
This is to certify that Cry-Spore (Sterile 5L) Activator Solution was tested on 2017-11-06 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear and free of matter	Conforms
SPECIFIC GRAVITY	1.015 – 1.035	1.017
pH	11.5 – 13.0	11.8
SODIUM CHLORITE	2.10% +/- 0.1%	2.14%
STERILITY	No growth	Conforms

Completed By:

Quality Department: *E. Andrews*

Date: *2018-01-16*

Reviewed By:

S. Kielinska

Date: *2018-01-16*





Specialists in Endotoxin and Glucan Detection

Sterility Testing Analytical Report

Please note the results below are not generated at Associates of Cape Cod Int. Inc., but reported from a subcontractor's final report.

Sample ID: CRY120 Cryspore Base
Lot No: P734602
ICN: 1217022F
Subcontractor's Report Number: 2017237488

Lab Book Reference: ST03-120
Date Received: 15 Dec 2017
Date Completed: 05 Jan 2018
No. of samples: 4

Sterility Test – Membrane Filtration

Medium	Result
Tryptone Soy Broth	No growth
Fluid Thioglycolate Medium	No growth

Conclusions:

The samples submitted comply with the test for sterility in accordance with the client's methodology.

Results Reported by:


Laboratory Technician/Designee: Daniel Jennings

Date: 05 JAN 2018

Reviewed by:


 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 05 JAN 2018

QA Approved by:


 Quality Assurance
 UK General Manager
 Technical Manager

Date: 09 JAN 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	D. Jennings	05 Jan 2018

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ST03-120

ICN: 1217022F

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REVISION NO: 1

DATE: 05 Jan 2018

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Web: www.acciuk.co.uk

Registered in England and Wales Company Registration Number: BR002906



Specialists in Endotoxin and Glucan Detection

Sterility Testing Analytical Report

Please note the results below are not generated at Associates of Cape Cod Int. Inc., but reported from a subcontractor's final report.

Sample ID: CRY120 Cryspore Activator
Lot No: P734601
ICN: 1217022F
Subcontractor's Report Number: 2017237489

Lab Book Reference: ST03-119
Date Received: 15 Dec 2017
Date Completed: 05 Jan 2018
No. of samples: 4

Sterility Test – Membrane Filtration

Medium	Result
Tryptone Soy Broth	No growth
Fluid Thioglycollate Medium	No growth

Conclusions:

The samples submitted comply with the test for sterility in accordance with the client's methodology.

Results Reported by:


.....
Laboratory Technician/Designee: Daniel Jennings

Date: 05 JAN 2018

Reviewed by:


.....
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 05 JAN 2018

QA Approved by:


.....
 Quality Assurance
 UK General Manager
 Technical Manager

Date: 09 JAN 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	D. Jennings	05 Jan 2018

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ST03-119

ICN: 1217022F

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REVISION NO: 1

DATE: 05 Jan 2018

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Registered in England and Wales. Company Registration Number: 118002906



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 24-Apr-2017

UK33S11858352-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075875
Customer Reference Number:	704663
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	20
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	11042017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	24-Apr-2017 12:23
Reference Dose Range kGy:	32.1 - 32.7
Calculated Minimum Dose kGy:	30.5
Calculated Maximum Dose kGy:	35.0

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 19-Apr-2017

UK33S11854017-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075628
Customer Reference Number:	704631
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	07042017

Irradiation Data

Date and Time of Irradiation:	19-Apr-2017 01:02
Reference Dose Range kGy:	32.1 - 32.6
Calculated Minimum Dose kGy:	30.6
Calculated Maximum Dose kGy:	35.6

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 28-Sep-2017

UK33S11968580-2-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075625
Customer Reference Number:	705597
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	20170919, 1 PLT

Irradiation Data

Date and Time of Irradiation:	27-Sep-2017 22:48
Reference Dose Range kGy:	32.4 - 32.4
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	36.4

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 15-Mar-2017

UK33S11829406-2-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1078033
Customer Reference Number:	704369
Product Description:	BAG002 DV4268 25-70kGy
Validation Reference:	4268
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	70.0
Customer Unit Lot/Batch Number:	21022017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	14-Mar-2017 18:57
Reference Dose Range kGy:	54.6 - 54.6
Calculated Minimum Dose kGy:	37.0
Calculated Maximum Dose kGy:	59.0

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
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