



Certificate of Analysis-CRY-120

PRODUCT batch number: P812101

BASE batch number: P812100

ACTIVATOR batch number: P812000

Product Name:	Cry-Spore (Sterile 5L)	
Product batch number:	P812101	
Reference:	CRY/SPO/023	
This is to certify that Cry-Spore (Sterile 5L) Working Solution bearing the batch no's: P812100 and P812000 were tested on 2018-04-30 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	1.000
pH	2.5 – 5.5	3.0
ClO ₂ concentration – after 10 minutes (ppm)	230 – 280	236

Product Name:	Cry-Spore (Sterile 5L) Base Solution	
Reference:	CRY/SPO/022	
Date of Manufacture:	2018-04-30	
Date of Expiry:	2020-04-30	
This is to certify that Cry-Spore (Sterile 5L) Base Solution P812100 was tested on 2018-04-30 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	1.000
pH	2.5 – 3.5	2.7
STERILITY	No growth	Conforms





Product Name:	Cry-Spore (Sterile 5L) Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	2018-04-25	
Date of Expiry:	2020-04-25	
This is to certify that Cry-Spore (Sterile 5L) Activator Solution P812000 was tested on 2018-04-25 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	1.015
pH	11.5 – 13.0	12.0
SODIUM CHLORITE	2.10% +/- 0.1%	2.1%
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E. Andrews

[Signature]

Date: 2018-05-30

Date: 2018-05-30



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: P812100
ICN: 0518003D
Subcontractor's Report Number: 2018079715

Lab Book Reference: ST03-165
Date Received: 02 MAY 2018
Date Completed: 24 MAY 2018
No. of samples: 10

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: L. Ellis

Date: 24 MAY 2018

Reviewed by:


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

Date: 25 MAY 2018

QA Approved by:


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

Date: 25 MAY 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L Ellis	24 MAY 2018

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ST03-165

ICN: 0518003D

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REVISION NO: 1

DATE: 24 MAY 2018

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Germany
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Fax: 0049 6105 96 10 15

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: P812000
ICN: 0518003D
Subcontractor's Report Number: 2018079716

Lab Book Reference: ST03-164
Date Received: 02 May 2018
Date Completed: 23 May 2018
No. of samples: 10

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:

[Signature]
 Laboratory Technician/Designee: C.Thornton

Date: 23 May 2018

Reviewed by:

[Signature]
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 23 May 2018

QA Approved by:

[Signature]
 Quality Assurance
 UK General Manager
 Technical Manager

Date: 23 May 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	23 May 2018

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 ST03-164

ICN: 0518003D

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REVISION NO: 1

DATE: 23 May 2018

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<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 21-Apr-2018

UK33S12091361-3-2

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	706954
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	15
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BN: 20180328, 1 PLT

Irradiation Data

Date and Time of Irradiation:	21-Apr-2018 21:48
Reference Dose Range kGy:	33.5 - 33.9
Calculated Minimum Dose kGy:	31.8
Calculated Maximum Dose kGy:	36.3

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 21-Apr-2018

UK33S12091361-3-4

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	706954
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	15
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BN: 20180328, 1 PLT

Irradiation Data

Date and Time of Irradiation:	21-Apr-2018 22:11
Reference Dose Range kGy:	33.3 - 33.7
Calculated Minimum Dose kGy:	31.6
Calculated Maximum Dose kGy:	36.1

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 21-Apr-2018

UK33S12091361-3-5

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	706954
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	15
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BN: 20180328, 1 PLT

Irradiation Data

Date and Time of Irradiation:	21-Apr-2018 22:11
Reference Dose Range kGy:	33.5 - 33.9
Calculated Minimum Dose kGy:	31.8
Calculated Maximum Dose kGy:	36.3

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 25-Feb-2018

UK33S12061299-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121930
Customer Reference Number:	706585
Product Description:	100ML BOTTLE CAP DV5165 25-45kGy
Validation Reference:	5165
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	07022018, 1 PLT

Irradiation Data

Date and Time of Irradiation:	24-Feb-2018 19:32
Reference Dose Range kGy:	33.5 - 33.5
Calculated Minimum Dose kGy:	30.7
Calculated Maximum Dose kGy:	37.3

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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
 Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069