



## Certificate of Analysis-CRY 119

**PRODUCT** batch number: P804503  
**BASE** batch number: P804403  
**ACTIVATOR** batch number: P804501

Product Name:	<b>Cry-Spore Working Solution</b>	
Product batch number:	P804503	
Reference:	CRY/SPO/021	
This is to certify that Cry-Spore Working Solution bearing the batch no's: P804403 and P804501 were tested on 2018-02-08 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	2.9
CIO <sub>2</sub> Concentration – after 10 minutes (ppm)	230 – 280	236

Product Name:	<b>Cry-Spore Base Solution</b>	
Reference:	CRY/SPO/020	
Date of Manufacture:	2018-02-07	
Date of Expiry:	2020-02-07	
This is to certify that Cry-Spore Base Solution was tested on 2018-02-08 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	1.020 – 1.060	1.022
pH	1.5 – 3.5	1.8
STERILITY	No growth	Conforms





Product Name:	<b>Cry-Spore Activator Solution</b>	
Reference:	CRY/SPO/019	
Date of Manufacture:	2018-02-07	
Date of Expiry:	2020-02-07	
This is to certify that Cry-Spore Activator Solution was tested on 2018-02-08 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	11.7
SODIUM CHLORITE	2.10% +/- 0.1%	2.17%
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: *E. Andrews*

*[Signature]*

Date: *2018-03-20*

Date: *2018-03-20*



**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:** Cry119 Cryspore Base  
**Lot No:** P804403  
**ICN:** 0218018D  
**Subcontractor's Report Number:** 2018034113

**Lab Book Reference:** ST03-135  
**Date Received:** 19 Feb 2018  
**Date Completed:** 15 Mar 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: C.Thornton

Date: 15 MAR 2018

**Reviewed by:**

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

Date: 16 Mar 2018

**QA Approved by:**

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

Date: 16 MAR 2018

**Revision History:**

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	15 Mar 2018

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**ST03-135**

**ICN: 0218018D**

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**TSCTS044-1 Rev 3**

**REVISION NO: 1**

**DATE: 15 Mar 2018**

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Web: [www.acciuk.co.uk](http://www.acciuk.co.uk)

### 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:** Cry119 Cryspore Activator  
**Lot No:** P804501  
**ICN:** 0218018D  
**Subcontractor's Report Number:** 2018034112

**Lab Book Reference:** ST03-136  
**Date Received:** 19 Feb 2018  
**Date Completed:** 15 Mar 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: C.Thornton

Date: 15 MAR 2018

#### Reviewed by:

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

Date: 16 Mar 2018

#### QA Approved by:

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

Date: 16 MAR 2018

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	15 Mar 2018

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ST03-136

ICN: 0218018D

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TSCS044-1 Rev 3

REVISION NO: 1

DATE: 15 Mar 2018

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Registered in England and Wales. Company Registration Number: BR002906



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

## Certificate of Irradiation

Date Issued: 24-Dec-2017

UK33S12027411-1-2

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

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121497
Customer Reference Number:	705881
Product Description:	BOTTLE 100ML DV5155 25-45kGy
Validation Reference:	5155
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	20171009, 1 plt

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### Irradiation Data

Date and Time of Irradiation:	24-Dec-2017 02:11
Reference Dose Range kGy:	31.0 - 31.3
Calculated Minimum Dose kGy:	29.1
Calculated Maximum Dose kGy:	33.9

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

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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



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## Certificate of Irradiation

Date Issued: 16-Dec-2017

UK33S12027152-2-3

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

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121497
Customer Reference Number:	706118
Product Description:	BOTTLE 100ML DV5155 25-45kGy
Validation Reference:	5155
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	20112017, 1 PLT

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### Irradiation Data

Date and Time of Irradiation:	16-Dec-2017 09:05
Reference Dose Range kGy:	31.7 - 31.9
Calculated Minimum Dose kGy:	29.8
Calculated Maximum Dose kGy:	34.6

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

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## Certificate of Irradiation

Date Issued: 08-Jan-2018

UK33S12037706-1-1

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  
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Suffolk CB8 7NY  
UNITED KINGDOM

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121930
Customer Reference Number:	706256
Product Description:	100ML BOTTLE CAP DV5165 25-45kGy
Validation Reference:	5165
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	CAP001-G, BN: 20122017, EXP: 20191230, 1 plt

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### Irradiation Data

Date and Time of Irradiation:	08-Jan-2018 11:20
Reference Dose Range kGy:	34.4 - 34.4
Calculated Minimum Dose kGy:	31.6
Calculated Maximum Dose kGy:	38.3

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

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

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# Certificate of Irradiation

Date issued: 11-Oct-2016

UK33S11712941-4-1

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

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1108122
Customer Reference Number:	703172
Product Description:	CAP030-G 25-45kGy SINGLE VAL
Quantity Received:	11
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	VALIDATION, 1 plt
Other Process Details:	Actual min dose: 29.1kGy Actual max dose: 34.7ky

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## Irradiation Data

Date and Time of Irradiation:	11-Oct-2016 11:41
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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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<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 15-Jan-2018

UK33S12041486-1-1

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

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121936
Customer Reference Number:	706279
Product Description:	BAG 004-G DV5175 25-45kGy
Validation Reference:	5175
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	06112017, 1 PLT

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### Irradiation Data

Date and Time of Irradiation:	15-Jan-2018 21:52
Reference Dose Range kGy:	33.7 - 33.7
Calculated Minimum Dose kGy:	25.9
Calculated Maximum Dose kGy:	36.1

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

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