



## Certificate of Analysis-CRY 119

PRODUCT batch number: P702601  
 BASE batch number: P702600  
 ACTIVATOR batch number: P628000

Product Name:	Cry-Spore Working Solution	
Product batch number:		
Reference:	CRY/SPO/021	
This is to certify that Cry-Spore Working Solution bearing the batch no's: P702600 and P628000 were tested on 24-JAN-17 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 <sub>2</sub> Concentration – after 10 minutes (ppm)	230 – 280	236

Product Name:	Cry-Spore Base Solution	
Reference:	CRY/SPO/020	
Date of Manufacture:	15-NOV-16	
Date of Expiry:	NOV-2018	
This is to certify that Cry-Spore Base Solution P702600 was tested on 15-NOV-16 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	1.024
pH	1.5 – 3.5	1.8
STERILITY	No growth	Conforms





Product Name:	Cry-Spore Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	16-SEP-2016	
Date of Expiry:	SEP-2018	
This is to certify that Cry-Spore Activator Solution P628000 was tested on 16-SEP-2016 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%	2.1%
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E Andrews

[Signature]

Date: 7 MAR 2017

Date: 07-MAR-2017



### 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:** P702600  
**ICN:** 0217005D  
**Subcontractor's Report Number:** 2017023945

**Lab Book Reference:** ST03-59  
**Date Received:** 02 Feb 2017  
**Date Completed:** 28 Feb 2017  
**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: Sophie Hughes


Date: 18 Feb 2017

#### Reviewed by:

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

Date: 02 Mar 2017

#### QA Approved by:

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

Date: 02 MAR 2017

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	28 Feb 2017

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ST03-59  
REVISION NO: 1

ICN: 0217005D  
DATE: 28 Feb 2017

TSCTS044-1 Rev 2

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

Registered in England and Wales. Company Registration Number: BR002906

### 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:** P628000  
**ICN:** 0217005D  
**Subcontractor's Report Number:** 2017023895

**Lab Book Reference:** ST03-62  
**Date Received:** 02 Feb 2017  
**Date Completed:** 28 Feb 2017  
**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: Sophie Hughes

Date: 28 Feb 2017

#### Reviewed by:

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

Date: 02 Mar 2017

#### QA Approved by:

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

Date: 02 Mar 2017

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	28 Feb 2017

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ST03-62  
REVISION NO: 1

ICN: 0217005D  
DATE: 28 Feb 2017

YSCTS044-1 Rev 2

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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 28-Nov-2016

UK33S11753022-3-2

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:	1075628
Customer Reference Number:	703612
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	22
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	11112016, 1 pit

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## Irradiation Data

Date and Time of Irradiation:	26-Nov-2016 07:58
Reference Dose Range kGy:	32.2 - 32.5
Calculated Minimum Dose kGy:	30.7
Calculated Maximum Dose kGy:	35.5

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



<http://www.synergyhealthplc.com>

# 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 plit
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  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



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# Certificate of Irradiation

Date Issued: 30-Jul-2016

UK33S11673290-1-1

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

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075628
Customer Reference Number:	702783
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	14
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BOTTLE 012, 1PLT

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## Irradiation Data

Date and Time of Irradiation:	30-Jul-2016 01:08
Reference Dose Range kGy:	31.5 - 31.9
Calculated Minimum Dose kGy:	30.0
Calculated Maximum Dose kGy:	34.8

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Irradiation Release Authorised By Synergy Health plc

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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: 11-Aug-2016

UK33S11678232-2-1

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

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075625
Customer Reference Number:	702828
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1 plt

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## Irradiation Data

Date and Time of Irradiation:	11-Aug-2016 02:38
Reference Dose Range kGy:	33.4 - 33.4
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	37.5

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





<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 04-Aug-2016

UK33S11669509-2-1

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

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1096575
Customer Reference Number:	702752
Product Description:	BAG004 DV4398 25-40kGy
Validation Reference:	4398
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG 004, 1PLT

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## Irradiation Data

Date and Time of Irradiation:	28-Jul-2016 00:05
Reference Dose Range kGy:	32.2 - 32.2
Calculated Minimum Dose kGy:	25.2
Calculated Maximum Dose kGy:	36.2

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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

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