



## Certificate of Analysis-CRY-120

**PRODUCT** batch number: P709701

**BASE** batch number: P709700

**ACTIVATOR** batch number: P709600

<b>Product Name:</b>	<b>Cry-Spore (Sterile 5L)</b>	
<b>Product batch number:</b>	P709701	
<b>Reference:</b>	CRY/SPO/023	
This is to certify that Cry-Spore (Sterile 5L) Working Solution bearing the batch no's: P709700 and P709600 were tested on 30-MAR-2017 and found to comply with all requirements as set out in the specifications and method of analysis.		
<b>PROPERTIES</b>	<b>SPECIFICATION</b>	<b>RESULTS</b>
<b>APPEARANCE</b>	Clear pale yellow liquid free of matter	Conforms
<b>SPECIFIC GRAVITY</b>	0.995 – 1.005	1.000
<b>pH</b>	2.5 – 5.5	3.1
<b>ClO<sub>2</sub> concentration – after 10 minutes (ppm)</b>	230 – 280	236

<b>Product Name:</b>	<b>Cry-Spore (Sterile 5L) Base Solution</b>	
<b>Reference:</b>	CRY/SPO/022	
<b>Date of Manufacture:</b>	24-MAR-2017	
<b>Date of Expiry:</b>	MAR-2019	
This is to certify that Cry-Spore (Sterile 5L) Base Solution was tested on 24-MAR-2017 and found to comply with all requirements as set out in the specifications and method of analysis.		
<b>PROPERTIES</b>	<b>SPECIFICATION</b>	<b>RESULTS</b>
<b>APPEARANCE</b>	Clear, blue liquid free of matter	Conforms
<b>SPECIFIC GRAVITY</b>	0.995 – 1.005	1.002
<b>pH</b>	2.5 – 3.5	2.9
<b>STERILITY</b>	No growth	Conforms





Product Name:	Cry-Spore (Sterile 5L) Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	13-MAR-2017	
Date of Expiry:	MAR-2019	
This is to certify that Cry-Spore (Sterile 5L) Activator Solution was tested on 13-MAR-2017 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	11.8
SODIUM CHLORITE	2.10% +/- 0.1%	2.13%
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E. Andrews

[Signature]

Date: 19 MAY 2017

Date: 19 May 17





ASSOCIATES OF  
**CAPE COD**  
INTERNATIONAL

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:** P709700  
**ICN:** 0417014F  
**Subcontractor's Report Number:** 2017074937

**Lab Book Reference:** ST03-77  
**Date Received:** 18 Apr 2017  
**Date Completed:** 17 May 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:

*[Signature]*  
.....  
Laboratory Technician: Sophie Hughes

Date: 17 May 2017

#### Reviewed by:

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

Date: 18 May 2017

#### QA Approved by:

*[Signature]*  
.....  
 Quality Assurance Manager  
 UK General Manager  
 Technical Manager

Date: 18 May 2017

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	17 May 2017

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ST03-77  
REVISION NO: 1

ICN: 0417014F  
DATE: 17 May 2017

TSCTS044-1 Rev 2

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Opelstrasse 14  
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Germany  
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Fax: 0049 6105 96 10 15

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

<b>Sample ID:</b> CRY120 Cryspore Activator <b>Lot No:</b> P709600 <b>ICN:</b> 0417014F <b>Subcontractor's Report Number:</b> 2017074934	<b>Lab Book Reference:</b> ST03-78 <b>Date Received:</b> 18 Apr 2017 <b>Date Completed:</b> 17 May 2017 <b>No. of samples:</b> 10
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### 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: 17 May 2017

### Reviewed by:

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

Date: 18 May 2017

### QA Approved by:

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

Date: 18 May 2017

### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	17 May 2017

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**ST03-78**  
**REVISION NO: 1**

**ICN: 0417014F**  
**DATE: 17 May 2017**

**TSCTS044-1 Rev 2**

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Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 24-Jan-2016

UK33S11548240-1-1

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:	1075875
Customer Reference Number:	701379
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	44
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	CRY/SP, 2pits

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## Irradiation Data

Date and Time of Irradiation:	24-Jan-2016 22:01
Reference Dose Range kGy:	35.4 - 36.0
Calculated Minimum Dose kGy:	33.6
Calculated Maximum Dose kGy:	38.5

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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: 03-Dec-2016

UK33S11753022-1-1

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

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 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:	1075875
Customer Reference Number:	703612
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	50
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	11112016, 2 plts

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### Irradiation Data

Date and Time of Irradiation:	03-Dec-2016 04:21
Reference Dose Range kGy:	31.6 - 32.5
Calculated Minimum Dose kGy:	30.0
Calculated Maximum Dose kGy:	34.8

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



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## Certificate of Irradiation

Date Issued: 12-Aug-2016

UK33S11678232-4-1

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:	1075628
Customer Reference Number:	702828
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BOTTLE 013, 1 plt

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### Irradiation Data

Date and Time of Irradiation:	11-Aug-2016 22:12
Reference Dose Range kGy:	33.0 - 33.0
Calculated Minimum Dose kGy:	31.4
Calculated Maximum Dose kGy:	36.0

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

Date Issued: 06-Mar-2017

UK33S11824859-3-1

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  
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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075625
Customer Reference Number:	704309
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	22022017, 1 plt

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### Irradiation Data

Date and Time of Irradiation:	06-Mar-2017 00:44
Reference Dose Range kGy:	35.2 - 35.2
Calculated Minimum Dose kGy:	30.6
Calculated Maximum Dose kGy:	39.5

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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  
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## Certificate of Irradiation

Date Issued: 09-Mar-2016

UK33S11555976-2-1

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:	1078033
Customer Reference Number:	701467
Product Description:	BAG002 DV4268 25-70kGy
Validation Reference:	4268
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	70.0
Customer Unit Lot/Batch Number:	BAG 002-G, 1 plt

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### Irradiation Data

Date and Time of Irradiation:	09-Mar-2016 09:29
Reference Dose Range kGy:	55.7 - 56.3
Calculated Minimum Dose kGy:	37.8
Calculated Maximum Dose kGy:	60.8

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Irradiation Release Authorised By Synergy Health plc

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