



## Certificate of Analysis-CRY-120

**PRODUCT** batch number: P632604

**BASE** batch number: P632603

**ACTIVATOR** batch number: P632600

|  |   |                |
|--|---|----------------|
| <b>Product Name:</b>   | <b>Cry-Spore RTU Working Solution</b>   |                |
| <b>Product batch number:</b>   | P632604                                 |                |
| <b>Reference:</b>  | CRY/SPO/023                             |                |
| This is to certify that Cry-Spore RTU Working Solution bearing the batch no's P632603 and 632600 were tested on 17-NOV-16 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 RTU Base Solution</b> |                |
| <b>Reference:</b>  | CRY/SPO/022                        |                |
| <b>Date of Manufacture:</b>  | 17-NOV-16                          |                |
| <b>Date of Expiry:</b>   | Nov-2018                           |                |
| This is to certify that Cry-Spore RTU Base Solution P632603 was tested on 17-NOV-16 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                      | 1.000          |
| <b>pH</b>  | 2.5 – 3.5                          | 2.8            |
| <b>STERILITY</b>   | No growth                          | Conforms       |





| Product Name:   | Cry-Spore Activator Solution |          |
|---|------------------------------|----------|
| Reference:  | CRY/SPO/019                  |          |
| Date of Manufacture:  | 14-NOV-16                    |          |
| Date of Expiry:   | NOV-2018                     |          |
| This is to certify that Cry-Spore Activator Solution P632600 was tested on 14-NOV-16 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                  | 11.5     |
| SODIUM CHLORITE   | 2.10% +/- 0.1%               | 2.14%    |
| STERILITY   | No growth                    | Conforms |

Completed By:

Reviewed By:

Quality Department: E. Andrews

[Signature]

Date: 22 Dec 2016

Date: 22.12.16



### 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 Base           | <b>Lab Book Reference:</b> ST03-49 |
| <b>Lot No:</b> P632603                           | <b>Date Received:</b> 29 Nov 2016  |
| <b>ICN:</b> 1116025D                             | <b>Date Completed:</b> 19 Dec 2016 |
| <b>Subcontractor's Report Number:</b> 2016270162 | <b>No. of samples:</b> 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: Charlotte Ray Date: 19 Dec 2016

#### Reviewed by:

.....  
 Quality Assurance Manager  
 UK General Manager  
 Technical Manager  
 Laboratory Manager  
Date: 19 Dec 2016

#### QA Approved by:

.....  
 Quality Assurance Manager  
 UK General Manager  
 Technical Manager  
Date: 19 Dec 2016

#### Revision History:

| DCCF No: | Revision: | Description:           | Originator: | Effective Date: |
|----------|-----------|------------------------|-------------|-----------------|
| N/A      | 1         | Revision 1, no changes | C RAY       | 19 Dec 2016     |

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ST03-49  
REVISION NO: 1

ICN: 1116025D  
DATE: 19 Dec 2016

TSCTS044-1 Rev 2

UK  
Deacon Park  
Moorgate Road  
Kingsley  
Liverpool L33 7RN  
Tel: +44 (0)151 547 7444  
Fax: +44 (0)151 547 7400

USA  
124 Bernard E. Saint Jean Drive  
East Falmouth  
MA 02536-4415  
USA  
Tel: 001 508 540 3444  
Fax: 001 508 540 8680

Germany  
PYROQUANT DIAGNOSTIK GmbH  
Opferstraße 14  
D-64546 Mörfelden-Walldorf  
Germany  
Tel: 0049 6105 96 10 0  
Fax: 0049 6105 96 10 15

### 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>Lab Book Reference:</b> ST03-50 |
| <b>Lot No:</b> P632600                           | <b>Date Received:</b> 29 Nov 2016  |
| <b>ICN:</b> 1116025D                             | <b>Date Completed:</b> 19 Dec 2016 |
| <b>Subcontractor's Report Number:</b> 2016270156 | <b>No. of samples:</b> 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: Charlotte Ray

Date: 19 Dec 2016

#### Reviewed by:

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

Date: 19 Dec 2016

#### QA Approved by:

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

Date: 19 Dec 2016

#### Revision History:

| DCCF No: | Revision: | Description:           | Originator: | Effective Date: |
|----------|-----------|------------------------|-------------|-----------------|
| N/A      | 1         | Revision 1, no changes | C RAY       | 19 Dec 2016     |

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**ST03-50**  
**REVISION NO: 1**

**ICN: 1116025D**  
**DATE: 19 Dec 2016**

**TSCTS044-1 Rev 2**

UK  
Deacon Park  
Moorgate Road  
Knowsley  
Liverpool L33 7RX  
Tel: +44 (0)151 547 7444  
Fax: +44 (0)151 547 7400

USA  
124 Bernard E. Saint Jean Drive  
East Falmouth  
MA 02536-4445  
USA  
Tel: 001 508 540 3444  
Fax: 001 508 540 8680

Germany  
PYROQUANT DIAGNOSTIK GmbH  
Opelstrasse 14  
D-64546 Morfelden-Walldorf  
Germany  
Tel: 0049 6105 96 10 0  
Fax: 0049 6105 96 10 15

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

Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 12-Aug-2016

UK33S11678232-1-1

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:           | 702828                     |
| Product Description:                 | BOTTLE 5LT DV4232 25-45kGy |
| Validation Reference:                | 4232                       |
| Quantity Received:                   | 23                         |
| Customer Minimum Specification kGy:  | 25.0                       |
| Customer Maximum Specification kGy:  | 45.0                       |
| Customer Unit Lot/Batch Number:      | BOTTLE 044, 1 plt          |

## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 12-Aug-2016 08:31 |
| Reference Dose Range kGy:     | 32.7 - 32.9       |
| Calculated Minimum Dose kGy:  | 31.1              |
| Calculated Maximum Dose kGy:  | 35.2              |

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: 14-Sep-2016

UK33S11705020-1-1

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:           | 703128                           |
| Product Description:                 | BOTTLE 5LT DV4232 25-45kGy       |
| Validation Reference:                | 4232                             |
| Quantity Received:                   | 23                               |
| Customer Minimum Specification kGy:  | 25.0                             |
| Customer Maximum Specification kGy:  | 45.0                             |
| Customer Unit Lot/Batch Number:      | Irradiation of Bottle 044, 1 plt |

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## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 13-Sep-2016 19:31 |
| Reference Dose Range kGy:     | 33.2 - 34.0       |
| Calculated Minimum Dose kGy:  | 31.6              |
| Calculated Maximum Dose kGy:  | 36.4              |

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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: 25-Jun-2015

UK33S11409135-1-1

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

EN ISO 11137-1:2006 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:           | 0000015650                   |
| Product Description:                 | BOTTLE 100ML DV4224 25-45kGy |
| Validation Reference:                | 4224                         |
| Quantity Received:                   | 6                            |
| Customer Minimum Specification kGy:  | 25.0                         |
| Customer Maximum Specification kGy:  | 45.0                         |
| Customer Unit Lot/Batch Number:      | CRY/ACT/2, 1 pit             |

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## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 25-Jun-2015 09:11 |
| Reference Dose Range kGy:     | 31.6 - 31.6       |
| Calculated Minimum Dose kGy:  | 30.1              |
| Calculated Maximum Dose kGy:  | 34.5              |

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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



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# Certificate of Irradiation

Date Issued: 04-Oct-2016

UK33S11715571-4-1

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: | 1075625                     |
| Customer Reference Number:           | 703200                      |
| 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:      | CAP001-G, 1 plt             |

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## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 03-Oct-2016 23:41 |
| Reference Dose Range kGy:     | 32.2 - 32.2       |
| Calculated Minimum Dose kGy:  | 28.0              |
| Calculated Maximum Dose kGy:  | 36.1              |

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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: 09-Mar-2016

UK33S11548367-2-1

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:           | 701365                 |
| Product Description:                 | BAG002 DV4268 25-70kGy |
| Validation Reference:                | 4268                   |
| Quantity Received:                   | 4                      |
| Customer Minimum Specification kGy:  | 25.0                   |
| Customer Maximum Specification kGy:  | 70.0                   |
| Customer Unit Lot/Batch Number:      | 1 plt                  |

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## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 09-Mar-2016 16:08 |
| Reference Dose Range kGy:     | 54.9 - 54.9       |
| Calculated Minimum Dose kGy:  | 37.2              |
| Calculated Maximum Dose kGy:  | 59.3              |

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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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