



Certificate of Analysis-CRY 119

PRODUCT batch number: P723601

BASE batch number: P723600

ACTIVATOR batch number: P723300

Product Name:	Cry-Spore Working Solution	
Product batch number:	P723601	
Reference:	CRY/SPO/021	
This is to certify that Cry-Spore Working Solution bearing the batch no's: P723600 and P723300 were tested on 2017-08-14 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
CIO ₂ Concentration – after 10 minutes (ppm)	230 – 280	236

Product Name:	Cry-Spore Base Solution	
Reference:	CRY/SPO/020	
Date of Manufacture:	2017-08-14	
Date of Expiry:	2019-08	
This is to certify that Cry-Spore Base Solution was tested on 2017-08-14 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

DRF1589 CRY/SPO/007/Issue6/October 2012





Product Name:	Cry-Spore Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	2017-08-14	
Date of Expiry:	2019-08	
This is to certify that Cry-Spore Activator Solution was tested on 2017-08-14 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	1.016
pH	11.5 – 13.0	11.6
SODIUM CHLORITE	2.10% +/- 0.1%	2.06%
STERILITY	No growth	Conforms

Completed By:

Quality Department: Canrews

Date: 2017-09-26

Reviewed By:

[Signature]

Date: 2017-09-26





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: Cry-Spore Base
Lot No: P723600
ICN: 0817022D
Subcontractor's Report Number: 2017159796

Lab Book Reference: ST03-96
Date Received: 21 Sep 2017
Date Completed: 21 Sep 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/Designee: C.Thornton

Date: 22 SEP 2017

Reviewed by:

-
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 22 Sep 2017

QA Approved by:

-
 Quality Assurance
 UK General Manager
 Technical Manager

Date: 22 SEP 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	21 Sep 2017

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ST03-96ICN: 0817022D

Page 1 of 1
TSCTS044-1 Rev 3

REVISION NO: 1

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Moongate Road
Knowsley
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USA **DATE: 21 Sep 2017**
124 Bernard E. Saint Jean Drive
East Falmouth
MA 02536-4445
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Fax: 001 508 540 8680

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

Web: www.acciuks.co.uk

Registered in England and Wales. Company Registration Number: BR002906



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: Cryspore Activator
Lot No: P723300
ICN: 0817022D
Subcontractor's Report Number: 2017159794

Lab Book Reference: ST03-94
Date Received: 30 Aug 2017
Date Completed: 18 Sep 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/Designee: Caroline Thornton

Date: 22 SEP 2017

Reviewed by:

-
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 22 SEP 2017

QA Approved by:

-
 Quality Assurance
 UK General Manager
 Technical Manager

Date: 22 SEP 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C. Thornton	20 Sep 2017

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ST03-94ICN: 0817022D

Page 1 of 1
TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 18 Sep 2017

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Registered in England and Wales. Company Registration Number: BR002906



<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

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 plit

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

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

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

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 26-Nov-2016

UK33S11753022-3-1

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
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

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:	19
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	10112016, 1 plt

Irradiation Data

Date and Time of Irradiation:	26-Nov-2016 06:56
Reference Dose Range kGy:	33.2 - 33.4
Calculated Minimum Dose kGy:	31.6
Calculated Maximum Dose kGy:	36.4

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: 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
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

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 pit

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

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: 10-Mar-2017

UK33S11819226-1-1

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:	1109474
Customer Reference Number:	704273
Product Description:	BAG004 DV4850 25-45kGy
Validation Reference:	4850
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1 plit

Irradiation Data

Date and Time of Irradiation:	10-Mar-2017 00:26
Reference Dose Range kGy:	35.0 - 35.0
Calculated Minimum Dose kGy:	27.8
Calculated Maximum Dose kGy:	40.4

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