Crystel

Certificate of Analysis-CRY-120

PRODUCT batch number: P713603
BASE batch number: P713602
ACTIVATOR batch number: P713600

Product Name:	**Cry-Spore (Sterile 5L)**
Product batch number:	P713603
Reference:	CRY/SPO/023

This is to certify that Cry-Spore (Sterile 5L) Working Solution bearing the batch no's: P713602 and P713600 were tested on 28-MAR-2017 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	1.002
pH	2.5 – 5.5	3.0
ClO2 concentration – after 10 minutes (ppm)	230 – 280	243

Product Name:	**Cry-Spore (Sterile 5L) Base Solution**
Reference:	CRY/SPO/022
Date of Manufacture:	28-MAR-2017
Date of Expiry:	MAR-2019

This is to certify that Cry-Spore (Sterile 5L) Base Solution was tested on 28-MAR-2017 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	0.995 – 1.005	1.000
pH	2.5 – 3.5	2.9
STERILITY	No growth	Conforms

Tristel Solutions Limited. Lynx Business Park, Fordham Road, Snailwell, Cambs CB8 7NY. Registered No: 3518312
Tel: +44 (0)1638 721500 Fax: +44 (0)1638 721911 Email: mail@tristel.com Web: www.tristel.com

Crystel

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:

Quality Department: E Andrews

Date: 13 Jun 2017

Reviewed By:

.....

Date: 13-JUN-17

Tristel Solutions Limited. Lynx Business Park, Fordham Road, Snailwell, Cambs CB8 7NY. Registered No: 3518312
Tel: +44 (0)1638 721500 Fax: +44 (0)1638 721911 Email: mail@tristel.com Web: www.tristel.com

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 Cry-Spore Base
Lot No:P713602
ICN: 0517018D
Subcontractor's Report Number:2017092080

Lab Book Reference: ST03-81
Date Received: 18 May 2017
Date Completed: 12 JUN 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:

..... Date:.....12.JUN.2017.....

Laboratory Technician/Designee: Ashleigh Middleton

Reviewed by:

..... Date:.....12 Jun 2017.....

☑ Quality Assurance Manager
☐ UK General Manager
☐ Technical Manager
☐ Laboratory Manager

QA Approved by:

..... Date:..12 JUN 2017.....

☐ Quality Assurance
☑ UK General Manager
☐ Technical Manager

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	A Middleton	12 JUN 2017

UK
Deacon Park
Moorgate Road
Knowsley
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 02536-4445
USA
Tel: 001 508 540 3444
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.acciuk.co.uk

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 Activator
Lot No: P713600
ICN: 0517018D
Subcontractor's Report Number: 2017092079

Lab Book Reference: ST03-80
Date Received: 18 May 2017
Date Completed: 07 Jun 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:

..... Date: 07 JUN 2017

Laboratory Technician/Designee: Sophie Hughes

Reviewed by:

..... Date: 07 Jun 2017

☐ Quality Assurance Manager
☐ UK General Manager
☐ Technical Manager
☑ Laboratory Manager

QA Approved by:

..... Date: 09 Jun 2017

☑ Quality Assurance
☐ UK General Manager
☐ Technical Manager

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	07 Jun 2017

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 Mörfelden-Walldorf
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15

Web: www.acciuk.co.uk

5166629

synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 30-Mar-2017 **UK33S11839089-2-1**

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

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075875
Customer Reference Number:	704464
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	20
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	01032017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	30-Mar-2017 05:18
Reference Dose Range kGy:	31.3 - 31.4
Calculated Minimum Dose kGy:	29.7
Calculated Maximum Dose kGy:	33.6

Irradiation Release Authorised By Synergy Health plc

synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 21-Mar-2017 UK33S11834458-2-1

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

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075875
Customer Reference Number:	704407
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	20
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	01032017, 1 plt

Irradiation Data

Date and Time of Irradiation:	21-Mar-2017 17:07
Reference Dose Range kGy:	35.3 - 36.1
Calculated Minimum Dose kGy:	33.5
Calculated Maximum Dose kGy:	38.6

Irradiation Release Authorised By Synergy Health plc

5241358

synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 19-Apr-2017 **UK33S11854017-1-1**

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:	1075628
Customer Reference Number:	704631
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	07042017

Irradiation Data

Date and Time of Irradiation:	19-Apr-2017 01:02
Reference Dose Range kGy:	32.1 - 32.6
Calculated Minimum Dose kGy:	30.6
Calculated Maximum Dose kGy:	35.6

Irradiation Release Authorised By Synergy Health plc

5064257

synergyhealth
our work protects your world

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

synergyhealth
our work protects your world

http://www.synergyhealthplc.com

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

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

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

Irradiation Release Authorised By Synergy Health plc