



## Certificate of Analysis

Product Name:	Crystel Silver CRY 104
Reference:	CRY/SIL/019
Batch Number:	P733800
Date of Manufacture:	08-MAR-17
Expiry Date:	MAR-2019

This is to certify that Crystel Silver solution above was tested on 08-MAR-17 and found to comply with all requirements as set out in the specifications and method of analysis.

PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear and free from suspended matter	Conforms
ODOUR	Alcohol Like	Conforms
SPECIFIC GRAVITY	0.875 – 0.895	0.882
STERILITY	No growth	Conforms
IRRADIATION	Achieves minimum dose	Conforms
ENDOTOXIN	<0.25EU/ml	<0.1
	Recovery 50-200%	136%

Completed By:

Quality Department: E Andrews

Date: 2018-01-16

Reviewed By:

Steph

Date: 2018-01-16

DRF1574 CRY/SIL/007/Issue5/Sept 2012

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**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:** CRY104 Silver  
**Lot No:** P733800  
**ICN:** 1217016D  
**Subcontractor's Report Number:** 2017238602

**Lab Book Reference:** ST03-125  
**Date Received:** 19 Dec 2017  
**Date Completed:** 15 Jan 2018  
**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: Daniel Jennings

Date: 15 JAN 2018

**Reviewed by:**

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

Date: 15 JAN 2018

**QA Approved by:**

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

Date: 15 JAN 2018

**Revision History:**

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	D. Jennings	15 Jan 2017

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ST03-125

ICN: 1217016D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 15 Jan 2018

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Specialists in Endotoxin and Glucan Detection

## LIMULUS AMEBOCYTE LYSATE (LAL) ANALYTICAL REPORT Release Test - Kinetic Turbidimetric Method (SOPCTS012)

**Sample ID:** CRY104 Silver  
**Lot No:** P733800  
**ICN No:** 1217016D

**Lab Book Reference:** EL193-105  
**Date Received:** 19 Dec 2017  
**Date Completed:** 05 Jan 2018

### Reagents

**Pyrotell®-T:** Lot Number 517-08-837-T. Pyrotell®-T was reconstituted with Pyrosol® Buffer and used to Assay all dilutions.

**Pyrosol® Buffer:** Lot Number 226-410.

**LAL Reagent Water (LRW):** Lot Number AC10244559. LRW was used to reconstitute endotoxin, prepare dilutions of endotoxin and sample(s), and serve as the negative control.

**Instrumentation:** Pyros® Kinetix Incubating Kinetic Tube Reader; S/N; 3G-1166.

**Control Standard Endotoxin (CSE):** Lot number 154, *Escherichia coli* O113:H10. The potency of the CSE is 12 EU/ng when measured against Reference Standard Endotoxin (RSE), lot number H0K354 (Food and Drug Administration, CBER) with Pyrotell®-T lot number 517-08-837-T.

The sensitivity of the assay is the lowest concentration of CSE used to construct the calibration curve. A series of 10-fold dilutions between 0.001 and 1.0 EU/mL was tested in duplicate and the results were used to construct the standard curve.

**Preparation and Testing of Sample:** The samples were diluted with LRW and analysed at a 1:100 dilution, in accordance with validation EL168-06. Positive product controls were tested, in parallel, on sample dilutions spiked with an Endotoxin concentration of 0.1 EU/ml. The sample to lysate ratio was 4:1.

**Results:** The Release Test is performed according to a validated method and is used to release finished products. The test can also be performed for release of raw/in-process materials. The absolute value for the correlation coefficient for the regression of log onset time versus log endotoxin concentration was greater than or equal to 0.980. The negative control (LRW) was tested in duplicate and contained less than 0.001 EU/mL. Inhibition or enhancement of the bacterial Endotoxin test by the sample is absent if the concentration of the Endotoxin assayed in the Positive Product Controls are within 50% to 200% of the nominal concentration.

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REVISION NO: 1

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

Registered in England and Wales. Company Registration Number: BR002906

**Sample Results:**

Sample Identification	% Spike Recovery	EU/mL
CRY104 Silver P733800	136	<0.1

All samples analysed passed the specification of <0.25 EU/mL.

**Approval:**

**Technician:** *D. Jennings*  
Laboratory Technician: Daniel Jennings

**Date:** *05 JAN 2018*

**Reviewed By:** *[Signature]*

**Date:** *05 JAN 2018*

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

**QA Approval:** *[Signature]*

**Date:** *08 JAN 2018*

- Quality Assurance Manager
- UK General Manager
- Technical Manager

**References:**

Associates of Cape Cod SOPCTS012, *General Kinetic LAL Turbidimetric Assay*  
United States Pharmacopoeia <85> *Bacterial Endotoxins Test*  
European Pharmacopoeia, *Section 2.6.14.*

**Revision History:**

DCCF No:	Revision:	Description:	Originator	Effective Date:
N/A	1	Revison 1, no changes.	D. Jennings	05 Jan 2018

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DATE: 05 Jan 2018

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<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 10-Dec-2017

UK33S12027152-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 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:	1108717
Customer Reference Number:	706118
Product Description:	ALCOHOL 1 LTR TRIGGER SPRAY DV4778 20-45kGy
Validation Reference:	4778
Quantity Received:	134
Customer Minimum Specification kGy:	20.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	P733800, 3 PLTS

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### Irradiation Data

Date and Time of Irradiation:	10-Dec-2017 15:24
Reference Dose Range kGy:	36.5 - 36.8
Calculated Minimum Dose kGy:	29.6
Calculated Maximum Dose kGy:	42.4

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Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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