



## Certificate of Analysis

Product Name:	Crystel Silver CRY 104
Reference:	CRY/SIL/019
Batch Number:	P624500
Date of Manufacture:	17-JUN-16
Expiry Date:	JUN-2018

This is to certify that Crystel Silver solution above was tested on 17-JUN-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 from suspended matter	Conforms
ODOUR	Alcohol Like	Conforms
SPECIFIC GRAVITY	0.875 – 0.895	0.880
STERILITY	No growth	Conforms
IRRADIATION	Achieves minimum dose	Conforms
ENDOTOXIN	<0.25EU/ml	<0.1
	Recovery 50-200%	119%

Completed By:

Reviewed By:

Quality Department: *E. Andrews*

*[Signature]*

Date: *24 Nov 2016*

Date: *24 Nov 16*

DRF1574 CRY/SIL/007/Issue5/Sept 2012



## 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> CRY104 Silver <b>Lot No:</b> P624500 <b>ICN:</b> 1116002D <b>Subcontractor's Report Number:</b> 2016252929	<b>Lab Book Reference:</b> ST03-38 <b>Date Received:</b> 02 Nov 2016 <b>Date Completed:</b> 21 Nov 2016 <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: 21 NOV 2016

#### Reviewed by:

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

Date: 22 NOV 2016

#### QA Approved by:

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

Date: 23 Nov 2016

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	21 Nov 2016

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**ST03-38**  
**REVISION NO: 1**

**ICN: 1116002D**  
**DATE: 21 Nov 2016**

**TSCTS044-1 Rev 2**

UK  
 Deacon Park  
 Moorgate Road  
 Knowsley  
 Liverpool L33 7RN  
 Tel: +44 (0)151 547 7441  
 Fax: +44 (0)151 547 7400

USA  
 124 Bernard E. Saint Jean Drive  
 East Falmouth  
 MA 02536-1445  
 USA  
 Tel: 001 508 540 3444  
 Fax: 001 508 540 8680

Germany  
 PYROQUANT DIAGNOSTIK GmbH  
 Opelstrasse 14  
 D-61546 Mordfelden-Walldorf  
 Germany  
 Tel: 0049 6105 96 10 0  
 Fax: 0049 6105 96 10 15



ASSOCIATES OF  
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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:** P624500  
**ICN No:** 1116002D

**Lab Book Reference:** EL186-73 (A)  
**Date Received:** 02 NOV 2016  
**Date Completed:** 17 NOV 2016

**Reagents**

**Pyrotell®-T:** Lot Number 516-05-784-T. Pyrotell®-T was reconstituted with Pyrosol® Buffer and used to Assay all dilutions.

**Pyrosol® Buffer:** Lot Number 226-391.

**LAL Reagent Water (LRW):** Lot Number AAH207245. 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 152, *Escherichia coli* O113:H10. The potency of the CSE is 20 EU/ng when measured against Reference Standard Endotoxin (RSE), lot number HOK354 (Food and Drug Administration, CBER) with Pyrotell®-T lot number 516-05-784-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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EL166-73 (A)  
REVISION NO: 1

ICN: 1116002D  
DATE: 17 NOV 2016

YSCTS015-3.1 Rev 17

UK  
Deaton Park  
Moogate Road  
Kinnosley  
Liverpool L33 7RN  
Tel: +44 (0)151 517 7444  
Fax: +44 (0)151 517 7400

USA  
124 Bernard E. Saint Jean Drive  
East Falmouth  
MA 02536-4445  
USA  
Tel: 001 508 510 3444  
Fax: 001 508 510 8680

Germany  
PYROQUANT DIAGNOSTIK GmbH  
Opelstrasse 14  
D-64516 Marfelden-Walkhof  
Germany  
Tel: 0049 6105 96 10 0  
Fax: 0049 6105 96 10 15

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

Registered in England and Wales. Company Registration Number: BR002906



**Sample Results:**

Sample Identification	% Spike Recovery	EU/ml
CRY104 SILVER P624500	119	<0.1

All samples analysed passed the specification of 0.25 EU/ml.

**Approval:**

**Technician:**.....  
Laboratory Technician: *Charlotte Ray*

**Date:**..... *17 NOV 2016*.....

**Reviewed By:**.....*Mickel*.....

**Date:**..... *17 NOV 2016*.....

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

**QA Approval:**.....*Amos*.....

**Date:**..... *18 NOV 2016*.....

- Quality Assurance Manager
- UK General Manager
- Technical Manager

**References:**

Associates of Cape Cod SCPCTS012, *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	Revision 1: No Changes	C RAY	17 NOV 2016



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 29-Oct-2016

UK33S11738289-1-1

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:	1108717
Customer Reference Number:	703075
Product Description:	ALCOHOL 1 LTR TRIGGER SPRAY DV4778 20-45kGy
Validation Reference:	4778
Quantity Received:	161
Customer Minimum Specification kGy:	20.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	CRY 104, P624500, 3PLTS

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## Irradiation Data

Date and Time of Irradiation:	29-Oct-2016 00:23
Reference Dose Range kGy:	35.0 - 35.8
Calculated Minimum Dose kGy:	28.3
Calculated Maximum Dose kGy:	41.3

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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

Registered Office: Ground Floor Stelia, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069