



## Certificate of Analysis

|                      |   |
|----------------------|---|
| Product Name:        | <b>Crystel Platinum RTU Solution CRY110</b> |
| Reference:           | CRY/PLA/032                                 |
| Batch Number:        | P807400                                     |
| Date of Manufacture: | 2018-03-08                                  |
| Expiry Date:         | 2020-03-08                                  |

This is to certify that Crystel Platinum RTU solution above was tested on 2018-03-08 and found to comply with all requirements as set out in the specifications and method of analysis.

| PROPERTIES       | SPECIFICATION                 | RESULTS  |
|------------------|-------------------------------|----------|
| APPEARANCE       | Clear Solution free of matter | Conforms |
| SPECIFIC GRAVITY | 0.995 – 1.005                 | 1.000    |
| pH               | 8.50 – 10.00                  | 9.29     |
| STERILITY        | No growth                     | Conforms |

Completed By:

Reviewed By:

Quality Department: *E. Andrews*

*Stielinska*

Date: *2018-04-20*

Date: *2018-04-20*

DRF1500 CRY/PLA/033/Issue3/June 2012





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:** CRY110 Platinum  
**Lot No:** P807400  
**ICN:** 0318020D  
**Subcontractor's Report Number:** 2018050550

**Lab Book Reference:** ST03-151  
**Date Received:** 19 Mar 2018  
**Date Completed:** 17 Apr 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: 17 APR 2018

#### Reviewed by:

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

Date: 17 APR 2018

#### QA Approved by:

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

Date: 17 APR 2018

#### Revision History:

| DCCF No: | Revision: | Description:           | Originator: | Effective Date: |
|----------|-----------|------------------------|-------------|-----------------|
| N/A      | 1         | Revision 1, no changes | D. Jennings | 17 Apr 2018     |

**CONFIDENTIAL**  
 ST03-151

**ICN: 0318020D**

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**TSCTS044-1 Rev 3**

**REVISION NO: 1**

**DATE: 17 Apr 2018**

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Registered in England and Wales. Company Registration Number: BR002906



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

## Certificate of Irradiation

Date Issued: 10-Feb-2018

UK33S12057071-1-1

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: | 1121939                           |
| Customer Reference Number:           | 706514                            |
| Product Description:                 | 1000ML T/S BOTTLE DV5171 25-45kGy |
| Validation Reference:                | 5171                              |
| Quantity Received:                   | 16                                |
| Customer Minimum Specification kGy:  | 25.0                              |
| Customer Maximum Specification kGy:  | 45.0                              |
| Customer Unit Lot/Batch Number:      | Bottle 009, B/N: 31012018, 1 plt  |

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### Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 10-Feb-2018 10:37 |
| Reference Dose Range kGy:     | 32.9 - 33.0       |
| Calculated Minimum Dose kGy:  | 31.6              |
| Calculated Maximum Dose kGy:  | 36.0              |

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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

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: 09-Mar-2018

UK33S12069394-3-1

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: | 1121921   |
| Customer Reference Number:           | 706678  |
| Product Description:                 | TRIGGER SPRAY HEAD CRYSTAL-G DV5170<br>25-45kGy |
| Validation Reference:                | 5170  |
| Quantity Received:                   | 20  |
| Customer Minimum Specification kGy:  | 25.0  |
| Customer Maximum Specification kGy:  | 45.0  |
| Customer Unit Lot/Batch Number:      | 20180221, 1 plt                                 |

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### Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 09-Mar-2018 14:45 |
| Reference Dose Range kGy:     | 28.7 - 34.9       |
| Calculated Minimum Dose kGy:  | 26.1              |
| Calculated Maximum Dose kGy:  | 38.6              |

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## Certificate of Irradiation

Date Issued: 07-Feb-2018

UK33S12051056-1-1

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EN ISO 13485 Quality System - Medical Devices

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Newmarket  
Suffolk CB8 7NY  
UNITED KINGDOM

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### Order Information

|                                      |                           |
|--------------------------------------|---------------------------|
| Account Number:                      | 100708                    |
| Synergy Health Sales Part Reference: | 1121938                   |
| Customer Reference Number:           | 706435                    |
| Product Description:                 | BAG 001-G DV5194 25-48kGy |
| Validation Reference:                | 5194                      |
| Quantity Received:                   | 5                         |
| Customer Minimum Specification kGy:  | 25.0                      |
| Customer Maximum Specification kGy:  | 48.0                      |
| Customer Unit Lot/Batch Number:      | 20171017, 1 PLT           |

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### Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 06-Feb-2018 18:57 |
| Reference Dose Range kGy:     | 38.4 - 38.4       |
| Calculated Minimum Dose kGy:  | 27.5              |
| Calculated Maximum Dose kGy:  | 42.8              |

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