



## Certificate of Analysis

Product Name:	<b>Crystel Platinum RTU Solution</b>	
Reference:	CRY/PLA/032	
Batch Number:	P822602	
Date of Manufacture:	2018-03-08	
Expiry Date:	2020-03-08	
This is to certify that Crystel Platinum RTU solution above was tested on 2018-03-09 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	9.3
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

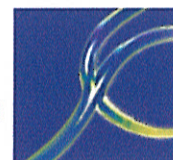
Quality Department: *Eandros*

*[Signature]*

Date: *2018-09-12*

Date: *2018-09-12*

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:** CRY111 Platinum  
**Lot No:** P822602  
**ICN:** 0818027F  
**Subcontractor's Report Number:** 2018154742

**Lab Book Reference:** ST03-185  
**Date Received:** 20 AUG 2018  
**Date Completed:** 07 SEP 2018  
**No. of samples:** 3

#### 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:

*L. Ellis*  
 .....  
 Laboratory Technician/Designee: L. Ellis

Date: *07 SEP 2018*

#### Reviewed by:

*[Signature]*  
 .....  
 Quality Assurance Manager  
 UK General Manager  
 Technical Manager  
 Laboratory Manager

Date: *07 SEP 2018*

#### QA Approved by:

*A. Roberts*  
 .....  
 Quality Assurance  
 UK General Manager  
 Technical Manager

Date: *07 SEP 2018*

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L Ellis	07 SEP 2018

**CONFIDENTIAL**  
**ST03-185**

**ICN: 0818027F**

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**TSCTS044-1 Rev 3**

**REVISION NO: 1**

**DATE: 07 SEP 2018**

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

Registered in England and Wales. Company Registration Number: BR002906



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

## Certificate of Irradiation

Date Issued: 21-Jul-2018

UK33S12139228-1-1

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:	1075875
Customer Reference Number:	707663
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/N: 20180710, 1 Pit

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### Irradiation Data

Date and Time of Irradiation:	21-Jul-2018 04:12
Reference Dose Range kGy:	33.2 - 33.7
Calculated Minimum Dose kGy:	31.6
Calculated Maximum Dose kGy:	36.1

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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





<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 15-Mar-2017

UK33S11829406-2-1

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

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1078033
Customer Reference Number:	704369
Product Description:	BAG002 DV4268 25-70kGy
Validation Reference:	4268
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	70.0
Customer Unit Lot/Batch Number:	21022017, 1 PLT

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## Irradiation Data

Date and Time of Irradiation:	14-Mar-2017 18:57
Reference Dose Range kGy:	54.6 - 54.6
Calculated Minimum Dose kGy:	37.0
Calculated Maximum Dose kGy:	59.0

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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  
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