



## Certificate of Analysis

|                      |                           |
|----------------------|---------------------------|
| Product Name:        | Crystel GOLD      CRY 101 |
| Reference:           | CRY/GOL/019               |
| Batch Number:        | WO45654                   |
| Date of Manufacture: | 2018-05-30                |
| Expiry Date:         | 2020-05-30                |

This is to certify that Crystel Gold solution above was tested on 2018-05-30 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 | 0.870 – 0.890                        | 0.874    |
| STERILITY        | No growth                            | Conforms |
| IRRADIATION      | Achieves minimum dose                | Conforms |
| ENDOTOXIN        | <0.25EU/ml                           | <0.1     |
|                  | Recovery 50-200%                     | 141%     |

Completed By:

Quality Department: E. Andrews

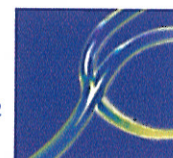
Date: 2018-08-10

Reviewed By:

[Signature]

Date: 2018-08-10

DRF1574 CRY/GOL/006/Issue4/Sept2012



### 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:** CRY101 Gold  
**Lot No:** WO45654  
**ICN:** 0718012D  
**Subcontractor's Report Number:** 2018133729

**Lab Book Reference:** ST03-180  
**Date Received:** 16 JUL 2018  
**Date Completed:** 08 AUG 2018  
**No. of samples:** 10

#### Sterility Test – Membrane Filtration

| Medium                      | Result    |
|-----------------------------|-----------|
| Tryptone Soy Broth          | No Growth |
| Fluid Thioglycollate Medium | No Growth |

#### Conclusions:

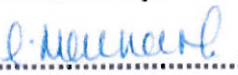
The samples submitted comply with the test for sterility in accordance with the client's methodology.

#### Results Reported by:

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


Date:..... 08 AUG 2018 .....

#### Reviewed by:

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

Date: 08 Aug 2018 .....

#### QA Approved by:

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

Date:..... 10 AUG 2018 .....

#### Revision History:

| DCCF No: | Revision: | Description:           | Originator: | Effective Date: |
|----------|-----------|------------------------|-------------|-----------------|
| NA       | 1         | Revision 1, no changes | L Ellis     | 08 AUG 2018     |

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ST03-180

ICN: 0718012D

Page 1 of 1  
TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 08 AUG 2018

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

**Sample ID:**CRY101 Gold  
**Lot No:**WO45654  
**ICN No:**0718012D

**Lab Book Reference:**EL189-96-B  
**Date Received:**16 JUL 2018  
**Date Completed:**18 JUL 2018

**Reagents**

**Pyrotell®-T:** Lot Number 517-10-848-T. Pyrotell®-T was reconstituted with Pyrosol® Buffer and used to Assay all dilutions.

**Pyrosol® Buffer:** Lot Number 226-425.

**LAL Reagent Water (LRW):** Lot Number AC10244546. 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 159, The potency of the CSE is 14 EU/ng when measured against Reference Standard Endotoxin (RSE), lot number H0K354 (Food and Drug Administration, CBER) with Pyrotell®-T lot number 517-10-848-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 EL168-03. 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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Page 1 of 2

EL189-96-B  
REVISION NO:1

ICN: 0718012D  
DATE:18 JUL 2018

TSCTS015-3.1 Rev 18

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**Sample Results:**

| Sample Identification | % Spike Recovery | EU/ml |
|-----------------------|------------------|-------|
| WO45654               | 141              | <0.1  |

All Samples analysed passed the specification of < 0.25 EU/ml.

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**Approval:**

**Technician:** ..... *L Ellis* .....  
Laboratory Technician: L. Ellis

**Date:** ..... *18 JUL 2018* .....

**Reviewed By:** ..... *A. M. S.* .....  
 Review Board  
 Laboratory Manager

**Date:** ..... *19 JUL 2018* .....

**QA Approval:** ..... *A. M. S.* .....  
 Review Board

**Date:** ..... *19 Jul 2018* .....

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**References:**

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

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**Revision History:**

| DCCF No: | Revision: | Description:          | Originator | Effective Date: |
|----------|-----------|-----------------------|------------|-----------------|
| NA       | 1         | Revision 1 No Changes | L Ellis    | 18JUL2018       |



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

## Certificate of Irradiation

Date Issued: 08-Jul-2018

UK33S12133266-1-2

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:           | 707546   |
| Product Description:                 | ALCOHOL 1 LTR TRIGGER SPRAY DV4778<br>20-45kGy |
| Validation Reference:                | 4778   |
| Quantity Received:                   | 159  |
| Customer Minimum Specification kGy:  | 20.0   |
| Customer Maximum Specification kGy:  | 45.0   |
| Customer Unit Lot/Batch Number:      | BN: W045654, 3 PLTS                            |

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### Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 08-Jul-2018 20:31 |
| Reference Dose Range kGy:     | 33.7 - 34.5       |
| Calculated Minimum Dose kGy:  | 27.3              |
| Calculated Maximum Dose kGy:  | 39.8              |

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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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