



## Certificate of Analysis-TITANIUM –CRY151

PRODUCT batch number: P714200

Product Name:	TITANIUM Working Solution	
Reference:	CRY/TTM/024	
This is to certify that TITANIUM Working Solution bearing the Batch No: P714200 was tested on 22-MAY-17 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear pale yellow liquid free of matter	Conforms
ODOUR	Chlorine like	Conforms
CLO <sub>2</sub> Concentration (ppm)	160-200	181

Product Name:	TITANIUM Base Solution	
Reference:	MED/SOL/449	
Date of Manufacture:	22-MAY-17	
Date of Expiry:	MAY-2019	
This is to certify that TITANIUM Base Solution was tested on 22-MAY-17 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear liquid free of matter	Conforms
SPECIFIC GRAVITY	1.000-1.200	1.018
pH	1.5 – 3.5	1.8
STERILITY	No growth	Conforms





Product Name:	TITANIUM Activator Solution	
Reference:	MED/SOL/450	
Date of Manufacture:	19-MAY-17	
Date of Expiry:	MAY-2019	
This is to certify that TITANIUM Activator Solution was tested on 19-MAY-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 of matter	Conforms
pH	10.0-11.0	10.8
SODIUM CHLORITE	0.1% +/- 0.005%	0.096%
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: Phil Prior

.....E Andrews.....

Date: 15-JUN-17

Date: .....15 Jun 2017.....





ASSOCIATES OF  
**CAPE COD**  
INTERNATIONAL

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:** CRY151 Titanium Base  
**Lot No:** P714200  
**ICN:** 0517023D  
**Subcontractor's Report Number:** 2017096672

**Lab Book Reference:** ST03-82  
**Date Received:** 26 May 2017  
**Date Completed:** 15 Jun 2017  
**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:

*Sophle Hughes*  
.....  
Laboratory Technician/Designee: Sophie Hughes

Date: 15 JUN 2017

#### Reviewed by:

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

Date: 15 JUN 2017

#### QA Approved by:

*Middle*  
.....  
 Quality Assurance  
 UK General Manager  
 Technical Manager

Date: 15 JUN 2017

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	15 Jun 2017

CONFIDENTIAL

ST03-82ICN: 0517023D

Page 1 of 1  
TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 15 Jun 2017

UK  
Deacon Park  
Mourgate Road  
Knowsley  
Liverpool L33 7RX  
Tel: +44 (0)151 547 7444  
Fax: +44 (0)151 547 7400

USA  
124 Bernard E. Saint Jean Drive  
East Falmouth  
MA 02536-4445  
USA  
Tel: 001 508 540 3444  
Fax: 001 508 540 8680

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

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

Registered in England and Wales. Company Registration Number: BR002906

### 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:** CRY151 Titanium Activator  
**Lot No:** P714200  
**ICN:** 0517023D  
**Subcontractor's Report Number:** 2017096673

**Lab Book Reference:** ST03-83  
**Date Received:** 26 May 2017  
**Date Completed:** 15 Jun 2017  
**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: Sophie Hughes

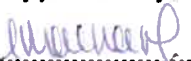
Date: 15 JUN 2017

#### Reviewed by:

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

Date: 15 JUN 2017

#### QA Approved by:

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

Date: 15 Jun 2017

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	15 Jun 2017

**CONFIDENTIAL**  
**STC3-83**

**ICN: 0517023D**

**Page 1 of 1**  
**TSCTS044-1 Rev 3**

**REVISION NO: 1**

**DATE: 15 Jun 2017**

**UK**  
Deacon Park  
Moorgate Road  
Knowsley  
Liverpool L33 7RN  
Tel: +44 (0)151 547 7444  
Fax: +44 (0)151 547 7400

**USA**  
124 Bernard E. Saint Jean Drive  
East Falmouth  
MA 02536-4445  
USA  
Tel: 001 508 540 3444  
Fax: 001 508 540 8680

**Germany**  
PYROQUANT DIAGNOSTIK GmbH  
Opelstrasse 14  
D-64546 Marfelden-Walldorf  
Germany  
Tel: 0049 6105 96 10 0  
Fax: 0049 6105 96 10 15

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

Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 13-Sep-2016

UK33S11702145-4-1

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

---

### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1077586
Customer Reference Number:	703090
Product Description:	JET TITANIUM DV4260 25-40kGy
Validation Reference:	4260
Quantity Received:	12
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	BOTTLE 051, 1PLT

---

### Irradiation Data

Date and Time of Irradiation:	13-Sep-2016 16:54
Reference Dose Range kGy:	33.2 - 35.1
Calculated Minimum Dose kGy:	31.2
Calculated Maximum Dose kGy:	38.1

---

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  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 12-Sep-2016

UK33S11702145-1-1

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

---

### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1077585
Customer Reference Number:	703090
Product Description:	JET TRIGGER HEAD DV4258 25-40kGy
Validation Reference:	4258
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	TS SPRAY HEAD TIT-G, 1PLT

---

### Irradiation Data

Date and Time of Irradiation:	12-Sep-2016 12:53
Reference Dose Range kGy:	32.7 - 33.2
Calculated Minimum Dose kGy:	29.4
Calculated Maximum Dose kGy:	36.2

---

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  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 04-Oct-2016

UK33S11715571-1-1

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

---

### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1077585
Customer Reference Number:	703200
Product Description:	JET TRIGGER HEAD DV4258 25-40kGy
Validation Reference:	4258
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	TS Head TIT-G, 1 plt

---

### Irradiation Data

Date and Time of Irradiation:	04-Oct-2016 04:44
Reference Dose Range kGy:	31.0 - 31.3
Calculated Minimum Dose kGy:	27.9
Calculated Maximum Dose kGy:	34.2

---

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  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 19-Sep-2016

UK33S11702145-2-1

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

---

### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1087393
Customer Reference Number:	703090
Product Description:	BAG 001-G DV4285 25-45kGy
Validation Reference:	4285
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG001-G, 1PLT

---

### Irradiation Data

Date and Time of Irradiation:	19-Sep-2016 11:35
Reference Dose Range kGy:	34.2 - 34.2
Calculated Minimum Dose kGy:	26.4
Calculated Maximum Dose kGy:	36.1

---

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  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069