



Certificate of Analysis-TITANIUM –CRY151

PRODUCT batch number: P729200

Product Name:	TITANIUM Working Solution	
Reference:	CRY/TTM/024	
This is to certify that TITANIUM Working Solution bearing the Batch No's: P729200 were tested on 2017-10-10 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 ₂ Concentration (ppm)	160-200	192

Product Name:	TITANIUM Base Solution	
Reference:	MED/SOL/449	
Date of Manufacture:	2017-10-10	
Date of Expiry:	2019-10	
This is to certify that TITANIUM Base Solution was tested on 2017-10-10 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	1.022
pH	1.5 – 3.5	1.9
STERILITY	No growth	Conforms





Product Name:	TITANIUM Activator Solution	
Reference:	MED/SOL/450	
Date of Manufacture:	2017-10-10	
Date of Expiry:	2019-10	
This is to certify that TITANIUM Activator Solution was tested on 2017-10-10 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	11.0
SODIUM CHLORITE	0.1% +/- 0.005%	1.002
STERILITY	No growth	Conforms

Completed By:

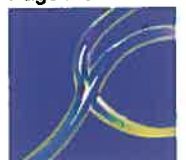
Reviewed By:

Quality Department: E. Andrews

S. Kielinska

Date: 2017-11-24

Date: 2017-11-24



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: P729200
ICN: 1017021D
Subcontractor's Report Number: 2017199633

Lab Book Reference: ST03-112
Date Received: 24 Oct 2017
Date Completed: 17 Nov 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: C.Thornton

Date: 17 Nov 2017

Reviewed by:

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

Date: 17 Nov 2017

QA Approved by:

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

Date: 17 Nov 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	17 Nov 2017

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ST03-112ICN: 1017021D

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REVISION NO: 1

DATE: 17 Nov 2017

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Opelstrasse 14
D-64546 Morfelden-Walldorf
Germany
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Fax: 0049 6105 96 10 15

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: P729200
ICN: 1017021D
Subcontractor's Report Number: 2017199634

Lab Book Reference: ST03-114
Date Received: 24 Oct 2017
Date Completed: 17 Nov 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: C.Thornton

Date: 17 Nov 2017

Reviewed by:


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

Date: 17 Nov 2017

QA Approved by:


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

Date: 17 Nov 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	17 Nov 2017

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ST03-114ICN: 1017021D

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REVISION NO: 1

DATE: 17 Nov 2017

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Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 05-Oct-2017

UK33S11974005-2-1

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:	1077586
Customer Reference Number:	705659
Product Description:	JET TITANIUM DV4260 25-40kGy
Validation Reference:	4260
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	BN: 20170921, 1 plt

Irradiation Data

Date and Time of Irradiation:	05-Oct-2017 05:19
Reference Dose Range kGy:	33.9 - 34.1
Calculated Minimum Dose kGy:	31.9
Calculated Maximum Dose kGy:	37.0

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: 05-Oct-2017

UK33S11974005-2-3

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:	705659
Product Description:	JET TITANIUM DV4260 25-40kGy
Validation Reference:	4260
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	BN: 20170921, 1 plt

Irradiation Data

Date and Time of Irradiation:	05-Oct-2017 05:19
Reference Dose Range kGy:	33.6 - 34.0
Calculated Minimum Dose kGy:	31.6
Calculated Maximum Dose kGy:	36.9

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: 03-Aug-2017

UK33S11930917-1-1

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:	705262
Product Description:	JET TRIGGER HEAD DV4258 25-40kGy
Validation Reference:	4258
Quantity Received:	32
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	Lot 25072017, 2 plts

Irradiation Data

Date and Time of Irradiation:	03-Aug-2017 12:23
Reference Dose Range kGy:	31.1 - 31.6
Calculated Minimum Dose kGy:	28.0
Calculated Maximum Dose kGy:	34.5

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 11-Mar-2017

UK33S11824859-2-1

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:	704309
Product Description:	BAG 001-G DV4285 25-45kGy
Validation Reference:	4285
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	21022017, 1 pit

Irradiation Data

Date and Time of Irradiation:	11-Mar-2017 06:48
Reference Dose Range kGy:	33.7 - 34.3
Calculated Minimum Dose kGy:	26.0
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