

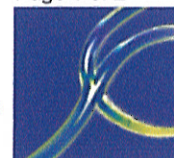


Certificate of Analysis-TITANIUM -CRY151

PRODUCT batch number: P822502

Product Name:	TITANIUM Working Solution	
Reference:	CRY/TTM/024	
This is to certify that TITANIUM Working Solution bearing the Batch No's: P822502 were tested on 2018-07-30 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	176

Product Name:	TITANIUM Base Solution	
Reference:	MED/SOL/449	
Date of Manufacture:	2018-07-30	
Date of Expiry:	2020-07-30	
This is to certify that TITANIUM Base Solution was tested on 2018-07-30 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	1.019
pH	1.5 – 3.5	1.9
STERILITY	No growth	Conforms





Product Name:	TITANIUM Activator Solution	
Reference:	MED/SOL/450	
Date of Manufacture:	2018-07-30	
Date of Expiry:	2020-07-30	
This is to certify that TITANIUM Activator Solution was tested on 2018-07-30 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear and free of matter	Conforms
pH	10.0-11.0	10.9
SODIUM CHLORITE	0.1% +/- 0.005%	0.096%
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: Andrews

[Signature]

Date: 2018-09-11

Date: 2018-09-11





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: P822502
ICN: 0818020F
Subcontractor's Report Number: 2018153831

Lab Book Reference: ST03-181
Date Received: 16 AUG 2018
Date Completed: 04 SEP 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: C.Thornton

Date: 05 Sep 2018

Reviewed by:

-
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 06 SEP 2018

QA Approved by:

-
 Quality Assurance
 UK General Manager
 Technical Manager

Date: 06 Sep 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	05 SEP 2018

CONFIDENTIAL
ST03-181

ICN: 0818020F

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 04 SEP 2018

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Web: 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: P822502
ICN: 0818020F
Subcontractor's Report Number: 2018153833

Lab Book Reference: ST03-182
Date Received: 16 AUG 2018
Date Completed: 04 SEP 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: C.Thornton

Date: 05 Sep 2018


Reviewed by:



 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 06 Sep 2018

QA Approved by:



 Quality Assurance
 UK General Manager
 Technical Manager

Date: 06 Sep 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	05 SEP 2018

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ST03-182

ICN: 0818020F

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 04 SEP 2018

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

Certificate of Irradiation

Date Issued: 29-Jul-2018

UK33S12142347-1-1

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

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121944
Customer Reference Number:	707724
Product Description:	JET TITANIUM BOTTLE DV5173 25-40kGy
Validation Reference:	5173
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	B/N. 20180606, 1 PLT

Irradiation Data

Date and Time of Irradiation:	29-Jul-2018 00:22
Reference Dose Range kGy:	31.7 - 32.0
Calculated Minimum Dose kGy:	30.1
Calculated Maximum Dose kGy:	35.9

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 17-Jan-2018

UK33S12041486-3-1

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

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121940
Customer Reference Number:	706279
Product Description:	JET TRIGGER HEAD DV5162 25-40kGy
Validation Reference:	5162
Quantity Received:	12
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	01112017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	17-Jan-2018 13:48
Reference Dose Range kGy:	32.2 - 32.4
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	35.5

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 07-Feb-2018

UK33S12051056-1-1

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

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

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

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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