PBL Pacific BioLabs
The Service Leader in Bioscience Testing

SPONSOR 14489

Tristel Solutions Limited
Unit 1B Lynx Business Park,
Fordham Road,
Snailwell, Cambridgeshire,
CB8 7NY,
United Kingdom

217F0417H-A01G

STUDY NUMBER

17F0417H-A01G

REPORT DATE

August 29, 2017

FINAL REPORT

STUDY TITLE

Analysis of Tristel Duo nucleic acid degradation properties

TEST ARTICLE

Tristel Duo
Lot Number: P708803

PRINCIPAL INVESTIGATOR

Erik Foehr
Analytical Services

PERFORMING LABORATORY

Pacific BioLabs
551 Linus Pauling Drive
Hercules, CA 94547
United States

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SIGNATURE PAGE

This report is being submitted by the following personnel:

Principal Investigator: Erik Foehr, Vice President

08/29/17

X 

I approve the content of this document.
Signed by: Erik Foehr

RESPONSIBLE PERSONNEL

1. Erik Foehr, Vice President, Analytical
2. F. Michael Yakes, Ph.D., Executive Vice President
3. Tom Spalding, President

:ahc

STATEMENT OF COMPLIANCE

All aspects of the study contained in this report were conducted according to Pacific BioLabs Standard Operating Procedures and in compliance with the United States Food and Drug Administration (FDA) Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies, Title 21 of the U.S. Code of Federal Regulations, Part 58 with the exception that Microsoft® Excel, a non-validated computer program, was used to perform some data entry and calculations.

Principal Investigator Signature

08/29/17

X 

I approve the content of this document.
Signed by: Erik Foehr

QUALITY STATEMENT

QUALITY ASSURANCE UNIT GLP MONITORING AND INSPECTION SUMMARY

In accordance with 21 CFR 58, this study, 17F0417H-A01G, was inspected by Quality Assurance at intervals adequate to assure the integrity of the study. The phase(s) of the study inspected, the date(s) of the inspection, QA auditor, and the date(s) that the QAU inspection report for this study were reported to the Principal Investigator, Study Director and Management are provided below.

Phase of Study	Date of Inspection	QA Auditor	Date QA Inspection Reported to PBL Principal Investigator/ Study Director / Management
Test Method	08/03/17	VT	08/04/17

The QAU inspection summary is routinely reviewed by the PBL Principal Investigator, sent to Study Director and Management. Management is notified immediately if there are any deviations which might affect the integrity of the study data.

DATA/REPORT REVIEW

Quality Assurance has conducted a thorough review of the test data generated during this study. Report Number 17F0417H-A01G represents an accurate description of the conduct and final results of the study. To the best of my knowledge and ability, this study has been conducted in compliance with applicable Good Laboratory Practice regulations.

Date of Data/ Report Review	Date Review Provided to PBL Principal Investigator/ Study Director / Management	QA Auditor
08/28/17	08/28/17	KAT

08/29/17

X Kenneth Tan

QA Review
Signed by: Kenneth Tan

1. GENERAL INFORMATION

1.1. Study Dates

Study Authorization:	Signed Protocol
Date Test Article Received:	April 17, 2017
Study Initiation Date:	July 25, 2017
Date On Test:	July 28, 2017
Date Off Test:	August 03, 2017
Report Date:	August 29, 2017

1.2. Protocol

This test was conducted according to Protocol Number: 17F0417H-A01G. There were no amendments to the protocol (Appendix II).

1.3. Deviations from Protocol

There were no deviations from the Protocol that affected the integrity of the study.

1.4. Key Personnel and Laboratories

Principal Investigator:	Erik Foehr Pacific BioLabs 551 Linus Pauling Drive Hercules, CA 94547 United States Phone: (510) 964-9000
Study Sponsor:	Florence Rowe Tristel Solutions Limited Unit 1B Lynx Business Park, Fordham Road, Snailwell, Cambridgeshire, CB8 7NY, United Kingdom Phone: +44 (0) 1638-721500

2. INTRODUCTION

The purpose of the this study is to evaluate methods of analysis and test conditions to measure the nucleic acid degradation properties of Tristel Duo solution. Polyacrylamide gel electrophoresis (PAGE) was used as a method to measure the ability of Tristel Duo to degrade DNA and RNA because of the visual nature of the analysis and the limited matrix effects. Tristel Duo degrades DNA and RNA within 0.5 minutes of contact. This study supports the intended use of Tristel Duo as a disinfectant.

3. MATERIALS AND METHODS

3.1. Test Materials

3.1.1. Test Article Identification

Test Article Name:	Tristel Duo
Physical Description:	Liquid
Batch Number:	P708803
Manufacture Date	March 2017
Expiration Date:	March 2019
Storage Conditions:	Room Temperature
Final Intended Use/Application:	Disinfectant

3.1.2. Test Article Characterization

The Sponsor is responsible for all test article characterization specified in the Good Laboratory Practices (GLP) regulations (21 CFR 58.105). The Sponsor has supplied sufficient information to Pacific BioLabs to assure characterization of the test article meets applicable requirements, including the unique identification and stability of the test article (Appendix I). The Sponsor is responsible for maintaining records of manufacture that would provide information on the composition of the test article, and would be able to supply those records if requested by regulatory authorities.

3.1.3. Reserve Sample and Sample Disposition

After completion of the study, all remaining test articles were disposed according to Pacific BioLabs SOPs.

3.2. Test Methods

To determine the ability of Tristel Duo to degrade RNA and DNA samples were prepared by mixing an equal volume of the nucleic acid with Tristel Duo for different amounts of time. 5 µL of 0.1 µg/µL DNA or 5 µL, of 4 µg/µL RNA sample were incubated with 5 µL of Tristel Duo for 0.5, 1 and 2 minutes. Samples containing only DNA, only RNA, or only Tristel Duo were used as controls. The reaction was stopped with 2 µL nucleic acid loading dye. The samples were then loaded at 12 µL/well onto 5% PAGE-TBE and run for 1 hour at 100 V. The gels were stained with Ethidium Bromide and imaged on GelDoc system.

4. RESULTS AND DISCUSSION

Tristel Duo was analyzed for the ability to degrade DNA and RNA. The Tristel Duo sample was pumped from the container closure system into a beaker to dispense and mix the solution. A sample of the mixture was then tested for nucleic acid degradation properties. The method, polyacrylamide gel electrophoresis (PAGE) of nucleic acids was validated according to USP recommendations and used to analyze the nucleic acid degradation properties of Tristel Duo. The results of the method validation for RNA and DNA analysis by PAGE are shown in Figures 1A and 1B respectively. The PAGE method of analysis is sufficiently sensitive and has the ability to resolve nucleic acids based on size. Based on visual inspection of the gel, it is possible to detect greater than 5 ng DNA and 0.2 µg of RNA. Therefore, the technique is fit for the purpose of analyzing nucleic acid degradation properties of Tristel Duo.

Figure 1A. Analysis of RNA by PAGE

Lane
1. 20 ug RNA
2. 10 ug RNA
3. 4 ug RNA
4. 0.2 ug RNA

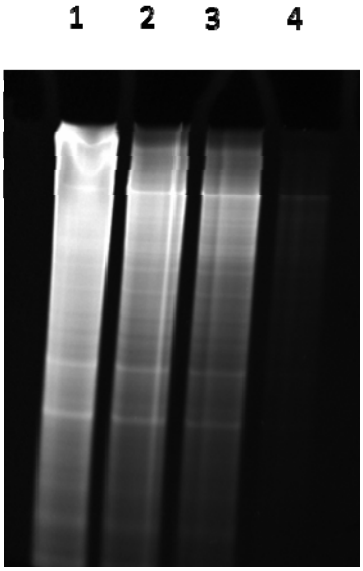
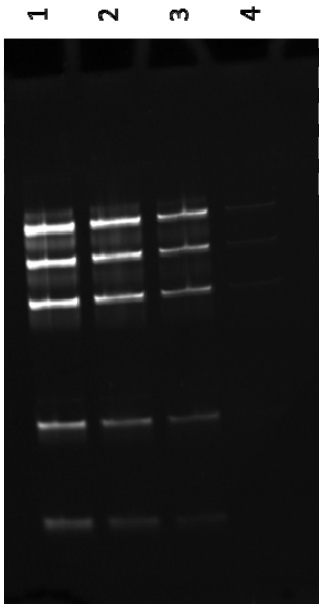


Figure 1B. Analysis of DNA by PAGE

Lane
1. 500 ng DNA
2. 250 ng DNA
3. 100 ng DNA
4. 5 ng DNA



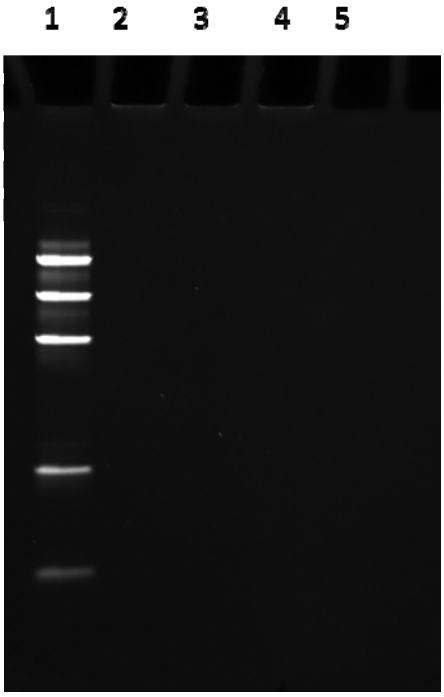
Samples of DNA and RNA were incubated with Tristel Duo for 0, 0.5, 1, and 2 minutes and then analyzed by PAGE. The results of the analysis are described in Figure 2A and 2B. Tristel Duo degrades DNA and RNA within 0.5 minutes.

Figure 2A. RNA Degradation properties of Tristel Duo

Lane
1. 20 ug RNA
2. 20 ug RNA + 5 uL Tristel Duo for 0.5 min
3. 20 ug RNA + 5 uL Tristel Duo for 1 min
4. 20 ug RNA + 5 uL Tristel Duo for 2 min
5. Tristel Duo

Figure 2B. DNA Degradation properties of Tristel Duo

Lane
1. 500 ng DNA
2. 500 ng DNA + 5 uL Tristel Duo for 0.5 min
3. 500 ng DNA + 5 uL Tristel Duo for 1 min
4. 500 ng DNA + 5 uL Tristel Duo for 2 min
5. Tristel Duo



5. CONCLUSION

Tristel Duo degrades DNA and RNA within 0.5 minutes of contact. This observation supports the intended use of Tristel Duo as a disinfectant effective against DNA and RNA.

6. REFERENCES

PBL Project 17F0082R-A01, *Analysis of Tristel Duo nucleic acid degradation properties*

PBL SOP 12H-03, rev. 1C.00, *Procedure for Development and Validation of Analytical Methods*

PBL SOP 12H-06, rev. 3A.00, *Development, Preparation and Use of Analytical Test Methods*

PBL SOP 06-08, rev. 7A.00, *Study Protocol*

PBL SOP 05G-15, rev. 1A.00, *Procedure for operation of the Bio-Rad GelDoc EZ system gel imager*

USP <1056>, *Biotechnology-derived articles-polyacrylamide gel electrophoresis*

USP <1126>, *Nucleic Acid-Based techniques-extraction, detection, and sequencing*

FDA GLP Good Laboratory Practice Regulations; Food and Drug Administration: 21 CFR Part 58.

APPENDIX I

Test Article Information

Tristel

CERTIFICATE OF ANALYSIS

Tristel Product:	Tristel Duo
Batch Number:	P708803

Product Name:	Tristel Duo Base Solution (Batch 707902)
Reference:	TRI/DUO/013
Date of Manufacture:	20-MAR-2017
Date of Expiry:	MAR-2019
Date of Testing:	20-MAR-2017

PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Light blue liquid, Clear and free of suspended matter	Conforms
SPECIFIC GRAVITY	1.020-1.030	1.022
pH	2.0-2.5	2.4
Citric Acid concentration (%)	4.5-5.5	5.1

Product Name:	Tristel Duo Activator Solution (Batch 707903)
Reference:	TRI/DUO/012
Date of Manufacture:	20-MAR-2017
Date of Expiry:	MAR-2019
Date of Testing:	20-MAR-2017

PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Colourless liquid, Clear and free of suspended matter	Conforms
SPECIFIC GRAVITY	1.000-1.010	1.005
pH	10.3-11.3	11.1
Sodium chlorite concentration (%)	0.45-0.55	0.49

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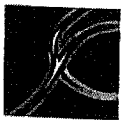
Tel: +44 (0)1638 721500 Fax: +44 (0)1638 721911 Email: mail@tristel.com Web: www.tristel.com



Tristel

Product Name:	Tristel Duo Working Solution	
Reference:	TRI/DUO/220	
Date of Testing:	22-MAR-2017	
PROPERTIES	**SPECIFICATION**	**RESULTS**
APPEARANCE	Yellow liquid, Clear and free of suspended matter	Conforms
Chlorine dioxide concentration (PPM)	In accordance with TRI/DUO/220 PASS/FAIL	PASS
Foam Stability	In accordance with QTM040 PASS/FAIL	PASS

This is to certify that Tristel Duo was found to comply with all requirements as set out in the specifications and method of analysis.

Completed By:

Quality Department: .....

Date: 2017-07-06

Reviewed By:

.....

Date: 2017.07.16

Tristel Solutions Limited. Lynx Business Park, Fordham Road, Snailwell, Cambs CB8 7NY. Registered No: 3518312
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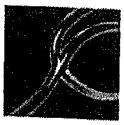

APPENDIX II

Protocol

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STUDY SPONSOR

Tristel Solutions Limited
Unit 1B Lynx Business Park,
Fordham Road,
Snailwell, Cambridgeshire,
CB8 7NY,
United Kingdom

GLP Study Protocol

Validation of polyacrylamide gel electrophoresis test and analysis of Tristel Duo for nucleic acid degradation properties

Study Number

17F0417H

PERFORMING LABORATORY

Pacific BioLabs
551 Linus Pauling Drive
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United States

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1. GENERAL INFORMATION

This GLP Protocol describes testing for test and control articles (TACA) submitted by the Sponsor in compliance with the Food and Drug Administration's Good Laboratory Practice (GLP) Regulations (21CFR Part 58). Pacific BioLabs will require a *Laboratory Service Request* (LSR) form with each TACA that details the characteristics of the TACA submitted for testing.

1.1. Study Number

17F0417H

1.2. Study Title

Validation of polyacrylamide gel electrophoresis test and analysis of Tristel Duo for nucleic acid degradation properties

1.3. Test Facility

Pacific BioLabs
551 Linus Pauling Dr.
Hercules, CA 94547
United States

1.4. Responsible Personnel

Study Sponsor:
Florence Rowe
Tristel Solutions Limited
Unit 1B Lynx Business Park,
Fordham Road,
Snailwell, Cambridgeshire,
CB8 7NY,
United Kingdom
Phone: (0) 1638-721500
E-mail: FlorenceRowe@tristel.com

Study Director:
Erik Foehr
Pacific BioLabs
551 Linus Pauling Dr.
Hercules, CA 94547
United States
Phone: 510-964-9000
Email:ErikFoehr@PacificBioLabs.com

1.5. Proposed Study Dates

The study dates may change due to unexpected events; and major delays in the study conduct will be communicated with the Sponsor. The actual study dates will be specified in the Study Report and will not be added by amendment to the Protocol.

Proposed Start Date: June 25th, 2017
Target Termination Date: June 30th, 2017
Proposed Report Date: At Study Director's Signature

1.6. Alterations to the Protocol

Alterations to the general scope of the Protocol may be made over the period that the Protocol is in effect. Alterations to the Protocol that apply to all subsequent testing will be documented by an amendment to the Protocol and signed and dated by Pacific BioLabs and the Sponsor. In the event that a protocol

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change is verbally authorized by the Sponsor, Pacific BioLabs will honor the change. However, written authorization from the Sponsor will be obtained thereafter. Administrative protocol changes may not require Sponsor signature. Any protocol amendments will be issued to the Sponsor and will be included in the Study Report.

Any deviations to the Protocol during the course of an individual study will be reported and justified by the Study Director as to impact on the study.

1.7. Statement of Compliance

This nonclinical laboratory study will be conducted in accordance with the appropriate Standard Operating Procedures of Pacific BioLabs (Hercules, CA) and the Food and Drug Administration Good Laboratory Practice (GLP) Regulations For Nonclinical Laboratory Studies (21 CFR Part 58) with the exception of Microsoft Excel®, which will be used for data analysis. This nonclinical study will be inspected by the Quality Assurance Unit (QAU) at Pacific BioLabs at intervals adequate to assure the integrity of the study. QAU inspection findings will be reviewed by the management of Pacific BioLabs; the Study Director and management will be notified immediately if there are any deviations which might affect the integrity of the data.

Supporting Studies Conducted by Pacific BioLabs Designated Laboratories

There are no supporting studies conducted by outside laboratories designated by Pacific BioLabs that contribute to this Protocol.

Supporting Studies Conducted by Sponsor

This Protocol does not incorporate supporting studies conducted by the Sponsor. All studies conducted by the Sponsor in conjunction with this Protocol will be reported separately by the Sponsor and will be the sole responsibility of the Sponsor.

1.8. Safety to the Laboratory

The Sponsor will provide safety information to Pacific BioLabs in the form of a Material Safety Data Sheet (MSDS) for each test article, if available. In the absence of specific safety requirements, standard laboratory safety procedures will be employed for handling the test and control articles, including the use of appropriate personal protective equipment.

1.9. Declaration of Intent

The design and scope of this study are consistent with the overall development strategy of the Sponsor, and this study may be submitted to regulatory agencies, including the United States Food and Drug Administration (FDA).

2. PURPOSE

The purpose of this study is to validate the test per USP <1056> Biotechnology-derived articles-polyacrylamide gel electrophoresis for sensitivity and target resolution range. The polyacrylamide gel electrophoresis test method will then be used to evaluate the nucleic acid degradation properties of Tristel Duo. Tristel Duo will be added to mixtures of DNA and RNA for specified times and then the sample analyzed by polyacrylamide gel electrophoresis and imaging.

2.1. Justification of Method Assay

Polyacrylamide gel electrophoresis (PAGE) is used for the qualitative and quantitative characterization of nucleic acids and proteins based on the sieving and size based resolution properties of polyacrylamide gels. Non-denaturing polyacrylamide gel electrophoresis is suitable for small- to mid- sized DNA and RNA fragments, according to USP <1126> Nucleic Acid-Based techniques-extraction, detection, and

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sequencing. The separated nucleic acids are visualized by staining with ethidium bromide and UV GelDoc imager. The test method conditions were developed under study 17F0082R-A01.

3. PROCEDURES

3.1. Test Materials

3.1.1. Test and Control Articles

Identification and characterization of test articles will be specified in the Study Report of test results, and will not be added by amendment to the Protocol. The following information, supplied by the Sponsor, may be included in the Study Report:

Test Article Name:	Tristel Duo
Physical Description:	Liquid
Batch Number:	P708803
Manufacture Date	March 2017
Expiration Date:	March 2019
Storage Conditions:	Room Temperature
Final Intended Use/Application:	Disinfectant

Control Articles will be provided by Pacific BioLabs and will be specified in the Final Report.

Reference Material Name:	Precision DNA MW ruler
Physical Description:	Liquid
Manufacturer:	Bio-Rad
Lot Number:	64074998
Expiration Date:	9/19/2019
Storage Conditions:	4-8 C

Reference Material Name:	RNA 16S and 23S
Physical Description:	Liquid
Manufacturer:	Sigma-Aldrich
Lot Number:	22531520
Expiration Date:	3/30/2018
Storage Conditions:	-20 C

Test and Control Article Characterization

The Sponsor will supply Certificates of Analyses and stability certifications for GLP required characterization of the composition, stability and other pertinent information for the test article. Documentation of the characterization of test articles, control articles will be included in the Study Report. The absence of documentation of the identity, composition, strength and stability of the test articles or control articles (e.g., a CofA) will be considered noncompliance with GLP expectations and will be documented in the Final Report.

The Sponsor's signature and approval of this Protocol indicates that appropriate documentation of the method of synthesis, fabrication or derivation of the test and control articles is available to the appropriate regulatory agencies if requested.

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Reserve Sample and Sample Disposition

Unless requested otherwise, unused test articles or control articles will be discarded or destroyed at the end of the study according to Pacific BioLabs SOPs.

FDA and US Environmental Protection Agency (EPA) regulations require that, for studies of more than four weeks duration, reserve sample from each batch of material be retained for the period of time provided in FDA GLP Regulations 21 CFR Parts 58.105 and 58.195. The various agencies have, in the past, recommended that the amount of reserve sample be enough to repeat the study two or three times. Sponsor is responsible for retention of test and control article reserves.

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3.2. Validation of the test

3.2.1. Target Resolution Range

The target resolution range of the gel is demonstrated by the distribution of appropriate molecular mass markers across the gel. The intended use of the test method is to demonstrate degradation properties of Tristel Duo product and not to evaluate the size of nucleic acids per se. Therefore, target resolution is intended to show that the 5% TBE-PAGE is appropriate for the intended use.

Procedure:

Prepare 5 uL, 0.1 ug/uL Precision MW ruler DNA or 5 uL, 4 ug/uL 16S and 23S RNA sample
Add 2 uL nucleic acid loading dye.
Add sufficient water (3 uL) to bring total volume to 10 uL.
Load entire amount (10 uL) sample onto 5% PAGE-TBE.
Run 1 hour at 100 V.
Stain with Ethidium Bromide and image on GelDoc.

Acceptance Criteria:

The DNA and RNA should migrate based on size and be sufficiently resolved across the length of the gel.

3.2.2. Sensitivity

Sensitivity is evaluated at desired concentration limit and can serve as a system suitability check of the experiment. Prepare decreasing amounts of DNA or RNA to evaluate sensitivity limit.

Procedure:

Prepare dilution series of DNA or RNA to evaluate sensitivity.
For example prepare and load DNA at 500 ng, 250 ng, 100 ng, 5 ng per well using appropriate dilution scheme. Prepare and load RNA at 20 ug, 10 ug, 4 ug, and 0.2 ug per well using appropriate dilution scheme.
Add 5 uL of DNA or RNA samples
Add 2 uL nucleic acid loading dye.
Add sufficient water (3 uL) to bring total volume to 10 uL.
Load entire amount (10 uL) sample onto 5% PAGE-TBE.
Run 1 hour at 100 V.
Stain with Ethidium Bromide and image using Bio-Rad GelDoc imager.

Acceptance Criterion:

The sensitivity limit of the assay is determined visually by the ability to distinguish nucleic acid markers on the gel image. The lowest concentration of samples that can be visually identified is considered the sensitivity of the test method.

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4. Test Method

The ability of Tristel Duo solution to degrade DNA and RNA will be evaluated by polyacrylamide gel electrophoresis. Previous method development and evaluation from study 17F0082R-A01 demonstrated a concentration dependent degradation of DNA and RNA. In this analysis the time dependency of Tristel Duo will be evaluated. Tristel Duo will be added to a known amount of DNA or RNA and incubated for 0, 0.5, 1, and 2 minutes. The samples will then be analyzed by 5% TBE-PAGE.

Procedure:

Prepare 5 uL, 0.1 ug/uL Precision MW ruler DNA or 5 uL, 4 ug/uL 16S and 23S RNA sample
Add 5 uL of Tristel Duo (liquid) solution (1 part base and 1 part activator, mixed for ~5 seconds) into beaker
Incubate samples for 0.5, 1, and 2 minutes.
Include DNA or RNA only controls (no Tristel Duo Solution added) and Tristel Duo only control
Add sufficient water to bring total volume to 10 uL.
Add 2 uL nucleic acid loading dye.
Load entire amount (12 uL) sample onto 5% PAGE-TBE.
Run 1 hour at 100 V.
Stain with Ethidium Bromide and image on GelDoc.

Acceptance Criterion:

DNA or RNA samples without added Tristel Duo should be clearly visible.

Report Results.

5. DATA ACQUISITION AND ANALYSIS

5.1. Analysis

Data analysis will be generated by Pacific BioLabs using, but not limited to, GelDoc Imager, Microsoft PowerPoint®, Microsoft Excel® and Microsoft Word®. Report Results of analysis by imaging using GelDoc and save file.

5.2. Statistical Analysis

No statistical analyses will be performed by Pacific BioLabs for this study.

6. REPORTS

6.1. General Description of Study Report

The Study Report will include all information necessary to provide a complete and accurate description of the experimental procedures and results. The Study Report will include a compliance statement signed by the Study Director that the report accurately reflects the raw data obtained during the performance of the study and that all applicable GLP regulations were followed in the conduct of the study.

6.2. Study Report

The Study Report will include, but not be limited to, the following:

Name and address of the test facility

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Study dates
Study summary
The objective of the study
Test and control article identification
A full description of the experimental design and methods
Study results in prose and tabular form as appropriate
Any deviations from the Protocol
Signed statement of compliance from the Study Director

The Study Report will not include results of analyses performed by the Sponsor. Communication of the results of these Sponsor-conducted analyses to the appropriate regulatory agencies will be the responsibility of the Sponsor. Upon finalization, copies of the Final Report will be provided to the Sponsor as hardcopies or PDF files.

7. MAINTENANCE OF RAW DATA, RECORDS AND SPECIMENS

Original data, test articles, and reports from this study are the property of the Sponsor. These materials will be available to the Sponsor to facilitate reviewing the study during its progress and before issuance of the Final Report. Records (including, but not limited to, protocol, protocol amendments(s), and correspondence related to the study, Final Report, and materials will be archived at Pacific BioLabs (Hercules, CA) for a period of one year after issuance of the Final Report. After one year, the Sponsor will be contacted concerning continued storage or return of materials.

Records and materials associated with activities external to Pacific BioLabs and activities conducted by the Sponsor will be archived by the individual performing laboratories or the Sponsor in a manner consistent with their individual operating SOPs and regulatory requirements.

8. REFERENCES

FDA GLP Good Laboratory Practice Regulations; Food and Drug Administration: 21 CFR Part 58.
PBL SOP 12H-03 1C.00 *Procedure for Development and Validation of Analytical Methods*
PBL SOP 12H-06 3A.00 *Development, Preparation and Use of Analytical Test Methods*
PBL SOP 06-08 7A.00 *Study Protocol*
PBL SOP 05G-15 *Procedure for operation of the Bio-Rad GelDoc EZ system gel imager*
USP <1056> *Biotechnology-derived articles-polyacrylamide gel electrophoresis*
USP <1126> *Nucleic Acid-Based techniques-extraction, detection, and sequencing*

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9. APPROVALS

FOR SPONSOR

Study Sponsor — Date: 25 JUL 17

FOR PACIFIC BIOLABS

Erik Foehr
Pacific BioLabs
Study Director — Date: 7/25/17

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