

Tristel Rinse Assure Water Quality Study GLP Report

Test Article: Rinse Assure Device
 P725800
 Exp: 05/2019
 Purchase Order: 705612 / 705611
 Study Number: 999667-S01.1 Amended
 Study Received Date: 30 Oct 2017
 Study Completion Date: 29 Dec 2017
 Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International
 6280 S. Redwood Rd.
 Salt Lake City, UT 84123 U.S.A.
 Test Procedure(s): Customer Specification Sheet (CSS) Number: 201706815 Rev 01
 Deviation(s): None

Summary: This report discusses the procedure for evaluating the pre-treatment and post-treatment water quality of the Rinse Assure Version 3 device. The input and output water of the device was evaluated for the following characteristics: chlorine dioxide residual with ChlordioXense CS300 Palintest, pH, bacterial endotoxin, conductivity, water hardness and water chloride content.

Appendix A Number of Pages: 7

Results:

Test	Pre-Treatment Result	Post-Treatment Result
Chlorine Dioxide	<0.02 mg/L	0.13 mg/L
	<0.02 mg/L	0.14 mg/L
	<0.02 mg/L	0.14 mg/L
pH	8.14	4.62
	8.17	4.47
	8.16	4.45
Endotoxin	2.34 EU/mL	0.413 EU/mL
	2.36 EU/mL	0.477 EU/mL
	2.93 EU/mL	0.407 EU/mL




 Technical Reviewer

19 Jan 2018
 Date


 Study Director Thomas K. Pace, B.S., RM(NRCM)

19 JAN 2018
 Amended Report Date





Test	Temperature (°C)	Pre-Treatment Result (µS/cm)	Temperature (°C)	Post-Treatment Result (µS/cm)
Water Conductivity Stage 1	9.9	276.9	10.0	53.7
	9.4	274.3	10.0	53.6
	9.9	278.4	11.0	55.3
Water Conductivity Stage 2	24.6	395	24.9	75.6
	24.8	396	24.9	75.7
	24.8	396	24.9	75.7

Procedures: Rinse Assure Device Installation: The sponsor installed the device while onsite at Nelson Laboratories LLC. (NL). Machine flow rates were calculated using calibrated electronic flow meters to inlet water and chlorine dioxide base and activator chemistry. The sponsor was responsible for determining that the device was installed appropriately.

Pre Treatment Water Analysis: Aliquots of the water supplied to the device were captured in order to perform the following tests:

Chlorine dioxide residual with the ChlordioXense CS300 Palintest: Three aliquots of at least 10 mL each were obtained to perform the Palintest. The test was performed according to the manufacturer's instructions with an instrument provided by the sponsor. The method has not been validated by NL.

pH: Three aliquots of at least 10 mL each were obtained to determine the pH of the incoming water.

Bacterial Endotoxin: Three aliquots of at least 10 mL each were obtained to determine the bacterial endotoxin of the incoming water.

Water Conductivity: Three aliquots of at least 10 mL each were obtained to determine the conductivity of the incoming water. Water conductivity testing was performed according to USP <645>.

Water Hardness: Three aliquots of at least 10 mL each were obtained to determine the hardness of the incoming water.

Water Chlorides: Three aliquots of at least 10 mL each were obtained to determine the chloride content of the incoming water.

Post Treatment Water Analysis Test: The Rinse Assure device was operated according to the sponsor's instructions.

Aliquots of the output water were captured from the device in order to perform the following tests:

Chlorine dioxide residual with the ChlordioXense CS300 Palintest: Three aliquots of at least 10 mL each were obtained to perform the Palintest. The test was performed according to the manufacturer's instructions with an instrument provided by the sponsor. The method has not been validated by NL.



pH: Three aliquots of at least 10 mL each were obtained to determine the pH of the incoming water.

Bacterial Endotoxin: Three aliquots of at least 10 mL each were obtained to determine the bacterial endotoxin of the incoming water. Water conductivity testing was performed according to USP <645>.

Water Conductivity: Three aliquots of at least 10 mL each were obtained to determine the conductivity of the incoming water.

Water Hardness: Three aliquots of at least 10 mL each were obtained to determine the hardness of the incoming water.

Water Chlorides: Three aliquots of at least 10 mL each were obtained to determine the chloride content of the incoming water.

Volumetric pressure and dosing parameters were recorded at the time of testing with a screen shot capturing the data generated by the Rinse Assure machine.

The water quality criteria from TIR34 are provided in Table 1 for informational purposes to compare to the results obtained from the pre and post-treatment water.

Table 1: Water specifications for critical and utility water according to TIR34

Water Specification	Units	Critical Water Specification	Utility Water Specification
Hardness	mg/L	<1	<150
Conductivity (mg/L = ppm)	µS/cm	<10	<500
pH		5-7	6-9
Chlorides	Mg/L	<1	<250
Endotoxin	EU/mL	<10	<20

Amendment Justification: An Appendix A was added to the final report.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	08 Nov 2017
Phase Inspected by Quality Assurance: Pre-Treatment Water Sample	15 Nov 2017
Audit Results Reported to Study Director	16 Nov 2017
Audit Results Reported to Management	16 Nov 2017

Scientists	Title
Eric Clark	Supervisor
Thomas Pace	Study Director
Kelly Walden	Scientist
Adam Michaud	Scientist

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.



 Quality Assurance

19 Jan 2018

 Date

Appendix A



Amended

12/7/2017

**Work Order: 17K1167
Project: NLI# 999667**

**Nelson Laboratories, Inc.
Attn: Scott Dimond
6280 South Redwood Road
Salt Lake City, UT 84123**

Client Service Contact: 801.262.7299

The analyses presented on this report were performed in accordance with the National Environmental Laboratory Accreditation Program (NELAP) unless noted in the comments, flags, or case narrative. If the report is to be used for regulatory compliance, it should be presented in its entirety, and not be altered.



Approved By:

Mark Broadhead, Project Manager



CHEMTECH-FORD
LABORATORIES

Amended Report Narrative

Report Changes:

The client project name was changed.

Change Justification:

The client changed the project name after the report was issued.

Nelson Laboratories, Inc.

Project: NLI# 999667

Project Manager: Scott Dimond

<u>Laboratory ID</u>	<u>Sample Name</u>
17K1167-01	Water Hardness Test Pre-Treatment Replicate 1-3 (pooled)
17K1167-02	Water Hardness Test Post Treatment Replicate 1-3 (pooled)
17K1167-03	Water Chlorides Pre-Treatment Replicate 1-3 (pooled)
17K1167-04	Water Chlorides Post Treatment Replicate 1-3 (pooled)

Work Order Report Narrative

Sample Preparation

All samples were prepared within method specified holding times. No preparation issues were noted.

Method Blanks

All blank values were within method acceptance criteria. No blank values exceeded the minimum reporting limit for any analysis in this work order.

Laboratory Control Samples

All laboratory control samples were within method acceptance criteria.

Method Spikes

All method spike recoveries were within method acceptance criteria, except as noted by qualifying flags.

Method Spike Duplicates

All method spike duplicates were within method acceptance criteria, except as noted by qualifying flags.

Corrective Actions

There are no corrective actions associated with this work order.

Project Name: NLI# 999667

CtF WO#: 17K1167

www.ChemtechFord.com



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Number: 999667-S01.1 Amended

9632 South 500 West
Sandy, UT 84070
O:(801) 262-7299 F: (866) 792-0093
www.ChemtechFord.com



Amended

Certificate of Analysis

Amended

Nelson Laboratories, Inc.
Scott Dimond
6280 South Redwood Road
Salt Lake City, UT 84123

PO#: CHE-2017
Receipt: 11/22/17 10:17 @ 20.9 °C
Date Reported: 12/7/2017
Project Name: NLI# 999667

Sample ID: Water Hardness Test Pre-Treatment Replicate 1-3 (pooled)

Matrix: As Received

Lab ID: 17K1167-01

Date Sampled: 11/15/17 0:00

Sampled By: Client

	<u>Result</u>	<u>Units</u>	<u>Minimum Reporting Limit</u>	<u>Method</u>	<u>Preparation Date/Time</u>	<u>Analysis Date/Time</u>	<u>Flag(s)</u>
Calculations							
Hardness, Total as CaCO3	ND	mg/L	1.3	SM 2340 B	11/27/17	11/27/17	
Metals							
Calcium, Total	ND	mg/L	0.2	EPA 200.7	11/27/17	11/27/17	
Magnesium, Total	ND	mg/L	0.2	EPA 200.7	11/27/17	11/27/17	



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Salt Lake City, UT 84123

PO#: CHE-2017
Receipt: 11/22/17 10:17 @ 20.9 °C
Date Reported: 12/7/2017
Project Name: NLI# 999667

Sample ID: Water Hardness Test Post Treatment Replicate 1-3 (pooled)

Matrix: As Received

Lab ID: 17K1167-02

Date Sampled: 11/15/17 0:00

Sampled By: Client

	<u>Result</u>	<u>Units</u>	<u>Minimum Reporting Limit</u>	<u>Method</u>	<u>Preparation Date/Time</u>	<u>Analysis Date/Time</u>	<u>Flag(s)</u>
Calculations							
Hardness, Total as CaCO3	ND	mg/L	1.3	SM 2340 B	11/27/17	11/27/17	
Metals							
Calcium, Total	ND	mg/L	0.2	EPA 200.7	11/27/17	11/27/17	
Magnesium, Total	ND	mg/L	0.2	EPA 200.7	11/27/17	11/27/17	



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PO#: CHE-2017
Receipt: 11/22/17 10:17 @ 20.9 °C
Date Reported: 12/7/2017
Project Name: NLI# 999667

Sample ID: Water Chlorides Pre-Treatment Replicate 1-3 (pooled)

Matrix: As Received

Lab ID: 17K1167-03

Date Sampled: 11/15/17 0:00

Sampled By: Client

	<u>Result</u>	<u>Units</u>	<u>Minimum Reporting Limit</u>	<u>Method</u>	<u>Preparation Date/Time</u>	<u>Analysis Date/Time</u>	<u>Flag(s)</u>
Inorganic							
Chloride	26	mg/L	1	EPA 300.0	11/22/17	11/22/17	



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PO#: CHE-2017
Receipt: 11/22/17 10:17 @ 20.9 °C
Date Reported: 12/7/2017
Project Name: NLI# 999667

Sample ID: Water Chlorides Post Treatment Replicate 1-3 (pooled)

Matrix: As Received

Lab ID: 17K1167-04

Date Sampled: 11/15/17 0:00

Sampled By: Client

	<u>Result</u>	<u>Units</u>	<u>Minimum Reporting Limit</u>	<u>Method</u>	<u>Preparation Date/Time</u>	<u>Analysis Date/Time</u>	<u>Flag(s)</u>
Inorganic							
Chloride	3	mg/L	1	EPA 300.0	11/22/17	11/22/17	



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Receipt: 11/22/17 10:17 @ 20.9 °C
Date Reported: 12/7/2017
Project Name: NLI# 999667

Report Footnotes

Abbreviations

ND = Not detected at the corresponding Minimum Reporting Limit (MRL).

1 mg/L = one milligram per liter or 1 mg/kg = one milligram per kilogram = 1 part per million.

1 ug/L = one microgram per liter or 1 ug/kg = one microgram per kilogram = 1 part per billion.

1 ng/L = one nanogram per liter or 1 ng/kg = one nanogram per kilogram = 1 part per trillion.