Environmental Technology Verification Report

Physical Removal of Microbial Contamination Agents in Drinking Water

Kinetico Incorporated Pall/Kinetico Purefecta™ Drinking Water Treatment System

Prepared by

NSF

NSF International

Under a Cooperative Agreement with
EPA U.S. Environmental Protection Agency

ETV ETV ETV

THE ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM

⊕EPA

U.S. Environmental Protection Agency

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NSF

NSF International

ETV Joint Verification Statement

TECHNOLOGY TYPE:	**POINT-OF-USE DRINKING WATER TREATMENT SYSTEM**
APPLICATION:	**REMOVAL OF MICROBIAL CONTAMINATION AGENTS IN DRINKING WATER**
PRODUCT NAME:	**PALL/KINETICO PUREFECTA™**
COMPANY:	**KINETICO INCORPORATED**
ADDRESS:	**10845 KINSMAN ROAD** PHONE: **800-944-9283**
	NEWBURY, OH 44065 FAX: **440-564-9541**
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NSF International (NSF) manages the Drinking Water Systems (DWS) Center under the U.S. Environmental Protection Agency's (EPA) Environmental Technology Verification (ETV) Program. The DWS Center recently evaluated the performance of the Pall/Kinetico Purefecta™ point-of-use (POU) drinking water treatment system. NSF performed all of the testing activities, and also authored the verification report and this verification statement. The verification report contains a comprehensive description of the test.

EPA created the ETV Program to facilitate the deployment of innovative or improved environmental technologies through performance verification and dissemination of information. The goal of the ETV Program is to further environmental protection by accelerating the acceptance and use of improved and more cost-effective technologies. ETV seeks to achieve this goal by providing high-quality, peer-reviewed data on technology performance to those involved in the design, distribution, permitting, purchase, and use of environmental technologies.

ETV works in partnership with recognized standards and testing organizations, stakeholder groups (consisting of buyers, vendor organizations, and permitters), and with the full participation of individual technology developers. The program evaluates the performance of innovative technologies by developing test plans that are responsive to the needs of stakeholders, conducting field or laboratory tests (as appropriate), collecting and analyzing data, and preparing peer reviewed reports. All evaluations are conducted in accordance with rigorous quality assurance protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

ABSTRACT

The Pall/Kinetico Purefecta[TM] was tested for removal of bacteria and viruses at NSF's Drinking Water Treatment Systems Laboratory. Kinetico submitted ten units for testing, which were split into two groups of five. One group received 25 days of conditioning prior to challenge testing, while the second group was tested immediately. Both groups were identically challenged. The challenge organisms were the viruses fr, MS2, and Phi X 174, and the bacteria *Brevundimonas diminuta* and *Hydrogenophaga pseudoflava*. The test units were challenged at two different inlet pressures – 40 and 80 pounds per square inch, gauge (psig). The virus challenges were conducted at three different pH settings (6, 7.5, and 9) to assess whether pH influences the performance of the test units. The bacteria challenges were only conducted at pH 7.5.

The $\log_{10}$ reduction data is shown in Tables 2 through 5. The unconditioned units reduced all three viruses to less than detectible levels in every challenge, and the conditioned units reduced all three viruses to less than detectible levels in every challenge but one. The bacteria effluent counts for the unconditioned units were all less than 10 colony forming units (CFU)/100mL, but there were two instances where the bacteria counts for the conditioned units were higher (83,000 CFU/100mL and 600 CFU/100 mL) for reasons unknown.

The test data does not show whether inlet pressure or pH influenced test unit performance.

TECHNOLOGY DESCRIPTION

The following technology description was provided by the manufacturer, and has not been verified.

The Purefecta[TM] is a five-stage POU drinking water treatment system. It uses carbon filtration and reverse osmosis to remove chemical contaminants from drinking water, and a mechanical filtration "biofilter" to remove microorganisms. It is sold with a faucet that is installed at the kitchen sink. The "biofilter" is manufactured by the Pall Corporation and supplied to Kinetico, who manufactures the system. The Purefecta[TM] is designed to produce approximately four gallons of reject water for every gallon of treated water.

The test units were evaluated without the carbon filters or sediment filter in place to eliminate the possibility that these filters could temporarily trap a portion of the challenge organisms, causing a positive bias of system performance.

VERIFICATION TESTING DESCRIPTION

Test Site

The testing site was the Drinking Water Treatment Systems Laboratory at NSF in Ann Arbor, Michigan. A description of the test apparatus can be found in the test/QA plan and verification report. The testing was conducted in November and December of 2003.

Methods and Procedures

The testing methods and procedures are detailed in the *Test/QA Plan for Verification Testing of the Pall/Kinetico Purefecta[TM] Point-of-Use Drinking Water Treatment System for Removal of Microbial Contamination Agents*. Ten Purefecta[TM] systems were tested for bacteria and virus removal performance using the bacteriophage viruses fr, MS2, and Phi X 174, and the bacteria *B. diminuta* and *H. pseudoflava*. The challenge organisms were chosen because they are smaller than most other viruses and bacteria, and so provide a conservative estimate of performance.

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VS-ii

The test units were randomly split into two groups of five. One group was conditioned for 25 days prior to challenge testing by operating the units daily using the test water without challenge organisms. The second group was challenged without receiving the 25-day conditioning period. The test units were challenged at both 40 and 80 psig inlet pressure. The test water for the bacteria challenges was set to pH 7.5 ± 0.5, and the virus challenges were conducted at pH 6.0 ± 0.5, 7.5 ± 0.5, and 9.0 ± 0.5. The challenge schedule is shown in Table 1. The different challenge conditions were intended to evaluate whether inlet pressure or pH influences bacteria and virus removal. However, the test water chemistry gave it little buffering capacity, which made it difficult to keep the pH within 9.0 ± 0.5 for the pH 9 virus challenges. During the 80 psig challenge for the unconditioned units, and the 40 psig challenge for the conditioned units, the initial pH was above 8.5, but it drifted down to 8.25 and 8.22, respectively, by the end of the challenge periods.

Table 1. Challenge Schedule

Day	Surrogate Challenge	pH	Inlet Pressure (psig)
1	*H. pseudoflava*	7.5 ± 0.5	40 ± 3
2	*H. pseudoflava*	7.5 ± 0.5	80 ± 3
3	*B. diminuta*	7.5 ± 0.5	40 ± 3
4	*B. diminuta*	7.5 ± 0.5	80 ± 3
5	All Viruses	6.0 ± 0.5	40 ± 3
6	All Viruses	6.0 ± 0.5	80 ± 3
7	All Viruses	7.5 ± 0.5	40 ± 3
8	All Viruses	7.5 ± 0.5	80 ± 3
9	All Viruses	9.0 ± 0.5	40 ± 3
10	All Viruses	9.0 ± 0.5	80 ± 3

On each challenge day, the test units were operated for one tank-fill period (approximately 2 to 3 hours). The end of this period was evident through engagement of the system's automatic shutoff mechanism, which causes the flow of reject water to cease. Influent water samples were collected at the beginning and end of the challenge period. After each test unit ceased operation, the entire contents of the product water storage tank were emptied into a sterile container, and a subsample was collected for microbiological analysis. All samples were enumerated in triplicate. Following each challenge period, the test units were flushed by operating them for one tank-fill period using the test water without challenge organisms.

VERIFICATION OF PERFORMANCE

Tables 2 and 3 show the virus reduction data for the unconditioned units and conditioned units, respectively. The unconditioned units reduced all three viruses to less than detectible levels in every challenge, while the conditioned units reduced all three viruses to less than detectible levels in every challenge except one. For the pH 7.5, 40 psig challenge, all three viruses were detected in the treated water from test unit number 1. However, the viruses were detected only in the first of three triplicate counts, which indicates that perhaps one of the subsamples became contaminated during the sample processing procedure.

Tables 4 and 5 show the bacteria reduction data for the unconditioned units and conditioned units, respectively. The bacteria counts for the unconditioned units were all less than 10 CFU/100mL, but there were two instances where the bacteria counts for the conditioned units were higher. The 3.15 $\log_{10}$ reduction for unit 1 corresponds to a *B. diminuta* count of 83,000 CFU/100mL, and the 4.0 $\log_{10}$ reduction for unit 5 corresponds to an *H. pseudoflava* count of 600 CFU/100 ml. The reason(s) for the two higher bacteria effluent counts are unknown.

Table 2. Virus Log$_{10}$ Reduction Data for Unconditioned Units

pH	Pressure (psig)	Challenge Organisms	Log$_{10}$ Influent Challenge	Log$_{10}$ Reduction Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
6.0	40	fr	5.5					
		MS2	5.2		All effluents non-detect			
		Phi X 174	5.5		Log reductions equal to influents			
6.0	80	fr	5.7					
		MS2	5.5		All effluents non-detect			
		Phi X 174	3.2		Log reductions equal to influents			
7.5	40	fr	6.3					
		MS2	5.7		All effluents non-detect			
		Phi X 174	5.8		Log reductions equal to influents			
7.5	80	fr	5.7					
		MS2	5.6		All effluents non-detect			
		Phi X 174	5.9		Log reductions equal to influents			
9.0	40	fr	5.6					
		MS2	5.5		All effluents non-detect			
		Phi X 174	5.5		Log reductions equal to influents			
9.0	80	fr	5.6					
		MS2	5.1		All effluents non-detect			
		Phi X 174	5.8		Log reductions equal to influents			

Table 3. Virus Log$_{10}$ Reduction Data for Conditioned Units

pH	Pressure (psig)	Challenge Organisms	Log$_{10}$ Influent Challenge	Log$_{10}$ Reduction Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
6.0	40	fr	5.2					
		MS2	5.2		All effluents non-detect,			
		Phi X 174	3.3		log reductions equal to influents			
6.0	80	fr	5.2					
		MS2	4.9		All effluents non-detect,			
		Phi X 174	2.6		log reductions equal to influents			
7.5	40	fr	4.5	4.2				
		MS2	4.8	4.5	Effluents from Units 2-5 non-detect,			
		Phi X 174	2.6	2.3	log reductions equal to influents			
7.5	80	fr	5.2					
		MS2	5.0		All effluents non-detect,			
		Phi X 174	3.0		log reductions equal to influents			
9.0	40	fr	5.7					
		MS2	4.9		All effluents non-detect,			
		Phi X 174	3.0		log reductions equal to influents			
9.0	80	fr	4.9					
		MS2	4.6		All effluents non-detect,			
		Phi X 174	3.3		log reductions equal to influents			

Table 4. Bacteria Log Reduction Data for Unconditioned Units

pH	Pressure (psig)	Challenge Organisms	Log$_{10}$ Influent Challenge	Log$_{10}$ Reduction Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
7.5	40	*H. pseudoflava*	6.5	6.5	5.9	6.5	6.5	6.5
		B. diminuta	8.4	7.9	7.9	7.9	8.4	8.4
7.5	80	*H. pseudoflava*	6.8	6.8	6.8	6.5	6.8	6.8
		B. diminuta	8.2	8.2	8.2	8.2	8.2	8.2

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VS-iv

Table 5. Bacteria Log Reduction Data for Conditioned Units

pH	Pressure (psig)	Challenge Organisms	Log_{10} Influent Challenge	Log_{10} Reduction				
				Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
7.5	40	*H. pseudoflava*	7.4	7.4	7.4	7.4	7.4	7.4
		B. diminuta	8.1	8.1	8.1	8.1	8.1	8.1
7.5	80	*H. pseudoflava*	6.8	6.8	6.8	6.8	6.8	4.0
		B. diminuta	8.1	3.2	8.1	8.1	8.1	8.1

Complete descriptions of the verification testing results are included in the verification report.

QUALITY ASSURANCE/QUALITY CONTROL (QA/QC)

NSF personnel conducted a technical systems audit during testing to ensure that the testing was in compliance with the test plan. NSF also conducted a data quality audit of 100% of the data. Please see the verification report referenced below for more QA/QC information.

Original signed by
E. Timothy Oppelt   *07/22/04*

E. Timoty Oppelt   Date
Director
National Homeland Security Research Center
United States Environmental Protection
Agency

Original signed by
Gordon Bellen   *07/27/04*

Gordon Bellen   Date
Vice President
Research
NSF International

Availability of Supporting Documents
Copies of the test protocol, the verification statement, and the verification report (NSF report # NSF 04/13/EPADWCTR) are available from the following sources:
(NOTE: Not all of the appendices are included in the verification report. The appendices are available from NSF upon request.)

1. ETV Drinking Water Systems Center Manager (order hard copy)
   NSF International
   P.O. Box 130140
   Ann Arbor, Michigan 48113-0140
2. NSF web site: http://www.nsf.org/etv/dws/dws_reports.html, and from
   http://www.nsf.org/etv/dws/dws_project_documents.html (electronic copy)
   EPA web site: http://www.epa.gov/etv (electronic copy)

June 2004

Environmental Technology Verification Report

Removal of Microbial Contamination Agents in Drinking Water

Kinetico Incorporated
Pall/Kinetico Purefecta™ Drinking Water Purifier

Prepared by:

NSF International
Ann Arbor, Michigan 48105

Under a cooperative agreement with the U.S. Environmental Protection Agency

Jeffrey Q. Adams, Project Officer
National Risk Management Research Laboratory
U.S. Environmental Protection Agency
Cincinnati, Ohio 45268

i

Notice

The U.S. Environmental Protection Agency (EPA) through its Office of Research and Development has financially supported and collaborated with NSF International (NSF) under Cooperative Agreement No. R-82833301. This verification effort was supported by the Drinking Water Systems (DWS) Center, operating under the Environmental Technology Verification (ETV) Program. This document has been peer-reviewed, reviewed by NSF and EPA, and recommended for public release.

Foreword

The U.S. Environmental Protection Agency (EPA) is charged by Congress with protecting the Nation's land, air, and water resources. Under a mandate of national environmental laws, the Agency strives to formulate and implement actions leading to a compatible balance between human activities and the ability of natural systems to support and nurture life. To meet this mandate, EPA's research program is providing data and technical support for solving environmental problems today and building a science knowledge base necessary to manage our ecological resources wisely, understand how pollutants affect our health, and prevent or reduce environmental risks in the future.

The National Risk Management Research Laboratory (NRMRL) is the Agency's center for investigation of technological and management approaches for preventing and reducing risks from pollution that threaten human health and the environment. The focus of the Laboratory's research program is on methods and their cost-effectiveness for prevention and control of pollution to air, land, water, and subsurface resources; protection of water quality in public water systems; remediation of contaminated sites, sediments and ground water; prevention and control of indoor air pollution; and restoration of ecosystems. NRMRL collaborates with both public and private sector partners to foster technologies that reduce the cost of compliance and to anticipate emerging problems. NRMRL's research provides solutions to environmental problems by: developing and promoting technologies that protect and improve the environment; advancing scientific and engineering information to support regulatory and policy decisions; and providing the technical support and information transfer to ensure implementation of environmental regulations and strategies at the national, state, and community levels.

This publication has been produced as part of the Laboratory's strategic long-term research plan. It is published and made available by EPA's Office of Research and Development to assist the user community and to link researchers with their clients.

Table of Contents

Appendices

List of Tables

List of Figures

Abbreviations and Acronyms

ANSI	American National Standards Institute
ASTM	American Society of Testing Materials
ATCC	American Type Culture Collection
°C	Degrees Celsius
CFU	Colony Forming Unit
cm	Centimeter
DWS	Drinking Water Systems
EPA	U. S. Environmental Protection Agency
ETV	Environmental Technology Verification
°F	Degrees Fahrenheit
L	Liter
mg	Milligram
mL	Milliliter
nm	Nanometer
NRMRL	National Risk Management Research Laboratory
NSF	NSF International (formerly known as National Sanitation Foundation)
PBDW	Phosphate-Buffered Dilution Water
PFU	Plaque Forming Unit
POU	Point-of-Use
psig	Pounds per Square Inch Gauge
QA	Quality Assurance
QC	Quality Control
QA/QC	Quality Assurance/Quality Control
RO	Reverse Osmosis
SOP	Standard Operating Procedure
TDS	Total Dissolved Solids
TSA	Tryptic Soy Agar
TSB	Tryptic Soy Broth
μg	Microgram
μl	Microliter
μm	Micrometer
μmho	Micromho
μS	MicroSieman

Acknowledgments

NSF International was responsible for all elements in the testing sequence, including collection of samples, calibration and verification of instruments, data collection and analysis, data management, data interpretation and the preparation of this report.

The Manufacturer of the Equipment was:

NSF wishes to thank the members of the expert technical panel for their assistance with development of the test plan.

Chapter 1
Introduction

1.1 Environmental Technology Verification (ETV) Program Purpose and Operation

The U.S. Environmental Protection Agency (EPA) has created the ETV Program to facilitate the deployment of innovative or improved environmental technologies through performance verification and dissemination of information. The goal of the ETV Program is to further environmental protection by accelerating the acceptance and use of improved and more cost-effective technologies. ETV seeks to achieve this goal by providing high-quality, peer-reviewed data on technology performance to those involved in the design, distribution, permitting, purchase, and use of environmental technologies.

ETV works in partnership with recognized standards and testing organizations; with stakeholder groups consisting of buyers, vendor organizations, and permitters; and with the full participation of individual technology developers. The program evaluates the performance of innovative technologies by developing test plans that are responsive to the needs of stakeholders, by conducting field or laboratory testing, collecting and analyzing data, and by preparing peer-reviewed reports. All evaluations are conducted in accordance with rigorous quality assurance protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

The EPA has partnered with NSF International (NSF) under the ETV Drinking Water Systems (DWS) Center to verify performance of drinking water treatment systems that benefit the public and small communities. It is important to note that verification of the equipment does not mean the equipment is "certified" by NSF or "accepted" by EPA. Rather, it recognizes that the performance of the equipment has been determined and verified by these organizations under conditions specified in ETV protocols and test plans.

1.2 Development of Test/Quality Assurance (QA) Plan

As part of the national Homeland Security effort, NSF has developed a test/QA plan under the EPA ETV Program for evaluating point-of-use (POU) reverse osmosis (RO) drinking water treatment systems for removal of biological contamination agents. This test/QA plan uses surrogate bacteria and viruses in place of testing with the actual agents of concern. The test organisms serve as surrogates not only for bacteria and viruses, but also protozoa, such as *Cryptosporidium* oocysts. Please note that this test plan does not cover chemical agents derived from microorganisms, such as ricin or botulism toxin.

To assist in this endeavor, NSF assembled an expert technical panel, which recommended the experimental design and surrogate choices prior to the initiation of testing. Panel members included experts from the EPA, United States Army, and United States Centers for Disease Control and Prevention, Division of Parasitic Diseases, as well as a water utility microbiologist,

a university professor, and an independent consultant in the POU drinking water treatment systems industry.

By participating in this ETV, vendors obtain EPA and NSF verified third–party test data indicating potential user protection against intentional biological contamination of potable water. POU RO systems are not typically marketed as water purifiers that remove bacteria and viruses from drinking water, but they may still remove significant numbers of the microorganisms, thus offering the user a significant level of protection. The verifications serve to notify the public of the possible level of protection against biological contamination agents afforded to them by the use of verified systems.

The test/QA plan called for testing ten Purefecta™ units with a standard test water set to pH 6, 7.5, and 9, containing bacterial or viral surrogates. The systems were also challenged at both 40 and 80 pounds per square inch gauge (psig). The test units were subjected to challenge scenarios that were unique combinations of the challenge organisms, pH, and inlet water pressure. Five units were challenged immediately after completion of the manufacturer's installation and conditioning instructions, while the other five underwent a 25-day conditioning period prior to being challenged with the surrogates.

1.2.1 Bacteria and Virus Surrogates

The expert technical panel recommended that NSF and the EPA use the bacteria *Brevundimonas diminuta* (American Type Culture Collection (ATCC) strain 19146, formerly *Pseudomonas diminuta*), and *Hydrogenophaga pseudoflava* (ATCC strain 33668) as surrogates for bacterial agents. These surrogates were chosen based on their small sizes, as the smallest identified bacterium of concern can be as small as 0.2 μm in diameter. *H. pseudoflava* has a minimum diameter of 0.1 to 0.2 μm, while *B. diminuta* has a minimum diameter of 0.2 to 0.3 μm (please note that these minimum diameters were not obtained during this study. See section 5.4.2 for discussion). *B. diminuta* is the accepted bacteria of choice for testing filters and membranes designed to remove bacteria. It is used in the American Society of Testing Materials (ASTM) "Standard Test Method for Retention Characteristics of 0.2-μm Membrane Filters Used in Routine Filtration Procedures for the Evaluation of Microbiological Water Quality" (2001).

The virus surrogates were the bacteriophages MS2, Phi X 174, and fr. The ATCC designation and host *E. coli* strain for each virus is given Table 1-1.

Table 1-1. Virus and Host ATCC Designations

Virus	ATCC Designation	Host Bacteria ATCC Strain
MS2	ATCC 15597-B1	E. coli ATCC 15597
Phi X 174	ATCC 13706-B1	E. coli ATCC 13706
fr	ATCC 15767-B1	E. coli ATCC 19853

The expert technical panel recommended these viruses based on their small sizes and isoelectric points. The isoelectric point is the pH at which the virus surface is neutrally charged. MS2 is 24 nm in diameter with an isoelectric point at pH 3.9, Phi X 174 is 27 nm in diameter with an isoelectric point at pH 6.6, and fr is 19 nm in diameter with an isoelectric point at pH 8.9. With varying isoelectric points, the viruses have different surface charges, or different strengths of negative or positive charge, depending on the pH. In solutions above the isoelectric point, the virus is negatively charged. Below the isoelectric point, the virus is positively charged. Using different pH settings for the virus challenges allowed an evaluation of whether electrostatic forces enhance virus retention in mechanical filtration scenarios. The pH 6 and 9 settings were chosen because they are just beyond the upper and lower boundaries for allowable pH in the EPA National Secondary Drinking Water Regulations. The pH 7.5 setting was chosen because it is the midpoint between the boundaries.

The bacteria reduction challenges were performed only at pH 7.5, because the expert panel believed that bacteria cell size and mass are too large for electrostatic interactions to play a significant role.

1.2.2 Inlet Pressure

The bacteria and virus challenge tests were performed at dynamic inlet pressures of both 40 and 80 psig to evaluate whether inlet pressure affects microorganism rejection by RO membranes. Forty psig is a worse case scenario for ionic rejection mechanisms, while 80 psig represents a poorer mechanical filtration scenario. In a traditional mechanical filtration scenario, the higher pressure could push suspended particles further into, and perhaps all the way through, the filtration media, and it could also distort seals to the point that they leak. However, this may or may not be the case with RO membranes, since they operate by a different principle.

1.2.3 Long-Term Conditioning

The expert technical panel was presented with anecdotal evidence that RO membrane performance could be erratic for approximately the first month of operation, so they recommended that NSF split the test units into two groups, one group to be tested immediately after installation and completion of the manufacturer's conditioning instructions (hereafter referred to as "unconditioned units"), and a second group to be tested after a 25 working day conditioning period (hereafter referred to as "conditioned units").

1.3 Testing Participants and Responsibilities

The ETV testing of the Pall/Kinetico Purefecta™ was a cooperative effort between the following participants:

    NSF
    Kinetico, Inc.
    EPA

The following is a brief description of each of the ETV participants and their roles and responsibilities.

1.3.1 NSF International

NSF is a not-for-profit organization dedicated to public health and safety, and to protection of the environment. Founded in 1946 and located in Ann Arbor, Michigan, NSF has been instrumental in the development of consensus standards for the protection of public health and the environment. The EPA partnered with NSF to verify the performance of drinking water treatment systems through the EPA's ETV Program.

NSF performed all verification testing activities at its Ann Arbor location. NSF prepared the test/QA plan, performed all testing, managed, evaluated, interpreted, and reported on the data generated by the testing, and reported on the performance of the technology.
Contact Information:

> NSF International
> 789 N. Dixboro Road
> Ann Arbor, MI 48105
> Phone: 734-769-8010
> Fax: 734-769-0109
> Contact: Bruce Bartley, Project Manager
> Email: bartley@nsf.org

1.3.2 Kinetico Incorporated

The verified system is manufactured by Kinetico Incorporated, a manufacturer of water treatment products for home and business.

The manufacturer was responsible for supplying the RO systems in accordance with the equipment selection criteria given in section 3.1.1, and for providing logistical and technical support as needed.

Contact Information:

> Kinetico Incorporated
> 10845 Kinsman Road
> Newbury, OH 44065
> Phone: 1-800-944-9283
> Contact Person: Mr. Rod Yoder
> Email: ryoder@kinetico.com

1.3.3 Pall Corporation

The Pall Corporation is a manufacturer of products for fluid filtration, separation, and purification. Pall manufactures and supplies to Kinetico the bacteria and virus removal filter component for the Purefecta™.

1.3.4 U.S. Environmental Protection Agency

The EPA, through its Office of Research and Development, has financially supported and collaborated with NSF under Cooperative Agreement No. R-82833301. This verification effort was supported by the DWS Center operating under the ETV Program. This document has been peer-reviewed, reviewed by the EPA, and recommended for public release.

Chapter 2
Equipment Description

2.1   RO Membrane Operation

Membrane technologies are among the most versatile water treatment processes with regard to their ability to effectively remove the widest variety of contaminants at the lowest costs. Reverse osmosis membranes operate by the principal of cross-flow filtration. In this process, the influent water flows over and parallel to the filter medium and exits the system as reject water. Under pressure, a portion of the water diffuses through the membrane becoming "permeate". Membrane pore sizes are small enough to reject bacteria and viruses, but they may still pass through imperfections in the membrane, or go around the membrane due to microscopic seal leaks. The Purefecta™ also uses a "biofilter" to remove bacteria and viruses.

2.2   Equipment Capabilities

The Purefecta™ is certified by NSF International to NSF/ANSI Standard 58 – *Reverse Osmosis Drinking Water Treatment Systems*. The system has a certified production rate of 19.8 gallons per day, and an efficiency rating of 25.9%. Efficiency rating as defined by NSF/ANSI Standard 58 is "a percentage measure of the amount of influent water that is delivered as permeate under a closed permeate discharge set of actual use conditions." These measurements are based on system operation at 50 psig inlet pressure, a water temperature of 77 °F, and a total dissolved solids (TDS) level of 750 mg/L. The amount and quality of treated water produced varies depending on the inlet pressure, water temperature, and level of TDS. These measurements were not subject to verification during this study.

2.3   System Components

The Purefecta™ is a five-stage treatment system. A cutaway diagram of the treatment components is shown in Figure 2-1, and a photograph of the full system is shown in Figure 2-2. The inlet water first passes through a carbon or sediment filter, and then through the reverse osmosis membrane element. The permeate water travels through the first stage of the Pall biofilter for virus removal. The water is then sent to a 3-gallon maximum capacity storage tank. Upon leaving the storage tank, the water passes through a carbon filter, and lastly through the bacteria removal portion of the Pall biofilter. Please note that this description, and the system operation description in section 2.4 are given for informational purposes only. This information was not subject to verification.

2.4   System Operation

When the flow of water into the system is started, treated water will be continually produced until the storage tank is nearly full. At that time, the water pressure in the tank causes an

automatic shut-off device to activate, stopping the flow of water through the system. After approximately two-thirds of the water is dispensed from the storage tank, the shut-off device

Figure 2-1. Cutaway Schematic Diagram of Purefecta™ Treatment Elements
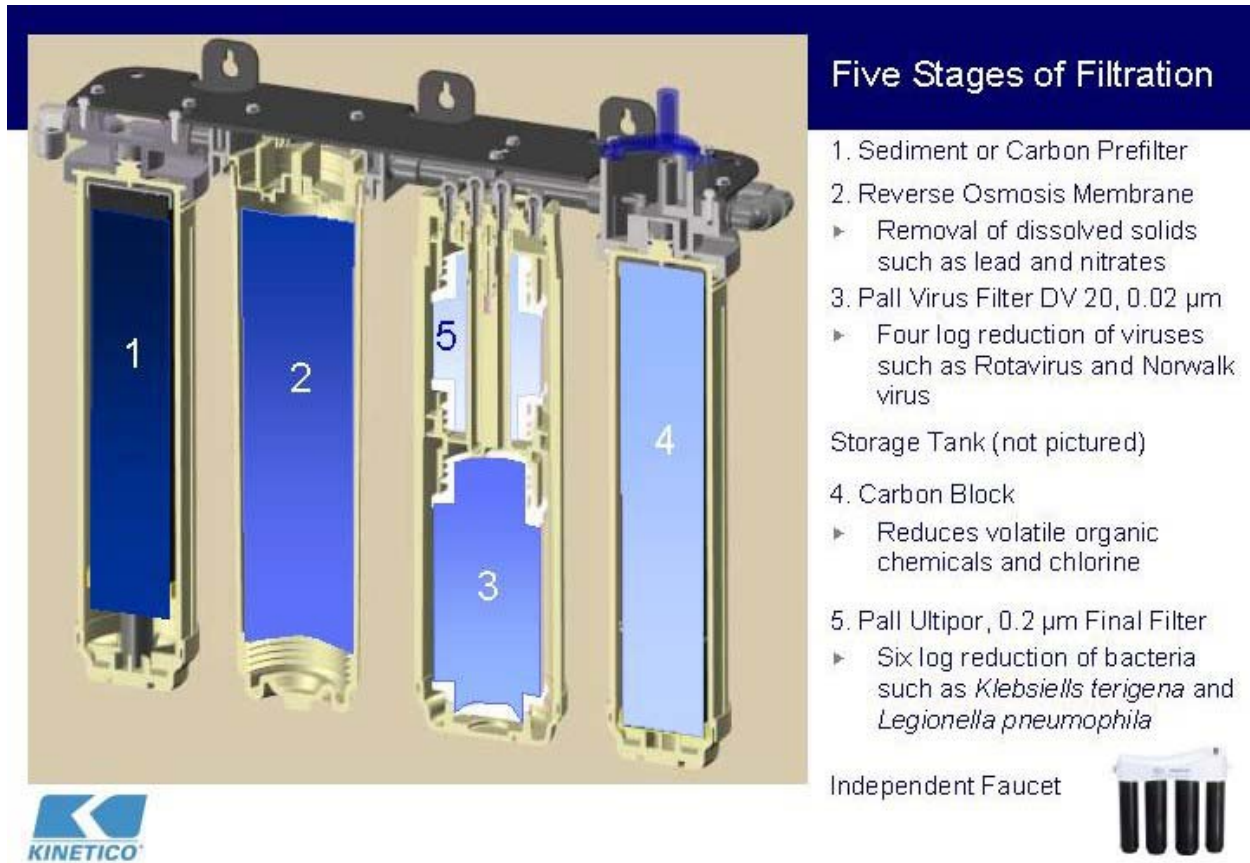
deactivates, allowing water to again flow into the system until the storage tank is nearly full. The operational storage tank capacity will vary slightly from unit to unit, and is also affected by the inlet water pressure, but is approximately two gallons under normal use conditions.

The Purefecta™ contains a meter that measures the volume of treated water produced. This meter is designed to shut down the system after approximately 500 gallons are produced. The meter is reset when the user replaces the post-membrane carbon filter.

2.5   Rate of Waste Production

The Purefecta™ produces approximately three gallons of reject water for each gallon of product water produced, as defined by the efficiency rating parameter in NSF/ANSI Standard 58.

Figure 2-2. Photograph of the Purefecta™

2.6 Equipment Operation Limitations

Kinetico gives the following limitations for the drinking water to be treated by the system:

- temperature of 35 – 100 °F;
- pressure of 40 – 100 psi;
- pH of 3 – 11;
- maximum TDS level of 3000 mg/L;
- hardness less than 10 grains per gallon; and
- iron less than 0.1 mg/L.

2.7 Operation and Maintenance Requirements

Kinetico recommends that all maintenance be done by qualified Kinetico professionals. The following are the operation and maintenance requirements:

- Replacement of carbon filters and the biofilter annually, or when the meter described in section 2.4 stops the production of treated water;
- Sanitization of the system when the carbon filters and biofilter are replaced; and
- Measurement of the TDS level of the product water when the other filters are changed. RO membrane replacement is recommended when the TDS reduction performance falls below 90%.

Chapter 3
Methods and Procedures

3.1 Test Equipment

3.1.1 Equipment Selection

Equipment selection criteria were developed to ensure that the test units were representative of product variability. The test/QA plan called for Kinetico to supply ten units from three different production runs. However, the product is new, and so at the time of testing was not being produced in large enough numbers to have three different production runs from which to choose test units. The test/QA plan also called for the RO membranes and Pall biofilters to be from across Kinetico's allowable QA/QC performance range. Six membranes were to be from the middle of the QA/QC range, two from the low end, and two from the high end. Kinetico did supply test units with RO membranes from three different lots, but they did not have a large enough selection to provide the membranes from the middle, low end, and high end of the QA/QC range. They supplied five membranes from lot one, two membranes from the second lot, and three membranes from the third lot. As reported in Kinetico's RO membrane QA/QC performance data, the membranes in the test units had TDS percent reductions ranging from 92 to 95. The product water conductivity readings ranged from 26 to 48 μmhos/cm.

The QA/QC data for the Pall biofilters only denoted "pass" or "fail", and did not give any other information that could have been used to order them across a performance range. The virus filter portions of the biofilters were from two different lots. The virus filters in units one and ten were from lot one, and the rest of the virus filters were from lot two. All of the bacteria filters were from one lot.

The test units were split into two groups of five as discussed in section 1.2.3, such that the first group was comprised of three membranes from lot one, and one membrane from each of lots two and three, while the second group had two membranes from lot one, one membrane from lot two, and two membranes from lot three.

3.1.2 Test Unit Configuration

The Purefecta™ was tested with only the RO membrane and biofilter in place. The carbon and sediment filters do not have pore sizes small enough to remove bacteria or viruses, but could temporarily retain significant numbers of the organisms through electrostatic interactions, giving a positive bias to the performance data. Empty filter cartridges were used in place of the carbon filters. Otherwise the systems were operated as sold to the consumer.

3.2 Verification Test Procedure

3.2.1 Test Rig

Each group of five test units was plumbed to a single test station. The test station used a 500-

gallon polyethylene tank to hold the influent challenge water. See Figure 3-1 for a schematic diagram of the test rig. Please note that the units of each group of five were attached to the rig, such that all were plumbed to the same influent feed line. Figure 3-2 shows one group of the test units installed on the test rig.

Figure 3-1. Schematic Diagram of Test Rig
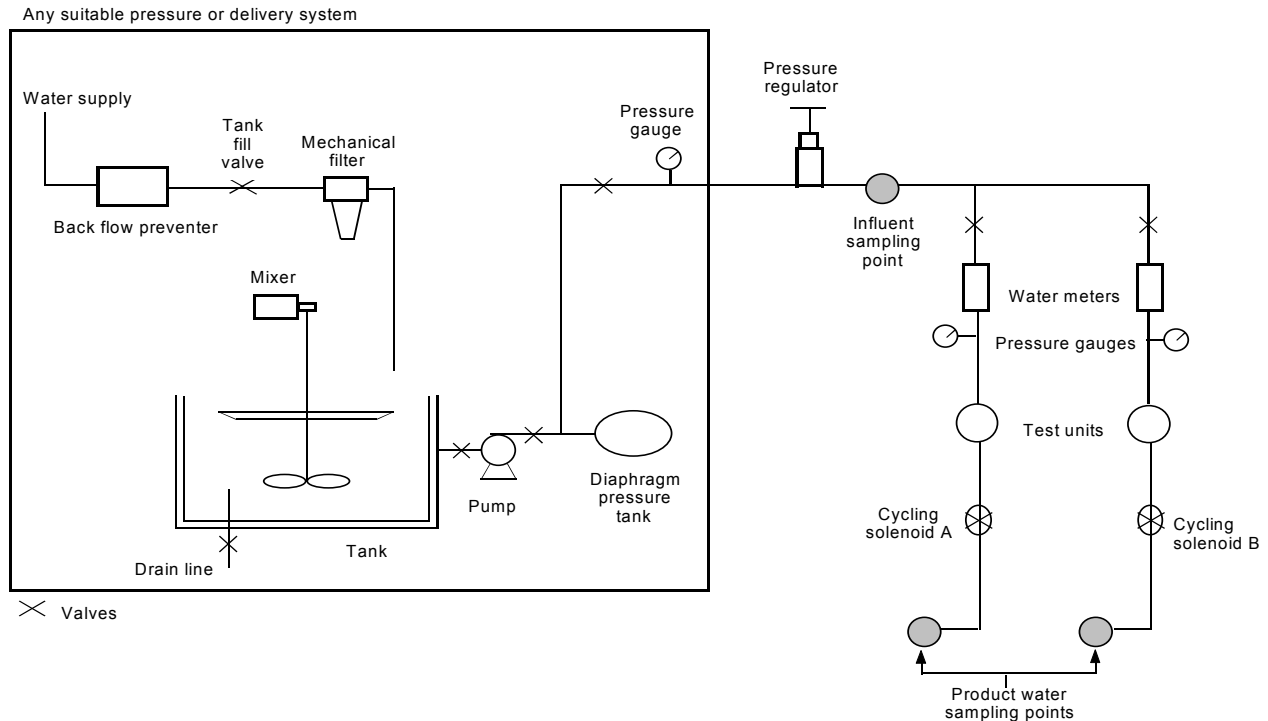
3.2.2   Test Rig Sanitization

The test apparatus was sanitized with a sanitization agent prior to the beginning of each test to keep the heterotrophic bacteria population to a minimum. After sanitization, the test apparatus was flushed until a less-than-detectable concentration of sanitizing agent was present.

3.2.3   Test Water

3.2.3.1   Base Water

Ann Arbor, Michigan municipal drinking water was deionized to make the base water for the tests. The base water had the following constraints:

- Conductivity ≤ 2 μS/cm at 25 °C;
- TOC < 100 μg/L; and
- Heterotrophic bacteria plate count < 100 colony forming units (CFU)/mL.

The base water was then adjusted to meet the following characteristics:

- Total chlorine < 0.05 mg/L;
- Addition of sodium bicarbonate to achieve an alkalinity (expressed as calcium carbonate) of 100 ± 5 mg/L prior to pH adjustment;
- pH adjustment with hydrochloric acid or sodium hydroxide to reach a value of 6.0 ± 0.5, 7.5 ± 0.5, or 9.0 ± 0.5 as required by challenge protocol*; and
- Temperature of 20 ± 2.5 °C.

*Note that the lab technicians experienced difficulty maintaining the pH below 6.5 and above 8.5. See Section 5.8.3 for more discussion.

The test water was made daily in 200-gallon volumes. In addition to the above characteristics, total hardness, TDS, and turbidity were measured daily.

Figure 3-2. Test Units Installed on Test Rig

3.2.3.2　　Bacteria and Virus Challenges

The viruses were purchased from Biological Consulting Services of North Florida, and the bacteria from ATCC. The viruses were purchased in adequate volumes so that the suspensions received were added directly to the test water. The bacteria were cultivated at NSF to obtain the challenge suspensions. Section 3.3.2.3 describes the method used to create the bacteria challenges.

Appropriate volumes of the suspensions were used to achieve influent challenge concentrations of at least $1x10^5$ CFU of bacteria per 100 milliliters, or $1x10^4$ plaque forming units (PFU) of virus per milliliter for all viruses except Phi X 174. This virus is more difficult to cultivate, and so was supplied at lower concentrations than the other viruses. As a result, the measured influent concentrations for the conditioned units were approximately two logs lower than those for fr and MS2. Achieving influents greater than $1x10^4$ PFU/mL would have been prohibitively expensive. The Phi X 174 suspensions used for the unconditioned group were more concentrated, so the desired minimum challenge level was exceeded on all but one day. See Appendix A for the measured influent challenge levels.

The test units were challenged with each bacteria separately, but all three viruses were mixed together for each virus challenge. After addition of the challenge organism to the base test water, the resultant challenge water was mixed for a minimum of 30 minutes using a recirculation pump prior to beginning the test.

3.2.4　Test Unit Operation

3.2.4.1　　Test Unit Installation

All test units were installed and sanitized by Kinetico representatives, and conditioned in accordance with the vendor's instructions using the base test water at pH 7.5 ± 0.5. The units were conditioned by operating them continuously for two tank-filling periods. Operation time to fill the storage tank varied from unit to unit, but was approximately two hours. At the end of the conditioning procedure, an effluent sample was collected from each unit as a negative control and analyzed for the challenge organisms.

3.2.4.2　　TDS Reduction System Check

After completion of the vendor's conditioning procedure, the test units underwent a one-day TDS reduction test using the test protocol in NSF/ANSI Standard 58. The Standard 58 test protocol was modified so that the units were operated continuously for one tank-fill period. Product water samples were then collected from each storage tank and analyzed for TDS. This test ensured that the products undergoing verification testing were representative of the expected performance of the system, and that there were no membrane integrity or membrane seal problems.

3.2.4.3 Long-Term Conditioning

After the TDS reduction system check test, the five units receiving long-term conditioning were operated using the test water without surrogate organisms for a period of 25 working days prior to challenge testing. On each day the units were operated continuously at a dynamic inlet pressure of 80 ± 3 psig for one tank-fill period. The units then sat idle overnight under pressure, and the tanks were emptied the next morning prior to resumption of unit operation.

3.2.4.4 Challenge Testing

Following the conditioning period, the conditioned units were challenged according to the schedule in Table 3-1. Prior to the start of challenge testing for this group, the test rig was sanitized again as described in section 3.2.2. The test units were taken off-line to prevent sanitizer from entering them, and the test rig was flushed free of sanitizer before they were reconnected to the rig.

Table 3-1. Challenge Schedule

Day	Surrogate Challenge	pH	Inlet Pressure (psig)
1	*H. pseudoflava*	7.5 ± 0.5	40 ± 3
2	*H. pseudoflava*	7.5 ± 0.5	80 ± 3
3	*B. diminuta*	7.5 ± 0.5	40 ± 3
4	*B. diminuta*	7.5 ± 0.5	80 ± 3
5	All Viruses	6.0 ± 0.5	40 ± 3
6	All Viruses	6.0 ± 0.5	80 ± 3
7	All Viruses	7.5 ± 0.5	40 ± 3
8	All Viruses	7.5 ± 0.5	80 ± 3
9	All Viruses	9.0 ± 0.5	40 ± 3
10	All Viruses	9.0 ± 0.5	80 ± 3

Challenge testing for the unconditioned units began the day after the TDS system check test. Testing for this group also followed the schedule in Table 3-1.

At the end of the day before each challenge, the base test water was prepared as described in section 3.2.3.1. The morning of the challenge, the pH was checked and adjusted, if necessary, and the bacteria or viruses were added as described in section 3.2.3.2.

The dynamic inlet water pressure for operation was set at either 40 ± 3 or 80 ± 3 psig according to the challenge schedule.

An influent sample was collected each day at the time test unit operation started. Each test unit was then operated continuously for one tank-fill period. At 40 psig, approximately 1.5-2 gallons of treated water were produced over approximately three hours, while at 80 psig, approximately 1.75-2.25 gallons were produced over approximately two hours of operation.

After each unit shut off, its storage tank was emptied into a sterile container, and a sub-sample was collected for challenge organism enumeration. The sub-sample volumes were 1 L for the bacteria challenges, and 150 mL for virus challenges. A second influent sample was collected after all units ceased operation. All samples were collected in sterile polypropylene bottles, and were enumerated in triplicate.

Following each day's challenge period, the systems were operated for one tank-fill period using the test water without any test organisms present. This served to flush the systems in-between challenge periods. The units rested overnight under pressure, and the storage tanks were emptied the next morning prior to initiation of that day's challenge period.

3.3   Analytical Methods

3.3.1   Water Quality Analytical Methods

The following are the analytical methods used during verification testing. All analyses followed procedures detailed in NSF Standard Operating Procedures (SOPs).

- pH – All pH measurements were made with an Orion Model SA 720 meter. The meter was operated according to the manufacturer's instructions, which are based on Standard Methods method 4500-H^+.
- Temperature – Water temperature was measured using an Omega model HH11 digital thermometer.
- TDS – TDS for the TDS reduction system check test was measured through conductivity according to Standard Methods method 2510 using a Fisher Scientific Traceable^{TM} Conductivity Meter.
- Total Chlorine – Total chlorine was measured according to Standard Methods method 4500-Cl G with a Hach Model DR/2010 spectrophotometer using AccuVac vials.

3.3.2   Microbiology Analytical Methods

3.3.2.1   Sample Processing, and Enumeration of Viruses

The viruses were enumerated using a double agar layer method published in *NSF/ANSI Standard 55 – Ultraviolet Microbiological Water Treatment Systems* for enumerating MS2. This method is similar to the double agar layer method in EPA Method 1601.

Four to eighteen hours prior to sample processing, 100 μL of the appropriate host *E.coli* suspension was pipetted into tubes containing 10 mL of fresh Tryptic Soy Broth (TSB), and incubated at 35 °C. After incubation, 100 μL volumes of the resulting *E. coli* culture were transferred to sterile, capped test tubes.

All samples were enumerated in triplicate. All samples were serially diluted for enumeration, and the effluent samples were also enumerated directly. One milliliter volumes of the sample or dilution were pipetted into the *E. coli* suspension test tubes. The tubes were vortexed for a minimum of 30 seconds to "mate" the bacteria and virus, and then 4 mL of molten, tempered TSB plus 1% agar was added to each tube. These mixtures were then poured over Tryptic Soy

Agar (TSA) plates, and allowed to solidify. The plates were incubated at 35 °C for 18-24 hours. Viral plaques were counted using a Quebec Colony Counter.

3.3.2.2 Bacteria Cultivation

The bacteria were purchased from ATCC and rehydrated with nutrient broth. After 48 hours of incubation at 30 °C, tubes containing 10 mL of TSB were inoculated with 100 μL of the nutrient broth suspension. These tubes were incubated for 48 hours at 30 °C. After this incubation period, 100 μL of these suspensions were pipetted into new tubes containing 10 mL of fresh TSB. These tubes were then also incubated for 48 hours at 30 °C. This process was repeated at least three times, up to a maximum of 30 times.

3.3.2.3 Preparation of Bacteria Challenge Suspensions

To obtain the challenge suspensions, 1 mL of a 48-hour TSB culture was pipetted onto an appropriate number of TSA slants. The slants were inoculated at 30 °C for 48 hours. After inoculation, 5 mL of sterile phosphate buffered dilution water (PBDW) was pipetted onto each slant, and the agar surfaces were scraped to suspend the cells. The suspensions were then pipetted out of the slants into an appropriate volume of PBDW. The resulting challenge suspensions were vortexed for approximately 30 seconds to disperse the cells. The challenge suspensions were refrigerated and added to the tank of test water within one hour. Samples of the resulting challenge suspension were collected and enumerated according to the method in 3.3.2.4.

3.3.2.4 Bacteria Sample Processing and Enumeration

All samples were enumerated in triplicate using a membrane filtration method based on Standard Methods method 9215 D. All samples were serially diluted for enumeration with sterile PBDW, and the effluent samples were also enumerated directly. One milliliter volumes of either the sample or dilution were pipetted into sterile vacuum filtration apparatuses, 25 mL of PBDW added, and the suspension vacuum filtered through sterile 0.1 μm membrane filters. The funnels were then rinsed three times with approximately 5 mL of PBDW, and the rinse water also suctioned through the filters. The membrane filters were aseptically removed from the apparatuses and placed onto R2A agar plates. The plates were incubated at 30 °C for 48 hours. Characteristic *B. diminuta* or *H. pseudoflava* colonies were counted with a Quebec Colony Counter.

Chapter 4
Results and Discussion

4.1 TDS Reduction

The performance data from the TDS reduction system check test described in 3.2.4.2 are presented in Table 4-1. Kinetico's reported TDS reduction performance for the Purefecta™ is 89.3%, so the units tested are representative of expected membrane performance.

Table 4-1. Short-Term TDS Reduction Test Results

Unconditioned Units			Conditioned units		
	TDS (mg/L)	Percent Reduction		TDS (mg/L)	Percent Reduction
Influent	960		Influent	707	
Effluents:			Effluents:		
Unit 1	2	99.8	Unit 1	53	92
Unit 2	15	98	Unit 2	59	92
Unit 3	32	97	Unit 3	53	92
Unit 4	38	96	Unit 4	52	93
Unit 5	73	92	Unit 5	59	92

4.2 Virus Reduction

The virus $\log_{10}$ reduction data for each challenge scenario are presented in Tables 4-2 and 4-3. The influent and effluent virus PFU count and $\log_{10}$ reduction data for each individual test unit are given in Appendix A. The triplicate influent and effluent counts in Appendix A were averaged by calculating geometric means. The means were then $\log_{10}$ transformed and $\log_{10}$ reduction values calculated for each test unit.

In all challenges but one, all test units removed the viruses to less-than-detectible levels. The only viruses detected were from unit 1 of the conditioned units group, during the pH 7.5, 40 psig challenge. An examination of the triplicate count data in Appendix A for this challenge shows that all of the PFU detected for each virus came from the first of the three counts. The second and third counts for each virus were all non-detect (< 1 PFU/mL). This indicates that perhaps there was contamination of the first subsample.

The variables of pH and pressure had no discernible impact on the performance of the test units. There was also no measurable difference in performance between the unconditioned units and conditioned units.

Table 4-2. Virus Log Reduction Data for Unconditioned Units

Target pH	Actual pH	Pressure (psig)	Challenge Organisms	Log₁₀ Influent Challenge	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
					Geometric Mean Log₁₀ Reduction				
6.0 ± 0.5	6.37	40	fr	5.5	5.5	5.5	5.5	5.5	5.5
			MS2	5.2	5.2	5.2	5.2	5.2	5.2
			Phi X 174	5.5	5.5	5.5	5.5	5.5	5.5
6.0 ± 0.5	6.40	80	fr	5.7	5.7	5.7	5.7	5.7	5.7
			MS2	5.5	5.5	5.5	5.5	5.5	5.5
			Phi X 174	3.2	3.2	3.2	3.2	3.2	3.2
7.5 ± 0.5	7.59	40	fr	6.3	6.3	6.3	6.3	6.3	6.3
			MS2	5.7	5.7	5.7	5.7	5.7	5.7
			Phi X 174	5.8	5.8	5.8	5.8	5.8	5.8
7.5 ± 0.5	7.77	80	fr	5.7	5.7	5.7	5.7	5.7	5.7
			MS2	5.6	5.6	5.6	5.6	5.6	5.6
			Phi X 174	5.9	5.9	5.9	5.9	5.9	5.9
9.0 ± 0.5	8.84	40	fr	5.6	5.6	5.6	5.6	5.6	5.6
			MS2	5.5	5.5	5.5	5.5	5.5	5.5
			Phi X 174	5.5	5.5	5.5	5.5	5.5	5.5
9.0 ± 0.5	8.71	80	fr	5.6	5.6	5.6	5.6	5.6	5.6
			MS2	5.1	5.1	5.1	5.1	5.1	5.1
			Phi X 174	5.8	5.8	5.8	5.8	5.8	5.8

Table 4-3. Virus Log Reduction Data for Conditioned Units

Target pH	Actual pH	Pressure (psig)	Challenge Organisms	Log₁₀ Influent Challenge	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
					Geometric Mean Log₁₀ Reduction				
6.0 ± 0.5	6.11	40	fr	5.2	5.2	5.2	5.2	5.2	5.2
			MS2	5.2	5.2	5.2	5.2	5.2	5.2
			Phi X 174	3.3	3.3	3.3	3.3	3.3	3.3
6.0 ± 0.5	6.44	80	fr	5.2	5.2	5.2	5.2	5.2	5.2
			MS2	4.9	4.9	4.9	4.9	4.9	4.9
			Phi X 174	2.6	2.6	2.6	2.6	2.6	2.6
7.5 ± 0.5	7.20	40	fr	4.5	4.2	4.5	4.5	4.5	4.5
			MS2	4.8	4.5	4.8	4.8	4.8	4.8
			Phi X 174	2.6	2.3	2.6	2.6	2.6	2.6
7.5 ± 0.5	7.18	80	fr	5.2	5.2	5.2	5.2	5.2	5.2
			MS2	5.0	5.0	5.0	5.0	5.0	5.0
			Phi X 174	3.0	3.0	3.0	3.0	3.0	3.0
9.0 ± 0.5	8.66	40	fr	5.7	5.7	5.7	5.7	5.7	5.7
			MS2	4.9	4.9	4.9	4.9	4.9	4.9
			Phi X 174	3.0	3.0	3.0	3.0	3.0	3.0
9.0 ± 0.5	9.19	80	fr	4.9	4.9	4.9	4.9	4.9	4.9
			MS2	4.6	4.6	4.6	4.6	4.6	4.6
			Phi X 174	3.3	3.3	3.3	3.3	3.3	3.3

4.3   Bacteria Reduction

Presented in Tables 4-4 and 4-5 are the $\log_{10}$ reduction data for the bacteria challenge portion of the verification test. The influent and effluent bacteria count and $\log_{10}$ reduction data for each individual test unit is given in Appendix A. As was done for the viruses, the triplicate influent and effluent counts were averaged by calculating geometric means. The means were then $\log_{10}$ transformed and $\log_{10}$ reduction values were calculated for each test unit.

Table 4-4. Bacteria Log Reduction Data for Unconditioned Units

pH	Pressure (psig)	Challenge Organisms	$\log_{10}$ Influent Challenge	Geometric Mean $\log_{10}$ Reduction				
				Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
7.5	40	*H. pseudoflava*	6.5	6.5	5.9	6.5	6.5	6.5
		B. diminuta	8.4	7.9	7.9	7.9	8.4	8.4
7.5	80	*H. pseudoflava*	6.8	6.8	6.8	6.5	6.8	6.8
		B. diminuta	8.2	8.2	8.2	8.2	8.2	8.2

Table 4-5. Bacteria Log Reduction Data for Conditioned Units

pH	Pressure (psig)	Challenge Organisms	$\log_{10}$ Influent Challenge	Geometric Mean $\log_{10}$ Reduction				
				Unit 1	Unit 2	Unit 3	Unit 4	Unit 5
7.5	40	*H. pseudoflava*	7.4	7.4	7.4	7.4	7.4	7.4
		B. diminuta	8.1	8.1	8.1	8.1	8.1	8.1
7.5	80	*H. pseudoflava*	6.8	6.8	6.8	6.8	6.8	4.0
		B. diminuta	8.1	3.2	8.1	8.1	8.1	8.1

In most instances the Purefecta™ removed the challenge bacteria to below the detection limit of 1 CFU/100 mL. The detected bacteria counts for the unconditioned units were all less than 10 CFU/100mL, but there were two instances in which the bacteria counts for the conditioned units were higher. The 3.15 $\log_{10}$ reduction for unit 1 corresponds to a *B. diminuta* count of 83,000 CFU/100mL, and the 4.0 $\log_{10}$ reduction for unit 5 corresponds to an *H. pseudoflava* count of 600 CFU/100 ml. Since bacteria are larger than viruses, it was expected that all of the bacteria effluent counts would be lower than the virus counts, but this was not the case. The reason(s) for observing higher numbers of bacteria in the treated water cannot be verified. It was not determined whether the results were affected by sampling or analysis contamination, or by an operational problem with the test units.

As with the virus reduction data, the conditioning procedure and inlet pressure had no discernible impact on the performance of the test units for bacteria reduction.

Chapter 5
QA/QC

5.1   Data Review

NSF QA/QC staff reviewed the raw data records for compliance with QA/QC requirements and checked 100% of the data against the reported results in the official laboratory reports.

5.2   Test Procedure QA/QC

The test procedure followed an NSF SOP created specifically for this ETV.

5.3   Water Chemistry Analytical Methods QA/QC

- pH – Three point calibration at pH 4, 7, and 10 was conducted daily using traceable buffers. The calibration was checked with a pH 8 buffer. The precision of the instrument was checked by collecting a sample of municipal drinking water and splitting it into two samples for pH measurement. The relative percent deviation (RPD) was calculated using the equation in section 5.7.3. The acceptable RPD limit was 10%. The daily pH 8 buffer readings and results of the duplicate analyses are given in Table B-1 of Appendix B.
- Temperature – The digital thermometer is calibrated every 6 months using a Hart Scientific Model 9105 Dry Well Calibrator.
- Total Chlorine – The spectrophotometer was calibrated daily according to the manufacturer's instructions. The precision of the instrument was checked daily by analyzing a sample of municipal drinking water in duplicate. The samples were diluted by approximately 50% with deionized water, and then split into subsamples for analysis. The RPD for the two samples was then calculated, with an acceptable RPD limit of 10%. The results of the duplicate analyses are given in Table B-3 of Appendix B.
- TDS –Two potassium chloride standards were used for instrument calibration. A third QC standard was then used to check the calibration. Ten percent of samples were analyzed in duplicate, and RPDs were calculated. The acceptable RPD limit was 10%. The calibration check standard measurements and results of the duplicate analyses are given in Table B-2 of Appendix B.

5.4   Microbiology Laboratory QA/QC

5.4.1   Growth Media

All media were checked for sterility and positive growth response when prepared and when used for microorganism enumeration. The media was discarded if growth occurred on the sterility check media, or if there was an absence of growth in the positive response check. All three *E. coli* hosts for the viruses were plated on TSA and incubated with the virus enumeration plates during sample enumeration as a second positive growth control. *B. diminuta* and *H. pseudoflava* from the stock cultures were plated on R2A agar and incubated with the bacteria enumeration plates as positive controls.

5.4.2   Bacteria Cell Size

The theoretical minimum size for *B. diminuta* and *H. pseudoflava* cells is 0.2 to 0.3 μm in diameter, however, the NSF Microbiology Laboratory was not able to achieve that size. The stock culture was examined microscopically using a stage micrometer, and the observed diameters were approximately 0.5 μm. To achieve the smallest cell size, the bacteria need to be grown in a medium such as Saline Lactose Broth that keeps the cells small due to osmotic pressure constraints. However, this medium is low in nutrients, so the Microbiology Laboratory had difficulty cultivating the bacteria in high titers. The Microbiology Laboratory instead cultivated the bacteria in TSB. TSB is more nutrient rich, and as a result yielded larger cells.

The larger cell size may have enhanced the bacteria reduction performance of the test units, and the results cannot be used to predict expected performance against bacterial agents smaller than 0.5 μm. However, the viruses used in this study are much smaller than any bacteria, so the virus results could be considered indicative of the system's minimum bacteria reduction performance.

5.4.3   Sample Processing and Enumeration

All samples were enumerated in triplicate. For each sample batch processed, an unused membrane filter and a blank with 100 mL of PBDW filtered through the membrane were also placed onto the appropriate media and incubated with the samples as negative controls. No growth was observed on any blanks.

5.4.4   Heterotrophic Bacteria Interference

As discussed in Section 3.2.4.5, heterotrophic bacteria also grew with the challenge organisms on the agar plates for the effluent samples, because the challenge organisms had to be grown on nonselective media. In many instances, the heterotrophic bacteria were present at levels that gave up to 250 colonies on the 10^{-4} dilution plates, and almost confluent lawns on the 10^{-2} dilution and undiluted sample plates. However, the microbiologists were able to observe and count the challenge organism colonies on these plates, due to their color and morphology. The *H. pseudoflava* and *B. diminuta* colonies were circular, entire, and convex, whereas the heterotrophic bacteria colonies were circular, but with slightly undulate edges, and they were flat or raised, instead of convex. The *H. pseudoflava* and *B. diminuta* colonies were also smaller than most of the heterotrophic colonies. The *H. pseudoflava* were bright yellow, and the *B. diminuta* colonies were an off-white, slightly grayish color. Most of the heterotrophic bacteria colonies were tan colored.

5.5   Sample Handling

All samples analyzed by the NSF Microbiology and Wet Chemistry Laboratories were labeled with unique ID numbers. These ID numbers appear on the NSF laboratory reports for the tests. All samples for bacteria and virus analysis were processed within one hour of collection. All water chemistry samples were analyzed within allowable hold times

5.6   Documentation

All laboratory activities were documented using laboratory bench sheets and NSF laboratory reports. This documentation can be found in the appendices.

5.7   Data Quality Indicators

The quality of data generated for this ETV can be established through five indicators of data quality: representativeness, accuracy, precision, statistical uncertainty, and completeness.

5.7.1   Representativeness

Representativeness refers to the degree to which the data accurately and precisely represent the expected performance of the RO system under normal use conditions. The test protocol was designed as to be a conservative evaluation of product performance. The test water was of very low turbidity to minimize the potential of microbial adhesion to suspended particles, which could enhance apparent log reduction. The surrogates were chosen because of their small size. The virus surrogate challenges were carried out at pH 6, 7.5, and 9 to assess whether pH affects the performance of the RO membrane.

5.7.2   Accuracy

Accuracy of the pH meter was evaluated with a pH 8.0 check standard after the daily calibrations. The calibration check measurements were all in the range 7.96 to 8.09.

Accuracy of the conductivity meter for TDS analysis was measured through the use of QC samples with every batch of samples analyzed. The percent recovery of the QC samples for both batches of samples analyzed for this verification was 101%.

The chlorine meter's accuracy was checked by measuring the chlorine level of deionized water samples. The calibration was acceptable if the measured chlorine level was 0.05 mg/L or less. Deionized water was chosen to be the calibration check because the test plan called for the use of chlorine-free ($\leq$ 0.05 mg/L) deionized water for the test water. Thus, the calibration check measured the accuracy of the meter for the range in which the test water samples fell.

Accuracy check results for these parameters are given in Appendix B.

5.7.3   Precision

Precision refers to the degree of mutual agreement among individual measurements and provides an estimate of random error. One sample per batch was analyzed in duplicate for the TDS measurements. Duplicate municipal drinking water samples were analyzed for pH and total chlorine as part of the daily calibration process. Precision of the duplicate analyses was measured by use of the following equation to calculate relative percent deviations (RPD):

$$RPD = \left| \frac{S_1 - S_2}{S_1 + S_2} \right| \times 200$$

where:

S_1 = sample analysis result; and

S_2 = sample duplicate analysis result.

The RPD calculations for individual duplicate pairs are given in the tables in Appendix B. The duplicate measurements for the two TDS sample batches gave RPD values of 1.0% and 1.2%. The RPD values for the pH measurements ranged from 0% to 1.11%. The RPD values for the total chlorine measurements ranged from 0% to 6.36%.

5.7.4 Statistical Uncertainty

Statistical Uncertainty is expressed using 95% confidence intervals. No confidence interval calculations were made for the performance data because most of the effluent levels were nondetects, and the sample sizes (triplicate counts) were too small to give very meaningful results.

5.7.5 Completeness

Completeness is the proportion of valid, acceptable data generated using each method as compared to the requirements of the test/QA plan. The completeness objective for data generated during verification testing is based on the number of samples collected and analyzed for each parameter and/or method.

Table 5-1. Completeness Requirements

Number of Samples per Parameter and/or Method	Percent Completeness
0-10	80%
11-50	90%
> 50	95%

Completeness is defined as follows for all measurements:

$$\%C = (V/T) \text{ X } 100$$

where:

%C = percent completeness;

V = number of measurements judged valid; and

T = total number of measurements.

5.7.5.1   Completeness Measurements

5.7.5.1.1   Number of Units Tested

Ten units were tested, as called for in the test/QA plan, giving a completeness measurement of 100% for this category.

5.7.5.1.2   pH, Temperature, and Total Chlorine

A total of 49 samples should have been analyzed for these parameters during the conditioning and challenge testing periods of the conditioned units. During the long-term conditioning period there were two days on which influent water samples were not analyzed for pH, temperature, and total chlorine, giving a completeness measurement of 96%.

During challenge testing of the unconditioned group, the second influent sample on day eight was not analyzed for pH, temperature, or turbidity. A total of 24 samples were to be analyzed for these parameters during the unconditioned units testing period. The one missed sample gives a completeness measurement of 96%.

5.7.5.1.3   Microbiological Analyses

During the challenge testing of the unconditioned units, the laboratory technician did not supply the Microbiology Laboratory with a second influent sample for *B. diminuta* analysis on the second challenge day for this organism (pH 7.5, 80 psig). A total of 14 samples were to be collected for *B. diminuta* enumeration during the course of the two-day test period for this organism (two influents per day, five effluents per day). The missed sample gives a completeness measurement of 93% for this organism. All unconditioned unit influent and effluent samples for *H. pseudoflava* and the three viruses were collected and analyzed as scheduled in the test plan, giving completeness measurements of 100% for these organisms.

All planned bacteria and virus samples were collected and analyzed for the conditioned units.

5.7.5.1.4   TDS

All samples for the TDS reduction system check tests were collected and analyzed as scheduled in the test plan, giving a completeness measurement of 100%.

5.8   Measurements Outside of the Test/QA Plan Specifications

5.8.1   Total Chlorine

The test/QA plan called for the test water to have a total chlorine level below 0.05 mg/L. During the challenge testing period for the unconditioned units, there were two influent samples for which total chlorine was measured at 0.05 mg/L. During the long-term conditioning period, there were three days on which the influent samples gave total chlorine measurements of 0.05 mg/L. During the challenge period for the conditioned units, three influent samples measured

0.05 mg/L total chlorine, and two influent samples measured 0.06 mg/L total chlorine. These measurements are likely are due to the instrument's random error and are not significant, since daily calibration blank sample readings on these days were 0.02 to 0.05 mg/L, not 0.0 mg/L.

5.8.2   Temperature

The test/QA plan called for the water temperature to be 20 ± 2.5 °C. On day 23 of the long-term conditioning period, the influent water temperature was measured at 15.2 °C. This is not a significant deviation. Temperature control was critical during the bacteria challenge periods because of its effect on organism viability. However, during the conditioning period, temperature only affects the production rate of treated water.

5.8.3   pH

The test water chemistry gave it little buffering capacity, which made it difficult to keep the pH of the test water within the specification of pH 9.0 ± 0.5 for the pH 9 virus challenges. During the pH 9, 80 psig challenge for the unconditioned units, and the pH 9, 40 psig challenge for the conditioned units, the pH decreased to below 8.5. The pH of the influent test water samples collected at the end of the challenge periods were 8.25 and 8.22, respectively. These two deviations are significant. However, since there is not any effluent count data with which to compare test unit performance at the three different pH values, these deviations do not affect any data analysis.

Chapter 6
References

American Society of Testing Materials (2001). D 3862-80, Standard Test Method for Retention Characteristics of 0.2-µm Membrane Filters Used in Routine Filtration Procedures for the Evaluation of Microbiological Water Quality. in *Annual Book of ASTM Standards, Volume 11.01*. West Conshohocken, PA. ASTM.

APHA, AWWA and WPCF (1998). *Standard Methods for Examination of Water and Wastewater*. 20th ed. Washington, D.C. APHA.

NSF International (2002). *NSF/ANSI 55-2002, Ultraviolet microbiological water treatment systems*. Ann Arbor, NSF International.

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Chapter 7
Vendor Comments

Kinetico submitted the following comments on the DRAFT report to the NSF. These comments were not included in the body of the text.

After reviewing the test data, Kinetico is pleased with the final results. There are 220 different sample points recorded in this report. Two sample points, though, didn't seem to make sense when compared to all of the other results.

Both sample points are in Table 4-5. The first is Unit 1 on the 80 psi effluent for *B. diminuta* and the second is Unit 5 on the 80 psi for *H. pseudoflava*. Engineers from Kinetico and Microbiologists from Pall Corporation reviewed the results and cannot arrive at a logical explanation for these somewhat contradictory results. For example, on Unit 1, a 6.8 log reduction (non-detect) was observed for *H. pseudoflava* and a 3.15 log removal for *B. diminuta*. Generally, *H. pseudoflava* is slightly smaller than *B. diminuta*. These results would then indicate that the Purefecta™ was capable of removing the smaller organism, and allowed the larger to pass. On Unit 5, the opposite was reported. The *H. pseudoflava* results indicated a 4.0 log reduction while *B. diminuta,* showed a non-detect level.

All values for the intermediate units 2-4 indicate non-detect for both organisms

These two contradictory data points are puzzling. There doesn't seem to be any reason to believe that a mechanical failure was the causal factor since both units had multiple tests done on them and only these two did not show the same removal as the other sample points. Purefecta uses a size exclusion technology for the mechanical removal of virus, bacteria and cysts. Because Purefecta uses this technology, and because viruses are smaller than bacteria, furthers our belief that the two data points are "fliers". Naturally, that raises the question of sampling or apparatus contamination error, but that is very difficult to point at.

Below are the test results from NSF International and from UL and BioVir for the microbiological certification testing we had previously done on Purefecta™. The test protocols for these certifications were based on the USEPA Guide Standard and Protocol for Testing Microbiological Water Purifiers. Three Purefecta™ units were tested for each certification.

NSF International – Microbiological Challenges

Challenge Organisms	Number of Samples		Influent Geometric Mean	Effluent Geometric Mean	% Reduction	Log$_{10}$ Reduction
	Influent	Effluent				
Klebsiella terrigena	6	24	5.3×10^7 CFU/100 ml	1.6 CFU/100 ml	>99.99999	7.5
Polio Lsc1	6	21	7.83×10^6 PFU/L	<200 PFU/L	>99.99	4.6
Rotavirus Sa-11	6	24	2.0×10^7 PFU/L	<200 PFU/L	>99.99	5.0
Cryptosporidium parvum oocysts	6	19	7.6×10^5 Cysts/L	1.7 Cysts/L	>99.999	5.6
MS-2 Coliphage	6	21	3.49×10^5 PFU/ml	<1 PFU/ml	>99.999	5.5

UL and BioVir – Microbiological Challenges

Challenge Organisms	Number of Samples		Influent Geometric Mean	Effluent Geometric Mean	% Reduction	Log$_{10}$ Reduction
	Influent	Effluent				
Klebsiella terrigena	12	24	2.9×10^8 CFU/100 ml	<1.0 CFU/100 ml	>99.999999	8.2
Polio Lsc1	12	2	2.3×10^5 PFU/L	<11 PFU/L	>99.99	4.3
Rotavirus Sa-11	12	24	2.3×10^5 PFU/L	<11 PFU/L	>99.99	4.3
Cryptosporidium parvum oocysts	12	24	1.9×10^4 Cysts/L	<4.0 Cysts/L	>99.99	4.0
MS-2 Coliphage	12	24	2.7×10^7 PFU/ml	<1x 10^3 PFU/ml	>99.99	4.4

Klebsiella terrigena was used as the test surrogate for bacteria (the USEPA's Guide Standard and Protocol for Testing Microbiological Water Purifiers specifies the use of *Klebsiella* for bacteria testing). As you can see in the results, greater than 7.5 log removal was recorded for the bacteria testing.

As stated above, Purefecta™ performed as expected. We were pleased with the results, except for the two fliers.