

Product Name: PURELAB Quest

Performance Test: Validation of primary product specifications

Test description:

A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 µS/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 3 month period and Type I and III product water was taken daily (10l and 30 l/day respectively) to simulate a typical usage pattern. Resistivity and TOC were logged on-line using a Mettler Toledo M300 meter and a Sievers 900 TOC analyser, respectively. Samples were taken for biological testing; Total viable counts were measured after membrane filtration and incubation at 27°C for 5 days on R2A agar.

Parameter	Type I Water Specification*	Typical Measured Values
Resistivity (Mohm.cm @ 25°C)	up to 18.2	up to 18.2
Conductivity (µS/cm @ 25°C)	down to 0.055	down to 0.055
TOC (ppb C)	<30	12-22
TVC (CFU/ml)	<0.1**	1-2 / <0.1**

Parameter	Type II Water Specification*	Typical Measured Values
Resistivity (Mohm.cm @ 25°C)	>1	3 - 10
Conductivity (µS/cm @ 25°C)	<1	0.3 - 0.1
TOC (ppb C)	<50	31- 51
TVC (CFU/ml)	<100	1 - 30

Parameter	Type III Water Specification*	Typical Measured Values
Conductivity (µS/cm @ 25°C)	<20	12 - 23
TOC (ppb C)	<200	50-69
TVC (CFU/ml)	<1000	146 - 915

Results:

* Subject to suitable feedwater, unit maintained and serviced as per recommendations

** With optional point-of-use filter fitted

Commentary:



Product Name:

PURELAB Quest

Performance Test: Compliance of Type 1 water with water standards

Test description:

A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 μ S/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 3 month period and Type I and III product water was taken daily (10l and 30 l/day respectively) to simulate a typical usage pattern. Type 1 water resistivity and TOC were logged on-line using a Mettler Toledo M300 meter and a Sievers 900 TOC analyser, respectively. Samples were taken for biological testing; Total viable counts were measured after membrane filtration and incubation at 27°C for 5 days on R2A agar. Endotoxin determination was carried out with an Ati 320. Nitrate and Chloride were determined by ion chromatography, sodium by ICP-MS, and silica by colourimetry.

Parameter	Typical Measured Values for Type I Water	CLSI CLRW Specification	USP Purified Water Specification	EP Purified Water Specification
Conductivity (µS/cm at 25°C)	down to 0.055	<0.1	<1.3	<5.1
TOC (ppb C)	12-22	<500	<500	<500
Bacteria (CFU/ml)	1-2 / <0.1*	<10	<100	<100
Particles	0.2µm filtration*	0.22µm stage	ns	ns
Nitrates (ppb)	<0.02	ns	ns	<200
Heavy Metals (as ppm Pb)	<0.1	ns	ns	<0.1

Parameter	Typical Measured Values for Type I Water	ISO Grade 1 Specification	ASTM Type IC Specification	ASTM Bio-applications Grade
Resistivity (MΩ-cm at 25°C)	up to 18.2	>10	>18	18.2
TOC (ppb C)	12-22	ns	<50	<20
Sodium (ppb)	<0.002	ns	<1	<1
Chloride (ppb)	<0.02	ns	<1	<1
Silica (ppb)	<1	<10	<3	ns
Bacteria (CFU/ml)	1-2 / <0.1*	ns	<10	<1
Absorbance/cm at 254nm	<0.001	<0.001	ns	ns
Endotoxin (EU/ml)	<0.001	ns	ns	<0.01

Results:

Water from the unit met or exceeded the following standards:

- US Pharmacopoeia Purified Water Specification (USP 32, 1.1.2009.)
- European Pharmacopoeia Purified Water Specification (EP 6th Edition, 2009)
- ASTM Type IC Reagent Water Specification (ASTM D1193 06)
- CLSI CLRW Specification (CLSI C3-A4 (2006)) BS3978/ISO 3696 Specification for "Water for laboratory use", Grade 1

ASTM Bio-Applications Grade Water (ASTM D5196 - 06)

* Point-of-use filter fitted



Product Name: PURELAB Quest

Performance Test: Inorganic Purity of water produced

Test description:

A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 μ S/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 1.5 month period and Type I and III product water was taken daily (10l and 30 l/day respectively) to simulate a typical usage pattern. Samples of Type I water were dispensed for analysis. Samples were analysed for elements by high-resolution ICP-MS, silica by colourimetry and for anions by ion chromatography after pre-concentration.

Results:

Owner

	ppt (ng/l)		ppt (ng/l)		ppt (ng/l)		ppt (ng/l)
Aluminium	<1	Germanuim	<1	Palladium	<2	Thorium	<1
Antimony	<0.2	Gold	<5	Platinum	<5	Thullium	<0.5
Arsenic	<2	Hafnium	<1	Potassium	<5	Tin	<0.5
Barium	<0.5	Holmium	<1	Praseodymium	<1	Titanium	<0.5
Beryllium	<3	Indium	<1	Rhenium	<3	Tungsten	<1
Bismuth	<0.2	Iridium	<2	Rhodium	<1	Uranium	<2
Boron	<10	Iron	<2	Rubidium	<1	Vanadium	<0.2
Cadmium	<0.5	Lanthanum	<1	Ruthenium	<2	Ytterbium	<1
Calcium	<2	Lead	<0.2	Samarium	<2	Yttrium	<1
Cerium	<1	Lithium	<0.2	Scandium	<5	Zinc	<2
Caesium	<1	Lutetium	<1	Selenium	<500	Zirconium	<5
Chromium	<1	Magnesium	<1	Silicon	<25		
Cobalt	<0.5	Manganese	<0.5	Silver	<0.5	Fluoride	<30
Copper	<1	Mercury	<5	Sodium	<2	Chloride	<20
Dysprosium	<1	Molybdenum	<0.5	Strontium	<0.2	Nirtite	<20
Erbium	<1	Neodymium	<1	Tantalum	<3	Bromide	<20
Europium	<1	Nickel	<2	Tellurium	<1	Nitrate	<20
Gadolinium	<1	Niobium	<1	Terbium	<1	Phosphate	<20
Gallium	<0.5	Osmium	<2	Thallium	<1	Sulphate	<50

Commentary:

ICP-MS is by far the most sensitive method for elemental analysis. We use Balazs Labs in California which is the best commercial lab of which we are aware. The limits of detection achievable are a function of the cleanliness of the equipment and the local environment.

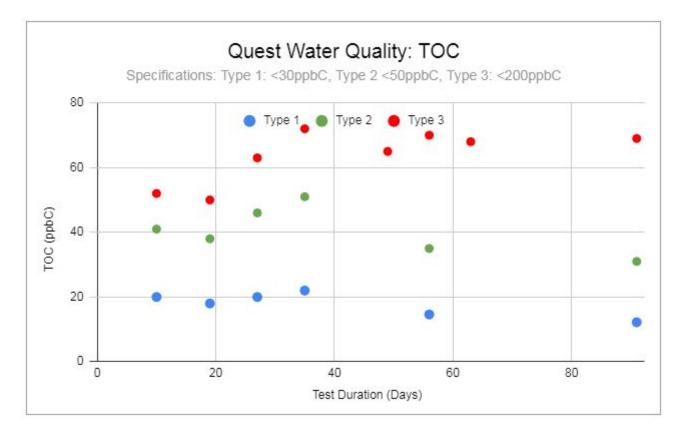


Product Name: PURELAB Quest

Performance Test: TOC performance

Test description:

A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 μ S/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 3 month period and Type I and III product water was taken daily (10I and 30 I/day respectively) to simulate a typical usage pattern. A Sievers 900 TOC analyser was connected to the product and used to measure TOC of each water type. Results are shown below.



Results:

TOC of Type I, II, & III waters were respectively measured at, 12-22, 31- 51, and 50-69 ppbC, during this test period.

Commentary:

Total organic carbon (TOC) provides a good indication of the overall levels of organic contaminants in purified water. On-line measurement is needed when testing ultra-pure water to give adequate sensitivity and freedom from contamination.



Product Name: PURELAB Quest

Performance Test: Thermal Desorption GC-MS Analysis of Product Water

A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 μ S/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 1.5 month period and Type I and III product water was taken daily (10I and 30 I/day respectively) to simulate a typical usage pattern. Samples of Type I water were dispensed for analysis. Analyses were carried out by Balazs Analytical Services, California, USA.

This test method is designed to determine semi-volatile organic compounds in the boiling range of n-heptane (ca. 100°C) to n-octacosane (430°C).

The water samples were passed through sample tubes containing an adsorbent to trap organic compounds. The sample tubes were analyzed by TD-GC-MS (Thermal desorption – Gas- Chromatograph – Mass – Spectrometry). The GC used a non-polar poly(dimethylsiloxane) phase capillary column. The following temperature program was used for the GC: Initial temperature held at 35C for 3.5 minutes then increased at a rate of 10C/minute to 280C then held at the final temperature for 10 minutes. Helium was used as the carrier gas for the GC-MS. An internal standard, toluene-d8, was added to each sample tube during the analysis.

In the absence of any detectable compounds the total ion count was used to estimate the total of components in the following boiling ranges:

Results:

Quest		
	ppb (µg/I)	
Low Boilers C7-C10	0.06	
Medium Boilers >C10-C20	0.09	
High Boilers >C20	0.06	
Sum >= C7	0.21	

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PURELAB Quest Performance Datasheet

Results:

	ppb (µg/
Hexanal	< 0.025
C8 Hydrocarbon	<0.025
xylene isomer	<0.025
1-chloro-2-methylpropene	<0.025
Dichlorocyclopentane	<0.025
2,2-bis(chloromethyl)-1-propanol	<0.025
ethyl-3-ethoxypropionate	<0.025
octanol	< 0.025
C10 hydrocarbon	< 0.025
nonanal	< 0.025
ethlyhexanoic acid	<0.025
decanal	<0.025
allyl benzene	<0.025
organic ether	<0.025
phthalic anhydride	<0.025
BHT-quinone-methide	<0.025
butylated hydroxytoluene	<0.025
TXIB+diethyl phthalate	<0.025
benzophenone	<0.025
1,3-dioxolane, 2,4,5-trimethyl-2-(p-tolyl0-di-isobutyl phthalate	<0.025
dibutyl phthalate	<0.025
tributyl aconitate	<0.025
tributyl acetylcitrate	<0.025
benzyl butyl phthalate	<0.025
bis(2-ethylhexyl) adipate	< 0.025

Commentary:

This test method was designed to analyze semi-volatile organic compounds in the boiling point range of nheptane (boiling point approximately 100 degrees C) to n-octacosane (boiling point approximately 430 degrees. The method is capable of detecting a wide variety of compounds, and is not limited to those listed above. The particular set of SVOCs `not detected', and the limits of detection will depend on the laboratory carrying out the work.

Product Name: PURELAB Quest

Performance Test: Purge and Trap GC-MS Analysis of Product Water

A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 µS/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 2 month period and Type I and III product water was taken daily (10l and 30 l/day respectively) to simulate a typical usage pattern. Samples of Type I water were dispensed for analysis by Purge & Trap-GC-MS according to EPA524.3.

	ppb (µg/l)	2	ppb (µg/
1-chorobutane	<0.05	chloromethane	<1
1,1-dichloroethene	<0.05	cis-1,2-dichloroethene	<0.05
1,1-dichloroethene	<0.05	cis-1,3-dichloropropene	<0.05
1,1-dichloropropene	<0.05	di-isopropyl ether (DIPE)	<0.05
1,1,1-trichloroethane	<0.05	dibromochloromethane	< 0.05
1,1,1,2-tetrachloroethane	<0.05	dibromomethane	<0.05
1,1,2-trichloroethane	<0.05	dichlorodifluoromethane	<1
1,1,2,2-tetrachloroethane	< 0.05	diethyl ether	<0.05
1.2-dibromo-3-chloropropane	< 0.05	ethyl methacrylate	< 0.05
1,2-dibromoethane	< 0.05	ethylbenzene	<0.05
1,2-dichlorobenzene	< 0.05	hexachlorobuadiene	<0.05
1.2-dichloroethane	< 0.05	hexachloroethane	<0.05
1,2-dichloropropane	< 0.05	isopropylbenzene	< 0.05
1,2,3-trichlorobenzene	< 0.05	methyl acetate	< 0.5
1,2,3-trichloropropane	<0.05	methyl iodide	<1
1,2,4-trichlorobenzene	< 0.05	methyl-t-butyl ether (MtBE)	< 0.05
1,2,4-trimethylbenzene	< 0.05	methylene chloride	<0.1
1.3-butadiene	<0.2	n-butylbenzene	<0.05
1,3-dichlorobenzene	< 0.05	n-propylbenzene	< 0.05
1,3-dichloropropane	< 0.05	napthalene	< 0.05
1,3,5-trimethylbenzene	<0.05	o-xvlene	<0.05
1.4-dichlorobenzene	< 0.05	p/m-xylene	< 0.05
2-chlorotoluene	< 0.05	sec-butylbenzene	< 0.05
4-chlorotoluene	<0.05	styrene	< 0.05
4-isopropyltoluene	< 0.05	t-amyl ethyl ether (TAME)	< 0.05
allyl chloride	< 0.5	t-amyl methyl ether (TAME)	< 0.05
benzene	< 0.05	t-butyl alcohol (TBA)	<1
bromobenzene	< 0.05	t-Butyl ethyl ether (ETBE)	< 0.05
bromochloromethane	< 0.05	t-butylbenzene	< 0.05
bromodichloromethane	< 0.05	tetrachloroethene	<0.05
bromoform	<0.05	tetrahydrofuran	<0.5
bromomethane	<1	toluene	< 0.05
carbon disulphide	<0.05	trans-1.2-dichloroethene	<0.1
carbon tatrachloride	< 0.05	trans-1,3-dichloropropene	<0.05
chlorobenzene	<0.05	trichloroethene	<0.05
chlorodifluoromethane	<1	trichlorofluoromethane	<0.5
chloroform	< 0.05	vinyl chloride	<0.2

Commentary:

This test detects volatile organics; that is compounds with a high-enough vapour pressure to be removed in a gas stream. The particular set of VOCs not detected and the limits of detection will depend on the laboratory carrying out the work. No additional components besides the EPA 524 standards were detected.



Product Name: PURELAB Quest

Performance Test: Amines Analysis of Product Water

Test description: A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 μ S/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 1.5 month period and Type I and III product water was taken daily (10l and 30 l/day respectively) to simulate a typical usage pattern. Samples of Type I water were dispensed for analysis. Analyses were carried out by Balazs Analytical Services, California, USA.

Results:

	ppt (µg/I)
Ammonium	<20
Tetramethylammonium	<50
Trimethylamine	<50

Commentary:

No traces of amines or ammonium originating from the ion-exchange resin could be detected.



Product Name: PURELAB Quest

Performance Test: Endotoxin Test

Test description:

A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 μ S/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 3 month period and Type I and III product water was taken daily (10l and 30 l/day respectively) to simulate a typical usage pattern. Samples of Type I water were dispensed and analysed for endotoxin using a kinetic tube reader.

Date	Type I Water Endotoxin (EU/ml)
07/11/2019	<0.001
04/12/2019	<0.001
08/01/2019	<0.001

Results:

Samples were taken with an LC197 point-of-use filter fitted; Values were less than the detection limit of 0.001 EU/ml

Commentary:

The PURELAB Quest produces ultra-pure water for laboratory uses. Low endotoxin levels are key for many applications.



Product Name: PURELAB Quest

Performance Test: Bacteria Test

Test description:

A PURELAB Quest was set up with a 30-litre 'external' reservoir, and fed with potable water (conductivity approx. 600 μ S/cm, TOC approx. 700 ppbC) at 4 bar. The system was operated over a 3 month period and Type I and III product water was taken daily (10I and 30 I/day respectively) to simulate a typical usage pattern. Samples were regularly taken and analysed for total viable counts by filtration and incubation on R2A agar at 27°C for 5 days.

Date	Type I Water Bacteria Level (CFU/ml)	Type II Water Bacteria Level (CFU/ml)	Type III Water Bacteria Level (CFU/ml)
29/10/2019	1	28	708
28/11/2019	0.9	12	515
6/12/2019	1.7	5	155
12/12/2019	1.4	7	146
03/01/2020	2.5	3	915
09/01/2020	1.3	0.9	231
21/01/2020	<0.1*	not tested	not tested
23/01/2020	2.3	3	295

Results:

Counts were typically 1-2, \leq 10 and \leq 500cfu/ml for Type I, II and III waters respectively. When a point-of-use filter was fitted to the Type I outlet product water bacteria was measured at <0.1cfu/ml.

*= Point-of-use filter fitted.

Commentary:

The PURELAB Quest produces ultra-pure water for laboratory use. It is especially suited for analytical, clinical, pharmaceutical and molecular biological applications. Additional point-of-use filtration can be used to achieve extreme levels of purity with respect to bacteria.

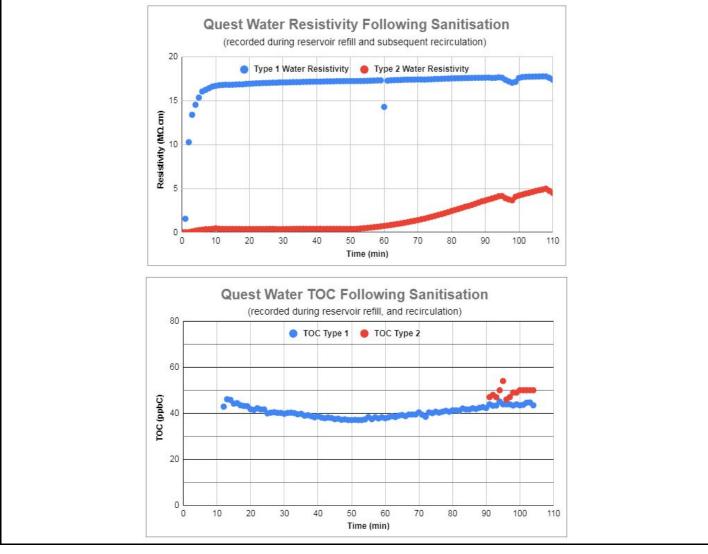
Product Name: PURELAB Quest

Performance Test: Rinse up after sanitization

Test description: TOC and resistivity of Type I and Type II water from a PURELAB Quest were recorded after carrying out a sanitisation procedure, to demonstrate water quality recovery following the procedure.

Results:

Following sanitisation Type I and Type II water specifications for resistivity were quickly achieved through normal process operation. While measured values were close to TOC specifications (<30 & <50ppbC for water Types I & II respectively), further operation (dispensing and refilling of water) was required before they were readily achieved.



Commentary:

Sanitisation cycles are available to help maintain microbiological performance or to recover water systems that have become contaminated with microorganisms. A chemical is distributed throughout the system during a sanitisation sequence. This chemical must subsequently be removed by the purification process before optimum inorganic and organic water purity is again achieved. For critical applications, this can be facilitated by dispensing water from the system at maximum flow following the process.



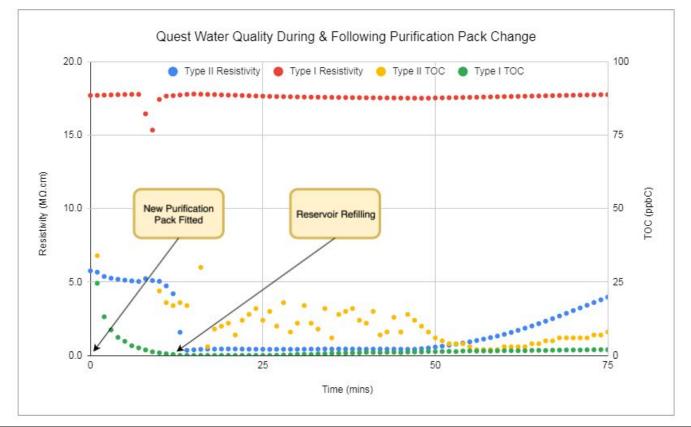
Product Name:PURELAB QuestPerformance Test:Time to reach optimum performance after fitting a new
purification pack (LC292)

Test description:

Product water TOC and resistivity of a PURELAB Quest were recorded after installation of a new purification pack, to determine the time required for the unit to achieve high product water quality.

Experimental conditions and method used:

A new purification pack was fitted into the Quest system following the 'purification-pack change' procedure. TOC and resistivity of Type I and Type II water were logged until the system filled its reservoir and during subsequent recirculation.



Results:

Type I and Type II water quickly met purity specifications after completion of the purification pack change procedure. Resistivity and TOC specifications for Types I and II water, are respectively, up to $18.2M\Omega.cm / <30ppbC$, and $>1M\Omega.cm / <50ppbC$.

Commentary:

The PURELAB Quest incorporates a purification pack that requires replacing as it becomes exhausted. On installation of a new purification pack chemicals used to preserve it during storage are released into the water and subsequently removed by the purification process. For critical applications, this can be facilitated by dispensing water from the system at maximum flow.