



CASE STUDY: GEMINI HP SYSTEM

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FORENSIC LABORATORY (Spring 1997)

During the validation of an ASTM Type I purified water system at a forensic laboratory, the following bacterial results were recorded at the influent (feed) and effluent (dispense nozzle) of two Gemini high purity point-of-use dispensing systems.

After the source of bacteria was located and the loop sanitized the bacterial counts and challenge to the Gemini's was greatly reduced, however the tests do illustrate for the purpose of this technical brief the Gemini dispensing systems' ability to control viable bacteria when challenged.

SYSTEM DESCRIPTION:

The laboratory consisted of two Gemini bench top laboratory dispensing systems (s/n 037, 038) each with 0.05µm final filters. Each Gemini was fed from the building central RO system and polypropylene loop which was to produce ASTM TYPE I water. The central RO system contained ultraviolet protection, mixed bed DI, a 0.2µm final filter and high purity piping materials to minimize bacteria.

TEST METHODS:

Testing was performed by Clancy Environmental Consultants, Inc. an independent laboratory providing consultation and microbiological laboratory services on the RO/DI system, supply loop, return loop, and both Gemini point-of-use dispensing systems.

Samples were drawn at the loop supply, loop return, and both point-of-use dispensing systems over a three day period. The Gemini's were allowed to recirculate for one minute and after recirculation, two samples were dispensed from the Gemini outlets and collected in 128 milliliter autoclaved bottles. No other water was dispensed from the Gemini's during the test period.

Viable bacteria in the samples were enumerated using the Heterotrophic Plate Count, membrane filtration (0.2µm), R2A Agar, 7-day incubation at 20°C technique. The membrane filters were aseptically plated and incubated at 28°C for seven days, and then the bacteria on the plates were enumerated. This procedure was repeated for samples collected each of three days. The Gemini panel resistivity meter reading was noted and the dispensing UV lamp was checked at each sampling.

RESULTS:

During the test period, the Gemini resistivity was equal to or greater than 18.1 megohm-cm @ 25°C. No significant quantities of viable bacteria were discovered from any of the dual 128 milliliter Gemini dispensed samples collected during the three-day period after appropriate incubation.

Primary test:

The CAP / NCCLS / ASTM standard for Type IA: <10 CFU/L Colony Forming Units per Liter (CFU/L)

Sample:	# 1	# 2	Type IA
<u>5/19</u>			
Loop supply	tntc	tntc	
Loop return	tntc	tntc	
Gemini, s/n 037	2	<1	<10
Gemini, s/n 038	<1	2	<10
<u>5/21</u>			
Loop supply	1,230	tntc	
Loop return	tntc	tntc	
Gemini, s/n 037	1	3	<10
Gemini, s/n 038	4	2	<10
<u>5/22</u>			
Loop supply	1,160	690	
Loop return	257	1,170	
Gemini, s/n 037	1	1	<10
Gemini, s/n 038	2	2	<10

tntc = too numerous to count

Secondary test:

The samples were also analyzed by the Kinetic Turbidimetric Method, for pyrogens with the following results:

	<u>Endotoxin Units per Milliliter</u>		
(EU/ml)	5/21	5/22	ASTM
Sample:			
Type IA			
Loop supply	<0.03	<0.03	<0.03
Loop return	<0.03	<0.03	<0.03
Gemini, s/n 037	<0.03	<0.03	<0.03
Gemini, s/n 038	<0.03	<0.03	<0.03