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STANDARDS

Laboratories are required to maintain copies of the pertinent editions of the Advancement of Medical Instrumentation (AAMI) / American National Standard Institutes (ANSI) publications, as well as, be knowledgeable in those standards, NYS Department of Health's Subpart 757.1 and 757.2 – Chronic Renal Dialysis Services and General Requirements, and 42 CFR 494.40 – Conditions for Coverage for End-Stage Renal Disease Facilities; Condition: Water and Dialysate Quality.

SAMPLE TYPES

Certifications to be held by a laboratory are dependent on the origin of the sample being tested. The sample either originates from the source (water from a tap (municipal system) or private groundwater well) or product water (water produced by a water treatment system or by an individual component of the system). If the testing is to be done on source waters, the laboratory is required to hold certification under the general drinking water subcategories. If the testing is performed on product water, the laboratory is required to certification under the dialysis water subcategories.

MICROBIOLOGY INCUBATION TEMPERATURE AND TIME

Per AAMI/ANSI RD 62:2006, Section A.5.1.1., "… the use of TSA or equivalent for 48 hours at 35 to 37º C remains the recommended method", and per Section 5.1.1, "incubation is at 35-37º C and colonies shall be counted after 48 hours of incubation." Section 7.2.3 of ANSI/AAMI RD 52:2004 also refers to 35 º C and 48 hours.

ELAP will require laboratories to meet the incubation temperature and time noted above.

THERMAL AND HOLD TIME PRESERVATION

MICROBIOLOGY – Refer to ELAP ***Certification Manual Item 245***.

CHEMISTRY – Refer to ELAP ***Certification Manual Item 241***.

SAMPLE COLLECTION

MICROBIOLOGY – As per ANSI/AAMI RD 52:2004, Section 7.2.2., for microbiological monitoring, "water samples should be collected directly from outlet taps situated in different parts of the water distribution system. In general, the taps should be opened and the water should be allowed to run for at least 60 seconds before a sample is collected in a sterile, endotoxin–free container. A minimum of 50 mL water, or volume specified by the laboratory performing the test, should be collected. Samples taps should not be disinfected. Users who insist on disinfecting taps should use sterile gauze saturated with alcohol to wipe the sample tap. The sample should not be collected until all the alcohol has evaporated so as to leave no disinfectant residual in the sample. Bleach or other disinfectant solutions should not be used."

Dialysate samples should be collected from a dialysate port of the dialyzer, if possible. Sample ports may be disinfected with an appropriate alcohol and allowed to air dry. A 30 mL sterile syringe should be used to aspirate dialysate out of and into the port before filling the syringe. The filled syringe should be discarded, and a fresh sample taken with a new syringe. At least 25 mL of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free containers. (Sterile, new plastic wear is endotoxin-free.)

Also, refer to ANSI/AAMI/ISO 23500: 2011, Section8.3.2.2 "Dialysis fluid samples" which details collection from sample ports using a syringe and disinfecting with 70 % ethanol or iso-propanol. "Alternatively, if the hemodialysis machine permits, samples can be collected immediately after the dialyzer …"

CHEMISTRY – As per ANSI/AAMI RD 62:2006, Section 5.1.2 and Table 2, for monitoring of chemical contaminants samples should be collected from the most distal point in each water distribution loop. Use appropriate containers as listed in ELAP Item 241.

DETECTION OF Ca, Na, Mg, AND K IN POTABLE (TAP) WATER

40 CFR 141, National Primary Drinking Water Regulations, currently only allows for the detection of these parameters by EPA 200.7. 40 CFR 136 (May 18, 2012, Method Update Rule), Guidelines Establishing Test Procedures for the Analysis of Pollutants (in non-potable water) does allow for these parameters to be tested by EPA 200.8.

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For laboratories, whose primary function is to test samples related to dialysate water, ELAP will allow these parameters to be tested by EPA 200.8 under the "Drinking Water Metals" subcategory. The laboratories will be assigned a unique method name and ELAP method code.

SPECIFICATION LIMITS

The laboratories must be able to meet the required detection limit (RDL) for chemical contaminants as listed in NYS Department of Health's Subpart 757.1 and 757.2 – Chronic Renal Dialysis Services and General Requirements. The chemical contaminants in product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to reprocess dialyzers for multiple uses must not exceed the regulatory limit or maximum allowable chemical contaminant levels (MACCL) as listed in Subpart 757.2 and 42 CFR 494.40 – Conditions for Coverage for End-Stage Renal Disease Facilities; Condition: Water and Dialysate Quality, which incorporates by reference the AAMI publication, "Dialysate for hemodialysis". The MAACL's are listed in the table on the next page. The action level for total viable microbial count in product water is also included in the table on the next page. The information for this table was gathered from the following specific resources: Subpart 757.2 (f), 3-4 and ANSI/AAMI RD 52:2004, Section 6, and ANSI/AAMI RD 62:2006, Section 4.1.1 and 4.1.2 and Table 1.

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Contaminants	**MACCL** (ANSI/AAMI RD 62:2006 & NYS Subpart 757.2)	**RDL** (NYS Subpart 757.2)
CHEMICAL (mg/L)		
Calcium	2	0.2
Magnesium	4	0.02
Potassium	8	0.10
Sodium	70[1]	0.03
Antimony	0.006	**na**
Arsenic	0.005	0.002
Barium	0.10	0.01
Beryllium	0.0004	**na**
Cadmium	0.001	0.001
Chromium	0.014	0.005
Lead	0.005	0.001
Mercury	0.0002	0.0002
Selenium	0.09	0.005
Silver	0.005	0.001
Aluminum	0.01	0.003
Chloramines	0.10[2]	**na**
Free Chlorine	0.50[2]	0.10
Copper	0.10	0.0005
Fluoride	0.20	0.10
Nitrate (as N)	2.0	0.05
Sulfate	100	1.0
Thallium	0.002	**na**
Zinc	0.10	0.0002
MICROBIAL		
Heterotrophic Plate Count	< 200 (50)[3] CFU/mL	**na**
Endotoxin[4]	2 EU/mL[5]	**na**

[1] 230 mg/L is the limit where sodium concentration of the concentrate has been reduced to compensate for the excess sodium in the water, as long as conductivity of the water is being continuously monitored.
[2] 42 CFR 494.40 (b)(2)(i) states "If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then the second component or carbon tank which removes chlorine/chloramine must be tested;"
[3] 50 CFU/mL is action level for total viable microbial count in the product water.
[4] This contaminant is not certified by ELAP. Also, it is not included in NYS Subpart 757.2 (4/11/90). However, the endoxin concentrations shall be determined by the Limilus Ambebocyte Lysate (LAL) assay as per ANSI/AAMI RD 62:2006.
[5] The action level shall be 1 EU/mL for endotoxin concentration in product water.