WATER SYSTEM QUALITY CONTROL

Technical Procedure 750.T

PURPOSE:

This procedure outlines the testing and tolerance limits of Clinical Laboratory Reagent Grade Water (CLRW) used by the Department of Pathology and Laboratory Medicine to ensure the quality of this water is equal to or exceeds the limits necessary to perform accurate patient testing. The tests employed are:

- 1. Monitoring of the resistivity (by meter reading installed directly into the deionized water system and/or resistivity light).
- 2. A test for bacterial growth.

PRINCIPLE:

The resistivity is used to measure the effectiveness of the ion exchange resin beds and is measured by means of resistivity meter and/or warning light. The microbiological test is used to establish the presence of bacterial contamination within the water system. Our CLRW must meet the following standards:

@ 25 Degrees C				
Maximum Microbial Content (CFU/mL)	10			
Minimum Resistivity (megohm-cm)	≥ 10 (inline)			
Total Organic Carbon (1)	< 500 ppb			
Particulate Matter (1)	0.22 µm filter			
(1) These specifications are process specifications and are not all measured by the end-user.				

PROCEDURE:

I. Resistivity

- **A. Main Hospital SESP Pavilion Lab** Water from this system is rated as CLRW water and may be used for any use needed in the Laboratory
 - 1. Resistivity is monitored daily by SARC staff and recorded on a log. There are two inline resistivity lights on the system and a resistivity meter installed directly into the deionized water system. When one system light goes out, this indicates that the active mixed-bed tanks are losing their effectiveness and *need to be switched over to the second bank of tanks* (see process below). The last tank will continue to deionize the water and keep the resistivity above 15 megohms/cm. If the reading falls below 15 megohms/cm, report this to the supervisor. If the meter drops below 10 megohms/cm the water is unsuitable as CLRW.
 - a. When one in-line resistivity light goes out, indicating the exhaustion of the first 2 mixed-beds, the system needs to be switch over to the second set of mixed-beds

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within a few days. Duplicate tank beds allow for the change over to the second set of tanks without the need of shutting off the supply of water.

- b. Notify the Pavilion Lab supervisor of this event.
- 2. <u>Tank Changes:</u> The water system tanks and pump are located in room 2P406. The tanks are changed on a routine basis by Evoqua Water Technologies (formerly Siemens Water Technologies). They will call on Monday of the week that service is scheduled to alert the lab of the specific day, and the tanks will then be changed at 0800 on that day. They should be called (564-9028) for tank change if the light goes off on one set of tanks before the routine scheduled change. The following process should be followed if the tanks have to be changed by lab personnel:
 - a. Open the two valves of the bank of new tanks being put into use.
 - b. Close the two values for the tank bed that is being removed from service.
 - c. Mark out the date on the tank label, denoting exhausted tanks.
 - d. Log changes, and water meter reading in the water system binder.
- 3. <u>Tank re-order:</u> Call Evoqua Water Technologies at 564-9028 and order replacement tanks. Ask them to call just prior to delivery for assistance with the security doors.
- **B.** Cancer Center Lab Water from this system is rated as Type II DI Water Only. This DI water is not used for making standards, controls or reagents.
 - 1. Resistivity is monitored daily by the Cancer Center Lab personnel and recorded on a log. There is an in-line resistivity light installed directly into the deionized water system. The light should go out when the mixed-bed tank loses its effectiveness.
 - 2. When the in-line resistivity light goes out, indicating the exhaustion of the mixed-bed, **Evoqua Water Technologies** must be called at 564-9028 for tank changes.
- C. Specialty Testing Center Water from this system is rated as CLRW water and may be used for any use needed in the Laboratory that is not affected by the presence of a small amount of bacteria. DO NOT USE where bacterial contamination will cause a problem.

The Specialty Testing Center (3740 Business Drive) is monitored under service contract by **Evoqua Water Technologies**. They will perform tank exchanges on a monthly basis and monitor resistivity.

D. PATH Building (Histology) - Water from this system is rated as CLRW water and may be used for any use needed in the Laboratory that is not affected by the presence of a small amount of bacteria. DO NOT USE where bacterial contamination will cause a problem.

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- 1. Resistivity is monitored daily by the Histology Lab personnel and recorded on a log. There is an in-line resistivity light installed directly into the deionized water system. The light should go out when the mixed-bed tank loses its effectiveness.
- 2. When the in-line resistivity light goes out, indicating the exhaustion of the mixed-bed, **Evoqua Water Technologies** must be called at 564-9028 for tank changes.

II. Microbiological Content QC Check

All lab sites will be checked biweekly. Follow manufacturer's instructions on use of Millipore sampler.

- 1. Label the Millipore sampler as to which room and faucet the sample was taken, the date and time of collection.
- 2. Allow the water to run for at least one minute before testing to allow for "dead" water not recirculated in the system.
- 3. Remove the sampler paddle and fill the case to the line.
- 4. Insert the sampler paddle into the case, and allow the case to lay flat, with the grid side facing down, for 30 seconds.
- 5. Remove the sampler paddle from the case and shake off the excess water and drain the case.
- 6. Insert the paddle into the case and place in a 35°C incubator, grid side down, for 48-72 hours
- 7. Inspect the sampler for any colonies. The total number of colonies on the paddle is counted and read as the number of colonies per ml. If none appear, record the results in the water log. If sporadic colonies appear and there are more than 10, repeat the test. If the repeat test is negative (<10), record the results in the log and proceed. If colony growth appears again, greater than 10 colonies per ml, record results in the log and report to the Quality Assurance Section for guidance in corrective action.

REFERENCES:

1. Clinical and Laboratory Standards Institute (CLSI). *Preparation and Testing of Reagent Water in the Clinical Laboratory* Approved Guideline- Fourth Edition. CLSI document C03-A4 AMD, (ISBN 56328-610-7) .Clinical and Laboratory Standards Institute 940 West Valley Road Suite 1400 Wayne, Pennsylvania, 19087-1989 USA, Reviewed- June 2018.

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PROCEDURE HISTORY

Date	Written/ Revised by	Review/Revision	Approved Date	Approved By
11/28/94	D. Shelby	Silica Testing removed, no longer required	12/6/94	R. Cardiff
5/96	D. Shelby	Annual Review	5/96	R. Cardiff
10/96	D. Shelby	Annual Review	10/96	R. Green
12/97	D. Shelby	Annual Review	1/98	R. Green
7/99	D. Shelby	Annual Review	7/99	R. Green
02/00	D.Shelby	Revised & Annual Review	02/00	R. Green
11/00	D.Shelby	Revised	11/00	R. Green
11/01	D. Shelby	Annual Review	11/01	R. Green
8/02	D. Shelby	Annual Review	8/02	R. Green
9/03	D. Shelby	Annual Review	9/03	R. Green
9/04	D. O'Sullivan	Revised	9/04	R. Green
9/05	D. O'Sullivan	Annual Review	9/05	R. Green
9/06	R. Becker	Revised	9/06	R. Green
9/07	D. O'Sullivan	Annual Review	9/07	R. Green
5/08	R. Olsen	Annual Review	5/08	R. Green
5/09	D. Wright	Annual Review	5/09	L. Howell
9/10	D. Wright	Revised	9/10	L. Howell
09/12	T. Cox	Biennial Review	10/12	L. Howell
09/14	T. Cox	Revision: Siemens changed to Evoqua	09/14	L. Howell
09/16	E. Villadolid/ S. Okimura	Biennial Review	09/2016	L. Howell
8/2018	E. Villadolid	Biennial Review	08/18	L. Howell
08/2020	E. Villadolid	Revised	08/20	L. Howell Via OnBase

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