

**D and D**  
LABORATORY, LLC

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DIALYSIS WATER TESTING

[www.DandDlab.com](http://www.DandDlab.com)

# CULTURES, ENDOTOXIN, AND AAMI WATER PROFILES

**D&D LABORATORY, LLC**  
**201-C Towers Drive**  
**(PO BOX 49862)**  
**GREENWOOD, SC 29649**  
**Tel: 864-942-0003 Fax: 864-942-0006**

# SAMPLE COLLECTION

Please send samples for Culture, Endotoxins, and AAMI Water Analysis to the laboratory in the collection tubes and bottles provided by the laboratory.

## Colony Count and LAL/Endotoxin Sample Collection

**\*Note – Collect only one tube for Colony Count and LAL. The one tube is used for both tests.**

- The CC/LAL tube comes individually wrapped in plastic.
- Do not touch the inside of the tube, cap or sample with fingers or foreign objects.
- Label each tube with the exact same description written on requisition.
- Use one tube, fill at least 2/3 full, and follow your internal or manufacturer sample collection procedures.
- Do not add any preservative.
- Chill culture and endotoxin specimens rapidly by placing in refrigerator prior to packaging.
- Include freezer pack to insure that samples remain cold during shipping. During summer months, a second freezer pack may be needed.
- Ship by overnight courier only (FedEx or UPS)!

## AAMI Water Sample Collection

- 1 Use one (1) 60ml screw cap bottle. Rinse bottle prior to filling and fill bottle **FULL**.
- 2 Label each bottle with the exact same description written on requisition.
- 3 Do not touch the inside of the bottle, cap or sample with fingers or foreign objects.
- 4 Do not add any preservative.

# COMPLETING REQUISITIONS

**\*\*Please annotate the following information in the appropriate box on each D & D Requisition:**

- Full name of facility - Do not abbreviate or use facility number.
- Address of facility.
- Contact Person and phone number- For problems or out of range results
- E-mail address/ Fax number for test results
- PO # reference number (if applicable)
- Sample Identification - Label tube exactly the same as description on the requisition.
- Source of sample - water, dialysate, bicarbonate. This is VERY IMPORTANT, please be specific.
- Date of sample collection
- Test(s) ordered (check "X" each box that is needed).
- See attached example of completed requisition (Page 9).

# **SHIPPING INSTRUCTIONS**

## **CULTURES**

- Ship samples with freezer packs in shipping boxes provided by the laboratory.
- Place a freezer pack in the bottom of the box.
- Place foam insert on top of the freezer pack.
- Place samples on top of the foam insert and place the lid on top.
- During hot summer months, place a second freezer pack in the box.
- Do not put samples directly on freezer packs, they may freeze or burst!
- Place requisition in plastic bag and put on top of Styrofoam lid.
- Samples may not be processed if received at room temperature, frozen, or greater than 24 hours old.

## **ENDOTOXINS (LAL TESTING)**

- Ship as outlined for cultures.
- Samples may not be processed if received at room temperature.

## **AAMI WATER CHEMISTRY PANELS**

- Frozen cold packs are not necessary if only AAMI water analysis samples are shipped, otherwise ship as outlined for cultures.

### **SHIP OVERNIGHT TO:**

**D & D Laboratory**

**201-C Towers Drive**

**Greenwood, South Carolina 29649**

**DO NOT SHIP ON FRIDAY WITHOUT CONTACTING THE  
LABORATORY FOR APPROVAL.**

# **SPECIMEN REJECTION CRITERIA**

- Customer will be contacted with any issue involving samples.
- Cultures or endotoxins received at room temperature
- Cultures received frozen
- Cultures greater than 24 hours old
- Unlabeled samples or improperly labeled samples
- Leaking sample containers
- Samples without requisition
- Inappropriate sample containers

**D & D Laboratory can perform testing to either the [AAMI RD52/RD62](#) or [AAMI 13959 & 11663](#). The customer defines which test standard they require.**

## **Colony Count Testing**

- Specimen is cultured on culture media using the spread plate method
- Specimen volume is measured with a sterile pipette.
- Culture is incubated for 48 hours at 33 - 37 degrees centigrade for AAMI STD RD52 & RD62. Culture is incubated for 7 days at 20 degrees centigrade for AAMI 13959 and 11663.
- Results are reported as total viable colony count of colony forming units per ml of fluid (CFU/ml).
- We can (upon customer request) e-mail, call or fax a report to your facility if results are outside of the following range:

<b><u>AAMI RD52 and RD62 (Colony Count) 2 day test</u></b>		
	<b><u>Action Level</u></b>	<b><u>Failure Level</u></b>
Water	50 CFU/mL	200 CFU/mL
Dialysate	50 CFU/mL	200 CFU/mL
Bicarb	50 CFU/mL	200 CFU/mL

<b><u>AAMI 13959 and 11663 (Colony Count) 2 day or 7 day test</u></b>		
	<b><u>Action Level</u></b>	<b><u>Failure Level</u></b>
Water	50 CFU/mL	100 CFU/mL
Dialysate	50 CFU/mL	100 CFU/mL
Bicarb	50 CFU/mL	100 CFU/mL

## **ENDOTOXIN (LAL TESTING)**

- Collect sample directly into sample tube provided by D & D Laboratory.
- D&D Laboratory test tubes are sterile and pyrogen free.
- Endotoxin results are tested by Kinetic Limulus Amoebocyte Lysate (LAL) method and is FDA approved.
- The results are reported in endotoxin units per ml (EU/ml).
- Test range is 0.01 – up to acceptable results.
- We can (upon customer request) e-mail, call or fax your facility if results are outside of the following range:

<b><u>AAMI RD52 and RD62 (LAL)</u></b>		
	<b><u>Action Level</u></b>	<b><u>Failure Level</u></b>
Water	1 Eu/mL	2 Eu/mL
Dialysate	1 Eu/mL	2 Eu/mL
Bicarb	1 Eu/mL	2 Eu/mL

<b><u>AAMI 13959 and 11663 (LAL)</u></b>		
	<b><u>Action Level</u></b>	<b><u>Failure Level</u></b>
Water	0.125 Eu/mL	0.250 Eu/mL
Dialysate	0.250 Eu/mL	0.50 Eu/mL
Bicarb	0.250 Eu/mL	0.50 Eu/mL

# ANALYTES REPORTED ON AAMI WATER CHEMISTRY PANEL

## ANSI/AAMI/ISO 13959:2009

<u>TEST</u>	<u>(PPM)*</u>	<u>AAMI LIMITS (PPM)*</u>
Aluminum (AL)		<0.010
Arsenic (As)		<0.005
Barium (Ba)		<0.100
Cadmium (Cd)		<0.001
Calcium (Ca)		<2.000
Chromium (Cr)		<0.014
Copper (Cu)		<0.100
Fluoride (F)		<0.200
Lead (Pb)		<0.005
Magnesium (Mg)		<4.000
Mercury (Hg)		<0.0002
Nitrate (NO <sub>3</sub> )		<2.000
Potassium (K)		<8.000
Selenium (Se)		<0.090
Silver (Ag)		<0.005
Sodium (Na)		<70.00
Sulfate (SO <sub>4</sub> )		<100.0
Zinc (Zn)		<0.100
Specific Conductance		N/A
Beryllium (Be)		<0.0004
Antimony (Sb)		<0.006
Thallium (Tl)		<0.002

\* NOTE: PPM and mg/L may be used interchangeably.

\* NOTE: Please note that **chloramines** are not offered, as they are too unstable to withstand the time required for shipping. Chloramines should be determined on-site, at the schedule defined at the site.