



AAMI STANDARD 108 CHART



ANSI/AAMI ST108:2023 sets specific requirements for both routine monitoring and performance qualification (PQ) sampling for water systems used in processing medical devices. The frequency and parameters tested depend on the type of water system and water quality category.

The standard defines three water categories based on their quality and use:

- **Utility Water:** Tap water that may require further treatment for cleaning and rinsing.
- **Critical Water:** Extensively treated water used for final rinses and steam generation.
- **Steam:** Water heated to a vapor phase for sterilization.

		Routine				
		Water Generation		Point of Use		
		Utility	Critical	Utility	Critical	Steam
Routine + PQ	Bacteria (HPC)	-	M	Q	M	-
	Endotoxin (LAL)	-	M	-	M	-
	Conductivity	Q	D	Q	M	Q
	pH	Q	M	Q	M	Q
	Total Alkalinity	Q	M	Q	M	Q
	Total Hardness	Q	M	Q	M	Q

X - Done during PQ
Q - Quarterly
M - Monthly
D - Daily
PQ - Performance Qualification
Source: ANSI/AAMI ST 108:2023

		Performance Qualification		
		Utility	Critical	Steam
Routine + PQ	Bacteria (HPC)	x	x	-
	Endotoxin (LAL)	-	-	-
	Conductivity	x	x	x
	pH	x	x	x
	Total Alkalinity	x	x	x
	Total Hardness	x	x	x
Only PQ	Total Organic Carbon (TOC)	-	x	-
	Aluminum	x	x	x
	Chloride	x	x	x
	Copper	x	x	x
	Iron	x	x	x
	Manganese	x	x	x
	Nitrate	x	x	x
	Phosphate	x	x	x
	Silica	x	x	x
	Sulfate	x	x	x
	Zinc	x	x	x

Categories and performance qualification levels of water quality for medical device processing

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @25 °C	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2**
Total Alkalinity	mg CaCO ₃ /L	<400	<8	<8
Bacteria	CFU/mL	<500***	<10	N/A
Endotoxin	EU/mL	N/A***	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1.0	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<1
Conductivity	(µS/cm)	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg CaCO ₃ /L	<150****	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

*Steam parameters are for monitoring as steam condensate

**For local steam generation, the condensate pH should be 5.0 to 7.5. For boiler-treated steam, most boilers should be treated to maintain a condensate pH of 7.5 to 9.2

***When Utility Water is used after chemical high-level disinfection as a final rinse, the bacteria should be <10 CFU/mL and endotoxin <10 EU/mL

****If hardness is greater than 150 mg/L a water softener is recommended unless used for washing where the cleaning chemistry is capable of handling higher levels of hardness