DEPARTMENT OF PRIMARY INDUSTRIES, PARKS, WATER AND ENVIRONMENT

Analytical Services Tasmania
18 St Johns Avenue New Town 7008
Phone (03) 6165 3300
Email: enquiries@ast.tas.gov.au
Web: www.analyticalservices.tas.gov.au

AS/NZ 4187 RMD steriliser sampling information

Reusable Medical Devices (RMDs) used in dental, medical and surgical procedures are required to be cleaned, disinfected and sterilized according to AS/NZ 4187:2014. As part of compliance with the standard, feed waters and final rinse waters of washer disinfectors, thermal disinfectors, and chemical disinfectors (both automated and manual) are required to be tested. Monitoring the water on a regular basis ensures water is not too hard that it impairs the activity of detergents or cause deposits, scaling or corrosion of items processed, or that the water is not re-contaminating disinfected items with microorganisms or toxins. Routine monthly testing is required, according to table 8.1 of the standard.

AST is able to provide NATA accredited analytical results that meet the requirements of AS/NA 4187:2014.

Testing against other standards or other analytical suites is also available (eg EN 285 table B1 – water (feedwater) supplied to steam generator; EN 285 table 10.1 and table E2 Steam purity tests; as per section 7.2.3.2 of AS/NZ 4187:2014).

AS/NZ 4187:2014 compliance testing

Required analysis and maximum concentration levels of supply and final rinse water quality are specified in table 7.2 of the standard:

Analyte	Maximum concentration levels		AST limit of reporting
	Cleaning process	Final Rinse	
Appearance	Clear, colourless	Clear, colourless	
pH		5.5 - 8.0	0.1 pH units
Conductivity 25°C		30 µS/cm	5 µS/cm
Total Dissolved Solids (TDS)		40 mg/L	20 mg/L
Total Hardness ($CaCO_3$)	60 mg/L	50 mg/L	1 mg/L
Chloride (Cl)	120 mg/L	10 mg/L	0.05 mg/L
Lead (Pb)		10 mg/L	0.5 µg/L
Iron (Fe)		2 mg/L	0.02 mg/L
Phosphate		0.2 mg P_2O_5/L	0.003 mgP/L
Silica (SiO_2)	2 mg/L	0.2 mg/L	0.1 mg/L
Total Viable Count		100 cfu/100 mL	100 cfu/100mL
Endotoxin		0.25 EU/mL	0.1 EU/mL

Sample water "Appearance" should be noted when sampling occurs. E.g. clear or cloudy; coloured or colourless; particulate matter present or absent. If you would like this information to appear on the analytical test report, please note Appearance Observations on the laboratory submission form and a request to include the information on the laboratory report.

AST has NATA accreditation for the Bacterial Endotoxins test. The test is a limulus amoebocyte lysate (LAL) gel formation method of assessing endotoxin concentration by kinetic turbidimetric reaction time. It is currently the analytical method of choice in Australia for quantitative endotoxin analysis.

AST is co-located with a microbiological testing laboratory in New Town, Hobart. This lends itself to the convenience of a simultaneous sample drop off for both chemistry and microbiological testing. Please contact AST for further details if a single drop-off service for your chemistry and microbiology testing may be of use to you.

References and further information

- AS/NZ 4187:2014 – Reprocessing of reusable medical devices in health service organizations.
- Australian Commission on Safety and Quality in Health Care – Advisory no: A16/03
- HTM 01-01: Management and decontamination of surgical instruments: Part D – Washer disinfectors

Analytical Services Tasmania
18 St Johns Avenue New Town 7008
Phone (03) 6165 3300
Email: enquiries@ast.tas.gov.au
Web: www.analyticalservices.tas.gov.au

AS/NZ 4187 RMD steriliser sampling information

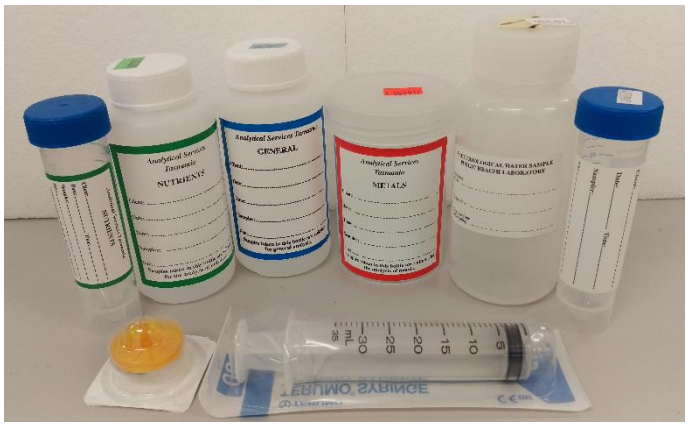
It is advised that you contact AST for a quote and advice before starting any sampling program.

As part of AST's testing service, sample bottles are provided specific to individual suites of analysis. This is included in the quoted analysis cost along with return postage costs. AST's sample bottles are prepared and assessed for appropriateness for each test according to our NATA accredited quality system, and every batch of bottles is tested to ensure it is contamination free.

When taking samples, prevent cross-contamination. Wear disposable gloves, do not touch inside surfaces of bottles or lids, and do not touch syringe tips or filter tips.

The following sample bottles should be filled at each **final rinse water** sampling point:

- Blue labelled plastic 250 mL
- Red labelled plastic 250 mL
- Green labelled plastic 250 mL
- Green labelled plastic 50 mL (filtered)
- White labelled sterile plastic 125 mL
- White labelled plastic 50 mL



And each **cleaning process supply water** point:

- Blue labelled plastic 250 mL
- Red labelled plastic 250 mL

Taking the water samples required for testing purposes is a relatively straight forward process. Water samples from steam sterilisers should be obtained from draw-off points installed at convenient locations within the system, as close to the washer-disinfector as possible. The first 50mL of sample taken at each sampling point should be run to waste. Samples for the chemistry tests (blue, red and green labelled bottles) can then be taken.

Filter a sub-sample from the green labelled 250mL bottle into a green labelled 50mL tube. Remove the syringe from its packet and draw up a full syringe of sample by dipping the tip into the full green labelled 250mL bottle. Remove the filter from its packet and screw it on to the filled syringe. Allow the first 2 – 5 mL of filtrate to go to waste. Collect the remainder of the filtered water in a green labelled 50mL tube labelled "Filtered for Dissolved Nutrients". One pass through the syringe will deliver ~ 30mL of sample. This is sufficient for analysis of soluble nutrients. Discard the used filter and syringe.

When sampling for the Total Viable Count and Endotoxin tests (white labelled bottles), all apparatus used for collecting samples should be sterile and pyrogen-free. The sampling point discharge surfaces should be wiped with alcohol and allowed to evaporate to dryness before sampling (**this evaporation step is very important**). Allow 200mL of water from the sampling point to run to waste. Using aseptic handling techniques collect the sample in the white labelled sterile/pyrogen-free sample bottles provided. Appearance of the sample should be noted (e.g. clear or cloudy, coloured or colourless).

Labels and submission forms should be filled out at the time of sampling. Samples should be kept cool and delivered to the laboratory on the same day as they are sampled.