

Technical Information Report

AAMI TIR58: 2021

Water testing
methodologies

Water testing methodologies

Approved 1 October 2021 by
AAMI

Abstract: The Technical Information Report (TIR) includes common test methods used to monitor hemodialysis water treatment systems and product water. The TIR identifies numerous contaminants of interest in the care of ESRD patients or that could impact the safe and effective operations of water purifications systems used in the care or treatment of ESRD patients; provides the maximum allowable levels and action levels from various standards (AAMI/ISO) and other references as applicable; describes symptoms that hemodialysis patients might experience with exposure to the contaminant; describes effects of the contaminant on hemodialysis equipment and water treatment systems; lists common test methodologies used for analysis/detection of the contaminant at the laboratory and clinic level; notes test interferences that can be associated with a specific test method.

Keywords: hemodialysis water, product water, chemical contaminants, test methods, test interference, clinical exposure symptoms, dialysis equipment, water treatment system

AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

Renal Disease and Detoxification Committee

This technical information report was developed by the AAMI Renal Disease and Detoxification Committee. Committee approval of this technical information report does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Renal Disease and Detoxification Committee** had the following members:

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NOTE Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report (TIR) was developed by the AAMI Renal Disease and Detoxification Committee. The objective is to provide dialysis practitioners with additional information and background related to recommendations made in ANSI/AAMI/ISO and ANSI/AAMI standards, in particular, the contaminants in water, the test methodologies available and suitable for testing to the requirements of these standards to keep dialysis patients safe. Some of the methods are complex, requiring sophisticated instrumentation and these are noted as laboratory test methods to distinguish them from those that can be done at the clinic level. Maximum allowable levels as well as action levels where applicable are provided and the source of the limits noted. The limits are often based on those specified for drinking water with a safety margin to allow for the larger exposure volume of this water to hemodialysis patients. Agents that can interfere with the accuracy and validity of a given type of test method are noted where relevant. Any adverse effects of a contaminant on components of the water treatment or hemodialysis delivery systems are also covered. Emphasis is placed upon known toxicities to hemodialysis patients, but other contaminants that may affect the dialysis treatment are also provided.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI TIR58, *Water testing methodologies* (AAMI TIR58:2021), but it does provide important information about the development and intended use of the document.

Introduction

While the ANSI/AAMI/ISO Standard 23500-3:2019 [8] specifies the maximum allowable levels of chemical contaminants acceptable in water used for hemodialysis and the recommended frequency of testing, it does not necessarily provide all the information that would be useful to the hemodialysis clinic personnel regarding water testing. This technical information report (TIR) provides maximum allowable levels, notes clinical symptoms in dialysis patients exposed to the various contaminants, provides toxic levels where available and applicable, and lists the updated test methods and any interfering substances that can result in inaccurate analysis. In addition, while ANSI/AAMI/ISO 23500-3:2019 [8] provides a list of acceptable tests, these have often been replaced by more up-to-date methods and techniques that are now commonly used by the testing labs providing such analyses to the hemodialysis community. Given that the typical hemodialysis clinic personnel may not be skilled in or have the necessary knowledge of the test methods, this updated list will ensure that the hemodialysis clinic personnel can assess whether the testing lab is using the appropriate testing methodologies. Historically, the AAMI Renal Disease and Detoxification Committee has recommended certain acceptable levels based on known toxicities and/or the Environmental Protection Agency (EPA) Drinking Water requirements, adding a safety margin based on the increased exposure volume for a hemodialysis patient during treatment. The committee has not evaluated methods for sensitivity and accuracy. Thus, there is a need, and a TIR is the appropriate vehicle to inform/educate the hemodialysis community regarding the nuances of testing for contaminants in water and what levels are known or suspected to be hazardous to the hemodialysis patient.

NOTE The Centers for Medicare and Medicaid Services (CMS) currently references ANSI/AAMI RD52, *Dialysate for Hemodialysis* [10] and ANSI/AAMI RD62, *Water Treatment Equipment for Hemodialysis Applications* [11], in their Conditions for Coverage. These American National Standards have been superseded by ANSI/AAMI/ISO 23500-1, *Guidance for the preparation and quality management of fluids for hemodialysis and related therapies* [3] [4] [5] [6]; ANSI/AAMI/ISO 23500-2, *Water treatment equipment for hemodialysis applications and related therapies* [7]; ANSI/AAMI/ISO 23500-3, *Water for hemodialysis and related therapies* [8]; and ANSI/AAMI/ISO 23500-5, *Quality of dialysis fluid for hemodialysis and related therapies* [9].

Water testing methodologies

1 Scope

This Technical Information Report (TIR) identifies common contaminants as well as the test methods commonly used to monitor contaminants in a hemodialysis water treatment system and product water. The TIR will: 1) identify each contaminant with its chemical symbol, as applicable; 2) list maximum allowable levels and action levels as applicable as found in AAMI/ISO Standards and other pertinent references; 3) identify symptoms in hemodialysis patients associated with exposure to a given contaminant; 4) describe adverse effects of a contaminant on hemodialysis equipment and the water treatment system; and 5) identify test(s) used to detect the contaminants while describing the pros and cons of each method, e.g. interference elements.

This TIR does not supersede *Standard Methods for the Examination of Water and Wastewater*, but rather provides common test methods used within the dialysis industry. The reader is advised to reference The Food and Drug Administration (FDA) approval as appropriate or for those tests that The Centers for Medicare and Medicaid Services (CMS) requires FDA approved methods (i.e., bacteria and endotoxin testing). This document excludes sampling recommendations. Check the manufacturer's instructions for use, test kit or test method instructions, AAMI and/or International Organization for Standardization (ISO) documents, CMS regulations as applicable for sampling guidance.

Applicability and use

This TIR contains information intended to assist end users in making informed decisions regarding which test methodologies are useful to test for the presence of specific contaminants commonly found in water in settings where hemodialysis is delivered, allowable limits and action levels and substances that can interfere with accurate test results.

Disclaimer: Users of any selected test methodology must understand the level of sensitivity, precision, and accuracy and how the test results will correlate to the selected action level/maximum allowable limits.

2 Normative references

There are no normative references for this report.

3 Terms and definitions

For the purposes of this AAMI TIR, the following acronyms and definitions apply.

3.1

accuracy

closeness of agreement between a measured quantity value and a true quantity value of a measurement

Note 1 to entry: A measurement is said to be more exact when it has a smaller measurement error [bias].

3.2

acid

chemical substance having a pH of less than 7 that neutralizes alkalis, dissolves some metals, and turns litmus red; typically, a corrosive or sour-tasting liquid of this kind

3.3

Act

Federal Food, Drug, and Cosmetic Act which establishes the U.S. Food and Drug Administration as the law enforcement agency with the authority to regulate food, drugs, and device manufacturing through a comprehensive Code of Federal Regulations (CFR)

3.4

action level

concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels

3.5

activated carbon

activated charcoal

carbon source material, processed and activated to increase its surface area and its ability to adsorb or chemically react with a wide range of water impurities and contaminants, including chlorine, chloramines, organics, odors, and pigments; activated carbon is typically found as granular activated carbon (GAC) or activated carbon blocks

Note 1 to entry: See ANSI/AAMI/ISO 23500-1:2019, B.2.5 [3] and ANSI/AAMI/ISO 23500-2:2019, 5.2.8 [7] for details on activated carbon.

3.6

activated carbon filter

pressurized container of activated carbon media used for removal of free chlorine, chloramines, and Total Organic Carbon (TOC)

3.7

adsorption

attraction and subsequent adhesion of impurities and contaminants to a surface; this process creates a film of the *adsorbate* on the surface of the *adsorbent* (Activated Carbon for example)

3.8

algae

any of various chiefly aquatic, eukaryotic, photosynthetic organisms, ranging in size from single-celled forms to the giant kelp; algae were once considered to be plants but are now classified separately because they lack true roots, stems, leaves, and embryos

3.10

alkali

basic, ionic salt of an alkali metal or alkaline earth metal chemical element; Alkali can also be defined as a base that dissolves in water; a solution of a soluble base has a pH greater than 7.0

3.11

amphoteric

chemical species that behaves both as an acid and as a base is called amphoteric; this property depends upon the medium in which the species is present

3.12

anion

ion carrying a negative charge; negatively charged atom or molecule

3.13

assay

test for a particular contaminant or effect

3.14

ASTM

American Society for Testing and Materials

3.15

bacteria

very large group of microorganisms comprising one of the three domains of living organisms; they are prokaryotic, unicellular, and either free-living in soil or water or parasites of plants or animals

3.16

base

chemical substance having a pH greater than 7.0, that neutralizes acids to form salts, turns litmus blue, in aqueous solution, is slippery to the touch, tastes bitter and promotes certain chemical reactions (base catalysis)

3.17

biofilm

microbially-derived sessile community characterized by cells that are irreversibly attached to a substratum or interface or to each other, are imbedded in a matrix of extracellular polymeric substances that they have produced, and exhibit an altered phenotype with respect to growth rate and gene transcription

[SOURCE: ANSI/AAMI/ISO 23500-1:2019, 3.6] [3]

Note 1 to entry: The matrix, a slimy material secreted by the cells, protects the bacteria from antibiotics and chemical disinfectants.

Note 2 to entry: A certain amount of biofilm formation is considered unavoidable in dialysis water systems. When the level of biofilm is such that the action levels for microorganisms and endotoxins in the dialysis water are routinely reached or exceeded, the operation of the system is compromised from a medical and technical point of view. This level of biofilm formation is often referred to as bio-fouling.

3.18

brackish water

water having more salinity than freshwater, but not as much as seawater, and containing dissolved solids in the range of 1000 – 10000 ppm (USGS)

3.19

buffer

solution that resists changes in pH when acid or alkali is added to it. Buffers typically involve a weak acid or alkali together with one of its salts

3.20

carbon source material

any of the following carbonaceous materials that are used to manufacture activated carbon: Bituminous coal, Sub Bituminous coal, Lignite, Coconut shell, wood, peat

3.21

carcinogen /carcinogenic

cancer causing substance

3.22

cation

ion carrying a positive charge. Positively charged atom or molecule

3.23

chlorine, combined

chlorine that is chemically combined

EXAMPLE Chloramine compounds.

Note 1 to entry: There is no direct test for measuring combined chlorine, but it can be established indirectly by measuring both total and free chlorine and calculating the difference.

[SOURCE: ANSI/AAMI/ISO 23500-1:2019, 3.10] [3]

3.24

chlorine, free

chlorine present in water as dissolved molecular chlorine (Cl₂), hypochlorous acid (HOCl), and hypochlorite ion (OCl⁻)

Note 1 to entry: The three forms of free chlorine exist in equilibrium.

[SOURCE: ANSI/AAMI/ISO 23500-1:2019, 3.11] [3]

3.25

chlorine, total

sum of free and combined chlorine

Note 1 to entry: Chlorine can exist in water as dissolved molecular chlorine, hypochlorous acid and/or hypochlorite ion (free chlorine) or in chemically combined forms (combined chlorine). Where chloramine is used to disinfect water supplies, chloramine is usually the principal component of combined chlorine.

[SOURCE: ANSI/AAMI/ISO 23500-1:2019, 3.12] [3]

3.26

chromatography

method of separating and analyzing mixtures of chemicals. The separation of closely related compounds, by allowing a solution or mixture to seep through an absorbent (such as clay, gel, or paper) so each compound becomes absorbed into a separate, often colored layer

3.27

colony forming unit

CFU

measure of bacterial or fungal cell numbers that theoretically arise from a single cell when grown on solid media

Note 1 to entry: Colonies can also form from groups of organisms when they occur in aggregates.

3.28

colorimetric measurement

means of measuring unknown chemical concentrations in water by measuring a sample's color intensity. The specific color of the sample, developed by addition of chemical reagents, is measured with a photoelectric colorimeter, or is compared with "color standards" (disc, vial, or chart) using or corresponding with known concentrations of the chemical

3.29

contaminant

substance that makes water impure

3.30

Delta P

ΔP

change in pressure, or pressure drop, that occurs across a piece of control equipment due to accumulation of material or fouling resulting in increased resistance

3.31

dilution

process of reducing the concentration of a solute in solution, usually achieved by adding/mixing with more water (solvent)

3.32

disinfection

destruction of pathogenic and other kinds of microorganisms by thermal or chemical means

Note 1 to entry: Disinfection is a less lethal process than sterilization because it destroys most recognized pathogenic microorganisms but does not necessarily destroy all microbial forms.

Note 2 to entry: Appropriate disinfection strategies need to include: disinfection type, disinfectant concentration, exposure time and temperature.

[SOURCE: ANSI/AAMI/ISO 23500-1:2019, 3.18]

3.33

distilled water

water that has many of its impurities removed through distillation. Distillation involves boiling the water and then condensing the steam into a clean container

water that has been heated to the boiling point, vaporized to remove non-volatile impurities, cooled, condensed into a liquid condensate, and collected so that no impurities are reintroduced

3.34

DPD

N-diethyl-p-phenylene-diamine is a reagent used to measure chlorine in water

3.35

electrolyte

compound that ionizes when dissolved in suitable ionizing solvents such as water; Ion capable of transferring or exchanging electrons; upon dissociation of salts in water, electrolytes or charged ions result; these ions are responsible for the conductivity of a solution

3.36

element

substance that cannot be chemically interconverted or broken down into simpler substances and are primary constituents of matter; each element is distinguished by its atomic number, i.e., the number of protons in the nuclei of its atoms; elements are typically those found in the periodic table; the periodic table is a tabular arrangement of the chemical elements, organized on the basis of their atomic numbers, electron configurations, and recurring chemical properties

3.37

endotoxin

major component of the outer cell wall of gram-negative bacteria

Note 1 to entry: Endotoxins are lipopolysaccharides, which consist of a polysaccharide chain covalently bound to lipid A. Endotoxins can acutely activate both humoral and cellular host defenses, leading to a syndrome characterized by fever, shaking, chills, hypotension, multiple organ failure, and even death if allowed to enter the circulation in a sufficient dose.

[SOURCE: ANSI/AAMI/ISO 23500-1:2019, 3.20] [3]

3.38

endotoxin retentive filter

ETRF

membrane filter used to remove endotoxins and microorganisms from dialysis water or dialysis fluid

Note 1 to entry: The performance of an endotoxin-retentive filter is usually expressed as the logarithmic reduction value (LRV), defined as $\log_{10}(\text{inlet concentration})/(\text{outlet concentration})$.

Note 2 to entry: Endotoxin-retentive filters can be configured in a cross-flow or dead-end mode. Some endotoxin-retentive filters also remove endotoxins by adsorption.

[SOURCE: ANSI/AAMI/ISO 23500-1:2019, 3.21] [3]

3.39

endotoxin units

EU

units assayed by the Limulus amoebocyte lysate (LAL) test when testing for endotoxins

Note 1 to entry: Because the activity of endotoxins depends on the bacteria from which they are derived, their activity is referred to as a standard endotoxin unit as extracted from *Escherichia coli* O113:H10.

Note 2 to entry: In some countries, endotoxin concentrations are expressed as international units (IU) and in others as endotoxin units (EU). EU and IU are equivalent.

3.40

EPA

U.S. Environmental Protection Agency

3.41

feed water

water entering a dialysis facility supplied to a water treatment system (e.g., pre-treatment system) or to an individual component of a water treatment system

Note 1 to entry: the water supplied to the water treatment system is potable water that meets drinking water requirements.

3.42

filtration

mechanical or physical process to separate solid particulates from fluids

3.43

fungus

large group of eukaryotic microorganisms that includes yeast, mold, and mushrooms. Some species have been implicated as contaminants of water used in hemodialysis

3.44

grains per gallon

GPG

unit of measure for water hardness 17.1 mg/L = 1 GPG

3.45

halogen

any of a group of five chemically related nonmetallic elements found in group 17 of the periodic table and includes fluorine, chlorine, bromine, iodine, and astatine

3.46

hardness

concentration of calcium and magnesium ions in water expressed as parts per million (ppm) or milligrams per liter (mg/L) of calcium carbonate (CaCO_3) equivalents

3.47

heavy metals

metallic elements with atomic weight greater than 5, e.g., mercury, chromium, cadmium, arsenic, and lead; heavy metals can be toxic to living organisms at low concentrations and tend to accumulate in the food chain

3.48

hydrophilic

having a strong affinity (liking) for water

3.49

hydrophobic

having a strong aversion (dislike) for water. Not readily absorbing water; insoluble in water

3.50

hypochlorous acid

HOCl

dominant reaction product of chlorine in water at a pH of less than 7, however, as you continue to lower the pH, especially below a pH of 2, the dominant chlorine species is chlorine not hypochlorous acid

3.51

Langelier saturation index

LSI

calculated number used to predict the calcium carbonate (CaCO_3) stability in water; that is, whether the water will precipitate, dissolve, or be in equilibrium with calcium carbonate

3.52

LAL test

***limulus* amoebocyte lysate test**

assay used to detect endotoxin

Note 1 to entry: The detection method uses the chemical response of an extract from blood cells of a horseshoe crab (*Limulus polyphemus*) to endotoxins.

Note 2 to entry: Amebocyte lysate from a second horseshoe crab, *Tachypleus tridentatus*, may also be used to detect endotoxin.

[SOURCE: ANSI/AAMI/ISO 23500-1:2019, 3.29] [3]

3.53

mass spectrometry

MS

instrumental method for identifying the chemical constitution of a substance by means of the separation of gaseous ions according to their differing mass and charge

3.54

nephelometric turbidity unit

NTU

standard unit of measurement used to measure turbidity in water.; it is a measure of the light scattering effect of fine suspended particles in a light beam

3.55

oxidation reduction reaction

redox reaction

chemical reaction that involves a transfer of electrons between two species; any chemical reaction in which the oxidation number of a molecule, atom, or ion changes by gaining or losing an electron

[SOURCE: Chemistry LibreTexts, <https://chem.libretexts.org>]

3.56

PPM

parts per million

way to quantify very low concentrations of substances. For example, 1 ppm is equivalent to 1 milligram per liter (abbreviated as mg/L)

3.57

pH

potential of hydrogen

expression of the acidity of a solution; the negative logarithm of the hydrogen ion concentration (pH 1 very acidic; pH 14, very basic; pH 7, neutral). e.g., pH 5 is 10 times the acidity of 6 and 100 times the acidity of 7; pH is a measure of intensity and not capacity; it is the logarithm of the reciprocal of the hydrogen ion concentration of a solution; the neutral point of 7 indicates the presence of equal concentrations of free hydrogen and free hydroxide ions; number denoting level of acidity or alkalinity

Note 1 to entry: The pH scale is logarithmic and runs from 0 to 14; the neutral point is 7; numbers below 7.0 indicate acidity, and those above 7.0 indicate alkalinity