# The Testing Behind the AAMI Standards

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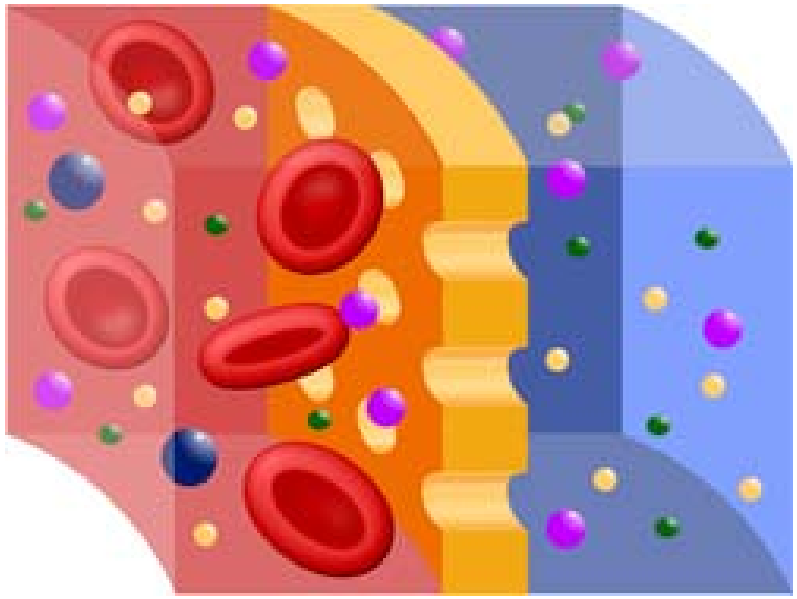
TESTING

# AAMI STANDARDS

# Why Test Water?

- Direct exposure
- Semi-permeable membrane
- Removal = exposure
- Water quality affects patient outcome



# Introduction

- **Tap water was first used for dialysis**
  - Resulted in the exposure to Al, Fe, Chlorine, organic compounds, and bacteria
  - Resulting conditions: hemolytic anemia and encephalopathy
  - Cause recognized as water contaminants
  - Lead to advancements in water purification

# Water Purification Systems

- **“Feed water” treated using various components**
- **Components determined by local water conditions and sources at initial setup**
  - Sediment filters
  - Charcoal tanks
  - Reverse Osmosis (RO)
  - Deionization (DI)
  - Ultraviolet light

# A Common Need For Water Purification

# AAMI Standards

- **RD62-2001: Water treatment equipment for hemodialysis applications (Water Treatment System Standard)**
  - Water bacteriology
    - < 200 CFU/mL total viable microbial count
      - -Action Level: 50 CFU/mL
    - < 2.0 EU/mL endotoxin concentration
      - -Action Level: 1.0 EU/mL
- **CMS adoption of AAMI**
  - Included with Conditions of Coverage changes, Oct. 2008

# AAMI Standards, cont.

- **RD52: 2004, Dialysate for Hemodialysis**
  - -Bacteriology of Dialysate: product that patients are exposed to
    - - Conventional Dialysate
    - - Lower than 200 CFU/mL total viable microbial count
      - •Action level of 50 CFU/mL
    - - Lower than 2.0 EU/mL of endotoxin
      - •Action level of 1.0 EU/mL
  - -Action Level:
    - - "The concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels"
- **Standards for Ultrapure Dialysate**
  - -Lower than 0.1 CFU/mL and lower than 0.03 EU/mL
    - - Home Hemodialysis application only- this is the manufacturer's limit for self contained dialysate products used in home hemodialysis systems

# Association for the Advancement of Medical Instrumentation(AAMI)

# Hemodialysis Water Quality

| Contaminant | Maximum Concentration (mg/L) |
|---|---|
| Aluminum | 0.01 |
| Antimony | 0.006 |
| Arsenic | 0.005 |
| Barium | 0.10 |
| Beryllium | 0.0004 |
| Cadmium | 0.001 |
| Calcium | 2 (0.1 mEq/L) |
| Chloramines | 0.10 |
| Chromium | 0.014 |
| Copper | 0.10 |
| Fluoride | 0.20 |
| Free Chlorine | 0.50 |
| Lead | 0.005 |
| Magnesium | 4 (0.3 mEq/L) |
| Mercury | 0.0002 |
| Nitrate (as N) | 2.00 |
| Potassium | 8 (0.2 mEq/L) |
| Selenium | 0.09 |
| Silver | 0.005 |
| Sodium | 70 (3.0 mEq/L) |
| Sulfate | 100 |
| Thallium | 0.002 |
| Zinc | 0.10 |

a) The physician has the ultimate responsibility for ensuring the quality of water used for dialysis.

# Clinical Applications of Test Results

## We use test results to…

- Evaluate the design and safety considerations in the installation of water treatment systems for dialysis
- Monitor the effectiveness of water treatment
- Identify problems before patient health is compromised
- Monitor changes in water sources
- Demonstrate compliance with federal regulations

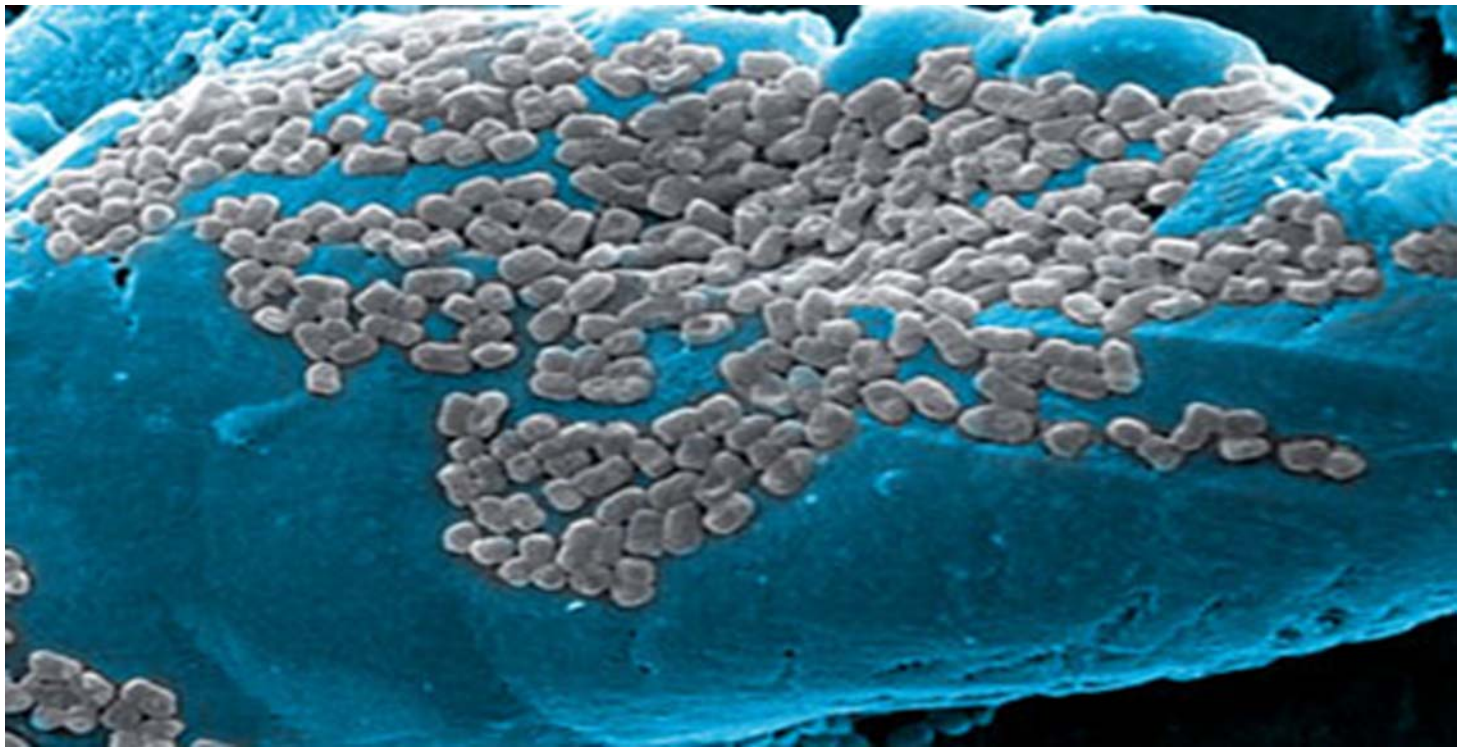
# Sources of Contamination

- **Municipal water treatment adds chlorine and fluoride**

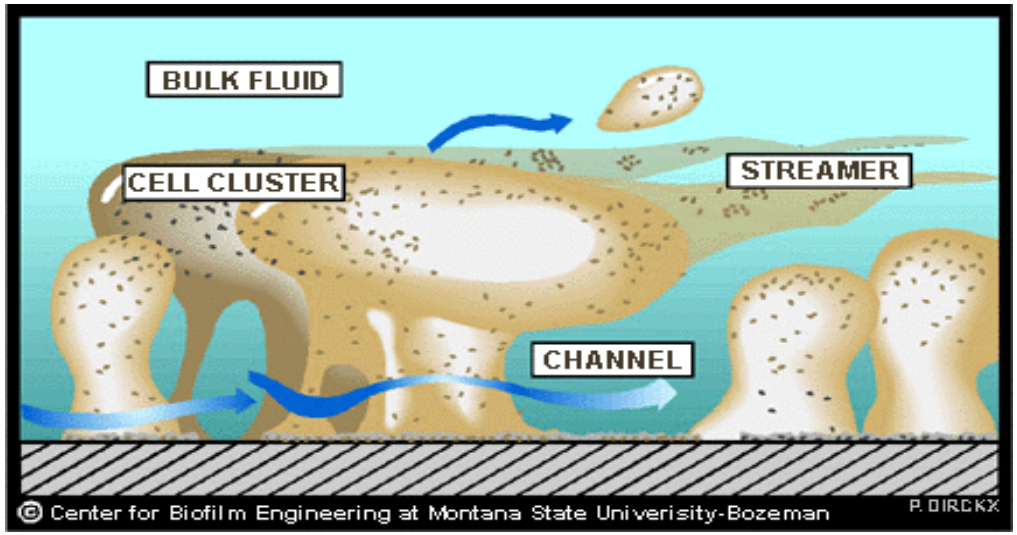
- **Trace element components vary seasonally due to run-off, reservoir or well water sources**

# Biofilm

## Bacterial contamination from source water and the water treatment system

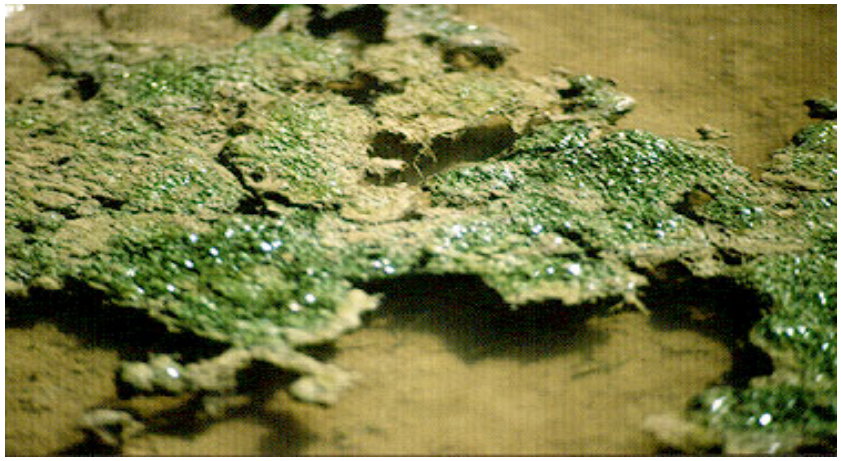


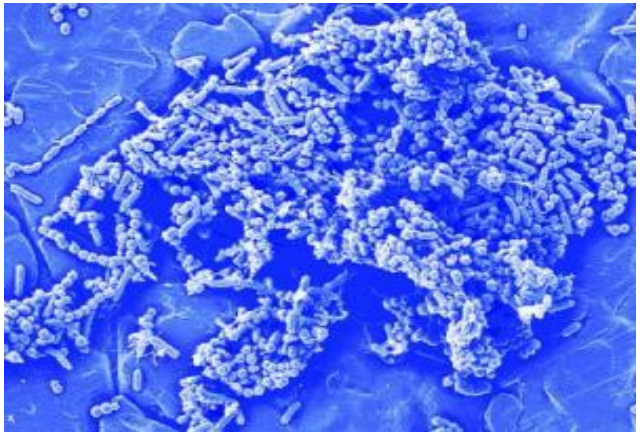
# Biofilm Formation

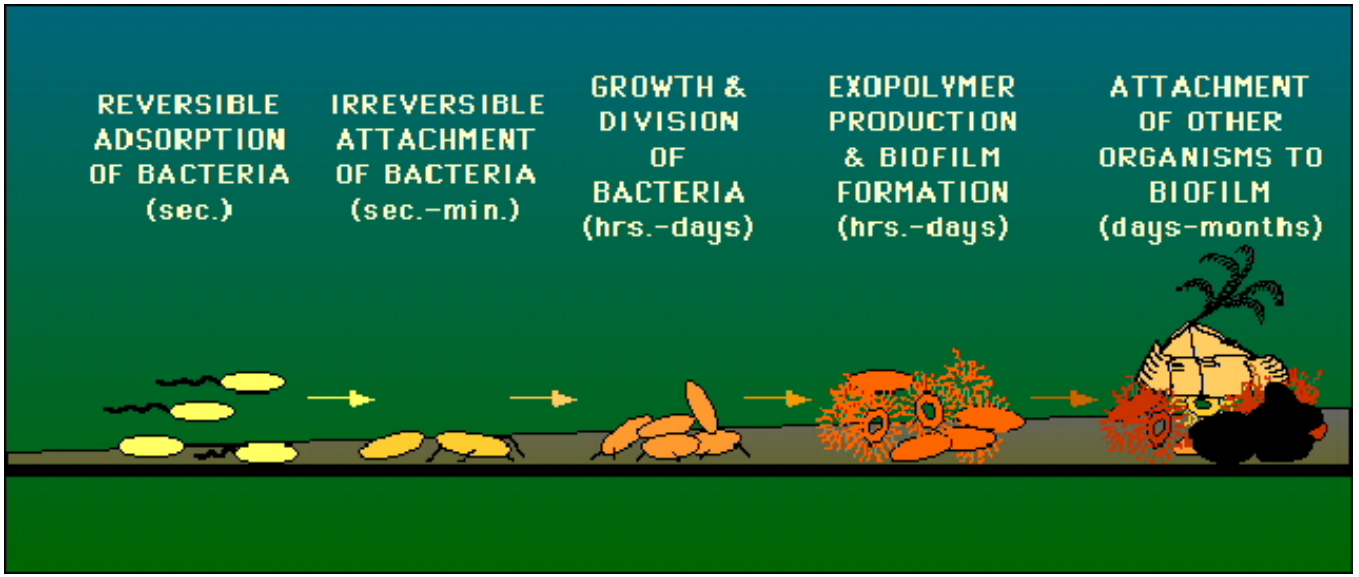



What is it? A **biofilm** is a complex aggregation of micro-organisms living in a protective and adhesive matrix.

Why is it important? **Biofilms protect bacteria** from the effects of detergents and antibacterial agents, as the dense extracellular matrix and the outer layer of cells actively prevent access to the interior of the bacterial community.






REVERSIBLE ADSORPTION OF BACTERIA (sec.)
IRREVERSIBLE ATTACHMENT OF BACTERIA (sec.-min.)
GROWTH & DIVISION OF BACTERIA (hrs.-days)
EXOPOLYMER PRODUCTION & BIOFILM FORMATION (hrs.-days)
ATTACHMENT OF OTHER ORGANISMS TO BIOFILM (days-months)

# Interpreting Results

- **A sudden increase in chemical contaminants**
  - Break in the integrity of water treatment system at the dialysis unit
  - Consistent elevated chloramines and other chemicals may indicate a change in municipal source water
- **Sudden increase in bacterial colony count**
  - Inadequate cleaning and disinfection
  - Improper specimen collection, preparation, packaging, and shipping
- **Intermittent positive colony count results**
  - Biofilm formation

# Importance of Proper Collection

- **Proper specimen collection, preparation, packaging and shipping is essential for accurate test results**
  - Use proper containers
  - Follow collection, preparation and packaging instructions carefully
  - Even the slightest contamination will cause false results
  - The most common cause of false positive results is improper handling of the sample after collection
- **Proper collection assures a confidence that positive results are in fact a problem within the water and dialysate delivery system**


Draw Date 6-15-07
Sample Source 100130
X035164
Acct 5819
Draw Date 6-15-07
Sample Source 100937
X035145
Acct 5819


CTLAL
Master

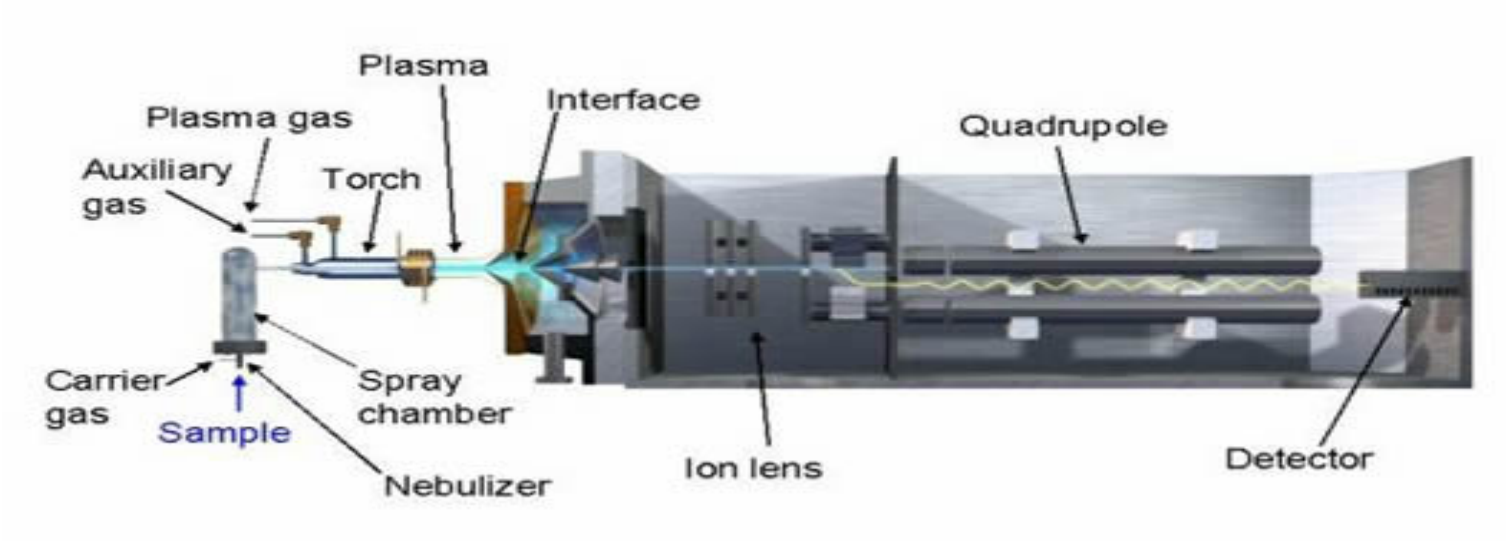
# Testing Specifics in the Lab

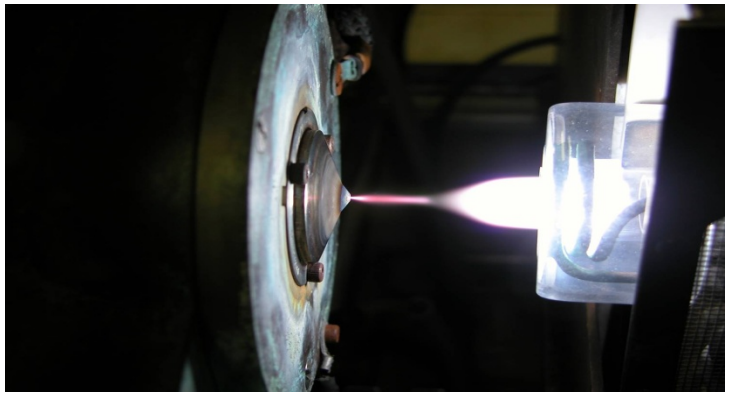
- Methods and test procedures
- Instrumentation
- Turnaround time

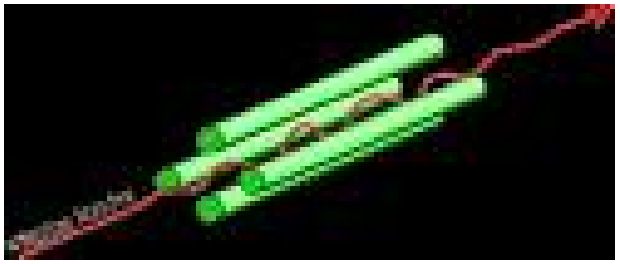
# AAMI Testing (aka Trace Elements)

- **Methods**
  - Ion Chromatography (IC):
    - Sulfates, Nitrates, Fluorides – not strictly trace elements
  - Inductively coupled plasma atomic emission spectrophotometer (ICP-AES)
  - Inductively coupled plasma mass spectroscopy (ICP-MS)
  - pH/conductivity

# ICP-MS Method



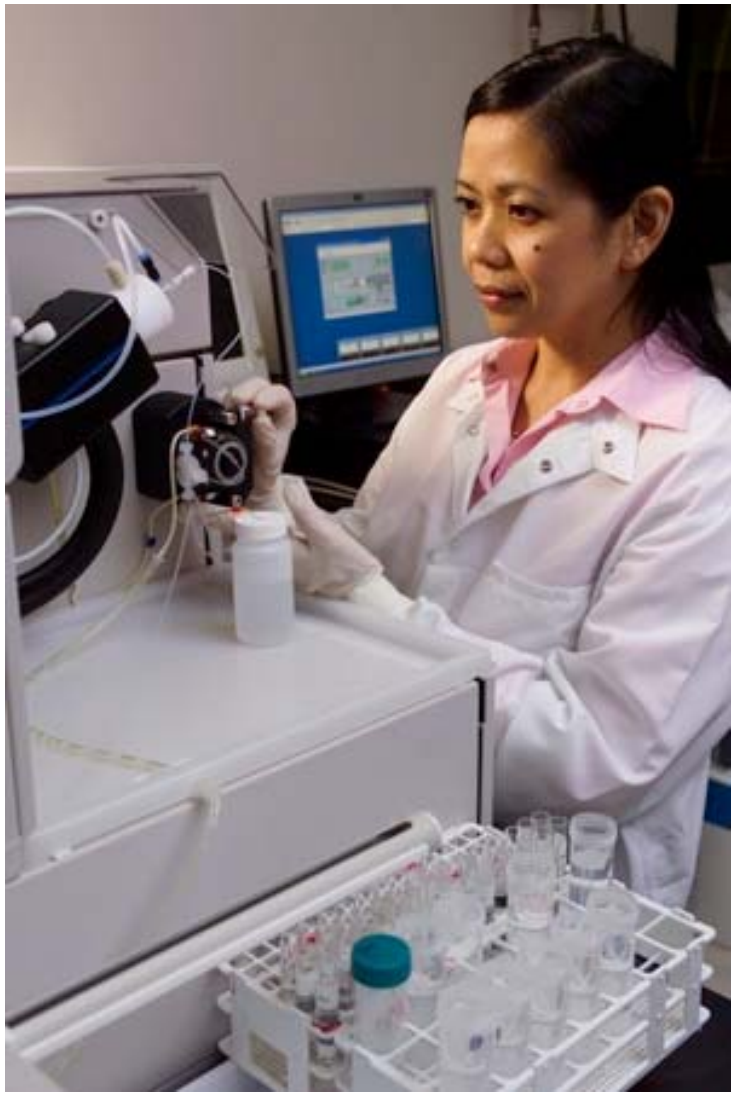





# ICP-MS 7500 ce

# Ion Chromatography

# ICP-Optima



# Turnaround Time

- **Water**
  - Multiple instruments required to complete all trace analyte testing
    - 16 hour acidification prior to any testing
    - IC (10 samples/hour)
    - ICP-MS (10 samples/hour)
    - pH/conductivity

# Bacterial Count (aka Colony Count)

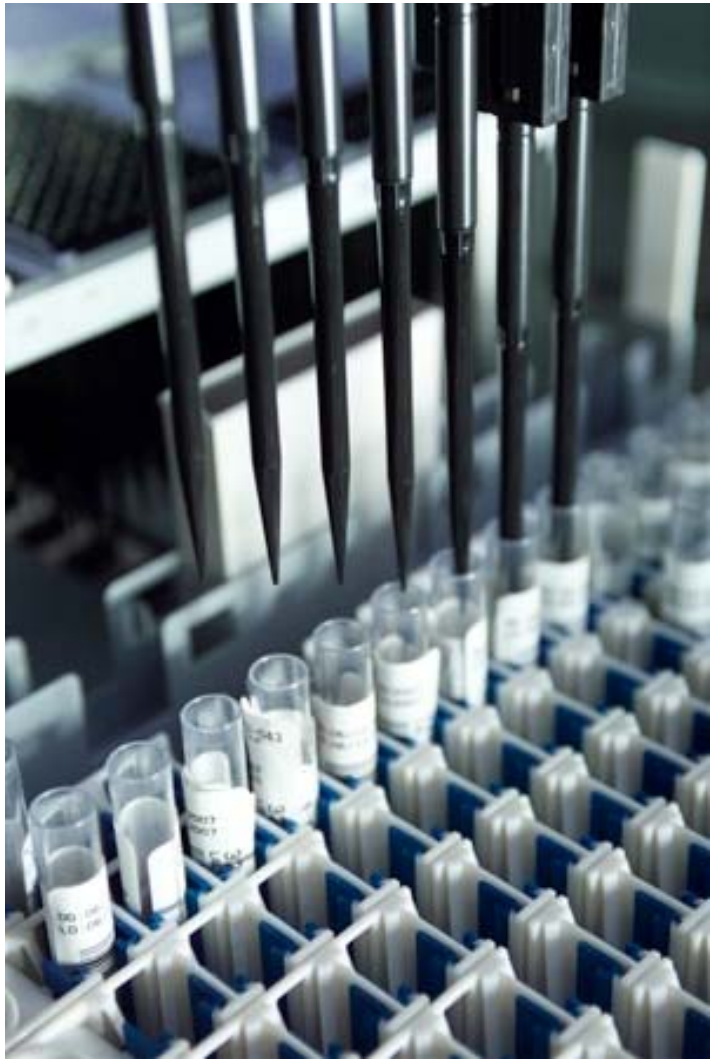
- **Spread plate method**
  - Manual inoculation
  - Automated plate counting
  - Interfaced result entry
- **Final results available 48 hours after inoculation**
- **Membrane filtration**
  - Specialized testing for home hemodialysis equipment


COUNTERMAT
Flash
DELL

# Endotoxin Detection (aka LAL)

- Kinetic chromogenic test method
- Tecan Freedom EVO automated pipettor
- Incubating spectrophotometers
- Manual interpretation of each result
- Specimens are tested the day they arrive

# Tecan EVO Automated Pipettor



# Review

## Why do we test water?

ICPMS

- Improve patient outcomes
- Comply with federal regulations
- Protect patient safety
- Monitor changing water supply
- Sustain long term patient health

# Thank You For the Opportunity!