

**North Texas NANT 11th Annual Symposium
2010 November 7**

**THREE MAJOR ISSUES TODAY
FOR BIOMED TECHS
REGARDING
HEMODIALYSIS WATER TREATMENT
SYSTEMS**

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1. Maintaining the 510 (k) status of hemodialysis water treatment system

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2. Chlorine and chlorine monitoring

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1. Maintaining the 510 (k) status of hemodialysis water treatment system
2. Chlorine and chlorine monitoring
3. Sample Port Maintenance

*GOALS

*To better protect patient health and safety

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- *To better protect patient health and safety
- *Make the Biomed Tech's job easier and more effective

Maintaining the 510 (k) Status of Hemodialysis Water Treatment System

Maintaining the 510 (k) Status of Hemodialysis Water Treatment System

What is 510 (k)-cleared?

Maintaining the 510 (k) Status of Hemodialysis Water Treatment System

510(k) Clearances

Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). . .

Ref: fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510k/default.htm

Maintaining the 510 (k) Status of Hemodialysis Water Treatment System

Class II Medical Device

“A water purification system for hemodialysis is described in the FDA regulation, 21CFR 876.5665(a), as a "device that is intended for use with a hemodialysis system" The classification for this device is class II as stated in 21 CFR 876.5820(b) and its product code is 78 FIP

REF: Food and Drug Administration, Center for Devices and Radiological Health
Document Issued on: May 30, 1997
Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal Devices Branch
FDA/CDRH/ODE/DRAERD

Maintaining the 510 (k) Status of Hemodialysis Water Treatment System

Scope of Device

The Hemodialysis water treatment system is everything from the city water after the backflow preventer(s) to the hemodialysis machine (pre-treatment, RO and storage tank, post-treatment, water loop(s) and patient stations.

Maintaining the 510 (k) Status of Hemodialysis Water Treatment System

“The scope of this standard includes all devices, piping, and fittings between the point at which potable water is delivered to the water treatment system and the point of use of the treated water. Examples of components included within the scope of this standard are water treatment devices, on-line water quality monitors (such as conductivity monitors), and piping systems for the distribution of treated water. Also included in the scope of this standard is the quality of water used to prepare dialysate, to prepare concentrates from powder at the dialysis facility, and to reprocess dialyzers for multiple use.”

Ref: AAMI RD62:2006 Section 1.2 Inclusions

Maintaining the 510 (k) Status of Hemodialysis Water Treatment System

Initial 510(k) Compliance

Hemodialysis water treatment system manufacturers will provide and install the water treatment system when a facility is being built.

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Maintaining the 510 (k) Status of Hemodialysis Water Treatment System

Initial 510(k) Compliance

- * Hemodialysis water treatment system manufacturers will provide and install the water treatment system when a facility is being built.
- * They will then train at least one operator of the system and document that the operator is trained to operate the system
- * Provide a certification that the system is compliant with the manufacturer's 510(k) system cleared by the FDA. This is to ensure that the system begins in a 510(k) compliant condition.

Hemodialysis Water Treatment System Manufacturers

National Manufacturers

- * AmeriWater
 - * Gambro (Licensed to MarCor)
 - * Siemens
- Better Water
 - MarCor

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Regional Manufacturers

- * Nelson Environmental Technologies
- * Water & Power Technologies
- * Plus about 12 to 15 others around the USA

Maintaining a Water Treatment System 510(k)-compliant

Any modifications to a 510(k) water treatment system must be made by manufacturers (or their certified agents) using 510(k)-cleared equipment and installed so that it complies with the system 510(k) certification. Biomed techs trained by the manufacturer can work on or modify their system providing it is in compliance with the manufacture's 510(k)-cleared system. An electrician, plumber, "handyman", or any other person may not modify the system and will accept total responsibility for any modifications he makes unless he is directed by the Biomed Tech who then assumes those liabilities.

Maintaining a Water Treatment System 510(k)-compliant

The FDA inspectors have advised us (and I presume all other manufacturers that have 510(k)-cleared systems) not to work on any illegal (non-510(k) compliant) system because if we do we accept the total liability for the system. We are, however, allowed to bring non-510(k) systems into compliance.

Maintaining a Water Treatment System 510(k)-compliant

Modifying systems with parts that you buy from the local hardware store is dangerous. For a manufacturer of 510(k) systems, a complete list of all wetted-surface materials must be documented and they all must be materials that are generally accepted by the FDA. Going to Ace Hardware or Lowes and getting a ¾" ball valve is dangerous. We have found some that are made in China and have Buna-N rubber parts in them. You may save a few dollars but you have violated the 510(k) status of the system.

Maintaining a Water Treatment System 510(k)-compliant

Always ask yourself -

Would I do this on a hemodialysis machine?

The answer had better be “Yes” because the FDA considers both medical devices.

Chlorine and Chlorine Monitoring

Chlorine in Municipal water supply

- . Free chlorine
- . Combined chlorine (mono-chloramine from city and naturally-occurring multi-chloramines and other chlorine compounds)
- . Chlorinated solids (organics)

Chlorine and Chlorine Monitoring

Free chlorine

Reacts with carbon on
contact

Chlorine and Chlorine Monitoring

Combined chlorine

These are dissolved chlorine compounds.

The city makes mono-chloramine by adding ammonia to free chlorine. This is to reduce the amount of THM (Trihalomethane) in the water that is classified as carcinogenic.

Other chlorine compounds (such as multi-chloramines) can occur naturally in the water distribution system by the reaction of free chlorine and other compounds.

Chorine and Chlorine Monitoring

Chlorinated solids (organics)

These are solids that react with free chlorine. They are not actually dissolved in the water but transported by the water

Chorine and Chlorine Monitoring

Chlorine Monitoring

1. DPD Kit with color wheel
2. DPD with Pocketcolorimeter
3. Test strips

Chlorine and Chlorine Monitoring

Chlorine Monitors



DPD Pocket Colorimeter



DPD Color Wheel



Test Strips

Chlorine and Chlorine Monitoring

Monitors

Chlorine Type	DPD Color wheel	DPD Pocket colorimeter	Test Strips (RPC type)
Free	Reacts	Reacts	Reacts
Combined	Reacts	Reacts	Reacts
Chlorinated solids	Reacts	Reacts	No reaction

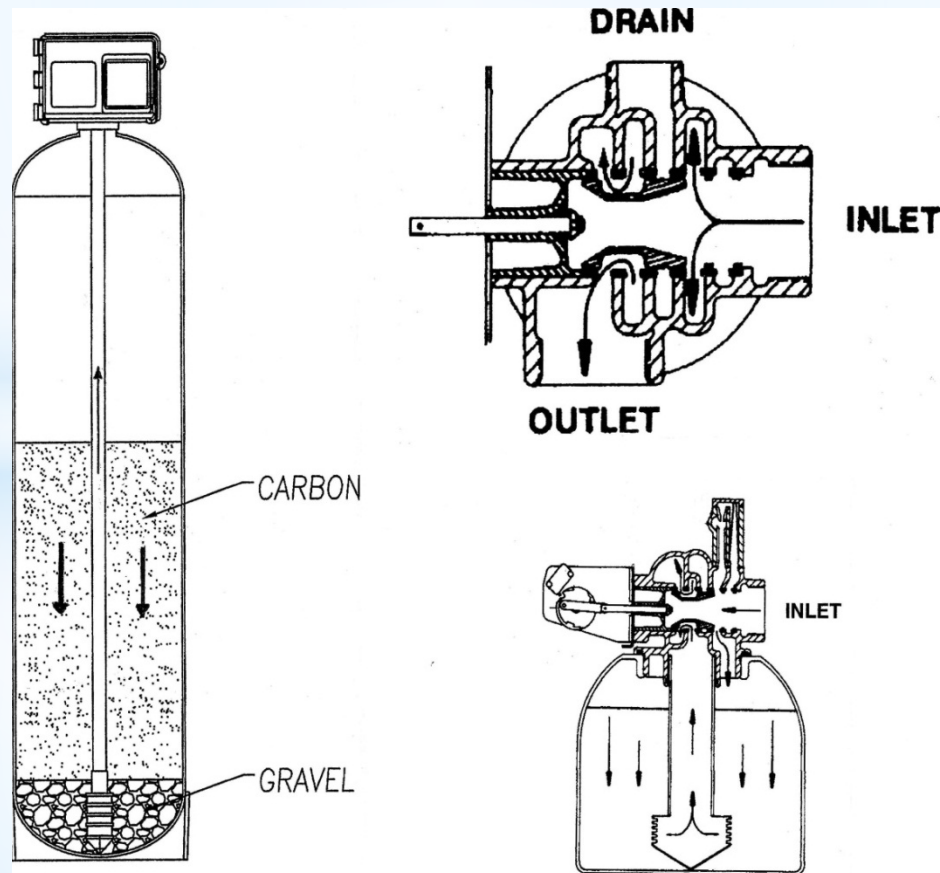
Chorine and Chlorine Monitoring

Four Possible Paths for chlorine to pass through carbon filter

1. Through the media
2. Through the valve
3. Between the head and riser
4. Between the distributor & riser

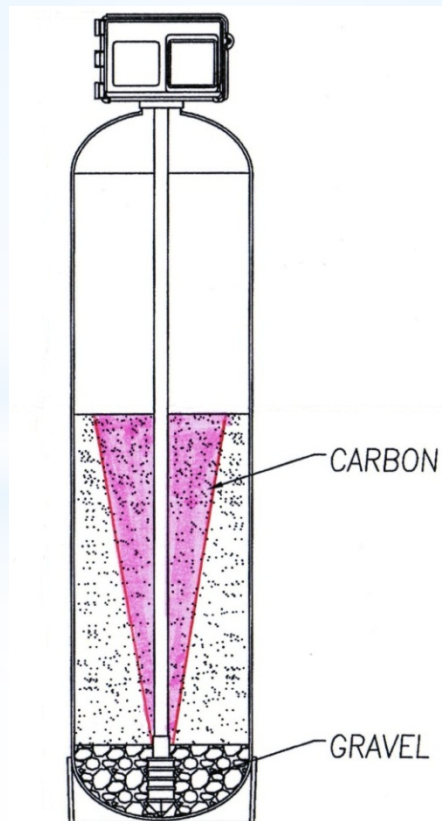
Chlorine and Chlorine Monitoring

Carbon Filter Service Mode



Chorine and Chlorine Monitoring

Carbon Filter Break Thorough Due To Distributor Problem



Chlorine and Chlorine Monitoring

100% Free Chlorine from City

Periodically municipal water systems will convert from a mixture of free chlorine and mono-chloramine to 100% free chlorine. The reason is to purge the water distribution system of nitrification bacteria that thrive on the mono-chloramine that is added at the watertreatment plant.

Chlorine and Chlorine Monitoring

100% Free Chlorine from City

Typically this is for a two week period.

The first few days of this shock treatment results in a significant bloom of dead bacteria in the water line. Because of the usually high dosage of the free chlorine in the water, this organic material is highly chlorinated.

Chlorine and Chlorine Monitoring

100% Free Chlorine from City

Hemodialysis facilities that are not prepared for this change in city water will typically go into panic mode as they get positive chlorine readings past both the worker and polisher carbon filters.

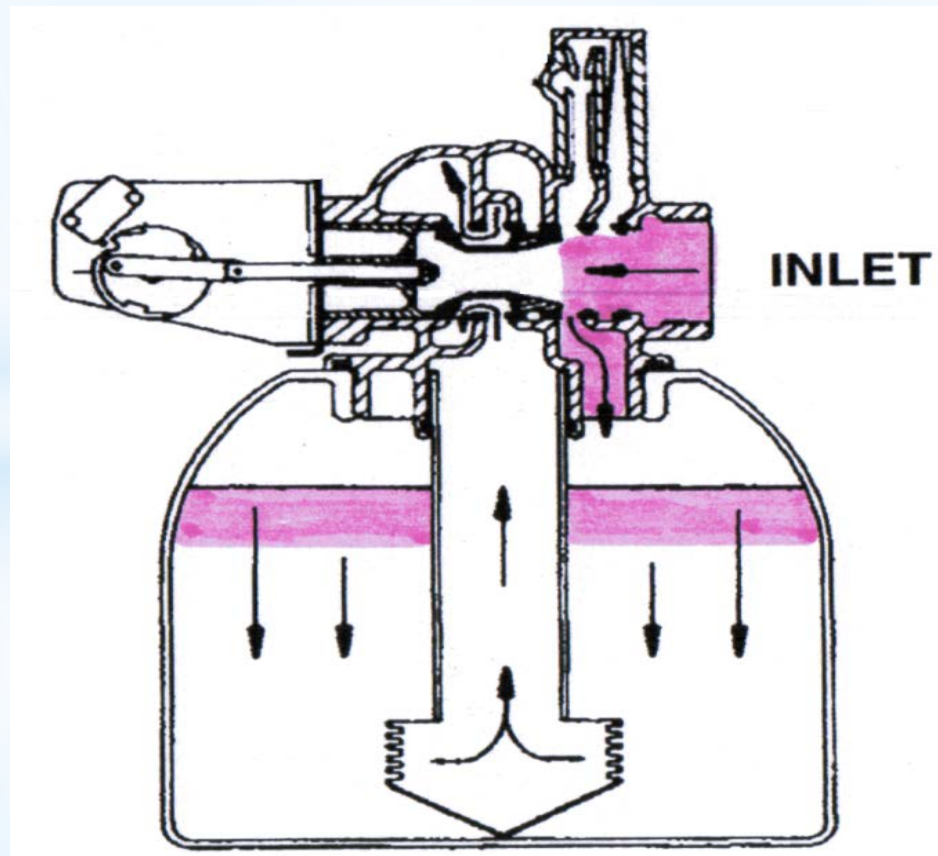
Chlorine and Chlorine Monitoring

Chlorine False Positives

Chlorine false positives are caused by chlorinated solids that are transported by the water. The chlorine is not dissolved in the water.

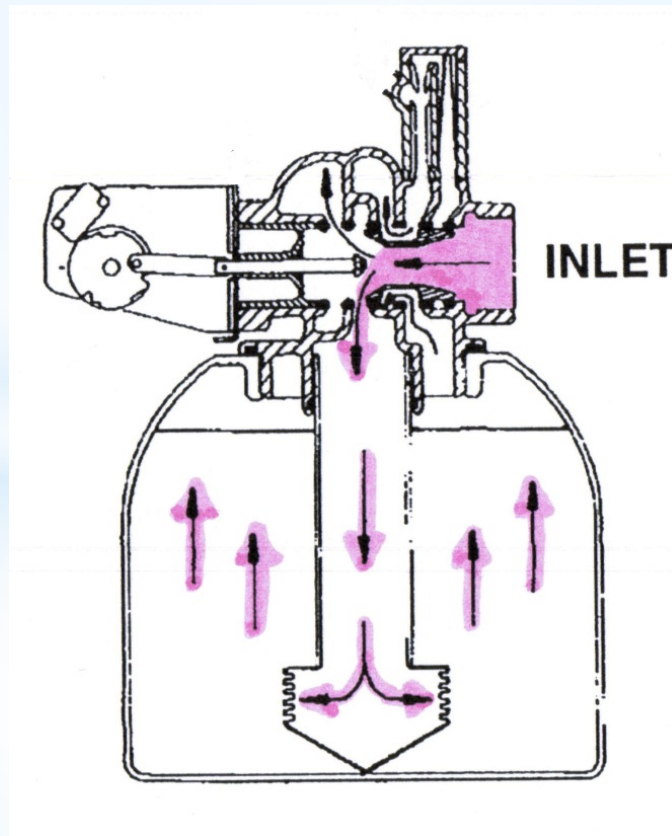
Chlorine and Chlorine Monitoring

Service Mode Flow Path



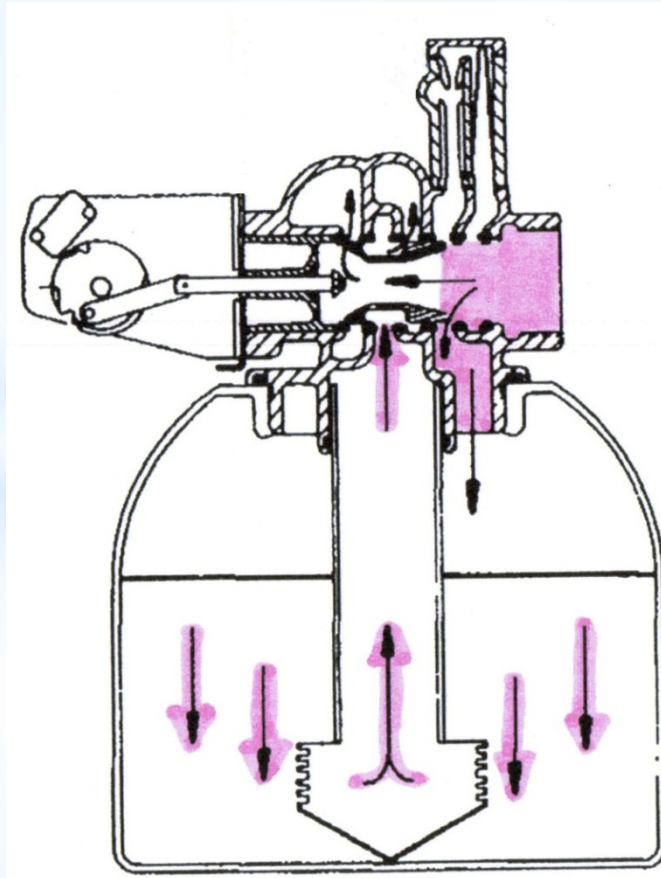
Chlorine and Chlorine Monitoring

Backwash Mode Flow Path



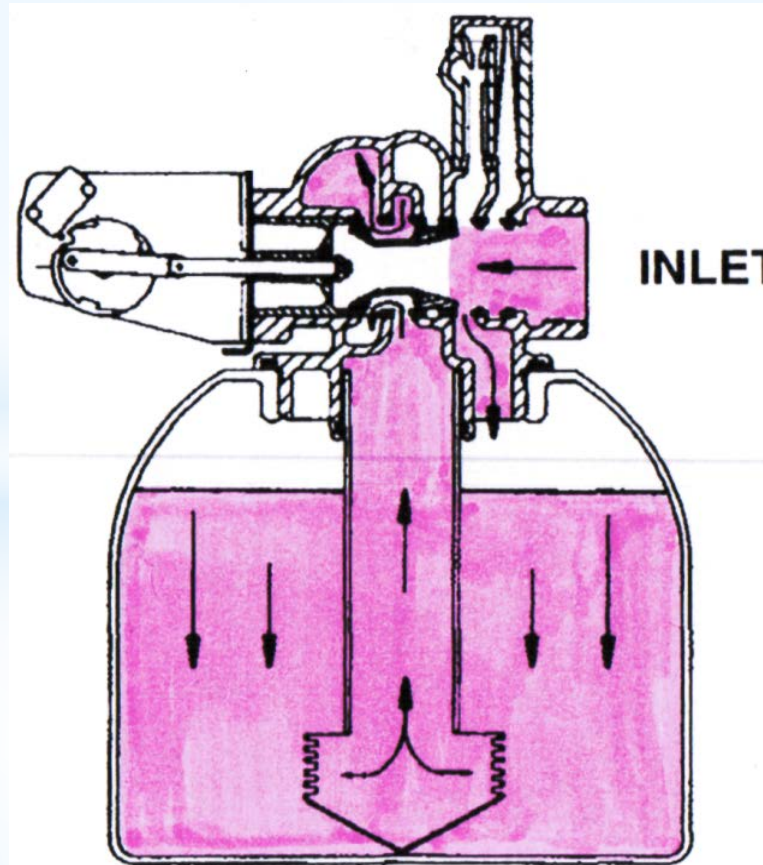
Chorine and Chlorine Monitoring

Forward Rinse Mode Flow Path



Chlorine and Chlorine Monitoring

Service Mode Flow Path



Chlorine and Chlorine Monitoring

Changes in Protocols during municipal distribution system flushing

1. Be proactive when advised by the city of the disinfection reformulation
2. Use test strips for chlorine monitoring
3. Test RO permeate water for chlorine.

Chlorine and Chlorine Monitoring

Sample Of Portable Carbon Filter Connection



Chlorine and Chlorine Monitoring

Sample Of Portable Carbon Filter Connection



Chorine and Chlorine Monitoring

Changes in Protocols during municipal distribution system flushing

Protect your bottom!!!

1. Put PE carbon tanks before carbon filters
2. Set carbon filter heads to not backwash during this period

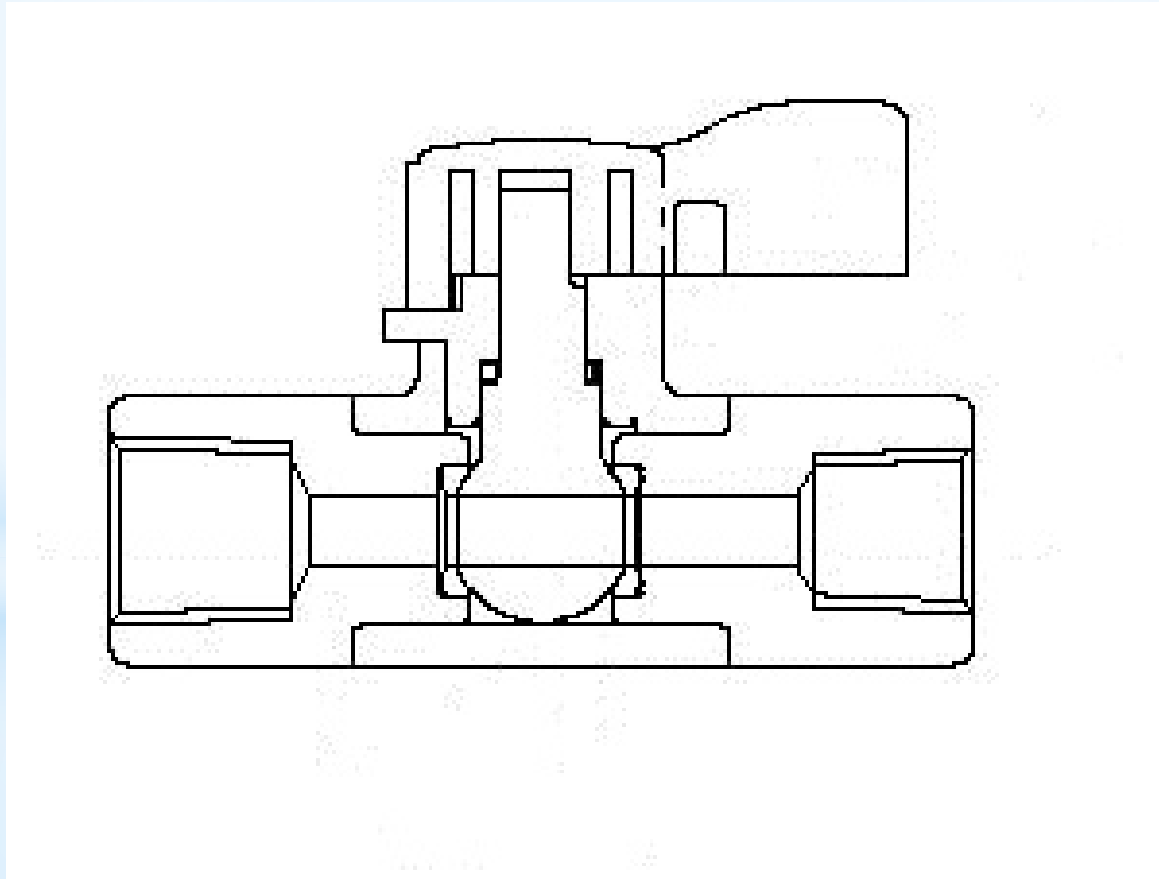
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Sample Port Maintenance

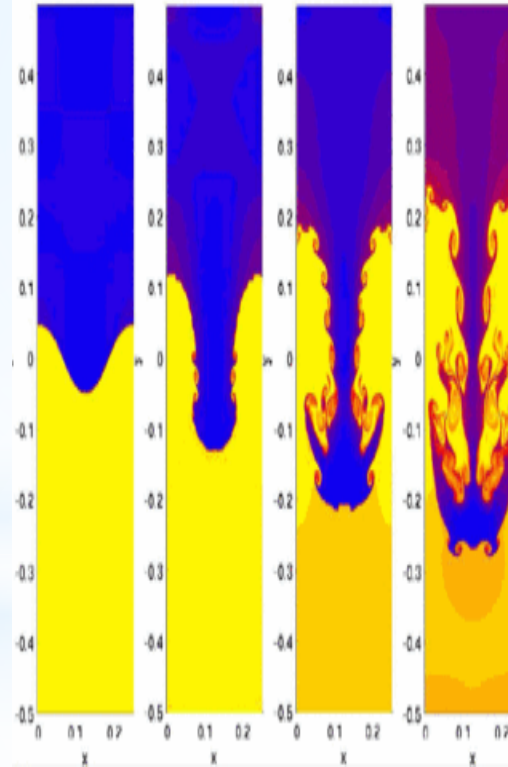
Proper disinfection of
the sample port during
loop disinfection is
critical

Sample Port Maintenance



Cross-sectional drawing of typical lab cock

Sample Port Maintenance



Laminar Flow vs. Turbulent Flow

Sample Port Maintenance

1. Full flow (turbulent flow)
2. Work valve (on - off)

Sample Port Maintenance



Adequate Drain Cup for Sample Port

Example Of Sample Drain Cup

