

# Test Strips:



## Tips, Techniques, Taboos



# Regarding the “Smiley” Graphic



Tip!

**“Humor is also a way of saying something serious.”**

**T. S. Eliot**

*British (US-born) critic, dramatist & poet (1888 - 1965)*

**“It is our responsibilities,  
not ourselves, that we should take seriously.”**

**Peter Ustinov**

*English actor & author (1921 - 2004)*

## Definition of Test Strip (typically used in dialysis)



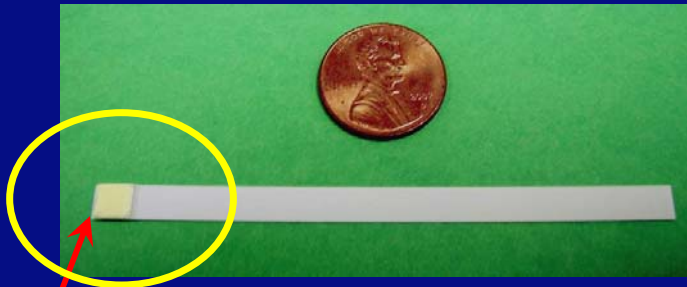
**Tip!**

- Small plastic strip with a pad or pads attached that has been impregnated with an appropriate amount of reagent(s) for measuring a specific substance in a fluid.
- May also be made from a reagent impregnated paper (with no pads attached).

# Typical Test Strip Construction (penny added for size reference)



Tip!



Block style reagent pad



Flow-through (aperture)  
style reagent pad



# Typical Test Strip Packaging



**Tip!**

- Plastic containers
  - Screw cap or flip-top cap bottles (50 or 100 strips)
  - Individual bottles or kits of multiple bottles
  - Flat packs with pull off-push on rectangular cap
- Metal tubes
  - Push off/on cap (can be used with **CapKeeper®**)
- Individual foil wrapped
  - Foil wrapped strips ship in poly bags

# Typical Test Strip Packaging



Tip!

Flip-top bottle

Flat pack

Screw-  
cap  
bottle

Metal tube:  
Push off/on  
cap



Individual foil wrapped

# History of Test Strips



**Tip!**

- More than 45 years of use in medical industry
  - Including more than 20 years use in dialysis
- Miles Labs (Bayer) introduced Clinistix® in late 1950's
  - First dip and read test (measured glucose in urine)
  - Followed by test strips for urine, blood, chemical analysis
- Widespread use today in many medical and non-medical applications

# Why Do We Use Test Strips?

- ✓ Ease of use
- ✓ Speed
- ✓ Accurate
- ✓ Inexpensive
- ✓ No messy clean up,  
no glass, waste, or  
MSDS concerns



**Tip!**



# How Do Test Strips Work?



**Tip!**

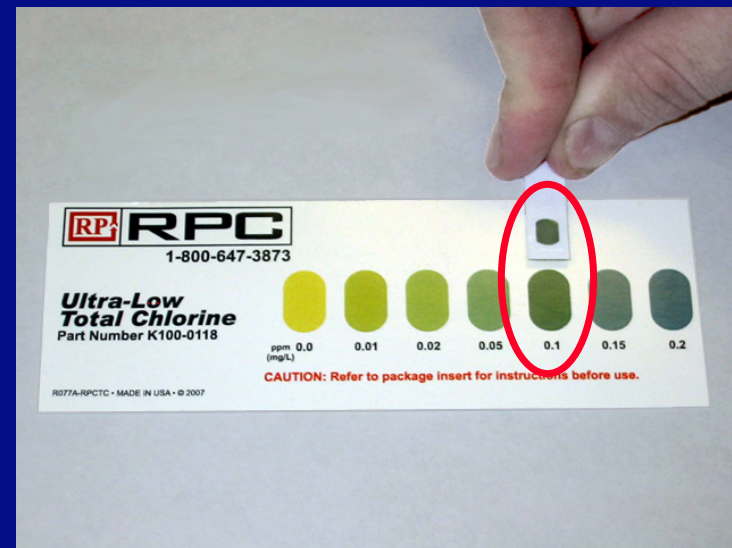
- In a typical assay (test analysis), you dip the reagent pad area into a solution to be tested for a specified time period, remove the strip, and compare the color of the reagent area with a color chart.
- Some test strips work by presence/absence of a color change at a threshold concentration, or by measuring a color change with a meter.

# How Do Test Strips Work? (continued)



Tip!

Compare reacted pad to color chart on bottle (or separate card)



# How Do Test Strips Work?

## (continued)



**Tip!**

- 10 million (estimated) distinguishable colors
  - Three components: lightness, hue, saturation.
  - “Color difference unit”: quantitative measurement.
- Test strip manufacturers
  - Strive to create greatest possible color difference, relative to concentration, in terms of color difference units.
  - Use color measurement tools for best color match
  - Check test strip colors in different light conditions.

# Types of Test Strips Typically Used in Dialysis



**Tip!**

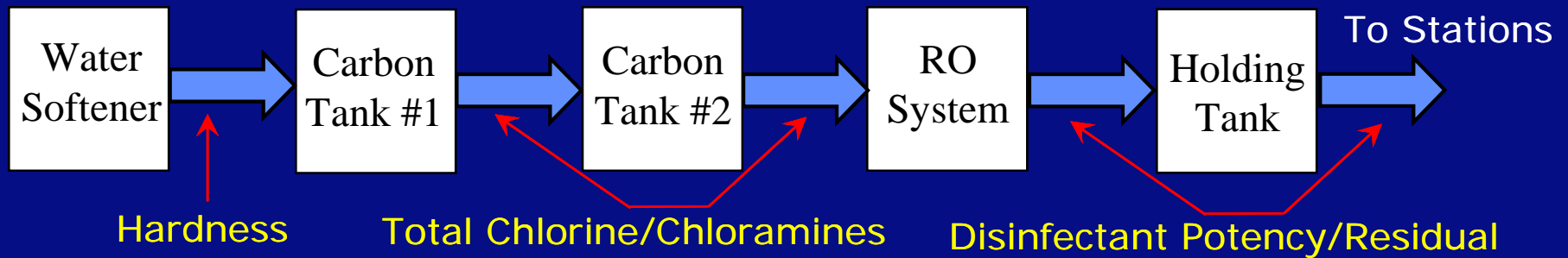
- Free/Total Chlorine
- Chlorine Potency
- Total Hardness
- Ozone (in water)
- pH
- Peroxide/Peracetic Acid Residual
- Peracetic Acid Potency
- Blood Leak
- Glucose (PD Catheter leaks)
- Formaldehyde & Glutaraldehyde

# Typical Test Strip Testing Locations in a Dialysis Center

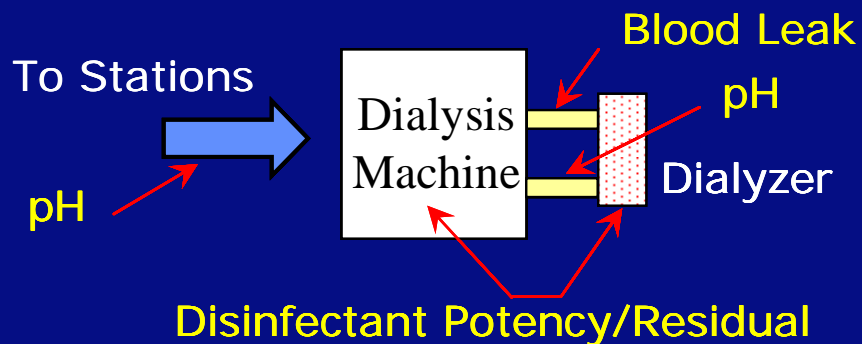


Tip!

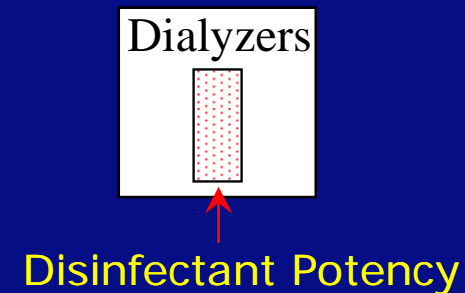
## Water Treatment System



## Dialysis Stations



## Dialyzer Reprocessing Area



# Interferences



**Tip!**

- Substances, other than label indicated test substance, that may potentially affect test result.
  - All reagent tests (tablets, powder, strips, etc.) have interferences.
- Different test types, used to test for same substance, may have different interferences, *e.g.*:
  - Manganese interferes with DPD kits, not with MTK/TMK/TMB strips.
- Non-factor at times, *e.g.*:
  - Post RO water tests.
  - Insufficient interfering substances in AAMI quality water or saline.

# Accuracy and Precision



**Tip!**

- Manufactured using standard reference procedures
  - Tested against most accurate industry standards available  
*e.g.* Total chlorine test strip vs. amperometric titration test per Standard Method of Wallace and Tiernan
- Lot-by-lot blind studies conducted by manufacturers
  - To verify accuracy and precision (repeatability)
- Fewer end user procedural steps compared to liquid, tablet, and powder test kits (and electronic devices).
  - Reduces chance for procedural error

**Are There Steps the End User Should  
Take to Ensure Test Strip Accuracy?**



**Tip!**

**Yes!**

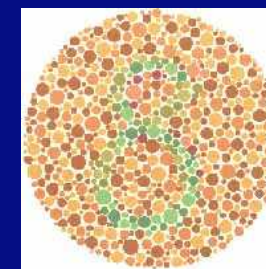
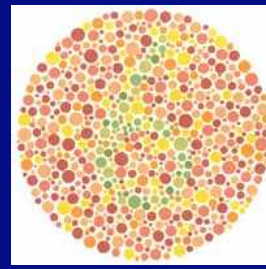
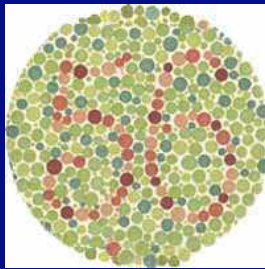
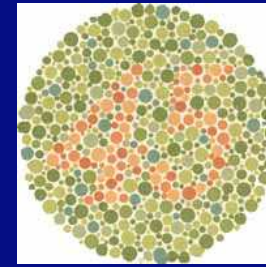
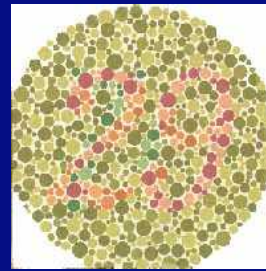
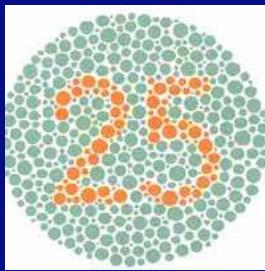
**Important techniques/methods are  
described on the following slides.**



# Color Blindness Test



Technique!



- ☑ All personnel who will be in a position to use test strips should first pass a color blindness test.
  - Color blindness tests available on internet (or from RPC).
  - Document test results and place in personnel file.
  - Answers: Top row (L to R): 25, 29, 45,  
Bottom row (L to R): 56, 6, 8

# Adhere to Instructions for Use (IFUs)



**Technique!**

## Important test strip procedures

- Test strip handling
- Test sample preparation
- Immersion (exposure) time and wetted test strip wait time
- Dip, swish, or flow-over procedure

# Adhere to Instructions for Use (continued)



Technique!

## Key test strip action items

- Make use of color interpolation
- Know test substance safe limit/range
- Understand "zero" color
- Comply with storage and shelf life
- Comply with test strip quality control
- Send vendor suspected failed strips (analysis)

# Test Strip Handling



**Technique!**

- Keep all unused strips in original container.
- Do not remove desiccant dryer from container.
- Dry hands before reaching into container.
- Replace cap immediately and tightly after removing a test strip.
- Do not touch the indicator (reagent) pad.
- Do not allow test strips to come into contact with non-test liquids or any vapors.

# Test Sample Preparation



**Technique!**

- ☑ Properly prepare test sample for each specific substance to be tested.

## *Example:*

- Prior to testing water:
  - Allow RO to process water for at least 15 minutes
  - Rinse sample cup (if test calls for use of cup) three times with water to be tested.
  - Chlorine/chloramines test: Complete test immediately after preparing sample (chlorine/chloramines are volatile).



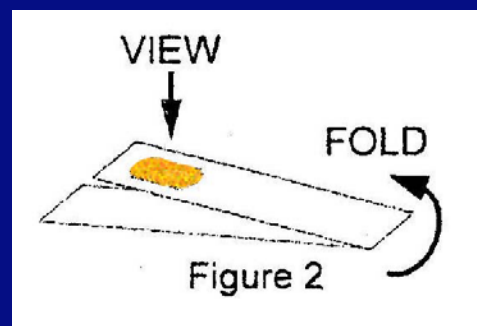
Technique!

# Immersion (Exposure) Time and Wetted Test Strip Wait Time

- ☑ To measure test strip times always use:
  - Stopwatch, or
  - Seconds counter of a digital watch, or
  - Second hand of a nearby clock



- ☑ Fold aperture style strips during wetted wait time



# Sample Cup "Swish" Procedure



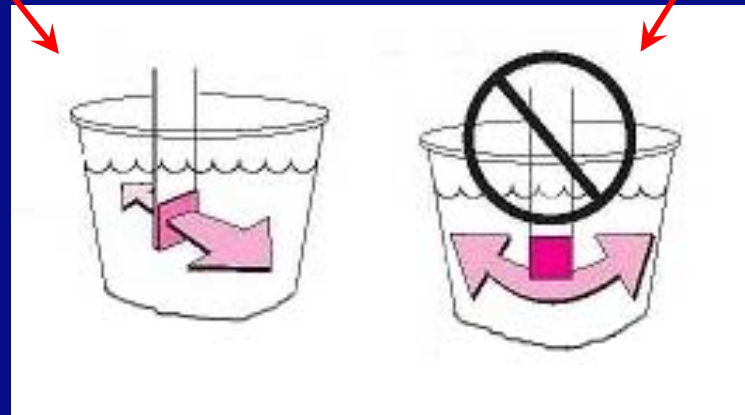
Technique!

## CORRECT

Pad perpendicular to direction of movement

## INCORRECT

Pad parallel to direction of movement



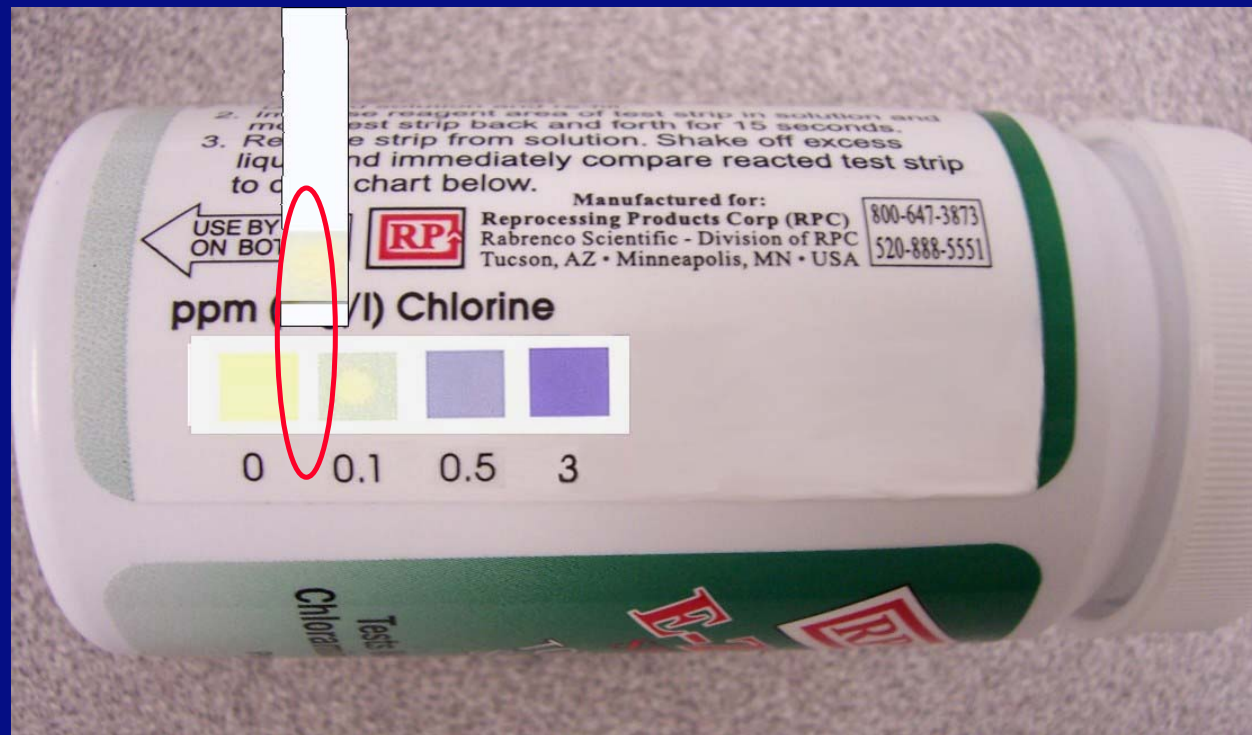
# Color Interpolation



**Technique!**

Definition of interpolation (mathematical):

“To estimate a value of (a function or series) between two known values.”





# Know Safe Limit or Range for Substance Under Test



Technique!

## *Examples:*

- Chloramines in water test (*total chlorine test strips*)
  - 0.1 ppm maximum per AAMI RD62
- Dialysate pH (*pH test strips*)
  - 6.9 to 7.6 per AAMI RD52
- Peracetic acid residual (*peroxide/PAA residual test strips*)
  - Less than 3 ppm per PAA manufacturer's IFU

# "Zero" Color



Technique!

- Reacted reagent pad matching color chart "zero" color indicates substance under test is below sensitivity of test strip and cannot be detected.
  - **Does not mean** substance level is actually zero.
  - **Does mean** substance is at level less than lowest color chart value.
- For some strip types, dry reagent pads direct from container, may not match chart zero color (little lighter/darker). Considered normal.
  - After reacted in fluid, free of the test substance, pad color changes to match zero on color chart.

# Storage



**Technique!**

- Low humidity environment (< 50% RH) is optimal.
- Standard room temperature 70-75° F is optimal.  
Range 59° -86° F
- Cap sealed tightly.
- Desiccant dryer should always be in container.

# Shelf Life



**Technique!**

- Typically 2 to 3 years after date of manufacture.
- Some strip types have reduced shelf life upon opening container.
  - Indicated in Instructions for Use (if applicable).
- Expiration date (and lot no.) printed on container.
- Do not use beyond expiration date.

# Test Strip Quality Control Methods



**Technique!**

- **QC Controls**
  - IFUs frequently call for field verification of test strips using QC control supplies.
  - Documentation of test strip field QC is required by CMS.
- **QC Control Field Verification Program**, e.g. Certi-Chek®
  - Program from vendor that performs **field** QC verification for you.
  - Download test results for any lot # from vendor's Web site.
  - Program accepted / endorsed by strip manufacturers.
  - Downloaded results from vendor Web site accepted by CMS.
  - Independent verification helps protect against test strip recalls.

# Do Not Expect Tap Water Chlorine Tests To Be Consistent or Uniform



**Taboo!**

- Levels of combined chlorine, from tap water faucets, in same building, can vary (affected by piping type, etc.).
- EPA range is 0.2 ppm (minimum) to 4.0 ppm (maximum).





Taboo!

# Do Not Use Qualitative Test for Tests Requiring Low End Precision

- ☑ Qualitative & quantitative (semi) procedures may both be listed in test strip IFUs.
  - At lowest measurement value, **precision** of qualitative test may be affected by speed of sample flow (flow rate).
  - **Precision** is defined as repeatability, or ability to repeat the test with consistent results.

# Definitions



**Taboo!**

- **Qualitative** analysis determines the constituents of a substance without regard to the quantity of each ingredient. [1913 Webster]
- **Quantitative** analysis determines the amount or quantity of each ingredient of a substance. [1913 Webster]
- **Analysis** is the separation of a compound substance, by chemical processes, into its constituents, with a view to ascertain either (a) what elements it contains, or (b) how much of each element is present. The former is called **qualitative**, and the latter **quantitative** analysis. [1913 Webster]



# Do Not Use Qualitative Test for Tests Requiring Low End Precision



**Taboo!**

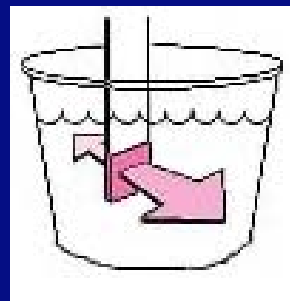
## *Example:*

- Total Chlorine *Sensitive* Test Strips typically list both qualitative and quantitative (semi) procedures.
- Use qualitative procedure for rinse residuals, e.g. water distribution loop, jugs, dialysis machines (0.5 ppm).
- Use quantitative (semi) for sensitive tests requiring precision at lowest value, e.g. chloramines (0.1 ppm).

Qualitative



Quantitative



# Do Not Compare Test Strip Results To Less Accurate Test Methods

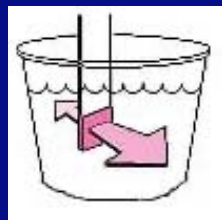


Taboo!

- ✓ Always compare test strip results to a standard reference test or QC standard solutions for the substance under test.

*Example:*

- Chlorine test strip results *should not be* compared with DPD test methods.
- Chlorine test strip results *should be* compared against a chlorine standard reference test (e.g. Amperometric Titration)



vs.



=



# Do Not Use Test Strips That Show Discoloration Direct from Container



**Taboo!**

- Reagent (test) pad direct from container (dry):
  - Should match color chart zero color...a little lighter or darker color is acceptable.
  - Color should be uniform (not "spotty").
  - If irregular brown/black, or spotted, do not use. Typically means strips were exposed to excessive moisture and/or heat. Return strips to vendor.



OR



=



# Summary



Training!

## Test Strips

- ☑ Widespread use in medical industry.
- ☑ Fast, convenient, accurate when used properly.
- ☑ Must adhere to specific IFU for each test strip type to ensure accuracy and repeatability.
- ☑ Avoid traps ("Taboos") that can cause problems.

# Has This Session Met Its Objectives?



Training!

## Objectives

- ☑ To describe the various test strips used in dialysis, how they work, and why we use them.
- ☑ To examine the methods and requirements for proper use of test strips in dialysis.
- ☑ To identify warnings and cautions associated with the use of test strips.

# Has it Met Your Expectations for an Educational Session on Test Strips?



**Training!**

- AAMI RDD Committee is working on a Technical Information Report (TIR) on tests used in dialysis. It will include information on test strips.
- This presentation, and further educational information on test strips, can be found in the "Technical Support Information" section of the RPC Web site at:

[www.rpc-rabrenco.com](http://www.rpc-rabrenco.com)