

Test Strips:



Tips, Techniques, Taboos



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 50 years of use in medical industry
 - Including more than 25 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!

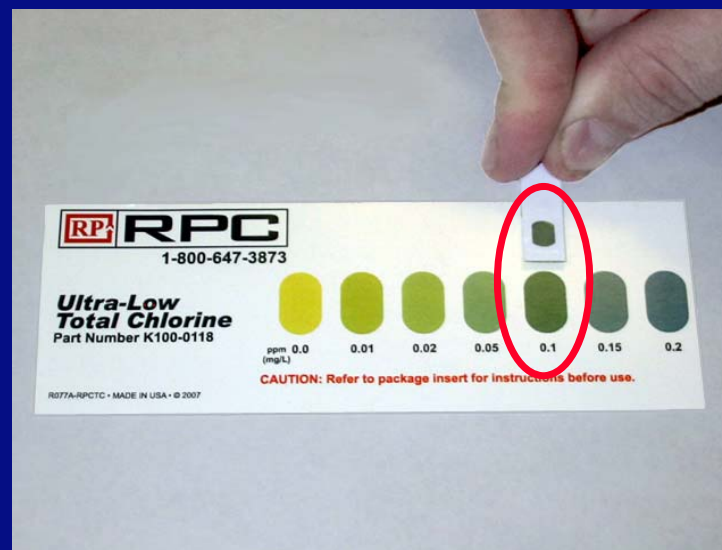
- In a typical assay (test analysis), you dip the reagent pad area into a solution to be tested for a specified time period, remove the strip, and compare the color of the reagent area with a color chart.
- Some test strips work by presence/absence of a color change at a threshold concentration, or by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

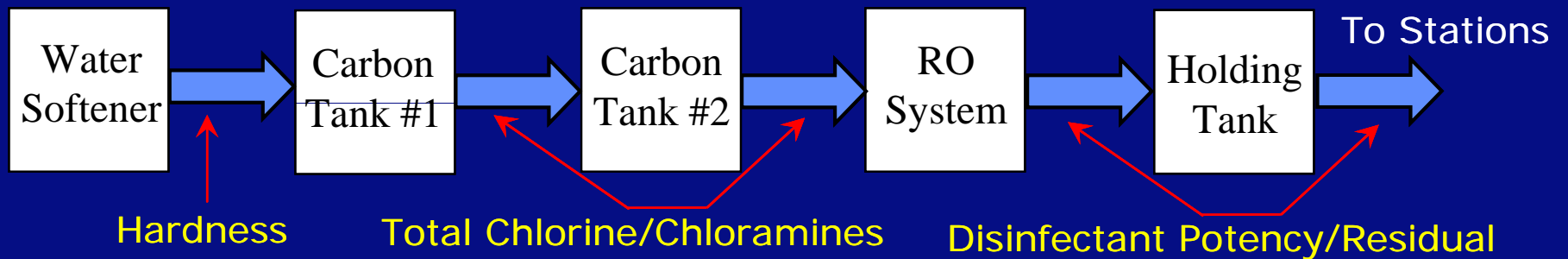
- Free/Total Chlorine
- Chlorine Potency
- Total Hardness
- Ozone (in water)
- pH (water & dialysate)
- Peroxide/Peracetic Acid Residual
- Peracetic Acid Potency
- Blood Leak
- Glucose (PD Catheter leaks)

Typical Test Strip Testing Locations in a Dialysis Center

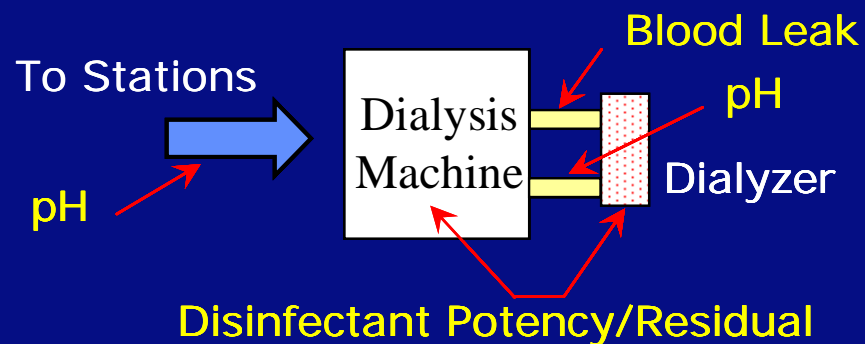


Tip!

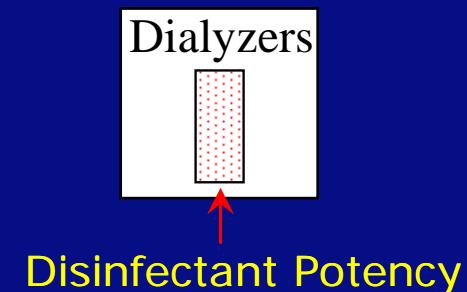
Water Treatment System



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!

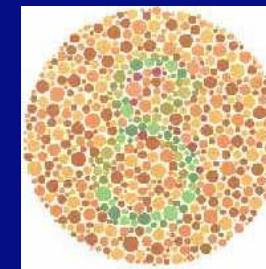
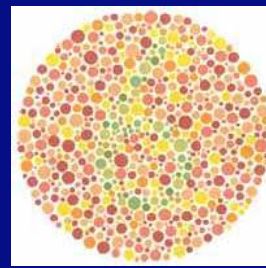
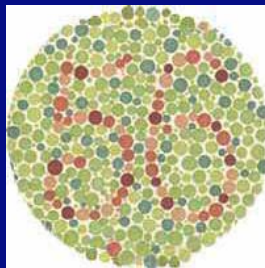
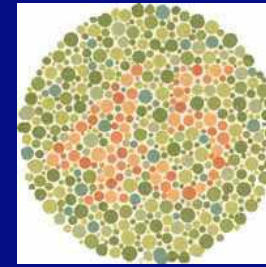
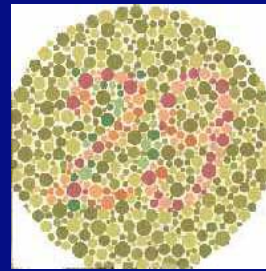
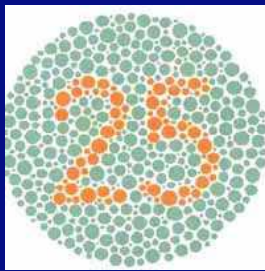
Yes!

**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. Use one type at a time.
- 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).



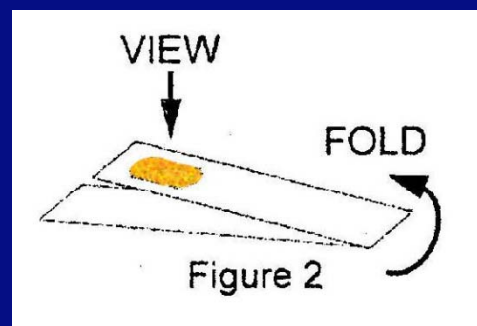
Technique!

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



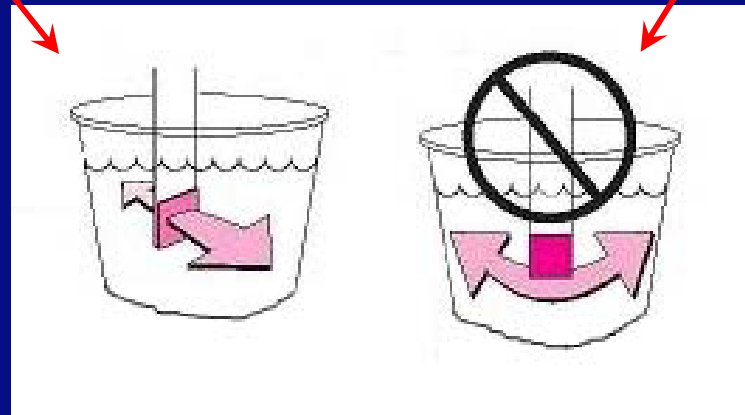
Technique!

CORRECT

Pad perpendicular to direction of movement

INCORRECT

Pad parallel to direction of movement



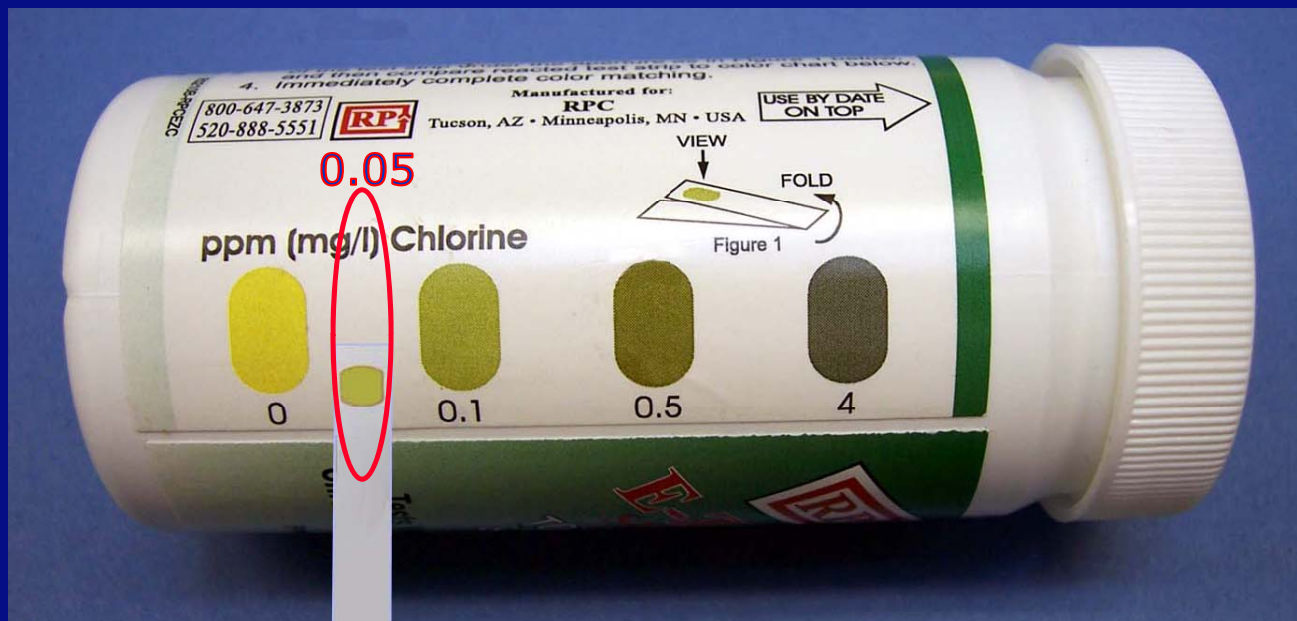
Color Interpolation



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 many 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.
- No MSDS required.

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 Check/Test Supplies
 - IFUs frequently call for test strip verification via QC supplies
 - Documentation of test strip QC check is required by CMS
- QC Control Verification Program, e.g. Certi-Chek®
 - Manufacturer performs QC verification for you on each lot
 - Download test results for any lot # from their website
 - Downloaded results are accepted by CMS as QC control proof
 - Secondary 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!

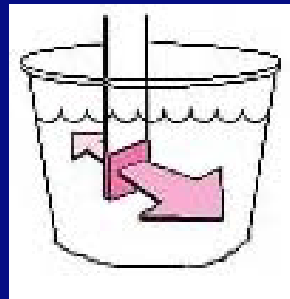
Example:

- Total Chlorine *Sensitive* Test Strips: Some IFUs 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

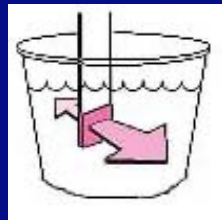


Taboo!

- ✓ 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



- Reagent (test) pad direct from container (dry): **Taboo!**
 - Does not need to match color chart zero color... a little lighter or darker color is acceptable.
Must match chart zero color when reacted in water known to be free of test substance and interfering substances.
 - 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



=



Do Not Laminate, Cover or Modify Color Chart



Taboo!

- Bottle labels and/or color charts are specially made to show the same color for each color circle/block under various lighting conditions.
- Laminating, covering with film, or modifying label/color chart in any way may cause the color circles/blocks to show a different color than that intended by the manufacturer.
 - May result in inaccurate test readings.

Summary

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.

Notes of Interest

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

www.rpc-rabrenco.com