Test Strips:

Tips, Techniques, Taboos

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Regarding the “Smiley” Graphic

“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)

- 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)

- Block style reagent pad
- Flow-through (aperture) style reagent pad
Typical Test Strip Packaging

- **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

- Flip-top bottle
- Flat pack
- Screw-cap bottle
- Metal tube: Push off/on cap
- Individual foil wrapped
History of Test Strips

• 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
How Do Test Strips Work?

- 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)

Compare reacted pad to color chart on bottle (or separate card)
How Do Test Strips Work?
(continued)

• 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

- 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

**Water Treatment System**

- Water Softener
- Carbon Tank #1
- Carbon Tank #2
- RO System
- Holding Tank

**Dialysis Stations**

- Dialysis Machine
- Blood Leak
- pH
- Disinfectant Potency/Residual

- pH
- To Stations

**Dialyzer Reprocessing Area**

- Dialyzers
- Disinfectant Potency

Tip!
Interferences

- 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

- 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?

Yes!

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

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)

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

- 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

☑ 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).
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

**CORRECT**
Pad perpendicular to direction of movement

**INCORRECT**
Pad parallel to direction of movement
**Color Interpolation**

**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

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

- 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

- 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

- 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

• 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

- 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).
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

- **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

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).
Do Not Compare Test Strip Results To Less Accurate Test Methods

- 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)
Do Not Use Test Strips That Show Discoloration Direct from Container

• 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.

Taboo!
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.
Has This Session Met Its Objectives?

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?

- 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