Serim® BICARB pH II TEST STRIPS

DESCRIPTION
SERIM BICARB pH II Test Strips (Product Code K100-0113) are designed to test bicarbonate concentrate and/or final dialysate solutions where bicarbonate and acid and water are mixed in closed systems. Determining the pH of these mixtures is difficult in that carbon dioxide gas is expelled once the solution is removed from theclosed system. With traditional pH indicator papers, this carbon dioxide diffusion causes a marked increase in the measured pH over the time required for color matching. While integral pH electrodes are an alternative, calibration, control and maintenance are demanding. Freestanding pH meters have the same demands and require care in removal, transport and dispensing of thesample. Additionally, compensation is required for the temperature of the specimen.

SERIM BICARB pH II Test Strips have been designed to indicate the appropriate pH at an immediate read time for samples warmed to temperatures of 32-40°C (90-104°F). Samples at room temperature, 15°-30°C (59°-86°F), can be read at 10 seconds.

Comparing the color developed on the indicator pad to the color chart on the bottle label provides an estimate of the pH.

CHEMICAL PRINCIPLES OF THE TEST
The test is based on a color change and is dependent on the hydrogen ion concentration.

The indicator is a combination of meta-cresol purple and tetrabromophenolsulfonephthalein.

WARNINGS AND PRECAUTIONS
- Do not use SERIM BICARB pH II Test Strips to test treated or untreated water or to test acetate dialysate.
- Keep all unused strips in the original bottle.
- Do not remove desiccant packet.
- Replace cap immediately and tightly after removing a strip; the strips must be protected from humidity.
- Do not touch the indicator pad.
- Do not allow the indicator pad to come in contact with liquids or with work surfaces that may be contaminated with potentially interfering substances.

STORAGE
- SERIM BICARB pH II Test Strips must be kept in the original bottle with the lid tightly closed to obtain the best results.
- Do not remove the desiccant packet.
- Store at temperatures between 15°C and 30°C (59°-86°F).
- Do not use a Test Strip (from an opened or unopened bottle) after the expiration date printed on the bottom of the bottle.

DIRECTIONS
Use care in collecting the sample. Agitation of the solution will accelerate the generation of carbon dioxide and cause an increase in the pH.

1. Immerse indicator pad of the Test Strip in sample solution for 1 second.
2. Remove strip and read immediately for warmed samples. (Wait exactly 10 seconds to interpret the results of a sample obtained at room temperature.)
3. Interpret the results by comparing the indicator pad to color chart on the bottle label.

QUALITY CONTROL
Serim supplies a reactive Control Solution for the SERIM BICARB pH II Test Strips. This solution is a stable phosphate buffer that yields a pH result of 7.5 ± 0.5. The Control Solution should be kept at room temperature (15°-30°C).

Follow the directions below to properly utilize the Control Solution:

1. Immerse the indicator pad into the SERIM BICARB pH II Control Solution for one second.
2. Remove the strip.
3. After 10 seconds, compare the indicator pad to the color chart on the bottle label.

Each facility should determine the frequency of testing and the optimal procedures for its own Quality Control Program. The regular use of procedures using the SERIM BICARB pH II Control Solution will increase user proficiency, minimize procedural errors and protect against the inadvertent use of outdated product or product that is deteriorated due to improper storage or handling.

Note: SERIM BICARB pH II Control Solution can only be used with SERIM BICARB pH II Test Strips.

RESULTS
Color development of the SERIM BICARB pH II indicator pad is different in final dialysate than in concentrated bicarbonate solutions. Because of this, two sets of color blocks have been developed.

The pH values of final dialysate are obtained by comparing the color developed on the indicator pad to the appropriate color blocks on the bottle label. The acid/bicarbonate color blocks indicate pH readings at 6.5, 7.0, 7.5, 8.0 and 8.5.

Concentrated bicarbonate pH can be determined by comparing the color developed on the indicator pad to the second set of color blocks (8.0 or 8.5 pH) on the bottle label.

Accurate evaluation requires that each type of solution be read and interpreted according to the temperature of the sample and the appropriate color block set.

PERFORMANCE CHARACTERISTICS
Performance characteristics of the SERIM BICARB pH II Test Strips are based on analytical studies using both acid/bicarbonate solutions and concentrated bicarbonate solutions. Final dialysate was contrived through adjustment of acidic or basic components to give discrete pH levels. Concentrated bicarbonate solutions were contrived through progressive conversion of the sodium bicarbonate to its carbonate form by aging. Standard potentiometric measurement, with calibration based on NIST traceable standard reference material, was used as the reference method for determining pH levels.

In 324 of 324 observations at each of five pH levels of final dialysate and at two pH levels of bicarbonate concentrate, seven different readers correctly read contrived solutions to within + or – 0.5 pH of the expected value.

Accuracy of the Test Strip result depends upon several factors including:

- temperature of sample
- timing error during strip readings
- variability in color perception
- sample handling technique
- lighting conditions

Performing the color match under cool white fluorescent lighting will produce the most accurate results. Incandescent lighting should be avoided for making the color comparisons.

The color development of the strip will continue; hence it is important to read the strip immediately after dipping for 1 second if testing samples that have been warmed to 32-40°C. If testing samples at room temperature, read the strip exactly 10 seconds after dipping for 1 second.

LIMITATIONS
The color generated in the indicator pad will reflect the pH of the solution absorbed in the matrix. Carbon dioxide will gradually dissipate from the indicator pad and the color intensity will increase with time.

If the bicarbonate solution is shaken, agitated during dispensing or allowed to stand prior to testing, the pH will increase as carbon dioxide is dissipated.

Like other dry reagent pH papers, SERIM BICARB pH II Test Strips are not suitable for use in unbuffered solutions; inaccurate measurements may occur with use in solutions containing less than 28 mEq/L bicarbonate concentrations.

Use of the product in solutions containing chlorine concentrations of 5 ppm or greater may produce inaccurate measurements.

RPC

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