

DESCRIPTION

HACH® STERICHEK® BLOOD LEAK Reagent Strips (Product Code 812014) provide a rapid method to test dialysate for blood if a dialyzer membrane leak is suspected during the hemodialysis procedure.

The Association for the Advancement of Medical Instrumentation (AAMI)¹ recommends that all hemodialysis systems shall have a method of detecting blood in the dialysate. In the alarm condition the detector shall initiate audible and visual alarms. The high alarm limit shall be not more than 0.35 mL/minute for a fixed alarm limit at a hematocrit of 25% (0.25). The leak rate of 0.35 mL/minute calculates to a level of 5.5 mg/dL of hemoglobin in the dialysate, assuming a hematocrit of 25% and a dialysate flow of 0.5 L/minute. For many years, hemodialysis technicians have used reagent strips to assist in differentiating an actual blood leak from a false alarm to avoid unnecessary interruption of the hemodialysis procedure.

SteriChek Blood Leak Reagent Strips detect very low levels of blood in dialysate. The reagent strips give positive readings at 1.5 mg/dL of hemoglobin. They are more sensitive than the AAMI recommended setting of 5.5 mg/dL for blood leak monitors. This increased sensitivity of the reagent strips provides a safety margin and protects the patient against blood loss.

! WARNING

- **Improper strip activation and color interpretation may result in patient injury.**
- **Keep all unused strips in the original bottle. Do not remove desiccant pack. Replace cap immediately and tightly after removing a strip; the strips must be protected from heat and humidity.**
- **Do not touch the reagent pad area. Do not allow pad to come into contact with liquids or with work surfaces, as these may be contaminated with potentially interfering substances.**
- **Do not expose the strips to strong oxidants such as chlorine since they may oxidize the indicator in the reagent pad and cause a false positive reaction.**
- **Do not leave the bottle or individual strips on the dialysis machine, as the heat from the machine will degrade the reactivity of the strips.**

! IMPORTANT

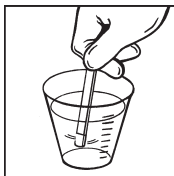
Always compare test results to the color chart on the SteriChek Blood Leak bottle for proper interpretation.

DIRECTIONS

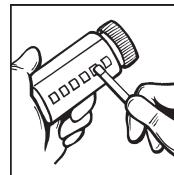
Follow these steps to test for blood in dialysate.

Directions in Sample:

1. Using a clean container, collect a dialysate sample either directly from the dialysis machine (by removing the line where the dialysate exits) or from the dialysate drain line.
2. Dip test pad in sample for 1 second and remove.

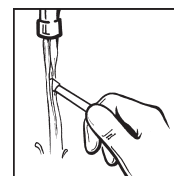


3. Compare test pad to color chart 60 seconds after removing from sample.

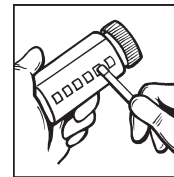


Directions in Stream:

1. Obtain the dialysate sample directly from the dialysis machine by removing the line where the dialysate exits.
2. Place test pad briefly (1 second or less) into the dialysate stream and remove.



3. Compare test pad to color chart on the bottle label 60 seconds after removing from sample.



Note: Consult the dialysis machine Operators Manual or check with the manufacturer for information regarding the response of the dialysis machine when the blood leak alarm is activated. Some machines cause dialysate to bypass the dialyzer. In this case dialysate collected from the drain may be “bypassed fluid” and will not contain blood even though the dialyzer has a leak. If the machine does not have a bypass mode, a sample of dialysate from the drain line can be used.

For Quality Control:

Each facility should determine its own quality control procedure. Testing and recording reagent strip results with control solutions provides the user with a warning of a possible test strip error, potential use of outdated test strips, or improperly stored or handled reagent strips.

Positive Control Solution:

Mix one drop of whole blood with one or two milliliters of dialysate. Test the solution according to the DIRECTIONS section of this insert. The reagent pad should develop a color equal to or darker than the Positive color block on the bottle label.

Negative Control Solution:

Use a sample of dialysate that has not been exposed to blood. Test the solution according to the DIRECTIONS section of this insert. The reagent pad should develop a color equal to or lighter than the Negative color block on the bottle label.

STORAGE

The SteriChek Blood Leak Reagent Strips must be kept in the original bottle with the lid tightly closed to obtain the best results. Do not remove the desiccant pack. Store at temperatures between 60° - 90°F (16° - 32°C). Use within 6 months after first opening the bottle. Do not use the test strips (from an opened or unopened bottle) after the expiration date.

RESULTS

SteriChek Blood Leak Reagent Strips are designed to indicate the presence or absence of blood in dialysate. At the 60-second reaction time, compare the color of the indicator pad to the color chart on the bottle label to determine the relative amount of blood present.

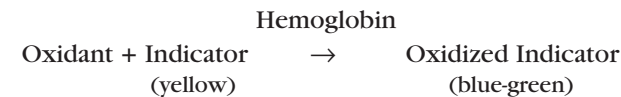
- Negative - if the indicator pad is equal to or lighter than the Negative color block, no blood is present in the dialysate.
- Positive - if the indicator pad is equal to or darker than the Positive color block, a significant leak is indicated.

Very small leaks may give colors between the Negative and Positive color blocks. Non-hemolyzed blood may cause a spotted color pattern on the reagent pad. Although a small leak may seal itself, close monitoring of the dialysate is recommended.

Note: It is important to read the results at 60 ± 10 seconds. The reagent pad can become darker after 60 seconds.

CHEMICAL PROPERTIES OF THE TEST

SteriChek Blood Leak Reagent Strip detection of blood is based on the peroxidase-like catalytic activity of hemoglobin, a protein that is carried by red blood cells. The reagent pad contains a chemical oxidant and an indicator which react with each other when hemoglobin is present in dialysate. The reagent pad turns from yellow to blue-green to indicate the presence of hemoglobin.



PERFORMANCE CHARACTERISTICS

Performance characteristics of SteriChek Blood Leak Reagent Strips are based on analytical studies using suspensions of human red blood cells in acid/bicarbonate buffer, solutions of human hemoglobin in dialysate. Hemoglobin was measured by the Drabkin (cyanmethemoglobin) spectrophotometric method.²

Studies in which the strip readers were unaware of the hemoglobin composition of the test samples showed that positive readings were obtained consistently with samples containing 0.26 and 1.5 mg/dL of hemoglobin. The catalytic threshold is 0.26 mg/dL. With increasing concentration the pad color was darker. The level of 1.5 mg/dL corresponds to a blood leak rate well below the AAMI standard equivalent of 5.5 mg/dL.

The accuracy and sensitivity of SteriChek Blood Leak Reagent Strips is contingent on lighting, potential presence of interfering substances, and color perception variation.

LIMITATIONS

SteriChek Blood Leak Reagent Strips should be read at 60 ± 10 seconds after sample application. Reading in less than 50 seconds can cause false negative readings. False positive readings can be obtained when the read time is greater than 70 seconds.

Strongly oxidizing substances such as chlorine and sodium hypochlorite will cause a positive reaction of the Blood Leak Reagent Strip. However, chlorine levels at which a false positive would occur far exceed the AAMI maximum recommended residual level of 0.5 ppm chlorine. (Positive reactions occur only at levels of chlorine greater than 5 ppm). Hydrogen peroxide at 5,000 ppm in acid/bicarbonate buffer gave negative readings on reagent strips.

Typical components in dialysis buffers, such as glucose, calcium chloride, sodium chloride, potassium chloride, sodium bicarbonate and magnesium chloride, and citric acid do not interfere with SteriChek Blood Leak reagent strips.

SteriChek Blood Leak Reagent Strips gave negative readings with acid/bicarbonate buffers at pH 6.0, 7.4 and 8.4. Blood in these buffers at 1.5 mg/dL gave positive readings.

AVAILABILITY

Product Code 812014 Hach SteriChek Blood Leak Reagent Strips includes 6 bottles of 10 reagent strips and a multilingual product manual. Also enclosed for your use are color-coded stickers that correspond to the color of the bottle label and kit box label. These stickers may be applied on the top of each bottle for easy product identification. Each sticker includes a space to record the date the bottle is opened.

These Hach SteriChek testing products are also available from your distributor:

811900	Residual Chlorine Reagent Strips
811902	0.1 ppm Total Chlorine DPD Kit
811903	0.1 ppm Total Chlorine DPD Refill Kit
811905	Residual Peroxide Reagent Strips
811906	Peracetic Acid Reagent Strips
811909	Sensitive 0.1 ppm Total Chloramines and Residual Chlorine Reagent Strips
811911	Sensitive 5 ppm Low-Range Hardness Reagent Strips
811912	Chlorine Control Tablets
811913	Residual Peroxide Control Tablets
811916	Bicarb pH Reagent Strips

Made and Printed in the U.S.A.