

E-Z Chek[®] Blood Leak Test Strips

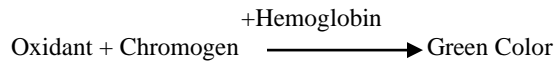
Instructions for Use

DESCRIPTION

E-Z Chek[®] Blood Leak Test Strips provide an easy and fast 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 blood leak monitors on the dialysis machine activate an alarm if blood escapes through the membrane at a rate of 0.35 mL/minute or more. This leak rate 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). E-Z Chek[®] Blood Leak Test Strips are more sensitive than the AAMI recommended setting for blood leak monitors; the test strips yield positive readings at 0.25 mg/dL of hemoglobin. This increased sensitivity provides a safety margin, thereby protecting the patient against blood loss. The strip can assist in differentiating an actual blood leak from a false alarm to avoid unnecessary interruption of the hemodialysis procedure.

CHEMICAL PRINCIPLES OF THE TEST

E-Z Chek[®] Blood Leak Test Strip chemistry is based on the peroxidase-like activity of hemoglobin. A reaction between an oxidant and a chromogen is catalyzed by hemoglobin to produce a green color on the yellow background of the indicator pad.

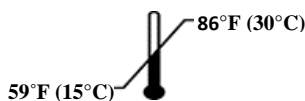


WARNINGS AND PRECAUTIONS

- Keep all unused strips in the original bottle.
- Tightly replace cap immediately after removing a strip. Strips must be protected from high levels of humidity. Dispose of test strips if cap has not been placed securely on the bottle immediately after removing a strip.
- Do not touch the indicator pad.
- Do not allow the indicator pad to come into contact with work surfaces that may be contaminated with potentially interfering substances.
- Do not leave the bottle or individual strips lying on the dialysis machine as the heat from the machine will degrade the reactivity of the strips.
- Do not expose the strips to vapors of strong oxidants such as chlorine.
- Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

STORAGE

- E-Z Chek[®] Blood Leak Test Strips must be kept in the original bottle with the lid tightly closed.



- Do not use a test strip from an opened or unopened bottle after the expiration date.
- Lot number and expiration date are printed on the bottle label.

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Product Quality at Discount PricingSM

E-Z Chek® Blood Leak Test Strips **Instructions for Use****DIRECTIONS**

Test for blood in dialysate:

- 1) Using a clean container, collect a dialysate sample either directly from the dialyzer (by removing the line where the dialysate exits) or from the dialysate drain line.
- 2) Immerse test pad into dialysate for one second.
- 3) Remove test strip and shake off excess liquid from strip.
- 4) Wait 60 seconds, then compare the color of the test pad to the color chart on bottle label.

RESULTS

E-Z Chek® Blood Leak Test 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 blood leak is indicated. Very small leaks may yield colors between the Negative and Positive color blocks. Non-hemolyzed blood may cause a spotted color pattern to develop on the indicator pad. A small leak may seal, however close monitoring of the dialyzer is recommended.

NOTE: Indicator pads can become darker if the reaction time is extended beyond 60 seconds; therefore, it is important to read the results of the test at 60 ± 10 seconds.

QUALITY CONTROL

RPC performs an independent Quality Control Test on each lot number of test strips (Certi-Chek™ Field Verification Program). The test procedure and/or a letter from RPC certifying the test results are available upon request and/or can be downloaded from the RPC Web site at www.rpc-rabrenco.com. Proper use of procedures, including storage and handling, must be documented to ensure accurate test results.

LIMITATIONS

E-Z Chek® Blood Leak Test Strips should be read at 60 ± 10 seconds after sample application. E-Z Chek® Blood Leak Test Strips will give a positive reaction with any substance which will oxidize the chromogen directly such as sodium hypochlorite and chlorine. However, chlorine levels at which a false positive reaction would occur far exceeds the AAMI maximum recommended residual level of 0.5 ppm. Positive reactions occur only at chlorine levels equal and greater than 5 ppm. Hydrogen peroxide at 5000 ppm in acid/bicarbonate buffer gave negative readings on test strips. Typical components of dialysis buffers, such as glucose, calcium chloride, sodium chloride, potassium chloride, sodium bicarbonate and magnesium chloride do not interfere with E-Z Chek® Blood Leak Test Strips. E-Z Chek® Blood Leak Test Strips gave negative readings with acid/bicarbonate buffers at pH 6.0, 7.4 and 8.4. Blood in these buffers at 0.25 mg/dL hemoglobin gave positive readings.

REFERENCE

1. American National Standard, Association for the Advancement of Medical Instrumentation, (ANSI/AAMI RD5-2003), Hemodialysis Systems, page 14.