

Serim[®]

GUARDIAN[™]

BLOOD LEAK TEST STRIPS

Test for blood
in dialysate

DESCRIPTION

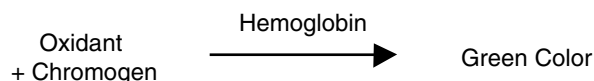
Serim[®] GUARDIAN[™] BLOOD LEAK Test Strips (Product Code 5119C) provide a rapid method to test dialysate for blood if a dialyzer membrane leak is suspected during the hemodialysis procedure.

The Association for Advancement of Medical Instrumentation¹ (AAMI) 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). Serim GUARDIAN BLOOD LEAK Test Strips are more sensitive than the AAMI recommended setting for blood leak monitors; the test strips yield positive readings at 1.5 mg/dL of hemoglobin. This increased sensitivity provides a safety margin, thereby protecting the patient against blood loss.

The test 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

Serim GUARDIAN 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

- Do not hold the Serim GUARDIAN BLOOD LEAK indicator pad in the sample or dialysate stream more than one second to avoid washing out the test strip reagents.
- Keep all unused strips in the original bottle.
- Do not remove the desiccant pack.

- Replace the cap immediately and tightly after removing a test strip; the strips must be protected from humidity.
- 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 laying 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.

STORAGE

- Serim GUARDIAN BLOOD LEAK Test Strips must be kept in the original bottle with the lid tightly closed.
- Do not remove the desiccant pack.
- Store at temperatures between 15°–30°C (59°–86°F).
- Do not use a test strip (from an opened or unopened bottle) after the expiration date.
- Lot number and expiration date printed on bottom of bottle.

DIRECTIONS

Test for blood in dialysate using either the Dip or Stream method:

Dip Method:

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. Dip the indicator pad of the test strip into the sample and remove immediately.
3. Allow the test strip to react for 60 seconds.
4. Compare the color of the indicator pad to the color blocks on the bottle label.
5. Record results and discard strip according to federal, state and local regulations.

Stream Method:

1. Obtain dialysate sample directly from the dialyzer by removing the line where the dialysate exits.
2. Wet the indicator pad of the test strip by placing the pad briefly (1 second or less) into the dialysate stream, then remove.
3. Allow the test strip to react for 60 seconds.
4. Compare the indicator pad to the color blocks on the bottle label.
5. Record results and discard strip according to federal, state and local regulations.

NOTE: Various models of dialysis machines respond differently when the blood leak alarm is activated. Some machines cause dialysate to bypass the dialyzer. In this case there is high probability that dialysate collected from the drain will 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 can be used. Consult the dialysis machine Operators Manual or check with the manufacturer for additional information.

RESULTS

Serim GUARDIAN 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 seconds.

QUALITY CONTROL

Implementing the routine use of Quality Control solutions 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. Each facility should establish its own Quality Control procedures.

Performance of Serim GUARDIAN BLOOD LEAK Test Strips can be confirmed by testing known positive and negative solutions as follows:

- **Positive Control Solution** – Prepare a Positive Control Solution by mixing one drop of whole blood with one to two milliliters of dialysate. Test the solution according to the DIRECTIONS section of this insert. The indicator 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 indicator pad should develop a color equal to or lighter than the Negative color block on the bottle label.

If unexpected results are obtained, call SERIM at 1-800-542-4670 or contact your local SERIM Representative.

PERFORMANCE CHARACTERISTICS

The performance characteristics of Serim GUARDIAN BLOOD LEAK Test Strips are based on analytical studies using suspensions of human red blood cells in acid/bicarbonate buffer. Hemoglobin in red blood cell suspensions was measured by the Drabkin spectrophotometric method.²

Studies in which the strip readers were unaware of the composition of the test samples showed that positive readings were obtained consistently with red blood cell

suspensions containing 1.5 mg/dL hemoglobin. This corresponds to a blood leak rate below the recommended AAMI standard of 0.35 mL/minute.¹

Sensitivity and accuracy of the test depends on variability in color perception, lighting conditions and the possible presence of interfering substances.

LIMITATIONS

- Serim GUARDIAN BLOOD LEAK Test Strips should be read 60 seconds after sample application. Reading in less than 50 seconds can cause false negative readings. Also, false positive readings can be obtained when the read time is greater than 70 seconds.
- The test will yield 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.³ (Positive reactions occur only at chlorine levels greater than 5 ppm).
- The test should not be used on dialysate samples of patients who have been administered rescue doses of hydroxocobalamin (vitamin B12) at concentrations above 0.14 g/L.
- Hydrogen peroxide at 5000 ppm in acid/bicarbonate buffer yielded negative results.
- Typical components of dialysis buffers, such as glucose, calcium chloride, sodium chloride, potassium chloride, sodium bicarbonate and magnesium chloride do not interfere with the test.
- The test yielded negative results in acid/bicarbonate buffers at pH 6.0, 7.4 and 8.4. Adding blood, at 1.5 mg/dL hemoglobin, to the buffers yielded positive results.

REFERENCES

- ¹ AAMI Standards and Recommended Practices: Dialysis, 2008 Edition. American National Standard, ANSI/AAMI RD5:2003/(R)2008, Hemodialysis Systems, page 6.
- ² RJ Eilers, Notification of final adoption of an International method and standard solution for hemoglobinometry; specifications for preparation of standard solution. Am J Clin Pathol 47:212 (1967).
- ³ AAMI Standards and Recommended Practices: Dialysis, 2008 Edition. American National Standard, ANSI/AAMI RD62:2006, Water treatment equipment for hemodialysis applications, page 5.



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