Serim®

GUARDIAN™

PERISCREEN™ TEST STRIPS

Presumptive test for peritonitis

DESCRIPTION

Serim® GUARDIAN™ PeriScreen™ Test Strips (Product Code 5122) provide a rapid and convenient method for indicating the presence of leukocytes (white blood cells) in peritoneal dialysate effluent.

A complication of peritoneal dialysis (PD) is peritonitis; a bacterial infection resulting in inflammation of the peritoneum. A diagnosis of peritonitis is made by a combination of clinical symptoms and laboratory findings. The presence of at least two of the following conditions are commonly used for diagnosis of peritonitis[1]:

1. Symptoms and signs of peritoneal inflammation, such as abdominal pain, fever, malaise, nausea/vomiting, diarrhea.
2. Cloudy peritoneal dialysate effluent with an elevated leukocyte count (>100 cells/µL) due mainly to neutrophils (>50%).
3. Demonstration of bacteria in the peritoneal dialysate effluent by Gram's stain or culture.

Leukocyte esterase activity in peritoneal dialysate increases when leukocyte counts increase in response to peritoneal infections.[1] Serim PeriScreen Test Strips are designed to give a semi-quantitative indication of the level of leukocytes present in peritoneal dialysate effluent, thereby providing a presumptive indication of peritonitis.

PRINCIPLE OF THE TEST

Esterase in granulocytic leukocytes catalyzes the hydrolysis of an indoxyl ester compound to yield indoxyl. The indoxyl formed in the reaction reacts with a diazonium salt to produce a purple color.[2,3]

WARNINGS AND PRECAUTIONS

- Do not hold the PeriScreen indicator pad in the sample more than one second to avoid washing out the reagents.
- Do not touch the indicator pad or allow it to come into contact with work surfaces that may be contaminated with potentially interfering substances.
- Used PeriScreen Test Strips are considered a potential biohazard and should be disposed of in an approved biohazard waste container.

STORAGE

- PeriScreen Test Strips must be kept in the original bottle with the lid tightly closed.
- Store test strips at temperatures between 15°- 30°C (59°- 86°F).
- Do not remove a test strip from the bottle until immediately before use.
- Replace cap immediately and tightly after removing a strip to protect the strips from humidity and light.
- Do not remove the desiccant pack.
- Do not use a test strip (from an opened or unopened bottle) after the expiration date printed on the bottle label.

REQUIRED ITEMS (not provided with the test strips)

- Stop watch or similar timer.
- Clean, dry sample collection cup.

SPECIMEN COLLECTION AND PREPARATION

The dialysate effluent can be tested directly from the drain bag or a sample can be transferred to a clean dry, container. Testing of the dialysate effluent should be done at room temperature (15°- 30°C/59°- 86°F).

DIRECTIONS

Dip Method:

1. Collect a sample of peritoneal dialysate effluent in a clean, dry container.
2. Remove one PeriScreen strip from the bottle and immediately replace the cap.
3. Completely immerse the indicator pad of the strip into the sample, remove immediately and start a timer.
4. Place the strip (indicator pad facing up) on a flat, clean surface.
5. Four (4) minutes after removing the strip from the sample, compare the color of the indicator pad to the color chart on the bottle.

Stream Method:

1. Remove one PeriScreen strip from the bottle and immediately replace the cap.
2. Immerse the indicator pad into the stream of peritoneal dialysate effluent for 1 second*, remove immediately and start a timer.
3. Place the strip (indicator pad facing up) on a flat, clean surface.
4. Four (4) minutes after removing the strip from the stream, compare the color of the indicator pad to the color chart on the bottle.

NOTE: Do not immerse indicator pad into dialysate stream for more than 1 second as reagents may be washed out causing a false "Negative" result.

RESULTS

Serim PeriScreen Test Strips give a semi-quantitative indication of the level of leukocytes present in peritoneal dialysate effluent based on the color of the reacted indicator pad.

- **Negative –** Normal peritoneal dialysate effluent will yield negative results; the indicator pad will match the "negative" color block. (If the color of the indicator pad is **between** "Negative" and "Trace", the results should be considered negative.).
- **Positive –** PeriScreen indicator pads matching the "Trace", "Small" or "Large" color blocks indicate significant leukocyte esterase activity and the peritoneal dialysate effluent should be tested further according to medically accepted procedures for diagnosis of peritonitis.

PERFORMANCE CHARACTERISTICS

The performance characteristics of Serim PeriScreen Test Strips were based on analytical studies in which peritoneal dialysate samples were tested with strips in a clinical setting. The results were compared to total leukocyte counts and differential counts using light microscopy.[4]

One hundred and eight (108) samples of peritoneal dialysate effluent from 23 patients were examined (Table 1). Seventy-three (73) specimens gave Negative results and had less than 44 neutrophils/µL. Thirty-five (35) dialysate samples gave results of Trace or above.

In general, Serim PeriScreen Test Strip results increased with the neutrophil counts.

Light Microscopy	PeriScreen Test Strip Results	
	Below Trace	Trace or Above
<50 neutrophils/µL	73	7
>50 neutrophils/µL	0	28

The sensitivity and specificity of Serim PeriScreen Test Strips were calculated as 100% and 91.3% respectively, using the definition of peritonitis stated in the "Description" section of this insert. Sensitivity and accuracy of the test strip can be affected by variability in color perception of individual readers and lighting conditions.

LIMITATIONS

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test.

The indicator pad of PeriScreen Test Strips may develop more of a red hue (than the color blocks displayed on the bottle label) when used to test peritoneal dialysate effluent from a dialysis solution that initially contained **more than 3%** dextrose **and** has a **high leukocyte count**. In such cases, the result is indicative of the presence of leukocytes.

Reading PeriScreen results earlier than the recommended time can cause false negative results. Late reading can give false positive results. EDTA (ethylenediaminotetraacetate), sometimes added to dialysate specimens as a preservative,[5] does not influence test strip results.

REFERENCES

[1] Leehey, DJ, Gandhi, VC and Daugirdas, JT, in Daugirdas, JT and Ing, TS, editors, Handbook of Dialysis (2nd editi on), Little Brown and Co., NY, Chapter 19, p. 339-40 (1994).

[2] Berger, Dieter, et al., Diagnostic agent for the detection of proteolytic enzymes. US Patent 4, 278,763.

[3] Skjold, AC, et al., New dip-and-read test for determining leukocytes in urine, Clin Chem. 33: 1242 - 45 (1987).

[4] Nelson, DA, in Henry, JB, editor, Clinical Diagnosis and Management by Laboratory Methods, Vol I (16th edition), W B Saunders Company, Philadelphia, PA, Chapter 27, p 881 (1979).

[5] Antonsen, S, et al., Leukocytes in peritoneal dialysis effluents, Perit. Dial. Int., 11: 43-7 (1991).

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