For the Per formance Monitor®, provide assurance that the guaiac test results are positive for occult blood. A distinct green color (no blue), appearing on or off the Test Card, as well as other unmodified positive test results, should be interpreted as positive for occult blood. A blue or blue-green color should be interpreted as negative. Therefore, as with any occult blood test, results with the Hemoccult® II SENSA® test cannot be considered conclusive evidence of colorectal neoplasia. 1-4, 22

INTERPRETIVE CRITERIA

The Hemoccult® II SENSA® test is a rapid, convenient and qualitative method for detecting fecal occult blood which may be indicative of colorectal disease. It is intended for symptomatic patients or patients with a family history of colorectal cancer or any other specific diseases.

The Hemoccult® II SENSA® test is recommended for professional use as a diagnostic aid during routine physical examinations, for hospital patients, for monitoring patients at risk for colorectal bleeding in patients with iron deficiency anemia or recovering from surgery; pediatric, urological, cardiac and other conditions, and in screening programs for colorectal cancer when the Patient Instructions are closely followed. 1-4

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The Per formance Monitor® is a diagnostic device for the qualitative detection of blood in human feces. The device is to be used as an additional test for the detection of blood in human feces. 9

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The function and stability of the test can be developed and the results obtained are valid only if performed according to the recommendations provided in the Manual. The positive Performance Monitor® also contains a holographic-drawn smear which can be used for testing after developing the Performance Monitor® slide. The hologram on such a card should not be blue after developing the card.

The Performance Monitor® provides an internal control for the elite Slide (Test Card). The Performance Monitor® package assures that the guaiac test card reads and the elite Slide (Test Card) are stable for the given shelf life. The Performance Monitor® area does not react as expected after application of developer on the elite Slide (Test Card).

If this occurs, this signal card should be handled as potentially infectious and disposed of according to local regulations.

1. Insert completed and overnight air-dried smear into Hemoccult® SENSA® Developer— a developing solution containing a gum guaiac, a vinyl polymer, lignin and a peroxidase catalyst. The Hemoccult® SENSA® Developer is a high-efficiency peroxidase catalyst.

2. Macrae F.A., St. John, D.J.B., "Relationship between patterns of disease was 1 to 3% depending on the population studied."


