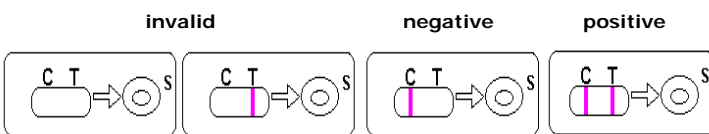


INTERPRETATION OF RESULT

Negative: Only one red line appears on the control region (C). No apparent red or pink line appears on the test region (T).

Positive: Two distinct red lines appear. In addition to a colored control band (C), a distinct colored band will also appear in the test region (T). The intensity of red color in the test line region will vary depending on the concentration of hemoglobin present in the specimen. Therefore, any shade in the test region indicates positive result.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural technique are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



INTERNAL QUALITY CONTROL

A procedural control is included in the test: a red line appearing in the control region confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied, however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

ANALYTICAL PERFORMANCES

Sensitivity

The present test can detect the levels of human occult blood as low as 50 ng/ml hemoglobin or 6 µg hemoglobin/g feces.

Correlation

The F.O.B. Test has been compared with another leading commercial rapid test. The correlation between these two systems is 98%.

Specificity

The test is specific for human hemoglobin.

Bovine, chicken, pork, goat, rabbit, horse and turkey hemoglobin up to 1 mg/ml do not effect on test results.

LIMITATIONS

As with all diagnostic tests, all results must be considered with other clinical information available. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.

PRECAUTIONS IN USE

The reagents contain inactive components such as preservatives (Sodium Azide or others), surfactants etc. The total concentration of these components is lower than the limits reported by 67/548/EEC and 88/379/EEC directives about classification, packaging and labelling of dangerous substances. However, the reagents should be handled with caution, avoiding swallowing and contact with skin, eyes and mucous membranes.

The use of laboratory reagents according to good laboratory practice is recommended.

Waste management

Please refer to local legal requirements.

REFERENCES

1. Simon J.B. "Occult blood screening for colorectal carcinoma: a critical review", Gastroenterology Vol. 88 820, 1985.
2. Blebea J. and Ncpherson RA. "False Positive Guaiac Testing With Iodine", Arch. Pathol. Lab. Med. 109:437-40, 1985.
3. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC.