

Thermo Scientific Fecal Occult Blood Control Kit

SUMMARY AND PRINCIPLE

Thermo Scientific Fecal Hemoglobin Controls are synthetic mixtures with the consistency and appearance of normal human feces. They are intended for use in monitoring quality control of qualitative fecal hemoglobin tests by the clinical laboratory.

For in vitro diagnostic use.

Not for internal use by humans or animals.

Positive Fecal Hemoglobin Control: a synthetic mixture with the consistency and appearance of normal human feces and containing sufficient human hemoglobin to give a positive test in currently used screening tests for occult blood feces.

Warning: Human sourced material. Treat as potentially infectious. Each donor unit used in the preparation of this product has been tested by an FDA-approved method and found non-reactive for the presence of HbsAg, HCV antibody, and antibody to Human Immunodeficiency Virus (HIV). Because no known test method can offer complete assurance that Hepatitis B virus, HIV or other infectious agents are absent, all human blood-based products should be handled in accordance with good laboratory practices, using appropriate precautions.¹

Negative Fecal Hemoglobin Control: a synthetic mixture with the consistency and appearance of normal human feces and of Thermo Scientific Positive Fecal Hemoglobin Control.

PROCEDURE

Test the controls in the same manner as a patient sample in accordance with the test kit package insert.

WARNING AND PRECAUTION

For in-vitro diagnostic use only.

STORAGE INSTRUCTIONS

Store at 2-8°C. Do not open container until ready for immediate use. Product will remain stable for 12 months when stored at Room Temperature (15-30°C).

INDICATIONS AND INSTABILITY

Product is unusable if it has dried out.

PERFORMANCE CHARACTERISTICS

Thermo Scientific Positive Fecal Hemoglobin Control will give a positive result for the presence of occult blood in human feces. Thermo Scientific Negative Fecal Hemoglobin Control will give a negative result for the presence of occult blood in human feces.

REFERENCES

1. Allison JE, Feldman R, Tekawa IS. Hemocult Screening in Detecting Colorectal Neoplasms: Sensitivity, Specificity and Predictive Value. Ann Intern Med. 1990; 112: 328-333.
2. Eddy DM. Screening for Colorectal Cancer. Ann Intern Med. 1990; 113: 373-84.
3. Fleischer DE, Goldberg SB, et. Al. Detection of Colorectal Cancers. JAMA. 1989; 261: 580-601. Medline: 89081463
4. Gilbertsen VA, McHugh R, et.al. The earlier Detection of Colorectal Cancers. Cancer. 1980; 45: 2899-2901.
5. Ransohoff DF, Lang CA. Screening for Colorectal Cancer. N Engl J Med. 1991; 325: 37-41.

Catalogue Number	Description
FEC5000-1	1x1.5 mL each control

¹Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 1984