alfresa

FIT NS-Prime Control

Product list

Catalogue No.	Product name
910873	FIT NS-Prime Control

Manufactured by:

Alfresa Pharma Corporation
18 Taiheidai Shouou-Cho, Katsuta-gun, Okayama, 709-4321, Japan

European Authorized Representative

Emergo Europe
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Refer to the following URL for the package inserts in languages other than English:

https://alfresa-pharma-global.com/fit/products/

CE

FOR *IN VITRO* DIAGNOSTIC USE ONLY

1.0 INTENDED USE
FIT NS-Prime Control is a daily control for routine quality assurance. It should be run every day before specimen assay to confirm that its value is within the acceptable range. FIT stands for fecal immunochemical test.

2.0 PRINCIPLE OF THE EXAMINATION METHOD

2.1 Summary and explanation of the test
Fecal immunochemical test (FIT) is used to diagnose hemorrhagic gastrointestinal diseases. FIT is particularly useful for colorectal cancer screening. **FIT Hemoglobin/Transferrin NS-Prime** is a kit to measure human hemoglobin/transferrin concentrations in feces using an immunochemical method combined with a colloidal gold colorimetric and turbidimetric method. This colloidal gold immune colorimetric and turbidimetric method is intended to measure an optical color change due to agglutination between colloidal gold-conjugated rabbit anti-human hemoglobin/transferrin polyclonal antibodies and fecal human hemoglobin/transferrin. This test is highly specific and sensitive.

2.2 Principle of the test
The reaction of colloidal gold-conjugated rabbit anti-human hemoglobin/transferrin polyclonal antibodies with human hemoglobin/transferrin in feces produces a color change due to agglutination of colloidal gold particles through the antigen-antibody reaction. Human hemoglobin/transferrin concentration in feces is determined by measuring the color change over time.

3.0 TRACEABILITY OF VALUES ASSIGNED TO CALIBRATORS AND TRUENESS-CONTROL MATERIALS
Human hemoglobin/transferrin is a reference material to calibrate calibrators and controls. Human hemoglobin/transferrin concentrations are determined using the cyanmethemoglobin method and the IRMM ERM-DA470k/IFCC, respectively.

4.0 COMPONENTS

4.1 FIT NS-Prime Control
FIT NS-Prime Control consists of five vials each of Control L (lyophilized) and Control H (lyophilized) and one bottle of Control Solution.

4.1.1 Control L (lyophilized)
Each vial is reconstituted with 2.0 mL of Control Solution. Each vial contains:

MES Buffer	6.4 mg/vial
Sucrose	40 mg/vial
Bovine serum albumin	2.0 mg/vial
Human hemoglobin	160–300 ng/vial
Human transferrin	60–140 ng/vial

4.1.2 Control H (lyophilized)
Each vial is reconstituted with 2.0 mL of Control Solution. Each vial contains:

MES Buffer	6.4 mg/vial
Sucrose	40 mg/vial
Bovine serum albumin	2.0 mg/vial
Human hemoglobin	400–700 ng/vial
Human transferrin	240–360 ng/vial

4.1.3 Control Solution
Control Solution is 30 mL per bottle. It contains:

MES Buffer	30 mmol/L
Sodium chloride	1.1 %
Bovine serum albumin	0.15 %
Boric acid	0.4 %
Sodium azide	< 0.1 %

Control Solution contains 0.4 % boric acid and less than 0.1 % sodium azide. For safety precautions, see **8.0 WARNINGS AND PRECAUTIONS**. Safety Data Sheet is available upon request by users.

Hazard statements:

- May damage fertility
- May damage unborn child

5.0 ADDITIONAL REQUIRED EQUIPMENT

5.1 Analyzer
Discrete Clinical Chemistry Analyzer NS-Prime
Discrete Clinical Chemistry Analyzer AA01
FIT NS-Prime Control is used with both **Discrete Clinical Chemistry Analyzers NS-Prime** and **AA01**.

5.2 Specimen Collection Container
Specimen Collection Container A

5.3 Reagent
FIT Hemoglobin NS-Prime
FIT Transferrin NS-Prime
FIT Hemoglobin AA01
FIT Transferrin AA01

5.4 Calibrator
FIT Hemoglobin NS-Prime Calibrator
FIT Transferrin NS-Prime Calibrator

5.5 Wash Solution
Wash Solution A

6.0 REAGENT PREPARATION
FIT NS-Prime Control
Allow Controls L and H and Control Solution to reach room temperature. Reconstitute the lyophilized Controls L and H with 2.0 mL of Control Solution. Let stand for 5 minutes. Mix well by inversion before use.

7.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

7.1 Storage
Store at 2–8 ˚C. Use FIT **NS-Prime Control** within expiry date on the box and bottle label.

7.2 Storage and shelf life after first opening
Once opened and reconstituted, with the control solution, store the Control L and Control H at 2–8 ˚C and use within seven days. Store the control solution between 2–8 ˚C. Mix well by inversion before each use. Do not freeze. Keep the lid on when storing.

8.0 WARNINGS AND PRECAUTIONS

8.1 General precautions
For *in vitro* diagnostic use
Only experienced laboratory personnel should use this; the test should be used in a manner consistent with Good Laboratory Practice.

8.2 Safety precautions
1. Do not pipet by mouth.
2. Control Solution contains 0.4 % boric acid. Reproductive toxicity: May damage fertility or the unborn child. Obtain special instructions before use. If exposed or concerned: Get medical advice/attention.
3. Control Solution contains less than 0.1 % sodium azide. Upon exposure to the eye or skin or accidental ingestion, take emergency measures such as washing with plenty of water. Consult a doctor if necessary.
4. Do not smoke, eat, or apply cosmetics in areas where patients' specimens or kit reagents are handled.
5. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
6. Take care to avoid self-inoculation, splashing to the mucous membrane, or generation of aerosols.
7. Wear laboratory gloves while handling patients' specimens or disposing of solid or liquid wastes.
8. Cautions upon disposal
   1) Some reagents contain less than 0.1 % sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. Regulations currently in use regarding dangerous waste elimination must be followed. If disposed in the sink, rinse with plenty of water.
   2) Upon disposal of reagents or other materials, comply with relevant legal provisions.
   3) Control Solution contains 0.4 % boric acid. Upon disposal comply with relevant legal provisions.
9. **FIT NS-Prime Control** contains bovine serum albumin free from known infectious agents. However they should be considered potentially infectious and handled with care to avoid infection.
10. All human specimens should be considered potentially infectious. Handle all specimens as if capable of transmitting HBV, HCV, HIV, or other microbes. Decontaminate and dispose of specimens and all potentially contaminated materials as if they contain infectious agents.
11. Human origin raw materials contained in **FIT NS-Prime Control** are negative for HBs antigen, HCV antibody, and HIV antibody. However, handle them with care as they are potentially infectious. No known test method can offer complete assurance that products derived from human sources will not transmit infectious agents.

8.3 Limitations
1. Do not use reagent bottles for purposes other than this test.
2. Do not damage or stain the bar codes on the labels of each bottle.
3. Do not replenish or mix reagents. Also, do not mix reagents of different bottles even if they have the same lot number.
4. Do not use combinations of different lot numbers within the products.
5. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
6. Reconstitute the control with the control solution supplied. Do not use other solution.
7. Do not recycle the bottle. It may be infectious.

9.0 CONTROL PROCEDURE
It is recommended that each laboratory should use quality control materials routinely such as **FIT NS-Prime Control**, and should establish its own control ranges. Multilevel controls should be tested for each run. The human hemoglobin/transferrin values obtained for the quality control materials should not fall repeatedly outside the control ranges established in each laboratory. If these control values fall repeatedly outside of the established control ranges, then proper instrument performance should be verified or perform recalibration.

10.0 CALCULATION OF EXAMINATION RESULTS
Specimen values are calculated by the **Discrete Clinical Chemistry Analyzer NS-Prime** and **AA01**.

11.0 LIMITATION OF THE EXAMINATION PROCEDURE
1. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing, because blood contamination may influence measurements.
2. Appearance changes, such as cloudiness and aggregation, in any of the reagents indicate the possibility of deterioration. Call your local dealer for advice.
3. Procedural directions must be followed exactly because any modification of the procedure may change the results.
4. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
5. Store the reagents according to the storage methods. Do not use them after the expiration date.

12.0 LITERATURE REFERENCES
1. Setsuko K et al. "Basic Evaluation of Hemotect NS-Prime, an Automated Immunochemical Analyzer for Fecal Occult Blood Testing". J Clin Lab Inst Reag. 2014; 37(3): 371–7.
2. Taira I et al. "Evaluation of the new automatic immunochemistry fecal occult blood analyzer "Hemo Techt NS-Prime"". Japanese Journal of Medical Technology. 2016; 65(2): 222–8.
3. Ahn A. et al. "Performance Evaluation of Two Automated Quantitative Fecal Occult Blood Tests". Lab Med Online. 2016; 6(4): 233–9.

13.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

Symbols	Meanings of the symbols
	Expiry date (Used by···)
LOT	Lot number
REF	Catalogue code
	Manufactured by
EC REP	Authorized EC representative
	Number of tests
IVD	*In vitro* diagnostic medical device (*In vitro* diagnostic use)
	Temperature limitation (store at···)
	See instruction for use
	May damage fertility May damage unborn child

14.0 DATE OF ISSUE OR REVISION
October 1, 2022