

FIT NS-Prime Control

Product list

Catalogue No.	Product name
910873	FIT NS-Prime Control

Note : FIT NS-Prime Control can be used with both *Discrete Clinical Chemistry Analyzer NS-Prime and AA01*.

Manufactured by:

Alfresa Pharma Corporation
2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan
For any incidents: incident-ivdr@alfresa-pharma.co.jp
For technical support: technical-support@alfresa-pharma.co.jp

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

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

CE 2797

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.

2.0 PRINCIPLE OF THE EXAMINATION METHOD

Fecal immunochemical test (FIT) is used to diagnose hemorrhagic gastrointestinal diseases. FIT is particularly useful for colorectal cancer screening. FIT Hemoglobin/Transferrin NS-Prime and AA01 are kits 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 that takes place due to agglutination between colloidal gold-conjugated rabbit anti-human hemoglobin/transferrin polyclonal antibodies and fecal human hemoglobin/transferrin. The color change is ascertained by measuring optical absorption using *Discrete Clinical Chemistry Analyzer NS-Prime and AA01*. Human hemoglobin/transferrin concentrations in feces is calculated with the optical absorption change of specimen and the calibration curve generated from the measured calibrator values.

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 ReCCS JCCRM912, which is assigned by the ICSH 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 %
Sodium azide	< 0.1 %

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

5.0 ADDITIONAL REQUIRED EQUIPMENT

5.1 Analyzer

Discrete Clinical Chemistry Analyzer NS-Prime
Discrete Clinical Chemistry Analyzer AA01

Note : FIT NS-Prime Control can be used with both *Discrete Clinical Chemistry Analyzer NS-Prime and AA01*.

5.2 Reagent

FIT Hemoglobin NS-Prime
FIT Transferrin NS-Prime
FIT Hemoglobin AA01
FIT Transferrin AA01

5.3 Calibrator

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

5.4 Wash Solution

Wash Solution A

5.5 Others

Sample cup
Pipette

6.0 REAGENT PREPARATION

1. Allow Control L (lyophilized), Control H (lyophilized) and Control Solution to equilibrate to room temperature.
2. Add 2.0 mL of Control Solution into both Controls (L and H) to reconstitute Controls and let stand for 5 minutes.
3. Mix well by slowly inversion before use.

7.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

7.1 Storage and shelf life

Do not freeze reagents. The shelf life of unopened FIT NS-Prime Control at 2–8 °C is 18 months: see the expiry date on the box and vial/bottle label.

7.2 Storage and shelf life after first opening

After use, remove the vial from *Discrete Clinical Chemistry Analyzer NS-Prime and AA01*, store back at 2–8 °C with cap closed and use within 7 days after first opening. Store the control solution between 2–8 °C with cap closed. Mix well by inversion before each use. Do not freeze.

8.0 WARNINGS AND PRECAUTIONS

8.1 General precautions

For *in vitro* diagnostic use

Procedures should only be undertaken by experienced laboratory personnel; tests should be conducted in a manner consistent with Good Clinical Laboratory Practice. If you become aware of a serious incident related to this product, be sure to report it to the manufacturer and the competent authorities. The Summary of safety and performance is available via European database on medical devices (EUDAMED).

* 8.2 Safety precautions

1. Do not pipet by mouth.
2. Control Solution contains less than 0.1 % sodium azide. In case of accidental ingestion or exposure to eyes or skin, take emergency measures such as washing with plenty of water. Consult a doctor if necessary.
3. Do not smoke, eat, or apply cosmetics in areas where patients' specimens or kit reagents are handled.
4. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
5. Take care to avoid self-inoculation, splashing to the mucous membrane, or generation of aerosols.
6. Wear laboratory gloves while handling patients' specimens or disposing of solid or liquid waste.
7. Cautions upon disposal
 - 1) Control Solution contains less than 0.1 % sodium azide. Sodium azide may react with heavy metal such as copper, plumbum and lead to form explosive metal azides. Regulations currently in use regarding dangerous waste elimination must be followed. When disposing of reagents in the sink, rinse with plenty of water.
 - 2) Upon disposal of reagents or other materials, comply with relevant legal provisions.
8. 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.
9. 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.
10. 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 vial/bottle for purposes other than this test.
2. Do not damage or stain the bar codes on vial labels.
3. Do not replenish or mix reagents. Also, do not mix reagents of different vials/bottles even if they have the same lot number.
4. Do not use combinations of products with different lot numbers.
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 vial/bottle. They may be infectious.

9.0 CONTROL PROCEDURE

The values obtained for the quality control materials should not fall repeatedly outside the acceptable ranges. If these control values fall repeatedly outside of the established control ranges, then proper instrument performance should be verified, or recalibration should be performed.

10.0 CALCULATION OF EXAMINATION RESULTS

Control values are automatically calculated and output by the Discrete Clinical Chemistry Analyzer NS-Prime and AA01 using calibration curves.

11.0 LIMITATION OF THE EXAMINATION PROCEDURE

1. Because blood contamination may affect measurements, all cuts, abrasions, wounds and other skin lesions should be completely covered by suitable protections like waterproof dressings or gloves.
2. Appearance changes, such as cloudiness and aggregation, in any of the reagents indicate the possibility of deterioration. Call your local distributor for advice.
3. As with all assays, the results of this test, can be influenced by factors present in some patients' specimens.
4. For diagnostic purposes, the results obtained from this assay should always be used in combination with a clinical examination, patient medical history, and other findings.
5. Procedural directions must be followed exactly, because any modification of the procedure may change the results. Read the instrument instruction manual and use it according to the described usage and operating environment.
6. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
7. Store the reagents according to the storage methods. Do not use them after the expiry date.
8. Use fresh feces.
9. This test should not be used to analyze specimens taken from a patient who is menstruating or who has hemorrhoids.
10. The test has not been validated for testing of patients with hemoglobinopathies.

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 Tech 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 Test". Lab Med Online. 2016; 6(4): 233–9.

* 13.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

Symbols	Meanings of the symbols
	CE marking
	Use by date (Expiry date)
	Batch code
	Catalogue number
	Manufacturer
	Authorized representative in the European Community (Authorized European representative)
	<i>In vitro</i> diagnostic medical device (<i>In vitro</i> diagnostic)
	Temperature limit (for store)
	Consult instructions for use
	Caution: Products containing hazardous substance

14.0 INFORMATION ON PACKAGING MATERIALS

The following materials are used in the packaging of FIT NS-Prime Control (accordance with Directive 94/62/EC on packaging and packaging waste).

Product box	
Outer box PAP 21	Outer box label PP 5
Others	
Instructions for use PAP 22	Assigned value sheet PAP 22