

FIT NS-Prime Dedicated Reagents

Catalogue No.	Product name	
910873	FIT NS-Prime Control	
910874	FIT NS-Prime Specimen Diluent	
910875	NS-Prime Wash Solution	

Manufactured by:

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

https://www.alfresa-pharma.co.jp/english/works/packageinserts.html

FOR IN VITRO DIAGNOSTIC USE ONLY

1.0 INTENDED USE

- 1.1 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.
- 1.2 FIT NS-Prime Specimen Diluent is a diluent for high concentration specimen. High concentration specimen over the assay range has to be diluted with FIT NS-Prime Specimen Diluent and be retested.
- 1.3 NS-Prime Wash Solution is a wash solution for cleaning reaction cuvette, sampling probe, reagent probes and mixing bar. It is a dedicated wash solution for Discrete Clinical Chemistry Analyzer NS-Prime.

2.0 PRINCIPLE OF THE EXAMINATION METHOD

2.1 Summary and explanation of the test

2.1.1 Fecal immunochemical test (FIT)

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 goldconjugated rabbit anti-human hemoglobin/transferrin polyclonal antibodies and fecal human hemoglobin/transferrin. This test is highly specific and sensitive.

2.1.2 Fecal calprotectin test (FCP)

Fecal calprotectin test (FCP) is used to aid in the assessment of intestinal mucosal inflammation in inflammatory bowel disease (IBD) patients, and aid in the differentiation of IBD from irritable bowel syndrome (IBS). NESCAUTO Cp Auto NS-Prime is a kit to measure human calprotectin 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 mouse anti-human calprotectin monoclonal antibodies and fecal human calprotectin. This test is highly specific and sensitive

2.2 Principle of the test

2.2.1 Principle of the Fecal immunochemical test (FIT)

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

2.2.2 Principle of the Fecal calprotectin test (FCP)

The reaction of colloidal gold-conjugated mouse anti-human calprotectin monoclonal antibodies with human calprotectin in feces produces a color change due to agglutination of colloidal gold particles through the antigen-antibody reaction. Human calprotectin 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,

4.0 COMPONENTS

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

40 mg/vial Sucrose Bovine serum albumir 2.0 mg/vial 160-300 ng/vial Human hemoglobin 60-140 ng/vial Human transferrin

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 40 mg/vial Sucrose Bovine serum albumin 2.0 mg/vial 400-700 ng/vial Human hemoglobin 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% 0.15% Bovine serum albumin < 0.1% Sodium azide

Control Solution contains less than 0.1% sodium azide. Attention, see 8.0 WARNINGS AND PRECAUTIONS. Material Safety Data Sheet is available upon request by users.

4.2 FIT NS-Prime Specimen Diluent

FIT NS-Prime Specimen Diluent consists of two bottles of Diluent.

4.2.1 Diluent Diluent

Diluent is 13 mL per bottle. Each bottle contains: MES Buffer 30 mmol/L Sodium chloride 1.1% Bovine serum albumin 0.15% Sodium azide < 0.1%

Diluent contains less than 0.1% sodium azide. Attention, see 8.0 WARNINGS AND PRECAUTIONS. Material Safety Data Sheet is available upon request

4.3 NS-Prime Wash Solution

NS-Prime Wash Solution is a dedicated Wash Solution for Discrete Clinical Chemistry Analyzer NS-Prime. NS-Prime Wash Solution consists of two bottles of Wash Solution.

4.3.1 Wash Solution

Wash Solution Concentrate (10X) is 500 mL per bottle. Wash Solution contains:

Polyoxyethylene alkyl ether 5% Sodium hydroxide Sodium Metaxylene sulfonate 2%

Material Safety Data Sheet is available upon request by users.

Precautions: Corrosive C

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5.0 ADDITIONAL REQUIRED EQUIPMENT

5.1 Analyzer

Discrete Clinical Chemistry Analyzer NS-Prime

Discrete Clinical Chemistry Analyzer AA01

FIT NS-Prime Specimen Diluent and NS-Prime Wash Solution are only used with Discrete Clinical Chemistry Analyzer NS-Prime.

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 NESCAUTO Cp Auto NS-Prime

FIT Hemoglobin AA01

FIT Transferrin AA01

FIT NS-Prime Specimen Diluent and NS-Prime Wash Solution are only used with FIT Hemoglobin/Transferrin NS-Prime and NESCAUTO Cp Auto NS-Prime, but FIT NS-Prime Control is used with both FIT Hemoglobin/Transferrin NS-Prime and FIT Hemoglobin/Transferrin AA01.

5.4 Calibrator

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

NESCAUTO Cp Auto Calibrator

5.5 Control

NESCAUTO Cp Auto Control

5.6 Wash Solution Wash Solution A

6.0 REAGENT PREPARATION

6.1 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.

6.2 FIT NS-Prime Specimen Diluent Diluent is ready for use.

6.3 NS-Prime Wash Solution

Dilute Wash Solution concentrate 10-fold with distilled or DI water and mix well before use. Do not use concentrated solution. Do not use at a dilution ratio other than 10 times

7.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

7.1 Storage

Storage temperature of all reagents is indicated on the box label. Store the unopened reagents using the indicated temperature on the box label until kit

7.2 Storage and shelf life after first opening

7.2.1 FIT NS-Prime Control

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.

7.2.2 FIT NS-Prime Specimen Diluent

Once opened, use it within one month and store at 2-8°C.

7.2.3 NS-Prime Wash Solution

Diluted Wash Solution (1X) is stable at 1-30°C until label expiry.

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. Some reagents contain 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.
- 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 wastes.
- 7. 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.
- 8. Some reagents contain 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. NS-Prime Wash Solution is strongly alkaline. In handling it, wear rubber gloves and protective glasses. Upon exposure to the eve or skin, take emergency measures such as washing with plenty of water. Consult a doctor if necessary. Upon accidental ingestion, seek medical attention immediately.
- 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.
- 8. Do not use glassware for the FCP. Calprotectin could be absorbed to the glass, resulting in incorrect results.
- 9. In the case of diarrhea, collection of feces may be inadequate and correct measurement values may not be obtained

9.0 CONTROL PROCEDURE

9.1 Fecal immunochemical test (FIT)

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.

9.2 Fecal calprotectin test (FCP)

It is recommended to use NESCAUTO Cp Auto Control as quality control materials. 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

Specimen values are calculated by the Discrete Clinical Chemistry Analyzer

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
- 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.
- 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 expiration date.
- 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 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.
- 4. Røseth AG. et al. "Assessment of the neutrophil dominating protein calprotectin in feces. A methodologic study". Scand J Gastroenterol. 1992; 27(9): 793-8.

13.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

Sym	ndois	ivieanings of the symbols
	3	Expiry date (Used by···)
LC	T	Lot number
RE	F	Catalogue code
	4	Manufactured by
EC	REP	Authorized EC representative
	5	Number of tests
ΙV	/D	In vitro diagnostic medical device (In vitro diagnostic use)
),		Temperature limitation (store at···)
	ì	See instruction for use
Dilu	ent	Diluent
		Corrosive

14.0 DATE OF ISSUE OR REVISION