alfresa

Specimen Collection Container A

500 tests

Manufactured by:

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

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

CE

FOR *IN VITRO* DIAGNOSTIC USE ONLY

Store at 1-30℃

SYMBOLS USED ON LABELS

	Manufactured by…
IVD	*In vitro* diagnostic medical device (*In vitro* diagnostic use)
LOT	Lot number
REF	Catalogue Code
	Expiry date (Use by…)
	Temperature limitation (store at…)
Σ	Number of tests
	See Instruction for use
EC REP	Authorized EC representative
2	Do not reuse
	Store in this position only Keep upright

1.0 INTENDED USE

Specimen Collection Container A is a specimen container used for the reagent kits below to determine the concentrations of target analytes in feces using a **Discrete Clinical Chemistry Analyzer NS-Plus**, **NS-Prime** or **AA01**. This assay can be used as not only quantitative but also qualitative.

Name of reagent kit	Analyte
i-FOBT Hemoglobin NS-Plus	Human Hemoglobin
i-FOBT Transferrin NS-Plus	Human Transferrin
FIT Hemoglobin NS-Prime	Human Hemoglobin
FIT Transferrin NS-Prime	Human Transferrin
NESCAUTO Cp Auto NS-Prime	Human Calprotectin
FIT Hemoglobin AA01	Human Hemoglobin
FIT Transferrin AA01	Human Transferrin
NESCAUTO Cp Auto AA01	Human Calprotectin

i-FOBT refers to immunological fecal occult blood test.
FIT refers to fecal immunochemical test.
Cp refers to fecal calprotectin.

2.0 SUMMARY AND EXPLANATION OF THE TEST

The fecal occult blood test (FOBT) or fecal immunochemical test (FIT) is used to diagnose hemorrhagic gastrointestinal disease. The 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). The reagent kits described in 1.0 are used to measure concentrations of target analytes in feces, using an immunochemical method combined with a colloidal gold colorimetric method. This colloidal gold immune colorimetric method is intended to measure optical color changes that arise due to agglutination between colloidal gold-conjugated polyclonal/monoclonal antibodies and antigens of the target analytes. These tests have both high specificity and high sensitivity. This assay can be used as not only quantitative but also qualitative.

3.0 PRINCIPLE OF THE TEST

The reaction of colloidal gold-conjugated polyclonal/monoclonal antibodies with target analytes in feces produces a color change due to agglutination of colloidal gold particles through an antigen-antibody reaction. Concentrations of the target analytes in feces are determined by measuring color changes over time.

4.0 PREPARATION AND STORAGE

Specimen Collection Container A is the specimen container used for the reagent kits described in 1.0. On receipt, store it at 1-30℃ until the expiration month as indicated on the label.

4.1 Specimen Collection Container A

Store at 1-30℃.
Each container is ready for use and contains 1.9 mL of the following solution:

MES Buffer, pH 6.30 (25℃):	30 mmol/L
Sodium chloride:	8.0 mg/mL
Bovine serum albumin:	0.15%
Sodium azide:	＜0.1%

The solution contains less than 0.1% sodium azide. Attention: see paragraph 6.0 PRECAUTIONS AND LIMITATIONS. Material Safety Data Sheet is available upon request from a professional user.

5.0 MATERIALS AND EQUIPMENT REQUIRED

5.1 IVD Provided

Specimen Collection Container A

5.2 Additional Materials and Equipment Required but Not Provided

Discrete Clinical Chemistry Analyzer NS-Plus
i-FOBT Hemoglobin NS-Plus
i-FOBT Transferrin NS-Plus
i-FOBT Hemoglobin NS-Plus Calibrator
i-FOBT Transferrin NS-Plus Calibrator
i-FOBT NS-Plus Control
i-FOBT NS-Plus Specimen Diluent
NS-Plus Wash Solution
Discrete Clinical Chemistry Analyzer NS-Prime
FIT Hemoglobin NS-Prime
FIT Transferrin NS-Prime
NESCAUTO Cp Auto NS-Prime
FIT Hemoglobin NS-Prime Calibrator
FIT Transferrin NS-Prime Calibrator
NESCAUTO Cp Auto Calibrator
FIT NS-Prime Control
NESCAUTO Cp Auto Control
FIT NS-Prime Specimen Diluent
NS-Prime Wash Solution
Discrete Clinical Chemistry Analyzer AA01
FIT Hemoglobin AA01
FIT Transferrin AA01
NESCAUTO Cp Auto AA01
FIT AA01 Specimen Diluent
Wash Solution A
Refer to each of the package insert for detailed information.

6.0 PRECAUTIONS AND LIMITATIONS

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.

6.1 Safety Precautions

1. Do not smoke, eat or apply cosmetics in areas where patient specimens are handled.
2. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
3. Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols.
4. Laboratory gloves should be worn while handling patient specimens or disposing of solid or liquid waste.
5. **Specimen Collection Container A** contains 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 respected. If discharge occurs via canalization, rinse with plenty of water.
6. **Specimen Collection Container A** contains bovine serum albumin that is free of infectious agents. However it should be considered potentially infectious nonetheless and handled with care.
7. **Specimen Collection Container A** contains 0.4% boric acid, which may damage fertility and the unborn child. Avoid contact or exposure. Regulations currently in use regarding effluent must be followed.

6.2 Limitations

1. Cloudiness, aggregation, or precipitation in any part of **Specimen Collection Container A** indicates the possibility of deterioration. Call your local dealer for advice.
2. As with all assays, the results of this test can be influenced by various factors present in some patient specimens.
3. 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.
4. Procedural directions must be followed exactly since any modification of the procedure may alter the results.
5. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
6. Do not damage or stain the bar-code label on each container. Do not remove the container label.
7. **Specimen Collection Container A** is for single-use only. Do not reuse it.
8. Do not recycle the bottle. It may be infectious.
9. **Do not use glassware** for the FCP. Calprotectin could be absorbed to the glass, resulting in incorrect result.
10. In the case of diarrhea, collection of feces may be inadequate and correct measurement values may not be obtained.

7.0 SPECIMEN COLLECTION AND STORAGE

1. Use fresh human feces.
2. To prepare a fecal sample, scrape several surfaces of a fecal specimen thoroughly with the stick from **Specimen Collection Container A**.
3. Shake the container sufficiently to dissolve the feces from the gutters on the stick.
4. Leave the container at room temperature for 1 hour. When measuring on the next day, refrigerate at 2-8℃. Depending on the specimen, dissolution of target analytes from feces may be insufficient in 1 hour.
5. Specimens whose concentrations exceed the upper limit of the calibration curve should be diluted with **i-FOBT NS-Plus Specimen Diluent**, **FIT NS-Prime Specimen Diluent** or **FIT AA01 Specimen Diluent** and retested.
6. This test should not be used to analyze specimens taken from patients who are menstruating or who have hemorrhoids.

7.1 Specimen Collection

Collect sample feces onto the gutters of the collector stick by scraping 4-5 areas on the surface of fecal specimens. Place the stick into the collector body one time only and fasten the stick tightly. See the instruction manual for **Specimen Collection Container A**.

7.2 Specimen Storage

The collected sample should be refrigerated between 2-8℃ until it can be tested. Once the sample is received for testing, store it between 2-8℃. Hemoglobin, transferrin and/or calprotectin are stable in the container buffer. However, assay should be done as soon as possible after a lab receives a container.

7.3 Hemoglobin Stability After Feces Sampling

The stability of human hemoglobin in the buffer of **Specimen Collection Container A** was examined both on the NS-Plus and NS-Prime analyzers. The residual ratios of human hemoglobin after storage of four different concentrations of human hemoglobin for 7, 14, and 33 days at -40, 7, 25, and 37℃ on the NS-Plus and NS-Prime analyzers, were as follows:

NS-Prime	-40℃, for 33 days	7℃, for 33 days	25℃, for 14 days	37℃, for 7 days
50 ng/mL	≥ 90%	≥ 90%	≥ 90%	≥ 90%
169 ng/mL	≥ 90%	≥ 90%	≥ 90%	≥ 70%
266 ng/mL	≥ 90%	≥ 90%	≥ 70%	≥ 50%*
381 ng/mL	≥ 90%	≥ 90%	≥ 50%*	≥ 30%*

*Hb residual ratios decreased to 37-55%, but the results were still positive (cut-off: 100 ng/mL).
This result is provided for reference only. The stability varies depending on the specimen.

NS-Plus	-40℃, for 33 days	7℃, for 33 days	25℃, for 14 days	37℃, for 7 days
52 ng/mL	> 90%	> 90%	> 90%	> 90%
168 ng/mL	> 90%	> 90%	> 90%	> 80%
280 ng/mL	> 90%	> 90%	> 70%	> 50%*
409 ng/mL	> 90%	> 90%	> 50%*	> 30%*

*Hb residual ratios decreased to 36-54%, but the results were still positive (cut-off: 100 ng/mL).
This result is provided for reference only. The stability varies depending on the specimen.

7.4 Transferrin Stability After Feces Sampling

The stability of human transferrin in the buffer of **Specimen Collection Container A** was examined on the NS-Prime analyzer.
After storage of four different concentrations of human transferrin for 6, 13, and 35 days at -40, 7, 25, and 37℃, the residual ratios of human transferrin were as follows:

NS-Prime	-40℃, for 35 days	7℃, for 35 days	25℃, for 13 days	37℃, for 6 days
39 ng/mL	≥ 90%	≥ 90%	≥ 80%	≥ 70%
66 ng/mL	≥ 90%	≥ 90%	≥ 80%	≥ 70%
157 ng/mL	≥ 90%	≥ 90%	≥ 80%	≥ 70%*
296 ng/mL	≥ 90%	≥ 90%	≥ 80%	≥ 70%*

*Tf residual ratios decreased to 70% or above, but the results were still positive (cut-off: 50 ng/mL).
This result is provided for reference only. The stability varies depending on the specimen.

7.5 Calprotectin Stability After Feces Sampling

After collection of the sample, it should be measured within 7 days in room temperature conditions (below 25℃). In order to assess human calprotectin stability, four different feces samples collected with the buffer of **Specimen Collection Container A** were examined. After storage for 32 days at −40℃ and 8 days at 4, 25, 37 and 50℃, the residual ratios of human calprotectin concenteration were as follows:

NS-Prime	−40℃, for 32 days	4℃, for 8 days	25℃, for 8 days	37℃, for 8 days	50℃, for 8 days
120 μg/g	109%	110%	99%	84%	81%
275 μg/g	100%	94%	97%	87%	78%
483 μg/g	104%	101%	93%	91%	79%
670 μg/g	103%	95%	99%	84%	81%

This result is provided for reference only. The stability varies depending on the specimen.

8.0 BIBLIOGRAPHY

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9.0 DATE OF ISSUE OR REVISION

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