alfresa

Specimen Collection Container A

REF 909214 (1-Day Method with Tissue Paper)

REF 911288 (1-Day Method with Tissue Paper)

Σ 400 tests

REF 909843 (Pink cap container Only)

REF 911405 (Yellow cap container Only)

Σ 500 tests

Manufactured by:

Alfresa Pharma Corporation
18 Taiheidai Shouou-Cho, Katsuta-gun, Okayama, 709-4321, Japan
www.alfresa-pharma.co.jp/english/

en

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
	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** or **NS-Prime**.

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

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

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 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 antibodies and antigens of the target analytes. These tests have both high specificity and high sensitivity.

3.0 PRINCIPLE OF THE TEST

The reaction of colloidal gold-conjugated polyclonal 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. Material Safety Data Sheets are 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 Hemoglobin NS-Prime Calibrator
FIT NS-Prime Control
FIT NS-Prime Specimen Diluent
NS-Prime Wash Solution
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 perform the tests using **Specimen Collection Container A** 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.

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.

7.0 SPECIMEN COLLECTION AND STORAGE

1. Use fresh human feces.
2. To prepare a fecal sample, scrape the surface 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 for 1 hour (at least for 30 minutes) to get the fecal sample homogenous well in the buffer after sampling before the assay.
   Store the sample at a refrigerator when you cannot perform the assay within the day you received the container. Store the sample at less than -20℃ if you cannot perform the assay for a long time.
5. Specimens whose concentrations exceed the upper limit of the calibration curve should be diluted with **i-FOBT NS-Plus Specimen Diluent** or **FIT NS-Prime 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℃. If a delay in testing of more than 7 days is anticipated, store the sample at -20℃ or lower. Avoid multiple freeze/thaw cycles. Hemoglobin and/or transferrin were 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 (cutoff: 100 ng/mL).

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%
162 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 (cutoff: 100 ng/mL).

8.0 LITERATURE REFERENCES

1) Fumio Yamagata et al., A Comparison of Six Models of Commercially Available Automated Immunologic Fecal Occult Blood Analyzers. Journal of Clinical Laboratory Instruments and Reagents, 29(2), p121-130, 2006 [Japanese].
2) Carroll MRR, Piggott C, Pearson S, Seaman HE, Halloran SP. Evaluation of quantitative faecal immunochemical tests for haemoglobin. Guildford Medical Device Evaluation Centre (GMEC), Guildford, UK, 2013.

Date of issue: Feb. 12, 2015

Date of issue: Feb. 12, 2015