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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:

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

CE

FOR *IN VITRO* DIAGNOSTIC USE ONLY

## 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-Prime** or **AA01**. This assay can be used as not only quantitative but also qualitative.

| Name of reagent kit | Analyte |
|---|---|
| **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 |

FIT refers to fecal immunochemical test.
Cp refers to fecal calprotectin.

## 2.0 SUMMARY AND EXPLANATION OF THE TEST

The 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 STORAGE AND COMPONENTS

**Specimen Collection Container A** is a specimen container used for the reagent kits described in 1.0. Store at 1-30 ℃. Use **Specimen Collection Container A** within expiry date on the container label.
**Specimen Collection Container A** contains 1.9 mL of the following buffer:

| | |
|---|---|
| MES Buffer, pH 6.30 (25 ℃): | 30 mmol/L |
| Sodium chloride: | 8.0 mg/mL |
| Bovine serum albumin: | 0.15 % |
| Boric acid: | ＜0.3 % |
| Sodium azide: | ＜0.1 % |

The buffer contains less than 0.3 % boric acid and less than 0.1 % sodium azide. For safety precautions, see **6.0 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**

### 5.2 Reagent

**FIT Hemoglobin NS-Prime**
**FIT Transferrin NS-Prime**
**NESCAUTO Cp Auto NS-Prime**
**FIT Hemoglobin AA01**
**FIT Transferrin AA01**
**NESCAUTO Cp Auto AA01**

### 5.3 Calibrator

**FIT Hemoglobin NS-Prime Calibrator**
**FIT Transferrin NS-Prime Calibrator**
**NESCAUTO Cp Auto Calibrator**

### 5.4 Specimen diluent

**FIT NS-Prime Specimen Diluent**
**FIT AA01 Specimen Diluent**

### 5.5 Wash solution

**Wash Solution A**

## 6.0 WARNINGS AND PRECAUTIONS

### 6.1 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. If you become aware of a serious incident related to this product, be sure to report it to the manufacturer and the component authorities.

### 6.2 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 0.3 % boric acid. Reproductive toxicity: May damage fertility or the unborn child. Obtain special instructions before use. If exposed or concerned: Get medical advice/attention. Regulations currently in use regarding effluent must be followed.
6. **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.
7. **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.

### 6.3 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 container. 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 SAMPLE PREPARATION AND STORAGE

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

### 7.1 Specimen collection

Collect feces on the grooved tip of the stick by scraping several surfaces of the fecal specimen. Place the stick with feces back into the container and fasten it tightly in place to close. Do not reopen it. See the instruction manual for **Specimen Collection Container A**.

### 7.2 Sample storage

After the specimen collection, the sample should be kept under 25 ℃ or below for maximum 7 days. If temperature control at room temperature below 25 ℃ is difficult to perform, refrigerate the sample at 2-8 ℃ until sample measurement can be executed.

### 7.3 Hemoglobin stability after specimen collection

The stability of human hemoglobin in the buffer of **Specimen Collection Container A** was examined on the **Discrete Clinical Chemistry Analyzer NS-Prime**.
After storage of four different concentrations of human hemoglobin for, 7, 14, and 33 days at -40, 7, 25, and 37 ℃, the residual ratios of human hemoglobin 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 fecal specimen.

### 7.4 Transferrin stability after specimen collection

The stability of human transferrin in the buffer of **Specimen Collection Container A** was examined on the **Discrete Clinical Chemistry Analyzer NS-Prime**.
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 fecal specimen.

### 7.5 Calprotectin stability after specimen collection

The stability of human calprotectin in the buffer of **Specimen Collection Container A** was examined on the **Discrete Clinical Chemistry Analyzer NS-Prime**.
After storage of four different concentrations of human calprotectin for 8 and 32 days at -40, 4, 25, 37 and 50 ℃, the residual ratios of human calprotectin 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 fecal specimen.

## 8.0 PERFORMANCE CHARACTERISTICS

Claimed repeatability: CV ≤ 10 %

## 9.0 BIBLIOGRAPHY

1) Fumio Y. et al."A comparison of six models of commercially available automated immunologic fecal occult blood analyzers". The Journal of Clinical Laboratory Instruments and Reagents. 2006; 29(2): 121−30. [Japanese]
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3) Kazuo F. et al."3 kishu niyoru bensenketsujidoubunsekisouchi no hikakukentou". The Journal of Clinical Laboratory Instruments and Reagents. 2013; 36(5): 679−85. [Japanese]
4) Rapi S. et al."Effects of fecal sampling on preanalytical and analytical phases in quantitative fecal immunochemical tests for hemoglobin". Int J Biol Markers. 2017; 32(3): 261−6.
5) Randell E. et al."Evaluation of Hemo Techt NS-Plus system for use in a province-wide colorectal cancer screening program". Clinical Biochemistry. 2013; 46(4−5): 365−8.
6) Demian WLL. et al."Evaluation of the analytical performance of the novel NS-Prime system and examination of temperature stability of fecal transferrin compared with fecal hemoglobin as biomarkers in a colon cancer screening program". Practical Laboratory Medicine. 2015; 2: 29−36.
7) Røseth AG. et al."Assessment of the neutrophil dominating protein calprotectin in feces. A methodologic study". Scand J Gastroenterol. 1992; 27(9): 793−8.

## 10.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

| Symbols | Meanings of the symbols |
|---|---|
| CE | CE marking |
| | Manufacturer |
| IVD | *In vitro* diagnostic medical device (*In vitro* diagnostic) |
| LOT | Batch code |
| REF | Catalogue number |
| | Use-by date (Expiry date) |
| | Temperature limit (for storage) |
| Σ | Contains sufficient for＜n＞tests |
| | Consult instructions for use |
| EC REP | Authorized representative in the European Community (Authorized European representative) |
| 2 | Do not re-use |
| | Store in this position only<br>Keep upright |
| | Caution: Products containing hazardous substance |

## ＊11.0 INFORMATION ON PACKAGING MATERIALS

The following materials are used in the packaging of this product (Accordance with Directive 94/62/EC on packaging and packaging waste).

| Product box | | |
|---|---|---|
| Outer box<br>PAP 20 | Outer box label<br>PP 5 | Inner box<br>PAP 20 |

| Others | |
|---|---|
| Stool collection instructions*<br>PAP 22 | Instructions for use<br>PAP 22 |

*Only if attached.