alfresa

FIT AA01 Specimen Diluent

Product list

Catalogue No.	Product name
912242	FIT AA01 Specimen Diluent

Manufactured by:

Alfresa Pharma Corporation
18 Taiheidai Shouou-Cho, Katsuta-gun, Okayama, 709-4321, Japan

European Authorized Representative

Emergo Europe
Prinsessegracht 20 2514 AP The Hague The Netherlands

CE

FOR *IN VITRO* DIAGNOSTIC USE ONLY

1.0 INTENDED USE

1.1 FIT AA01 Specimen Diluent is a diluents for high concentration specimen. High concentration specimen over the assay range has to be diluted with **FIT AA01 Specimen Diluent** and be retested.

2.0 PRINCIPLE OF THE EXAMINATION METHOD

2.1 Summary and explanation of the test

Fecal immunochemical test (FIT) is used to diagnose hemorrhagic gastrointestinal diseases. FIT is particularly useful for colorectal cancer screening. **FIT Hemoglobin AA01** is a kit to measure human hemoglobin 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 rabbit anti-human hemoglobin polyclonal antibodies and fecal human hemoglobin. This test is highly specific and sensitive.

2.2 Principle of the test

The reaction of colloidal gold-conjugated anti-human hemoglobin polyclonal antibodies with human hemoglobin in feces produces a color change due to agglutination of colloidal gold particles through the antigen-antibody reaction. Human hemoglobin concentration in feces is determined by measuring the color change over time.

3.0 COMPONENTS

3.1 FIT AA01 Specimen Diluent

FIT AA01 Specimen Diluent consists of two bottles of Diluent.

3.1.1 Diluent Diluent

Diluent is 8mL 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 **7.0 WARNINGS AND PRECAUTIONS.** Material Safety Data Sheet is available upon request by a professional user.

4.0 ADDITIONAL REQUIRED EQUIPMENT

4.1 Analyzer

Discrete Clinical Chemistry Analyzer AA01

4.2 Specimen Collection Container

Specimen Collection Container A

4.3 AA01 dedicated reagent

FIT Hemoglobin AA01
FIT Hemoglobin NS-Prime Calibrator
FIT NS-Prime Control
Wash Solution A

5.0 REAGENT PREPARATION

Diluent is ready for use.

6.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

6.1 Storage

Store at 2–8˚C.

6.2 Storage and shelf life after first opening

Once opened, use it within one month and store at 2–8˚C.

7.0 WARNINGS AND PRECAUTIONS

7.1 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.

7.2 Safety precautions

1. Do not pipet by mouth.
2. **FIT AA01 Specimen Diluent** contains 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) **FIT AA01 Specimen Diluent** 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 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. **FIT AA01 Specimen Diluent** contains bovine serum albumin free from known infectious agents. However it 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.

7.3 Limitations

1. Do not use reagent containers for purposes other than this test.
2. Do not damage or stain the bar codes on the labels of each container.
3. Do not replenish or mix reagents. Also, do not mix reagents of different bottles even if they have the same lot number.
4. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
5. Do not recycle the bottle. It may be infectious.

8.0 CONTROL PROCEDURE

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 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.

9.0 CALCULATION OF EXAMINATION RESULTS

Specimen values are calculated by the **Discrete Clinical Chemistry Analyzer AA01**.

10.0 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 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.
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.
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.

11.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

Symbols	Meanings of the symbols
	Expiry date (Used by···)
LOT	Lot number
REF	Catalogue code
	Manufactured by
EC REP	Authorized EC representative
IVD	*In vitro* diagnostic medical device (*In vitro* diagnostic use)
	Temperature limitation (store at···)
	See instruction for use
	Infectious substances: Handle with care
Diluent	Diluent

12.0 DATE OF ISSUE OR REVISION

January 1, 2019

610329-1

平成31年１月改訂
平成30年４月作成

免疫学的便中ヘモグロビン及びヒトトランスフェリン測定用

ネスコート® Hbオート 検体希釈液
（AA01）

危　険
生殖能または胎児への
悪影響のおそれ
成分：ほう酸

この説明書をよく読んでから使用して下さい。

本品はネスコート Hb オート及びネスコート Tf オート(いずれも弊社取扱い)専用の検体希釈液です。

【使　用　法】
そのまま使用します。
高値検体は，本検体希釈液を用いて，希釈を行い測定して下さい。
開封後は冷蔵保存(2～8℃)し，1ヶ月以内に使用して下さい。

【使用上又は取扱い上の注意】
1. 本品はネスコート Hb オート及びネスコート Tf オート(いずれも弊社取扱い)専用の検体希釈液です。他の製品には使用しないで下さい。
2. 本品にはほう酸が含まれております。濃度は0.4%です。また，アジ化ナトリウムが含まれております。濃度は0.1%以下ですので毒物には該当しません。
   本品が誤って目や口に入ったり皮膚に付着した場合は，水で十分に洗い流す等の応急処置を行い，必要があれば医師の手当て等を受けて下さい。
3. 本品は冷蔵保存(2～8℃)し，使用期限を過ぎたものは使用しないで下さい。
4. 試薬容器，付属品等は当検査以外の目的に転用しないで下さい。
5. 試薬容器に貼り付けてあるバーコードを傷つけたり汚したりしないで下さい。
6. 測定操作時には，ディスポーザブルの手袋等を着用して下さい。
7. 廃棄上の注意
   1) 本品にはアジ化ナトリウムが含まれており，鉛，銅等の重金属と反応して，爆発性のアジ化物を形成することがあります。廃棄するときは，アジ化物が形成されないように大量の水で洗い流して下さい。
   2) 本品を廃棄するときは，廃棄物の処理及び清掃に関する法律，水質汚濁防止法等の規定に従って処理して下さい。

【貯法・有効期間】
1. 貯　　法：冷蔵保存（２～８℃）
2. 有効期間：１年６箇月
   （使用期限は外装等に記載）

【包 装 単 位】
ネスコート Hb オート 検体希釈液　　検体希釈液　　2×8mL

【問い合わせ先】
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