alfresa

FIT Transferrin AA01

Product list

Catalogue No.	Product name
913936	FIT Transferrin AA01

Manufactured by:

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

CE

FOR *IN VITRO* DIAGNOSTIC USE ONLY

1.0 INTENDED USE

FIT Transferrin AA01 is a reagent to quantitatively determine human transferrin concentrations in feces using the **Discrete Clinical Chemistry Analyzer AA01**, which employs a colloidal gold immune colorimetric and turbidimetric method. This reagent is intended for colorectal cancer screening. FIT stands for fecal immunochemical test.

2.0 PRINCIPLES 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 Transferrin AA01** is a kit to measure human 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 gold-conjugated rabbit anti-human transferrin polyclonal antibodies and fecal human transferrin. This test is highly specific and sensitive.

2.2 Principles of the test

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

3.0 COMPONENTS

3.1 FIT Transferrin AA01

A kit contains two sets of Reagent 1 and Reagent 2 bottles. Each bottle is for 125 tests. Total 250 tests can be assayed per kit.

3.1.1 Reagent 1 REAG 1

FIT Transferrin AA01 contains 2 bottles of 11mL of Reagent 1. Each bottle contains:

MES Buffer	150 mmol/L
Sodium azide	< 0.1%

Reagent 1 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.

3.1.2 Reagent 2 REAG 2

FIT Transferrin AA01 contains 2 bottles of 5mL of Reagent 2. Each bottle contains:

TES Buffer	4.4 mmol/L
Bovine serum albumin	0.03%
Sodium azide	< 0.1%
Colloidal gold-conjugated anti-human transferrin polyclonal antibodies	333 μL/mL

Reagent 2 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 Transferrin NS-Prime Calibrator
FIT NS-Prime Control
FIT AA01 Specimen Diluent
Wash Solution A

5.0 REAGENT PREPARATION

Mix the reagent 2 thoroughly before each use, because colloidal gold particles may precipitate during storage. Mix it by slowly inverting to avoid creating bubbles. If bubbles occur, the instrument sensor will read an incorrect volume and the bottle will be deleted from the system. Pipette out any bubbles down to the level of the liquid before placing the bottle on board.

6.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

6.1 Storage

Store at 2–8°C. Do not freeze.

6.2 Storage and shelf life after first opening

Once opened, use the reagent 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. 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) Reagent 2 of **FIT Transferrin AA01** contains 0.20 g/L ethylenediaminetetraacetic acid copper (Ⅱ) disodium (27 mg/L as copper). Upon disposal, comply with relevant legal provisions.
   2) 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.
   3) 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.

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. 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. Do not recycle the bottle. It may be infectious.

8.0 PRIMARY SAMPLE COLLECTION, HANDLING, AND STORAGE

Use human fecal specimens for measurement.
1. Scrape the surface of fecal specimen with the stick of **Specimen Collection Container A** thoroughly to prepare a sample.
2. Specimens whose concentrations exceed the upper limit of the calibration curve should be diluted with **FIT AA01 Specimen Diluent** and retested.

8.1 Specimen collection

Sample feces onto the gutters of the collector stick by scraping several surfaces of fecal specimen. Place the stick into the collector body once only and fasten the stick tightly. See the instruction manual for **Specimen Collection Container A.**

8.2 Specimen storage

The collected sample should be refrigerated between (2–8°C) until the sample can be tested. Once the sample is received for testing store between 2–8°C.

8.3 Transferrin stability after feces sampling

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

	–40°C, for 35 days	7°C, for 35 days	25°C, for 13 days	37°C, 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.

9.0 EXAMINATION PROCEDURE

9.1 Preparation of specimens

1) Sample feces using **Specimen Collection Container A.** See the instruction manual for the container.
2) Shake the container sufficiently to dissolve the feces from the gutters of the stick.
3) Leave the container at room temperature for 1 hour. When measuring on the next day, refrigerate at 2–8°C. Depending on the specimen, dissolution of transferrin from feces may be insufficient in 1 hour.

9.2 Assay

1) Prepared specimen solution 9 μL
   Reagent 1 75 μL
   Reagent 2 30 μL
   Mix the reaction liquid and incubate at 37°C.
   Formula to calculate the change of Absorbance (Abs) is (Am1–As1)–(Am2–As2).
   Am1 : Abs of main wavelength at measurement point 1
   As1 : Abs of sub wavelength at measurement point 1
   Am2 : Abs of main wavelength at measurement point 2
   As2 : Abs of sub wavelength at measurement point 2
   main wavelength: 525 nm
   sub wavelength: 660 nm
   measurement point 1: 0 minutes
   measurement point 2: 4.0 minutes
2) Construct a calibration curve using **FIT Transferrin NS-Prime Calibrator** in place of the specimen solution. Read the human transferrin concentration in the specimen solution from the calibration curve.

All routine maintenance procedures defined in the instrument manual for the **Discrete Clinical Chemistry Analyzer AA01** should be performed to obtain optimal performance.

10.0 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 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.

11.0 CALCULATION OF EXAMINATION RESULTS

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

12.0 INTERPRETATION OF RESULTS

The cut-off value widely used in Japan for mass-screening is less than 50 ng/mL (equivalent to 10 μg of human transferrin per 1 g of feces). Colorectal cancer is suspected if human transferrin is detected above that level.
<In-house data>
Note : This value is indicative only and may differ from other published values because of differences in methods and in the population being studied. It is recommended that each laboratory establish its own cut-off value.

13.0 PERFORMANCE CHARACTERISTICS

The following performance data was obtained using the **Discrete Clinical Chemistry Analyzer AA01.**

13.1 Analytical performance characteristics

13.1.1 Precision

Precision: CV ≤ 15%

13.1.2 Interference

Some studies have been conducted to determine the levels of interference. The following substances do not affect the assay at the following concentrations:
Conjugated and unconjugated bilirubin: 0–20,000 ng/mL
Ascorbic acid: 0–100,000 ng/mL
Glucose: 0–100,000 ng/mL
Bovine serum albumin: 0–100,000 ng/mL
Peroxidase: 0–100,000 ng/mL
Barium sulfate: 0–1,000,000 ng/mL
The cross-reactivities of the reagents with serum in animal species other than humans (bovine, swine, equine, ovine, leporine, and avian) did not exist at concentration of 0.4%.

13.1.3 Correlation

FIT Transferrin AA01 assay was compared with **FIT Transferrin NS-Prime** on 107 specimens. A linear regression analysis was performed and the following results were obtained:
x : **FIT Transferrin NS-Prime**
y : **FIT Transferrin AA01**
r = 0.998
y = 0.966x – 2.6

13.2 Diagnostic performance characteristics

13.2.1 Analytical sensitivity

The difference in the amounts of change in absorbance between transferrin concentrations of 0 and 50 ng/mL is 0.05 or above.

13.2.2 Analytical accuracy

Within 100±15% of known concentration in the measurement of a control specimen of known concentration.

13.3 Measuring interval

13.3.1 Assay range

1) Upper limit : 500ng/mL (equivalent to 100 μg human transferrin per 1g of feces)
2) Lower limit
   Limit of quantitation : 20ng/mL (equivalent to 4 μg human transferrin per 1g of feces)
   Limit of detection : 5ng/mL (equivalent to 1 μg human transferrin per 1g of feces)

14.0 BIOLOGICAL REFERENCE INTERVALS

Less than 50 ng/mL (10 μg /g feces)
Note : This value is indicative only and may differ from other published values because of differences in methods and in the population being studied. It is recommended that each laboratory establish its own local reference ranges.

15.0 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. Mix the reagent 2 thoroughly before each use, because colloidal gold particles may precipitate during storage. Mix it by slowly inverting to avoid creating bubbles. If bubbles occur, the instrument sensor will read an incorrect volume and the bottle will be deleted from the system. Pipette out any bubbles down to the level of the liquid.
4. As with all assays, the results of this test can be influenced by factors present in some patients' specimens.
5. 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.
6. Procedural directions must be followed exactly because any modification of the procedure may change the results.
7. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
8. Store the reagents according to the storage methods. Do not use them after the expiration date.
9. Use fresh feces.
10. This test should not be used to analyze specimens taken from a patient who is menstruating or who has hemorrhoids.
11. The test has not been validated for testing of patients with hemoglobinopathies.

16.0 LITERATURE REFERENCES

1. Kazuyoshi Yamashita et al., The Usefulness of Fecal Transferrin Test, Medical Journal of Sendai Red Cross Hospital, 19(1), p75–78, 2010.
2. Ichiro Hirata et al., Early Colorectal Cancer Screening-an Immunochemical Fecal Occult Blood Test Using Hb/Tf Simultaneous Assay, Stomach and Intestine, 45(5), p725–733, 2010.
3. Setsuko Kato et al., Basic Evaluation of Hemotect NS-Prime, an Automated Immunochemical Analyzer for Fecal Occult Blood Testing, J Clin Lab Inst Reag, 37(3), p371–377, 2014.
4. Yoshinori Takashima et al., Clinical benefit of measuring both haemoglobin and transferrin concentrations in faeces: demonstration during a large-scale colorectal cancer screening trial in Japan, Diagnosis, 2(1), p53–59, 2015.
5. Yoshinori Takashima et al., Corrigendum to: Clinical benefit of measuring both haemoglobin and transferrin concentrations in faeces: demonstration during a large-scale colorectal cancer screening trial in Japan, Diagnosis, 2(3), p199–200, 2015.
6. Wael L.L.Demian 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, 2, p29–36, 2015.
7. Taira Inagaki et al., Evaluation of the new automatic immunochemistry fecal occult blood analyzer "Hemo Techt NS-Prime", Japanese Journal of Medical Technology, 65(2), p222–228, 2016.

17.0 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
Σ	Number of tests
IVD	*In vitro* diagnostic medical device (*In vitro* diagnostic use)
	Temperature limitation (store at···)
	See instruction for use
	Infectious substances: Handle with care
REAG 1	Reagent 1
REAG 2	Reagent 2

18.0 DATE OF ISSUE OR REVISION

November 1, 2023

体外診断用医薬品

610303-02B
令和２年10月作成（第1版）
製造販売認証番号
224ADAMX00140000

トランスフェリンキット
免疫学的便中ヒトトランスフェリン測定用
ネスコート® Tf オート
金コロイド凝集法
（AA01）

この添付文書をよく読んでから使用して下さい。

【全般的な注意】
1. 本製品は,体外診断用でありそれ以外の目的に使用しないで下さい。
2. 診断は他の関連する検査結果や臨床症状等に基づいて総合的に判断して下さい。
3. 添付文書以外の使用方法については保証を致しません。
4. 使用する機器の添付文書及び取扱い説明書をよく読んでから使用して下さい。
5. 本製品には，保存剤としてアジ化ナトリウムが含まれていますので，誤って目や口に入れたり，皮膚に付着した場合には水で十分に洗い流す等の応急措置を行い，必要があれば医師の手当て等を受けて下さい。

【形状・構造等（キットの構成）】
R１緩衝液……11mL
緩衝剤他
R2金コロイド液…… 5mL
金コロイド標識抗ヒトトランスフェリンポリクローナル抗体（ウサギ）
……333μL/mL

【使 用 目 的】
糞便中のヒトトランスフェリンの測定

【測 定 原 理】
試料とR2金コロイド液を反応させると，試料中のヒトトランスフェリンと試薬中の金コロイド標識抗ヒトトランスフェリンポリクローナル抗体（ウサギ）が抗原抗体反応を起こします。この反応によって抗体に標識された金コロイド粒子が凝集して色調変化を生じます。この色調変化を光学的に測定することにより，試料中のヒトトランスフェリン濃度を求めます。

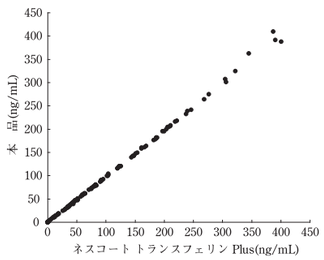
【操作上の注意】
1. 測定試料の性質
1）糞便は新鮮なものを使用して下さい。
2）糞便は採便容器A（弊社取扱い）に採取して溶解し，試料として下さい。
3）被検測定試料は採便後すみやかに検査を実施して下さい。
測定試料をやむを得ず保管する場合は冷所保存(2～8℃)して下さい。
4）測定範囲の上限を超える試料は，ネスコート Hb オート 検体希釈液（AA01用 弊社取扱い）で希釈した後，再測定して下さい。
5）生理中又は痔疾患による出血がある場合は試料として適していません。
2. 試料の採取法
採便は便の表面をスティックで4～5ヶ所まんべんなくこすり，溝に付着させます。次にスティックを一回だけ採便容器に差し込み，しっかり締めます。詳細は採便容器Aの説明書を参照して下さい。
3. 妨害物質など
1）ビリルビン（20μg/mL），アスコルビン酸（100μg/mL），グルコース（100μg/mL），BSA（100μg/mL），ペルオキシダーゼ（100μg/mL），硫酸バリウム（1,000μg/mL）で影響がありません。
2）ヒト以外の動物トランスフェリン（ウシ，ブタ，トリ，ウマ，ウサギ；30,000ng/mL）で影響がありません。

【用法・用量（操作方法）】
1. 使用液の調製方法
1）R１緩衝液　：そのまま使用します。
開封後は密封冷蔵保存（2～8℃）し，１ヶ月以内に使用して下さい。
2）R２金コロイド液：そのまま使用します。
開封後は密封冷蔵保存（2～8℃）し，１ヶ月以内に使用して下さい。また測定前に十分転倒混和して下さい。

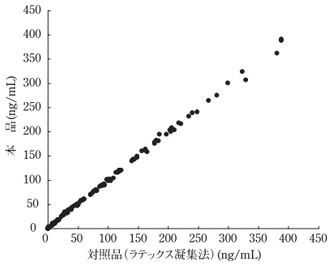
2. 操作方法
1）試料の準備
(1) 採便容器A（弊社取扱い）を用いて糞便を採取して下さい。詳細は，採便容器Aの説明書を参照して下さい。
(2) よく振とうしてスティックの溝に付着した便を溶解し，試料とします。
2）測　定
(1) 試料12μLにR１緩衝液120μLを加え，この液にR２金コロイド液48μLを加えます。
(2) R2金コロイド液の添加後，所定の温度で，反応開始約1分後と約7分後に主波長500～600nm，副波長650～750nmでの吸光度を測定し，2点間の吸光度変化量を求めます。（全自動便尿分析装置 AA01で測定する場合は，別途お問い合わせ下さい）
(3) ネスコート Tf オート 標準（弊社取扱い）を試料と同様に操作し，標準曲線を作成します。これと試料の吸光度変化量を比較して試料中のヒトトランスフェリン濃度を算出します。

【測定結果の判定法】
参考正常値：50ng/mL（10μg/g便に相当）未満（社内データ）

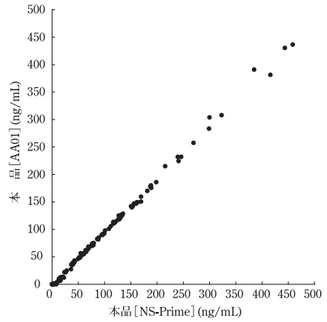
【性　　能】
1. 感　　度：トランスフェリン濃度0ng/mLの吸光度変化量と50ng/mLの吸光度変化量の差は，0.05以上
2. 正 確 性：既知濃度の管理用試料を測定する場合，既知濃度の100±15%の範囲内
3. 再現性（同時）：n=5　C.V.=15%以下
4. 測定範囲
1）上限：500ng/mL（100μg/g 便に相当）
2）下限 定量限界：20ng/mL（4μg/g 便に相当）
検出限界：5ng/mL（1μg/g 便に相当）
5. 相 関 性：
本品（y）と弊社製造「ネスコート トランスフェリン Plus」（x）との相関
例　　数：n=120
相関係数：r=0.999
回 帰 式：y=0.999x−1.9



本品（y）と対照品（ラテックス凝集法）（x）との相関
例　　数：n=119
相関係数：r=0.999
回 帰 式：y=0.982x+1.7



本品［AA01］（y）と本品［NS-Prime］（x）との相関
例　　数：n=107
相関係数：r=0.998
回 帰 式：y=0.966x−2.6



6. 較正用基準物質
ヒトトランスフェリン

【使用上又は取扱い上の注意】
1. 検体及び試料中にはHBV，HCV，HIV，細菌等の病原体が存在する可能性がありますので，感染予防のため取扱いに注意して下さい。また，検体及び試料に接触した器具，試薬及び試薬容器等は感染の危険性があるものとして廃棄物処理法等に従い適切な処理を実施して下さい。
2. 試薬は貯蔵方法に従って保存し，使用期限を過ぎたものは使用しないで下さい。
3. 標準及び検体希釈液は，指定の製品を使用して下さい。他の製品を使用した場合，測定値に影響を及ぼします。
4. R２金コロイド液は保存中，金コロイドが沈殿することがありますので，必ずよく転倒混和した後に使用して下さい。
5. 試薬容器等は当検査以外の目的に転用しないで下さい。
6. R１緩衝液とR２金コロイド液は，必ず同じ製造番号のものを組み合わせて使用して下さい。異なる製造番号の試薬を混合して使用しないで下さい。また，製造番号が同じであっても異なるボトルの試薬どうしを混合しないで下さい。
7. 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。
8. 廃棄上の注意
1）R2金コロイド液には，エチレンジアミン四酢酸二ナトリウム銅（Ⅱ）0.20g/L（銅として27mg/L）を含有しますので，廃液は水質汚濁防止法（銅含有量許容限度：3mg/L）等関連法規に従って処理して下さい。
2）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。
3）試薬及び容器等を廃棄する場合には，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。

【貯蔵方法・有効期間】
1. 貯蔵方法：２～８℃
2. 有効期間：１年
（使用期限は外装等に記載）

【包 装 単 位】
250回（R1緩衝液 2×11mL　R2金コロイド液 2×5mL）

【主 要 文 献】
1. 内田壱夫，他：新しい免疫学的便潜血反応ーヘモグロビン，トランスフェリン同時測定．臨床病理，**37**(1)，58，1989.
2. 三好博文，他：免疫学的便潜血検査における糞便中ヘモグロビン，トランスフェリン同時測定の有用性．日消集検誌，**83**(6)，97，1989.

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