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alfresa

FIT Hemoglobin NS-Prime Calibrator

Product list

Catalogue No.	Product name
910870	FIT Hemoglobin NS-Prime Calibrator

*Note : **FIT Hemoglobin NS-Prime Calibrator** can be used with both **Discrete Clinical Chemistry Analyzer NS-Prime** and **AA01**.*

Manufactured by:

Alfresa Pharma Corporation
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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 2797

FOR *IN VITRO* DIAGNOSTIC USE ONLY

1.0 INTENDED USE
FIT Hemoglobin NS-Prime Calibrator is a calibrator to construct a calibration curve on **Discrete Clinical Chemistry Analyzer NS-Prime** and **AA01**. Specimen hemoglobin concentration is determined using the calibration curve.

2.0 PRINCIPLE OF THE EXAMINATION METHOD
Fecal immunochemical test (FIT) is used to diagnose hemorrhagic gastrointestinal diseases. FIT is particularly useful for colorectal cancer screening. **FIT Hemoglobin NS-Prime** and **AA01** are kits 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 that takes place due to agglutination between colloidal gold-conjugated rabbit anti-human hemoglobin polyclonal antibodies and fecal human hemoglobin. The color change is ascertained by measuring optical absorption using **Discrete Clinical Chemistry Analyzer NS-Prime** and **AA01**. Human hemoglobin concentrations in feces is calculated with the optical absorption change of specimen and the calibration curve generated from the measured calibrator values.

3.0 TRACEABILITY OF VALUES ASSIGNED TO CALIBRATORS AND TRUENESS-CONTROL MATERIALS
Human hemoglobin is a reference material to calibrate calibrators and controls. The reference value are determined using the ReCCS JCCRM912, which is assigned by the ICSH method.

4.0 COMPONENTS

4.1 FIT Hemoglobin NS-Prime Calibrator
Four Calibrator (lyophilized) vials and one Calibrator Solution bottle are packaged, permitting four times calibration.

4.1.1 Calibrator (lyophilized)
Each vial contains a quantity of lyophilisate to be restored with 1.0 mL of Calibrator Solution. Each vial contains:

MES Buffer	3.2 mg/vial
Sucrose	10 mg/vial
Bovine serum albumin	1.0 mg/vial
Human hemoglobin	1,000-1,400 ng/vial

4.1.2 Calibrator Solution
Calibrator Solution contains 12 mL per bottle. It contains:

MES Buffer	30 mmol/L
Sodium chloride	1.1 %
Bovine serum albumin	0.15 %
Boric acid	0.4 %
Sodium azide	< 0.1 %

Caution: Calibrator Solution contains 0.4 % boric acid and less than 0.1 % sodium azide. For safety precautions, see **8.0 WARNINGS AND PRECAUTIONS**. Safety Data Sheet is available upon request by users.
Hazard statements:

- May damage fertility
- May damage unborn child

5.0 ADDITIONAL REQUIRED EQUIPMENT

5.1 Analyzer
Discrete Clinical Chemistry Analyzer NS-Prime
Discrete Clinical Chemistry Analyzer AA01
*Note : **FIT Hemoglobin NS-Prime Calibrator** can be used with both **Discrete Clinical Chemistry Analyzer NS-Prime** and **AA01**.*

5.2 Reagent
FIT Hemoglobin NS-Prime
FIT Hemoglobin AA01

5.3 Control
FIT NS-Prime Control
FIT Hb/Tf Liquid Control

5.4 Wash Solution
Wash Solution A

5.5 Others
Sample cup
Pipette

6.0 REAGENT PREPARATION
1. Allow Calibrator(lyophilized) and Calibrator Solution to equilibrate to room temperature.
2. Add 1.0 mL of Calibrator Solution into Calibrator to reconstitute Calibrator.
3. Mix well by gentle inversion.

7.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

7.1 Storage and shelf life
Do not freeze reagents. The shelf life of unopened **FIT Hemoglobin NS-Prime Calibrator** at 2−8 ˚C is 18 months: see the expiry date on the box and vial/bottle label.

7.2 Storage and shelf life after first opening
Once opened and reconstituted Calibrator with the Calibrator Solution, use by the same day. After use Calibrator Solution, keep it the lid on and refrigerate at 2−8 ˚C for storage.

8.0 WARNINGS AND PRECAUTIONS

8.1 General precautions
For *In vitro* diagnostic use
Procedures should only be undertaken by experienced laboratory personnel; tests should be conducted in a manner consistent with Good Clinical Laboratory Practice. If you become aware of a serious incident related to this product, be sure to report it to the manufacturer and the competent authorities. The summary of safety and performance is available via european database on medical devices(EUDAMED).

8.2 Safety precautions
1. Do not pipet by mouth.
2. Calibrator Solution contains 0.4 % boric acid. Reproductive toxicity: May damage fertility or the unborn child. Obtain special instructions before use. If exposed or concerned: Get medical advice/attention.
3. Calibrator Solution contains less than 0.1 % sodium azide. In case of accidental ingestion or exposure to eyes or skin, take emergency measures such as washing with plenty of water. Consult a doctor if necessary.
4. Do not smoke, eat, or apply cosmetics in areas where patients' specimens or kit reagents are handled.
5. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
6. Take care to avoid self-inoculation, splashing to the mucous membrane, or generation of aerosols.
7. Wear laboratory gloves while handling patients' specimens or disposing of solid or liquid waste.
8. Cautions upon disposal
   1) Calibrator Solution contains less than 0.1 % sodium azide. Sodium azide may react with heavy metal such as copper, plumbum and lead to form explosive metal azides. Regulations currently in use regarding dangerous waste elimination must be followed. When disposing of reagents in the sink, rinse with plenty of water.
   2) Upon disposal of reagents or other materials, comply with relevant legal provisions.
   3) Calibrator Solution contains 0.4 % boric acid. Upon disposal comply with relevant legal provisions.
9. **FIT Hemoglobin NS-Prime Calibrator** contains bovine serum albumin free from known infectious agents. However they should be considered potentially infectious and handled with care to avoid infection.
10. 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.
11. **FIT Hemoglobin NS-Prime Calibrator** contains raw materials of human origin. The raw materials are from human blood that has been tested and found to be negative for HBVs antigen, HCV antibody, HIV antibody, HIV RNA, HCV RNA, and syphilis. However, handle them with care as they are potentially infectious. No known test method can offer complete assurance that products derived from human sources will not transmit infectious agents.

8.3 Limitations
1. Do not use reagent vial/bottle for purposes other than those stated.
2. Do not damage or stain the bar codes on vial labels.
3. Do not replenish or mix reagents. Also, do not mix reagents of different vials/bottles even if they have the same lot number.
4. Do not use combinations of products with different lot numbers.
5. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
6. Reconstitute the calibrator with the calibrator solution supplied. Do not use other solution.
7. Do not recycle vial/bottle. They may be infectious.

9.0 EXAMINATION PROCEDURE
FIT Hemoglobin NS-Prime Calibrator is used to construct a calibration curve. Set Calibrator and Calibrator Solution on the analyzer according to the analyzer manual. Calibration curve (7 points) is created on the analyzer automatically. A new calibration must be performed for each new reagent lot. Otherwise, calibration should be performed in the following cases:
1) Every 30 days, and/or.
2) When abnormality occurs in daily quality control.

10.0 CONTROL PROCEDURE
It is recommended to use **FIT NS-Prime Control** or **FIT Hb/Tf Liquid Control** as quality control materials. The values obtained for the quality control materials should not fall repeatedly outside the acceptable ranges. If these control values fall repeatedly outside of the established control ranges, then proper instrument performance should be verified, or recalibration should be performed.

11.0 CALCULATION OF EXAMINATION RESULTS
Specimen values are calculated and constructed a calibration curve by the **Discrete Clinical Chemistry Analyzer NS-Prime** or **AA01**.

12.0 LIMITATION OF THE EXAMINATION PROCEDURE
1. Because blood contamination may affect measurements, all cuts, abrasions, wounds and other skin lesions should be completely covered by suitable protections like waterproof dressings or gloves.
2. Appearance changes, such as cloudiness and aggregation, in any of the reagents indicate the possibility of deterioration. Call your local distributor for advice.
3. Procedural directions must be followed exactly because any modification of the procedure may change the results. Read the instrument instruction manual and use it according to the described usage and operating environment.
4. Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
5. Store the reagents according to the storage methods. Do not use them after the expiry date.

13.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

Symbols	Meanings of the symbols
CE	CE marking
	Use-by date (Expiry date)
LOT	Batch code
REF	Catalogue number
	Manufacturer
EC REP	Authorized representative in the European Community (Authorized European representative)
IVD	*In vitro* diagnostic medical device (*In vitro* diagnostic)
	Temperature limit (for store)
	Consult instructions for use
	Caution: Products containing hazardous substances
	May damage fertility May damage unborn child

14.0 INFORMATION ON PACKAGING MATERIALS
The following materials are used in the packaging of **FIT Hemoglobin NS-Prime Calibrator** (accordance with Directive 94/62/EC on packaging and packaging waste).

Product box	
Outer box PAP 21	Outer box label PP 5

Others
Instructions for use PAP 22