

11.0 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 the assay recalibrated.

12.0 CALCULATION OF EXAMINATION RESULTS

Specimen values are calculated by the Discrete Clinical Chemistry Analyzer NS-Prime.

13.0 INTERPRETATION OF RESULTS

The cut-off value widely used in Japan for mass-screening is less than 100 ng/mL (equivalent to 20 µg of human hemoglobin per 1 g of feces). Colorectal cancer is suspected if human hemoglobin 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.

14.0 PERFORMANCE CHARACTERISTICS

The following performance data was obtained using the Discrete Clinical Chemistry Analyzer NS-Prime.

14.1 Analytical performance characteristics

14.1.1 Precision

Within-run precision: n = 5, CV ≤ 15%

14.1.2 Interference

Some studies have been conducted to determine the levels of interference. The levels of interference due to interfering substances were in the range of 90–110% 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 hemoglobin in animal species other than humans (bovine, swine, equine, ovine, caprine, and leporine) were 0.2–3.5% at concentrations of 0–2,000 ng/mL.

14.1.3 Correlation

FIT Hemoglobin NS-Prime assay was compared with the reference method on 95 specimens. The specimen concentrations were between 0 and 1,200 ng/mL. A linear regression analysis was performed and the following results were obtained:

x : FIT Hemoglobin NS-Prime

y : Reference method

r = 0.993

y = 1.003x – 3.812

14.2 Diagnostic performance characteristics

14.2.1 Analytical sensitivity

The difference in the amounts of change in absorbance between hemoglobin concentrations of 0 and 100 ng/mL is 0.05 or above.

14.2.2 Analytical specificity

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

14.3 Measuring interval

14.3.1 Assay range

1) Upper limit: 1,200 ng/mL (equivalent to 240 µg human hemoglobin per 1 g of feces)

2) Lower limit

limit of quantitation: 50 ng/mL (equivalent to 10 µg human hemoglobin per 1 g of feces)

limit of detection: 20 ng/mL (equivalent to 4 µg human hemoglobin per 1 g of feces)

15.0 LIMITATION OF THE EXAMINATION PROCEDURE

- Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing, because blood contamination may influence measurements.
- Appearance changes, such as cloudiness and aggregation, in any of the reagents indicate the possibility of deterioration. Call your local dealer for advice.
- Mix the Reagent 1-Reagent 2 combined bottle thoroughly before each use, because colloidal gold particles may precipitate during storage. Mix it by slowly inverting to avoid creating bubbles. If bubbles form, the instrument sensor cannot detect the liquid surface correctly and misunderstands as if the reagent volume increased (reagent from another bottle was added). As the result, the bottle will be deleted from the system. Pipette out any bubbles down to the level of the liquid.
- As with all assays, the results of this test can be influenced by factors present in some patients' specimens.
- 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.
- Procedural directions must be followed exactly because any modification of the procedure may change the results.









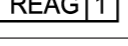
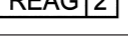
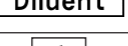


- Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.
- Store the reagents according to the storage methods. Do not use them after the expiration date.
- Use fresh feces.
- This test should not be used to analyze specimens taken from a patient who is menstruating or who has hemorrhoids.

16.0 LITERATURE REFERENCES

This reagent is used for NS-Prime developed as a successor to fecal occult blood measuring device NS-Plus, which is evaluated in the following literatures:

- 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]
- Yasuhiro Oono et al., A retrospective study of immunochemical fecal occult blood testing for colorectal cancer detection, Clinica Chimica Acta, 411 p802–805, 2010.
- Jeong Hyun Kim et al., Evaluation of Hemo Techt NS-plus C15 Automatic Analyzer for Fecal Occult Blood Test, Journal of Laboratory Medicine and Quality Assurance, 32, p237–241, 2010. [Korean]
- Edward Randell et al., Evaluation of Hemo Techt NS-Plus system for use in a province-wide colorectal cancer screening program, Clinical Biochemistry, 46(4-5), p365–368, 2013.

17.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

Symbols	Meanings of the symbols
	Expiry date (Used by...)
	Lot number
	Catalogue code
	Manufactured by
	Number of tests
	<i>In vitro</i> diagnostic medical device (<i>In vitro</i> diagnostic use)
	Temperature limitation (store at...)
	See instruction for use
	Reagent 1
	Reagent 2
	Diluent
	Corrosive
	Hazard (See 8.0 WARNINGS AND PRECAUTIONS)

18.0 DATE OF ISSUE OR REVISION

August 1, 2021