

Hemoglobin

Transferrin

Calprotectin



## Simultaneous Multi Assays on NS-Prime<sup>®</sup>

FIT **Hemoglobin**

NS-Prime<sup>®</sup> C €

FIT **Transferrin**

NS-Prime<sup>®</sup> C €

NESCAUTO<sup>®</sup> **Cp Auto** (Cp: Calprotectin)

NS-Prime<sup>®</sup> C €

These assays can be simultaneously performed on NS-Prime<sup>®</sup> using one sample collection device.

NS-Prime<sup>®</sup>  
Discrete Clinical Chemistry Analyzer



**alfresa**

Alfresa Pharma Corporation

	FIT Hemoglobin NS-Prime®	FIT Transferrin NS-Prime®	NECAUTO® Cp Auto
<b>Intended Use</b>	CRC <sup>1</sup> screening	CRC <sup>1</sup> screening	<ul style="list-style-type: none"> <li>Assessment of intestinal mucosal inflammation in IBD<sup>2</sup> patients</li> <li>Differentiation of IBD<sup>2</sup> from IBS<sup>3</sup></li> </ul>
<b>Assay Range</b>	Upper limit: 1200 ng/mL (240 μg/g feces) Lower limit: LOQ 50 ng/mL (10 μg/g feces) LOD 20 ng/mL (4 μg/g feces)	Upper limit: 500 ng/mL (100 μg/g feces) Lower limit: LOQ 20 ng/mL (4 μg/g feces) LOD 5 ng/mL (1 μg/g feces)	Upper limit: 1200 μg/g feces Lower limit: LOQ 40 μg/g feces LOD 35 μg/g feces
<b>Storage</b>	2-8°C	2-8°C	2-8°C
<b>Recommended Cut-off</b>	Less than 100 ng/mL (20 μg/g feces)	Less than 50 ng/mL (10 μg/g feces)	<ul style="list-style-type: none"> <li>Negative IBD: less than 50 μg/g feces</li> <li>Active IBD: more than 118 μg/g feces</li> </ul>

<sup>1</sup>CRC: Colorectal cancer

<sup>2</sup>IBD: Inflammatory Bowel Diseases such as Ulcerative Colitis and Crohn's Disease

<sup>3</sup>IBS: Irritable Bowel Syndrome

Source: Instruction For Use (IFU)

## 1 FIT Hemoglobin NS-Prime®

### 1-1. Reproducibility

Hb Concentration	CV
59 ng/mL	1.4 %
113 ng/mL	1.4 %
252 ng/mL	0.9 %
485 ng/mL	1.8 %

Source: Data on file

### 1-2. Hb stability after feces sampling

After storage of three different concentrations of Hb at 7, 25, or 37 °C for 12 days in buffer of Specimen Collection Container A, a dedicated collection device for NS-Prime®, the residual ratios of Hb were as follows.

	7°C, for 12 days	25°C, for 12 days	37°C, for 12 days
43 ng/mL	> 90%	> 90%	> 80%
170 ng/mL	> 90%	> 90%	> 70%
270 ng/mL	> 90%	> 90%	> 50%

Source: Data on file

Hb residual ratios at -80°C for 14 days in 7 repeats of freeze-thaw were as follows.

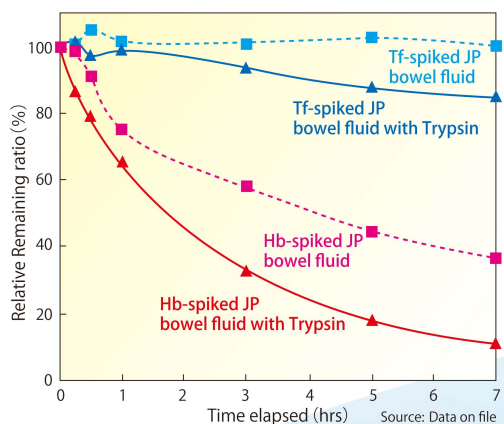
	-80°C, for 14 days, in 7 repeats of freeze-thaw
99 ng/mL	> 90%
150 ng/mL	> 90%
185 ng/mL	> 90%

Source: Data on file

## 2 FIT Transferrin NS-Prime®

### 2-1. Stability of Tf compared to Hb

As shown in the figure below, Tf is more stable than Hb.



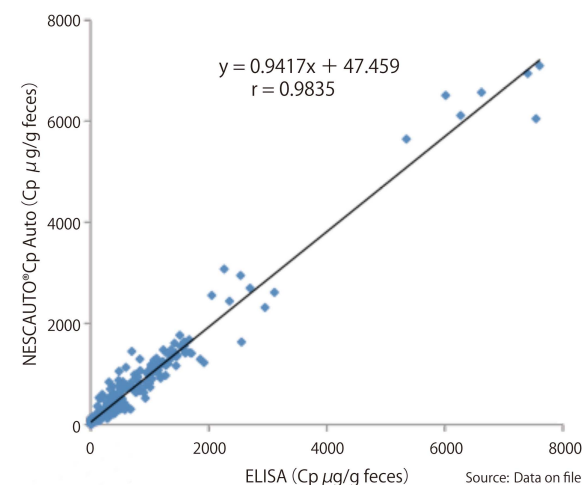
Spike Hb/Tf into Japanese Pharmacopoeia bowel fluid (JP bowel fluid), 50 mM phosphate buffer pH 6.8, with/without 0.01 % of trypsin, then store at 37°C for 7 hours.

### 2-2. Tf test confirms false negative of Hb test.

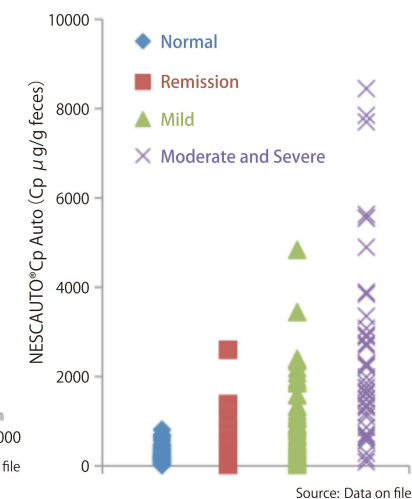
The effectiveness of Hb test is an established medical fact. However, false negative underlain by Hb instability has also been indicated. Although Tf concentration is only one percent of Hb concentration in blood, Tf stability is high and allows physicians to diagnose bleeding accompanied with long retention of feces in bowel such as constipation or bleeding in distal colon.

## 3 NESCAUTO® Cp Auto

### 3-1. Correlation between NS-Prime® and ELISA



### 3-2. Distribution of normal subjects, and remission-, mild-, moderate-, and severe-state patients with IBD.





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NS-Prime® and NESCAUTO® are registered in many countries.