

HM-JACK

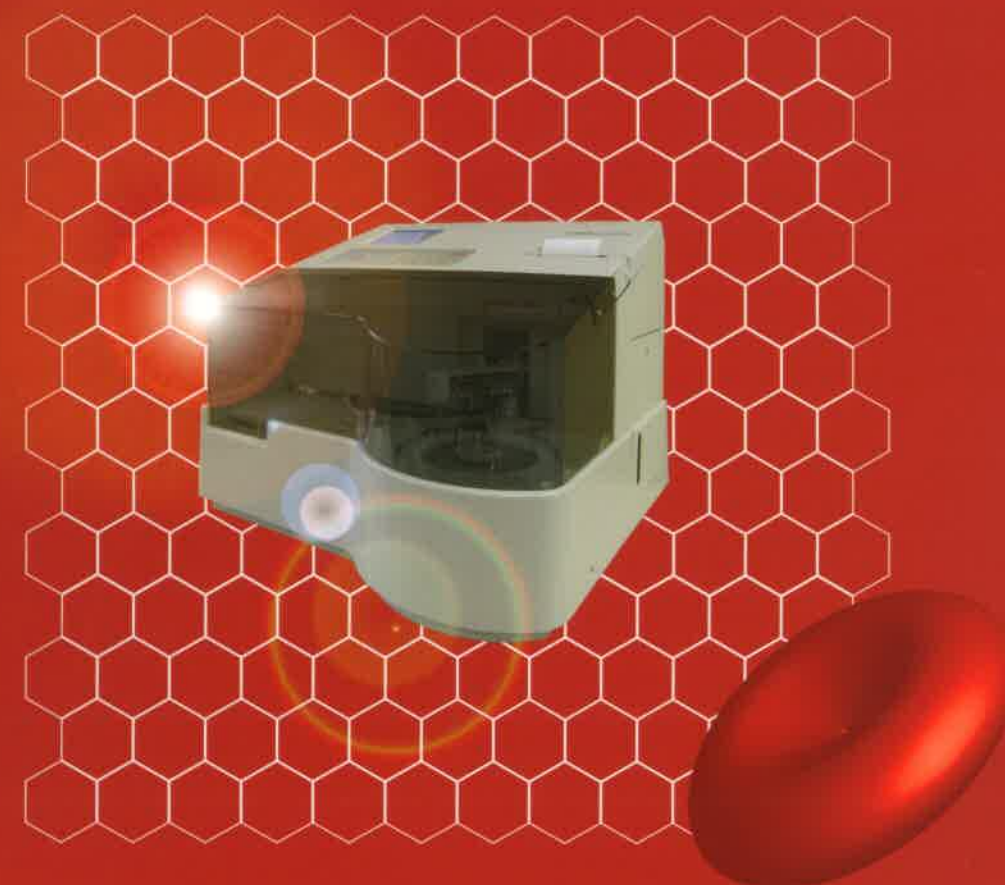
FECAL OCCULT BLOOD TEST ANALYZER



Kyowa Medex Co.,Ltd.

New HM-JACK

HM-JACK, with our extensive experience in FOB testing, will promise –
Bringing Accuracy, Secure, and Reliability to your FOB testing



HM-JACK is the Fully Automated Fecal Occult Blood Analyzer with integrated spherical nephelometry system, utilizing latex-agglutination method.

The superiority in the stability of human hemoglobin and combination in use of its exclusive reagents (HEMO·AUTO) and consumables provide highly sensitive and reliable results with broad measurement range (17.5 – 2,000 $\mu\text{g/g}$ feces).

Also, there is no influence from Prozone within the measurement range, contributing to reduction of False Negative results.

Also, user-friendly feature, Sample barcode, 2-point calibration of Master Curve, Easy operation and more, will help your FOB screening test.

HM-JACK, fully automated analyzer, is reliable and superior system for screening test for colon cancer today.

High performance and fully automated functions (Easy operation for colon cancer screening test)

HM-JACK employs latex-agglutination method possessing speedy and superior measurement sensitivity. Maximum 80 samples can be loaded on Sample Table, and new Reaction Cell will be supplied automatically. Furthermore, internal Barcode Reader for Sample and external Barcode Reader for Master Curve/Calibrator are available.

4. Use MENU function (STAND BY, WASH, etc) and start the measurement



The reaction cells are automatically discharged.



5. Dispense Reagent/Buffer to Reaction Cell



6. Dispense Calibrator/Control/ Sample to Reaction Cell



7. Stir and incubate reaction mixture



8. Detect IST (Integrating Sphere Turbidity) value at scheduled points and calculate concentration

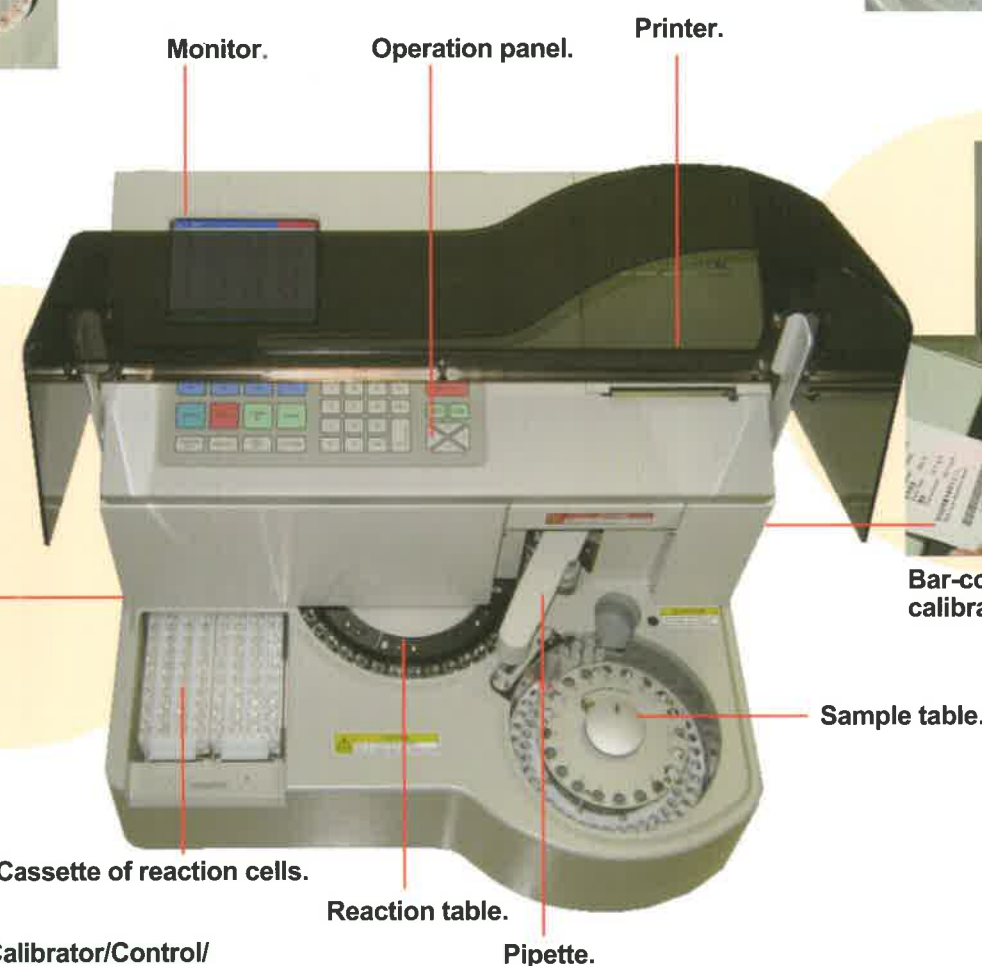
1. Set Reagent Bottle (18mL)



2. Set Cell Cassette (40X2)



3. Set Calibrator/Control/Sample



Bar-code input system for calibration curve is available.

Figure of calibration curve.

9. Printout/Send results



Specifications

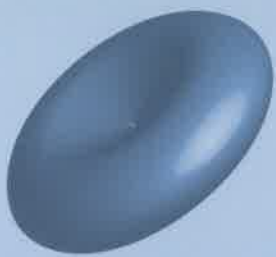
Analysis method	Latex agglutination method
Principles of measurement	Integrated spherical nephelometry determination
Through put	180samples/hour
Items of simultaneous measurement	One item
Volume of test sample	10 ~ 20 μ L
Volume of reagent	Latex:20 ~ 100 μ L Buffer solution:50 ~ 300 μ L
Total volume	300 μ L
Sample table	80test sample (Inside:40 Outside:40)
Test sample tube	Exclusive feces pickers
Pipette for test sample	Direct insertion into feces pickers
Pipette for reagents	Pressed off nozzle system with buffer solution
Reaction table	Capacity for reaction cells placed:40cells
Reaction time	4.5minutes
Supply of reaction cells	Automatic supply and discharge
Total number of reaction cells	80cells (two cassettes with 40reaction cells each)
Reaction temperature	Room temperature
Light source	Halogen lamp 5V 9W
Detector	Silicon photodiode
Calibration of concentration	Seven-point calibration curve. Three-dimensional formula
Calibration curve	Master-curve system, tow-point correction
Monitor	Liquid-crystal monitor with back-light view
Printer	36-figures thermal printer
Power supply	AC100V or AC220V
Power consumption	300VA
Sizes	H500×W550×D500
Weight	45kg
External output	RS232C

There is a case to change specification without a notice for improvement.

Kyowa Medex Co.,Ltd.

Head Office
Harumi Triton Square X-4F.1-8-10,Harumi,Chuo-ku,Tokyo
104-6004,Japan
TEL. +81-3-6219-7605
FAX. +81-3-6219-7614

Fuji Plant
600-1 Minami-ishiki,Nagaizumi-cho, Sunto-gun,Shizuoka
411-0932,Japan
TEL. +81-559-88-6000
FAX. +81-559-88-6005

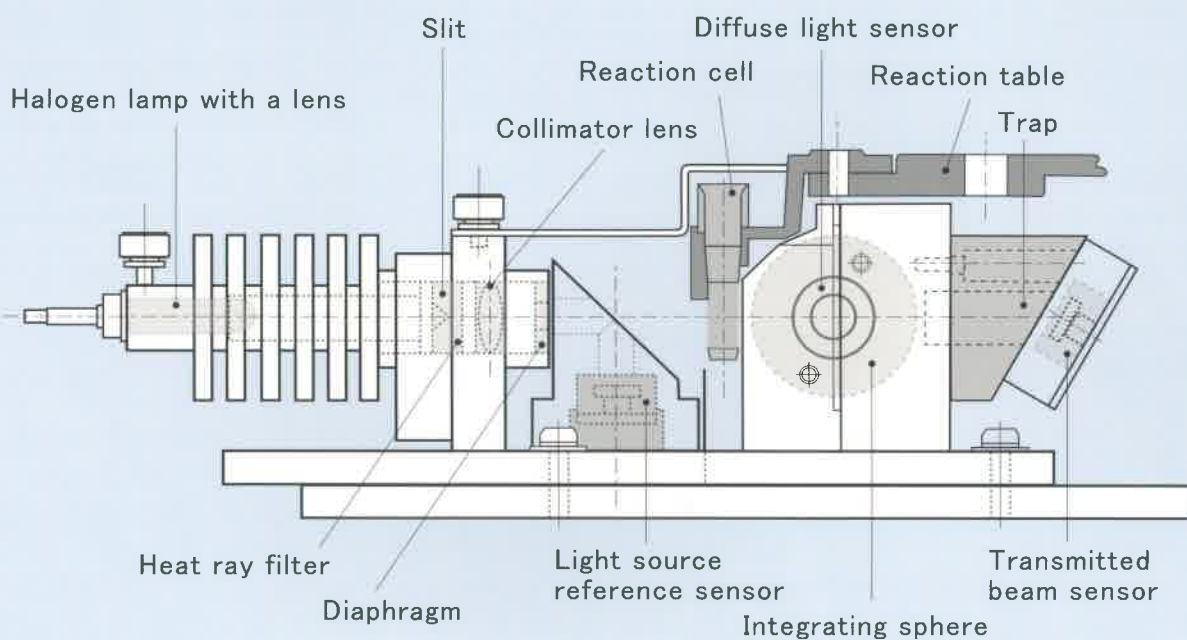


HM-JACK

Features

- 1 Combination of exclusive reagent EXTEL "HEMO·AUTO" and EXTEL "HEMO·AUTO" feces pickers excellent in maintaining activity of human hemoglobin allows clean and fully automatic fecal occult blood tests with simple operation.
- 2 With higher sample throughput (180 samples/hour), it takes only 4.5 minutes to complete steps from collection of samples up to printing out the results.
- 3 Adopting a master curve method for preparation of the calibration curve, the calibration is simply completed with two standards at different concentrations (two-point correction). Therefore, the dilution is unnecessary.
- 4 The exclusive feces picker can be set on the sample table as it is, without removing the cap. A piercing method is adopted for sample collection.
- 5 Pipetting allows high precision sample dispensing.
- 6 The one-day method and the two-day method are available.

Measurement principle



Reaction of human hemoglobin antigen in a sample with human hemoglobin antibody-sensitized latex may cause antigen-antibody reaction leading to agglutination. The intensity of diffuse light and transmitted light emitted during the agglutination reaction is detected with the integrating sphere nephelometer, and then the integrating sphere nephelometry is derived from the variation ratio (intensity of diffuse light/intensity of transmitted light). The hemoglobin concentration in the sample will be calculated from the multipoint calibration curve prepared from solutions with predetermined concentration.



Exclusive Reagent for Fully Automated Fecal Human Hemoglobin Analyzer
HM-JACK

EXTEL HEMO·AUTO

Features

- 1 Highly sensitive and quick quantification of human hemoglobin in feces
- 2 Broad measurement range of 7-800 ng/mL (17.5-2000 μ g/g feces)
- 3 Adopting a master curve method in preparation of the calibration curve, the calibration is simply completed with two standards at different concentrations (two-point calibration). Therefore, the dilution is unnecessary.
- 4 No false negative due to influence of prozone
- 5 Excellent specificity saves dietary restriction before examination.

Intended use

Measurement of hemoglobin in feces

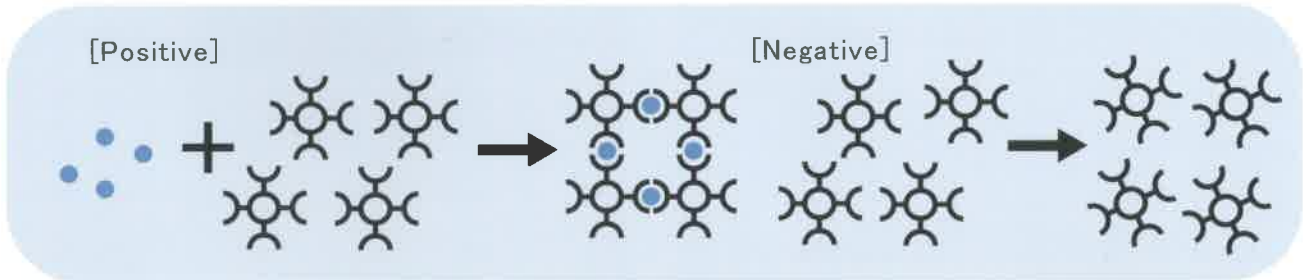
Constitution

Reagents	Volume	Ingredients	Content
Antibody-sensitized latex suspension	18 mL \times 2	Anti-human hemoglobin antibody-sensitized latex	2 mg/mL
Buffer solution for hemoglobin	250 mL	Buffer substances	

* A master curve card is attached to the antibody-sensitized latex suspension.
* All the reagents are optional. For standard, use the hemoglobin standard (optional) for fecal occult blood measurement.

Measurement principle

- Human hemoglobin \times Anti-human hemoglobin AO antibody-sensitized latex particles



Human hemoglobin in feces may cause antigen-antibody reaction with anti-human hemoglobin AO antibody-sensitized latex, leading to nephelometry change. Since the nephelometry change is proportional to the hemoglobin concentration in the sample, the hemoglobin concentration is determined by optically measuring this change with an exclusive automated analyzer.

Measuring method

Preparation of reagent

- 1 **Antibody-sensitized latex suspension**
Let the antibody-sensitized latex suspension stand at 15-25°C, and use it without dilution. Just before use, repeatedly invert the bottle to mix until the latex particles are fully suspended. Immediately after use, store the suspension at 2-8°C.
- 2 **Buffer solution for hemoglobin**
Let the buffer solution for hemoglobin stand at 15-25°C, and use it without dilution. Immediately after use, store the buffer solution at 2-8°C.

Preparation of samples

Carry out fecal collection by following the instructions attached to the feces picker. Let the feces picker stand at 15-25°C before use.

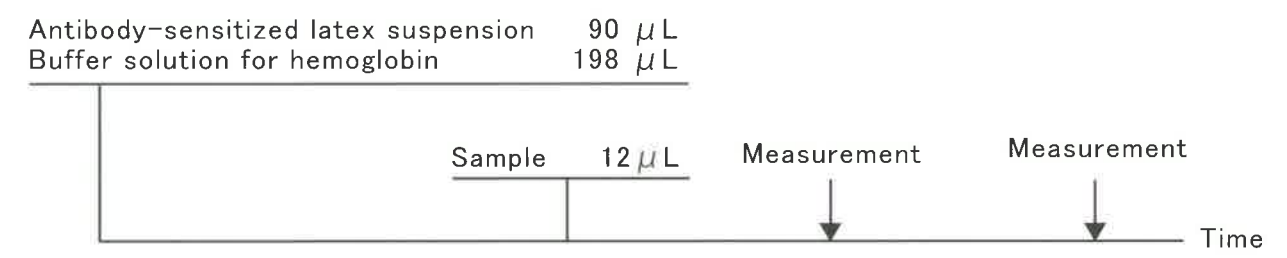
Preparation of a calibration curve

- 1 For every lot change of the EXTEL "HEMO·AUTO" antibody-sensitized latex suspension, input a master curve by using a master curve card attached to the kit.
- 2 Calibrate the master curve using a standard at every lot change of the EXTEL "HEMO·AUTO" antibody-sensitized latex suspension and at least once every two days. For standard, use the hemoglobin standard for fecal occult blood measurement.

Procedures

- 1 Input a measurement menu into the fully automated fecal human hemoglobin analyzer.
- 2 Set the sample on the sample table and the reagent at designated position.
Note: Set the feces picker upside down without any other changes.
- 3 Press the start key. All steps from collection of samples up to processing of measurement data will be carried out automatically (See page 1-2 for details).

[Standard procedure]



Precautions for operation

Collection method of samples

- Use EXTEL "HEMO·AUTO" feces picker.
- Use fresh feces.
- Perform a test immediately after collection of samples.
- Store in a cool and dark place (in refrigerator at 10°C or lower) by necessity in storage.
- If feces are too hard, moisten before collection.

Interfering substance

- Hardly reacts with animal-derived hemoglobin contained in our diet.
- Free from influences by foods containing peroxidase-like activity or reducing materials such as ascorbic acid.

Others

- Just before use of the antibody-sensitized latex suspension, repeatedly invert the bottle to mix until the latex particles are fully suspended.
- Before placing the feces picker on the analyzer, shake it vertically until the feces are fully suspended.

Evaluation of results

- 1 It is recommended to set criteria for evaluating the measurement results at each facility.
- 2 When making a clinical diagnosis, a doctor should take clinical symptoms and other test results into consideration besides the measurement results obtained with this kit.
- 3 Reference criteria 30 $\mu\text{g/g}$ feces (12 ng/mL) or lower

Performance

The results of our tests for sensitivity, specificity, reproducibility and measurement range conducted according to the applicable procedures were as follows.

1 Sensitivity test

- Turbidity change in a blank (purified water) was 100 or less.
- Difference in turbidity changes between the hemoglobin 10 ng/mL standard solution and the blank was 80–450.

2 Specificity test

When using the sample with predetermined concentration, measured concentrations stayed within $\pm 15\%$ of the predetermined concentration.

- 3 Repeatability test
One sample was repeatedly measured 10 times, and the CV of the measured values was 15% or less.
- 4 Measurement range
7–800 ng/mL (17.5–2000 $\mu\text{g/g}$ feces)

Precautions for use

- 1 Use EXTEL "HEMO·AUTO" in combination with the exclusive feces picker.
- 2 Be sufficiently careful to prevent infection by wearing gloves or the like, since there is a risk of infection by HBV, HCV, HIV or bacteria when handling feces.
- 3 All constitution reagents contain sodium azide as an antiseptic agent, which may react with lead to produce explosive lead azide. Dilute it with a large quantity of water before disposal.
- 4 Store the antibody-sensitized latex suspension at 2–8°C. Do not freeze it for any purpose.
- 5 Store the reagents with the lid closed under the specified storage condition. Do not use the expired reagent.
- 6 Do not use the antibody-sensitized latex suspension left open for 20 hours in total or longer at 20–30°C or the buffer solution for hemoglobin left open for one week in total or longer at 20–30°C. They may involve an impact on measurement due to concentration.
- 7 Do not mix different lots of the antibody-sensitized latex suspension in the middle of examination. Do not replenish the reagent.
- 8 Samples, test tubes and other devices should be disposed in one of following procedures. In other cases, follow the disposal procedures of the infectious medical waste of your facility.
 - Autoclave for 15 minutes or longer at 121°C. Waste containing sodium hypochlorite solution should not be autoclaved.
 - Soak in a sodium hypochlorite solution (effective chlorine concentration: 1000 ppm or higher) for 1 hour or longer.
 - Burnable waste may be incinerated.
- 9 Use the cells and accessories of the kit for intended purpose only.

Storage condition and shelf-life

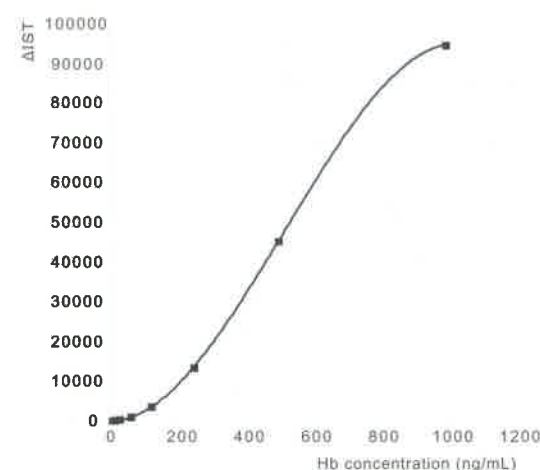
Storage condition: Store in a cool and dark place at 2–8°C. Do not freeze for any purpose.
Shelf-life: One year after manufacturing (indicated on the label and the case)

Main references

- Masahiro Tada, et al.; Japanese Journal of Clinically Pathology, 751, 36, 1988
- Takeshi Fujiyoshi, et al.; Journal of Gastroenterological Mass Survey, 138, 95, 1992
- Keiichi Hojo; Journal of Medical Technology, 495, 3, 1992
- Company data

Reference data

Measurement range (master curve)



Repeatability

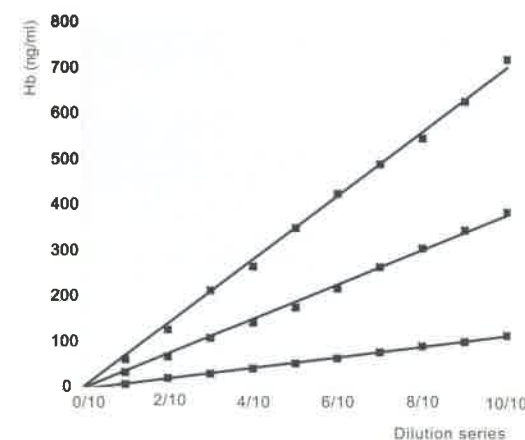
Pooled feces were used as a sample.

No.	Sample 1	Sample 2	Sample 3	Sample 4
1	20.5	39.3	115.0	375.2
2	20.5	40.8	113.0	368.4
3	19.1	42.2	113.7	377.7
4	21.4	41.1	110.7	390.2
5	19.4	43.4	111.5	387.9
6	20.5	38.9	115.6	370.1
7	19.6	40.3	113.5	374.9
8	19.5	42.5	110.9	388.9
9	21.0	39.3	115.8	390.8
10	18.5	38.2	114.1	388.9
n	10	10	10	10
Mean	20.0	40.6	113.4	381.3
SD	0.87	1.63	1.76	8.44
CV (%)	4.34	4.00	1.55	2.21

Unit: ng/mL

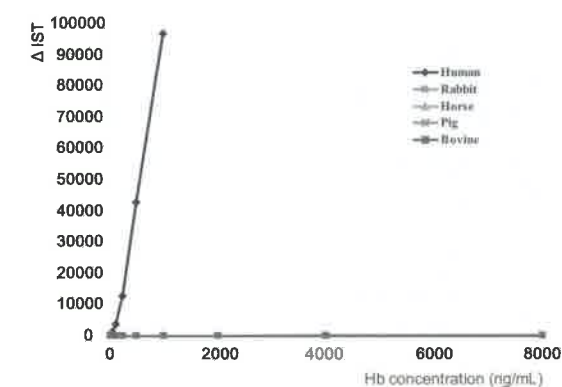
Dilution linearity

Hemoglobin standard was used.



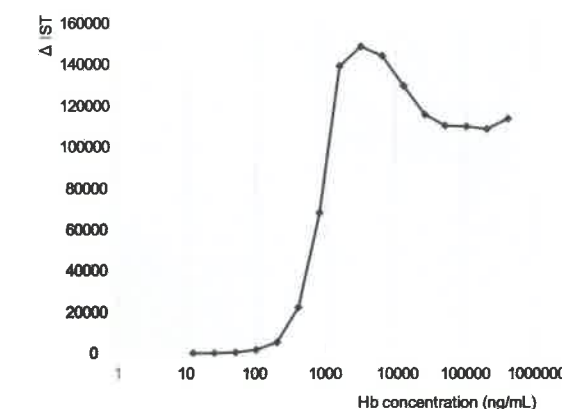
Cross-reactivity

Results of tests in rabbits, horses, pigs and bovines at concentrations up to 800 ng/mL, measurements were below the minimum detection limit.

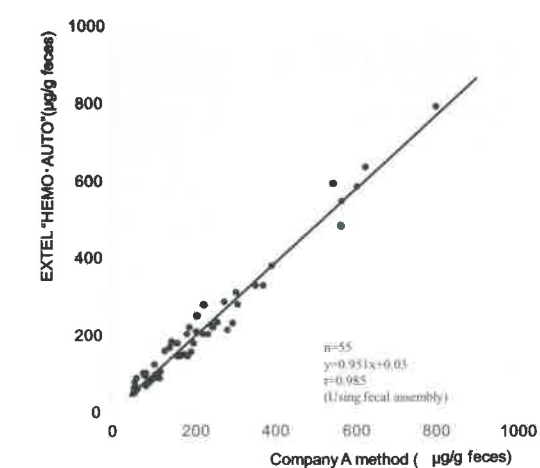


Prozone

Even when the hemoglobin concentration is 410 $\mu\text{g/mL}$ (it is 400 $\mu\text{g/mL}$ if the whole feces is hemoglobin), over-range measurement was achieved at or higher than the upper quantification limit, 1000 ng/mL.



Correlation





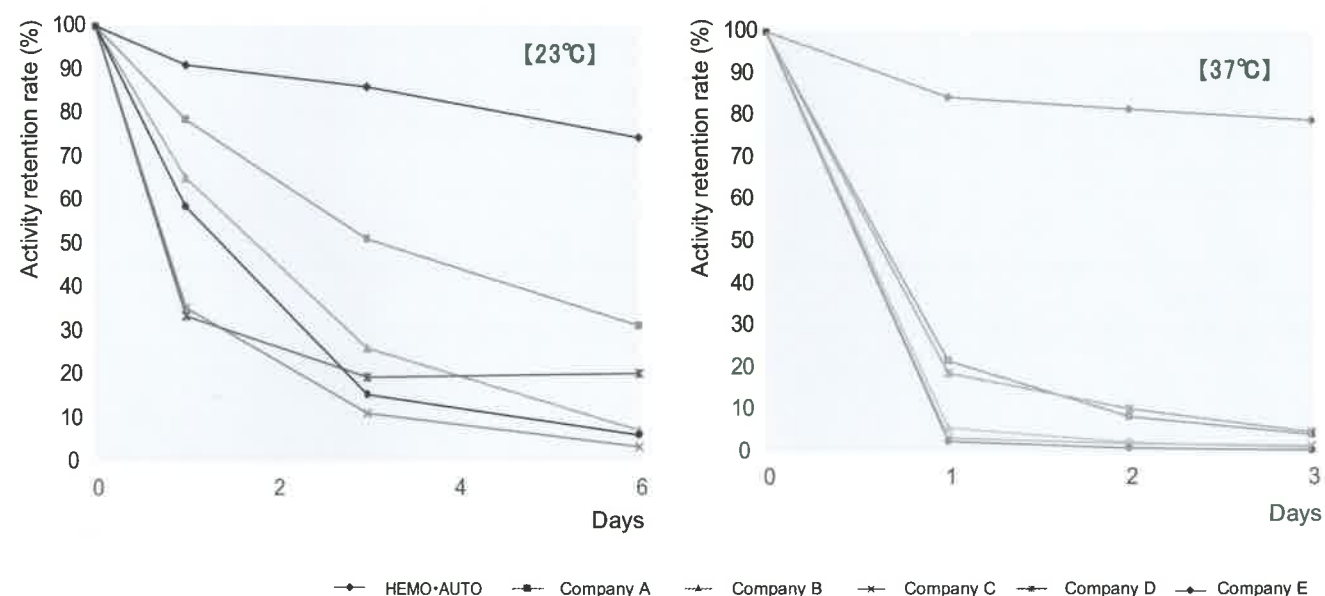
EXTAL HEMO-AUTO Feces Picker

Features

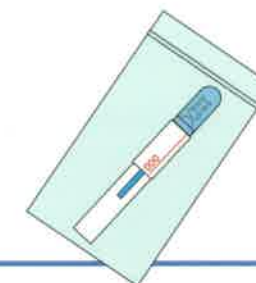
- 1 Excellent in maintaining activity of fecal human hemoglobin and provides reliable data. It is also excellent in performance under a high temperature condition, maintaining the sample activity during mailing.
- 2 Scrubbing method without requirement to wipe feces.
- 3 A groove structure and a separator provide accurate collection of feces.
- 4 With small quantity of feces as 0.5mg in requirement, the odor and visual displeasure should be reduced.
- 5 It can be set in the fully automated fecal human hemoglobin analyzer HM-JACK without removing the cap.

Reference data

Stability of hemoglobin after collection of feces



Procedure of Collecting feces



Be sure to read the following notes for the correct examination.

- As reliable results will be obtained from fresh samples, attempt to collect the feces on the day of submitting the sample.
- The feces picker containing feces sample should be stored at dark-cold place. (not higher than 10°C, in a refrigerator)

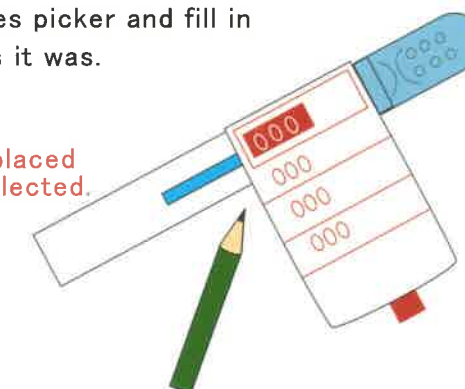
Preparation

Partially peel and unroll the label attached to the feces picker and fill in the date and name on it. Then, re-roll up the label as it was.



*Bathroom tissues should be placed in a bowl which feces are collected.

Bathroom tissues



Procedure of collecting feces

1. Turn over the light-blue cap to pull out.
2. Scrub the surface of stool with the groove of the feces picking stick.
 - *The groove is filled with feces.
3. Push it completely one time only. Never open again.

Precautions for storage

The feces picker containing feces sample should be stored at dark-cold place. (Upon the submission of two-day samples)
On the previous day of submitting the samples, collect feces sample with the first picker (feces picker with red label) and store it under the above conditions. On the day of submitting the samples, collect feces sample with the second picker (feces picker with blue label) and then submit them.

