



ENGLISH

**Revised in May 2022 (Revision.03)
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Fecal sampling device

EXTEL HEMO • AUTO MC Collection Picker

For Professional Use only

[INTENDED USE]

EXTEL HEMO • AUTO MC Collection Picker is the fecal sampling and storing device used with fully automated immunoassay analyzer HM-JACK series.**

[MATERIAL PROVIDED]

Code	Product Name	Component	Quantity
63927	EXTEL HEMO • AUTO MC Collection Picker	Sample collection picker	400 pcs

[COMPOSITION]**

The buffer solution contains N-(2-Acetamido)iminodiacetic acid (30 mM or less)

[STORAGE AND SHELF LIFE]

Shelf life: 24 months

Storage: 2-30°C

[STORAGE AFTER SAMPLING]

The storage condition of individual collection device is recommended at 2-8°C and in the dark place after the sampling for the accuracy of analysis.

[COLLECTION PROCEDURE]

Refer to the instruction provided by the local healthcare provider in detail.

1. Remove picker part from main unit by twisting (loosing) and pulling gently.
2. Scratch the surface of stool with picker part several times and fill the two dimples with stool.
3. Carefully insert the picker with sample into main unit and twist to close securely.
4. Invert the collection picker 10 times or more.
5. Store sampled device in dark and cool place if necessary prior to analysis.
6. Mix and homogenize the content before the assay.
7. Follow the instruction for use for other parts of analysis.

[PRECAUTIONS FOR USE & RECOMMENDATIONS]














- Avoid the contact with blood and use of stool during the menstruation.
- Collect from fresh stool. DO NOT use the old stool (i.e. stool from yesterday) for accurate result.
- Shorten the time between collection and measurement as minimum as possible.
- This product is specially designed for use with fully automated immunoassay analyzer HM-JACK series. DO NOT use with any other analyzers.**
- DO NOT use if there is damage or leakage observed.
- DO NOT repeat the collection procedure.
- DO NOT use the device that have expired its shelf life.**
- DO NOT use the device for any other purpose.
- Be sure to wear protective equipment when handling the device. Treat as medical waste and dispose them in accordance with local regulation.**
- The device contains sodium azide (0.1% or less). When it has entered the eye or mouth or contacted the skin by accident, be sure to take the necessary emergency measures by rinsing with copious running water. If necessary, seek medical treatment and consult a physician.**
- Prevent the buffer solution containing sodium azide from contacting with lead. They react vehemently with formation of highly explosive metal azide.**

[STABILITY AFTER SAMPLING]**

To demonstrate the storage performance of the device, specimen stability was evaluated using fecal occult blood test. In our performance evaluation study, recovery rate (vs initial dose) of hemoglobin in samples were 77-173% for 120 days at the storage of 2-8°C and 43-124% for 32 days at the storage of 25°C. However, since analyte such as hemoglobin in some feces samples may degrade rapidly due to physiological diversity in each patient, it is recommended to analyze samples as soon as possible.

		2-8°C		25°C	
		for 32 days	for 120 days	for 7 days	for 32 days
Recovery rate (vs initial dose)	Max	151%	173%	116%	124%
	3rd quartile	103%	105%	106%	112%
	Median	97%	101%	102%	105%
	1st quartile	92%	89%	91%	80%
	Minimum	82%	77%	84%	43%

[DEFINITION OF SYMBOLS]**

Symbol	Definition
	<i>In vitro</i> diagnostic medical device
	Manufacturer
	CE Mark
	Consult instructions for use
	Contents
	Catalog number
	Batch/Lot code
	Temperature limitation
	Use by
	Authorized Representative in the European Community
	Do not re-use
	For professional use only
	Fecal sampling and storing device

[CONTACT]

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Quality Assurance and Regulatory Affairs Department
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Please report any serious incident associated with the product to the above address and the competent authority of the Member State.**



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