EB (No.150186)

ENGLISH

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EXTEL HEMO • AUTO HS Control

IVD CE 0123 UKCA

For use with EXTEL HEMO・AUTO HS Latex

SSP is available in EUDAMED.**

"For Professional Use Only"

This product is an *in vitro* diagnostic reagent for professional use. Before using the product please read carefully this instruction for use.

[Intended Use]

This product is intended for use as the quality control of EXTEL HEMO・AUTO HS, a reagent for quantitative measurement of human hemoglobin in feces using the fully automated immunoassay analyzer, HM-JACKarc and HM-JACKarcⅡ.

[Material Provided]

Code	Product Name	Constituent	Quantity
65557	EXTEL HEMO・AUTO HS Control	Low concentration control solution High concentration control solution	1 mL x 4 each

This product is provided with a Control Range Sheet. The concentration of hemoglobin is indicated on the sheet.

[Material Necessary but not provided]

・EXTEL HEMO • AUTO HS Latex
・EXTEL HEMO • AUTO Buffer
・EXTEL HEMO • AUTO HS Calibrator
・EXTEL HEMO・AUTO MC Collection Picker

[Reference Material]

Internal reference material made from human hemoglobin is used and its concentration is determined using the cyanmethemoglobin method. In the case calibrators and controls are analyzed using the internal reference material, traceability is controlled to keep the deviation between the measured value and their assigned value within ±8% for high concentration and ±10% for low concentration.

[Procedure]

This product is specially designed to perform quality control of EXTEL HEMO・AUTO HS Latex reagent using fully automated immunoassay analyzer, HM-JACKarc and HM-JACKarcⅡ. Do not use with any other reagents or analyzers. Assay two levels of control materials according to the following steps. For further details about the intervals at which the quality control should be performed, or the operating procedures, refer to the instruction for use for EXTEL HEMO・AUTO HS and HM-JACKarc or HM-JACKarcⅡ.

1. Reagent Preparation

Reconstitute the content with addition of exact 1 mL of distilled water. After the solution has been kept for 20 minutes at room temperature, gently turn upside down to homogenize and start using.

2. Assay Procedure

(a) Input the assay menu into the analyzer.
(b) Gently mix the prepared control solution, introduce 200 µL into the sample cup and place in the specified position on the sample rack. Do not make any addition to supplement the shortage. Prepare a new cup in each time from vial.
(c) Place the reagent in the specified position.
(d) After you have depressed the START key, the entire process from sampling of the specimen up to the processing of the data after measurement will be fully automated.

[Warnings and Precautions]

1. This product contains ingredients of human origin substances with negative result found for HBsAg, HIV and HCV antibodies, however that other infectious factors may be present. Be sure therefore to take the same precautions as you would do when handling patient samples by wearing gloves or other protective methods to avoid infection.
2. Do not attempt pipetting by mouth.
3. Be cautious while removing the aluminum cap. Edge or any part of the cap may be sharp.
4. This product contains sodium azide (0.1% or less). Be sure therefore to wear protective gloves, protective clothing, protective mask and eye protection when handling or disposing of this product.** 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.
5. Sodium azide (0.1% or less) is used as an antiseptic in this product. In contact with lead, it reacts vehemently with formation of highly explosive metal azides. When you discard it, be sure therefore to dilute and wash with plenty of water.
6. Do not mix different lots of controls for use.
7. Do not use controls that have expired their shelf life or controls that have been dissolved and kept for 1 week or longer even when stored at 2-8°C.
8. Do not use controls which show obvious changes in appearance such as discoloration. That indicates possibility of deterioration.
9. It is recommended to dispose of all waste material in accordance with local regulation.
10. Do not use the container of this product for any other purpose.

[Storage and Shelf Life]

1. Storage: Store in a dark and cool place (at 2-8°C).
2. Shelf life: 20 months*

[Storage after Once Opening]

1. After reconstitution, do not store at room temperature and immediately store the remaining solution at 2-8°C. The solution is stable for 1 week at 2-8°C and for 1 month at -30°C.

[References]

1). Allison JE, Fraser CG, Halloran SP, Young GP. Population screening for colorectal cancer means getting FIT: the past, present, and future of colorectal cancer screening using FIT. Gut and Liver 2014;8:117-30.

2). Godbler IM, Todd LM, Fraser CG, MacDonald LR, Younes HB; Use of a faecal immunochemical test for haemoglobin can aid in the investigation of patients with lower abdominal symptoms. Clin Chem Lab Med. 2015 Oct 10

3). Passamonti B, Malaspina M, Fraser CG, Tintori B, Carlani A, D'Angelo V, Galeazzi P.Di Dato E, Mariotti L, Bulletti S, et al; A comparative effectiveness trial of two faecal immunochemical tests for haemoglobin (FIT). Assessment of test performance and adherence in a single round of a population-based screening programme for colorectal cancer.Gut. 2016 Dec 14;.Epub 2016 Dec 14

Definition of Symbols:

Symbol	Definition
IVD	*In vitro* diagnostic medical device
	Manufacturer
CE 0123	CE Mark with identification number of notified body
UK CA	UKCA Mark
	Consult instructions for use
CONT	Contents
REF	Catalog number
LOT	Batch/Lot code
	Temperature limitation
	Use by
EC REP	Authorized Representative in the European Community
UKRP	UK Responsible Person
	Biological risk
High	High concentration
Low	Low concentration
FOBT	Fecal occult blood test reagent
P	For professional use only

For all inquiries, contact:

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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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