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Hemo One+, Human haemoglobin (FOB)

REF R33300000058

R1 1x 18.3mL | **R2** 1x 2.5mL

Instructions For Use

100 Tests

Doc Control: IFU90050-B-00
Rev. B – 26/05/2022

CE IVD

Intended Use

Hemo One+, Human haemoglobin (FOB) is a latex turbidimetric assay for the quantitative detection of haemoglobin, Faecal Occult Blood (FOB) in human stool samples and is intended for use on the I.S.E. S.r.l. **Hemo One** analyser.

For professional in vitro diagnostic use only.

Diagnostics Application

Colorectal cancer is the second leading cause of illness and death in Western world. The screening with faecal occult blood tests is based on the concept that important target colonic neoplasm, such as early-stage cancer and large adenomatous polyps. Colorectal cancer is also associated with local acute inflammatory reaction being visualized, in some cases, by white cell neutrophil scanning.
Haemoglobin is the iron-containing oxygen-transport protein in the red blood cells of all vertebrates that may be leaked into gastrointestinal tract and then discharged with the faeces in gastrointestinal bleeding diseases.
When gastrointestinal blood is lost, the stool will contain a combination of intact or nearly intact haemoglobin, intact heme and heme-derived porphyrins in amounts that depend on the site and amount of bleeding and the transit time through the gut. FOB tests detect intact or nearly intact human haemoglobin, being a very specific technique for detecting loss of blood from the lower intestine.

Method

FOB turbidimetric assay is based on agglutination reactions. These involve in vitro aggregation of microscopic latex particles. This aggregation consists in the specific reaction between antigen and antibodies, antigen contained in the sample and the antibodies anti-antigen coated on polystyrene latex particles. The sample is mixed with a suspension containing antibodies against the antigen bound to latex particles. If antigen is present in the sample it will react with the antibodies and form an aggregate. If no antigen is present in the sample the mixture will keep its appearance as a smooth suspension. Such turbidity is measured as an increase in absorbance at the determinate wave and is proportional to the quantity of antigen contained in the sample.

Reagents Provided

R1	**Reagent 1**:	1 Vials x 18.3 mL	Ready to Use
R2	**Reagent 2**:	1 vials x 2.5 mL	Ready to Use

Stability and Storage

The reagents are stable until expiry date on the label when stored at 2-8°C. DO NOT FREEZE
After opening the reagents are stable for 1 month at 2-8°C.

Reagents required but not supplied.

Reference	Description
R3330000061	Universal Stool Extraction Vials
R3330000064	Standard Set FOB
R3330000068	Control Set FOB

Sample collection and preparation

Samples should be collected utilising the Universal Stool Extraction Vials. Homogenize stool samples as thoroughly as possible prior to preparation.

- R3330000061 Universal Stool Extraction Vials

Consult the Universal Stool Extraction Vial instructions for use for correct stool sample extraction.

The samples can be stored in the refrigerator (2-8°C) for 7 days prior to testing.

ASSAY PROCEDURE

Application parameters

The Application parameters are included in the Hemo One software. In the event of a missing the FOB protocol please contact your authorised ISE representative.

Any application not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance.

Hemo One Use

Consult the I.S.E. S.r.l. Hemo One user manual for instructions on the proper use of the analyser.

Material Preparation

- Ensure samples are collected correctly in accordance with the sample preparation procedure.
- Allow reagents and stool samples to reach room temperature (15-30°C) prior to testing.
- Allow any calibrator or control material to reach room temperature (15-30°C) prior to testing.

Calibration curve establishment

A calibration curve must be performed prior to running samples. The curve must be validated with controls.

Calibration Stability

The calibration is recommended to be run every 7 days on the Hemo One analyser.

Quality control

For quality control purposes only use the following materials:

- R3330000068 Control Set FOB

Concentration is indicated on the label of the vial. The use of control materials at two different concentrations is recommended in order to verify test precision across the measuring range. Control frequency should be run in accordance with the laboratory's quality management system.

If the obtained results are out of the tolerance range;
- Ensure all materials are not expired
- Ensure all materials have been stored and prepared correctly
- Perform a calibration

In the event of controls results not meeting the defined tolerances

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please contact you local ISE authorised representative for support.

ANALYTICAL CHARACTERISTICS / PERFORMANCE

NORMAL VALUES

Haemoglobin (FOB) cut-off value:

< 50 hHb/mL	not indicative of an inflammation
50 - 200 hHb/mL	Possible bleeding of gastrointestinal tract, additional testing recommended
> 200 hHb/mL	indicative of bleeding in the gastrointestinal tract

Method Comparison

An evaluation was performed comparing I.S.E. S.r.l. FOB against EIKEN latex FOB. The results were as follows:

	Sensitivity	Specificity
ISE FOB vs EIKEN FOB	**96%**	**> 99%**

Linearity

Using the calibrator kit FOB is linear in the calibration range of **0-1000** hHb/mL

Limit of detection (LOD):

Limit of detection (LOD): **15** hHb/mL
The lower limit of detection of FOB was determined on 20 samples and 2 sample replicates as the mean value + 2 SD

Limit of quantification (LOQ):

Limit of quantification (LOQ): **20** hHb/mL
The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected; imprecision is < 20% as CV%

Precision

Precision was assessed with 3 different controls

Precision	Low	Medium	High
Number	20	20	20
Mean (ng/mL)	19.7	83.1	261.2
SD	1.1	5.3	14.5
CV (%)	6	6	6

Prozone effect

Studies have been made up to a concentration of 10 µg of hHb/mL and no false negative results have been observed.

Disposal of reagent

Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".

Symbols on labels and packaging

IVD	In vitro diagnostic medical device
REF	Catalog Number
LOT	Lot or batch number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use

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