

FOB Calibrator Set			CE	
EN	REF	R3330000064	Instructions for Use	
	CAL	A		1 x 1mL
	CAL	B		1 x 1mL
	CAL	C		1 x 1mL
	CAL	D		1 x 1mL
	CAL	E		1 x 1mL
	CAL	F		1 x 1mL
			Control:R3330000065_v1.0.A.E	

Intended Use

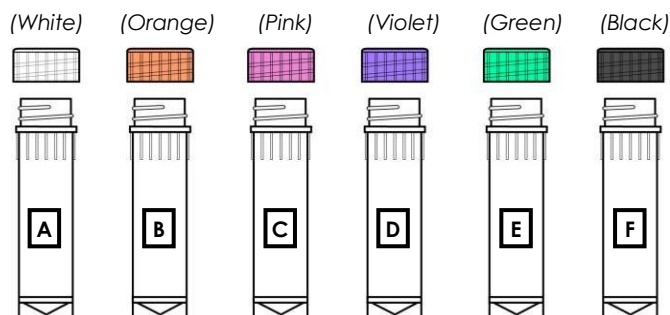
The FOB Calibration Set is designed to be used exclusively with the ISE FOB detection in human stool samples;

REF R3330000058 – Hemoglobin (FOB) detection kit – 100 test

KIT Components

The FOB calibrator set contains liquid calibrators containing recombinant human FOB at different concentrations. Calibrators are supplied ready to use with colour coded caps;

Calibrator Name	Assigned Value	Supplied Volume	Cap Colour
CAL A	0 ng/mL	1x 1mL	White
CAL B	50 ng/mL	1x 1mL	Orange
CAL C	100 ng/mL	1x 1mL	Pink
CAL D	250 ng/mL	1x 1mL	Violet
CAL E	500 ng/mL	1x 1mL	Green
CAL F	1000 ng/mL	1x 1mL	Black



Instrument and Materials Required but not supplied

The FOB control set is designed to be used on the **Miura / Hemo One** family of systems.

Reagents Required:

REF R3330000058	FOB detection kit
REF R3330000068	FOB Control Set

Storage and Stability

Store at 2 to 8 °C. **Do not freeze.**

Note: Store control tightly capped when not in use.

Unopened vial: stability is up to the expiration date on label when stored at 2 to 8 °C.

Opened Vial: stability 30 days after opening, if calibrator material is recapped and returned to 2-8°C immediately after use.

Preparation

1. Extract/aliquot the volume necessary for the run into appropriate vials or tubes.
2. Recap the FOB calibrators and replace at 2 -8°C
3. Ensure the Instrument has been calibrated and run the extracted aliquots.
4. Discard the aliquots after use.

Calibration Frequency

It is recommended to calibrate the FOB kit in the following instances:

- When a new lot is utilized
- When the controls are out of the assigned range

Continued failure of any controls may indicate an instrument or reagent issue and the local authorized ISE representative must be contacted as soon as possible.

Precautions

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. For use only on the Miura / Hemo One instruments
4. Package Insert instructions must be read and understood prior to use of all instruments and kits.
5. Do not use beyond expiry date.
6. Do not mix materials from different lot numbers.
7. Safety data sheets are available.
8. All materials have been tested but should be handled as potentially hazardous and good laboratory practice should be followed.

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



ISE S.r.l.

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FOR YOUR LABORATORY

EN			FOB Calibrator Set		CE
			REF	R33300000064	Instructions for Use
CAL	A	1 x 1mL	Control:R33300000065_v1.0.A.E		
CAL	B	1 x 1mL			
CAL	C	1 x 1mL			
CAL	D	1 x 1mL			
CAL	E	1 x 1mL			
CAL	F	1 x 1mL			
					IVD

Document Control

Date	Version	Changes	Author
	Version	Date	
14.09.2019	1.0	A.E Initial Release	S.Middleton

