

ISE	FOB Control Set		IVD
	REF R3330000068	LOT XXXXXX	CE
	FOBQC1 1x 1mL FOBQC2 1x 1mL	XXXX/XX	

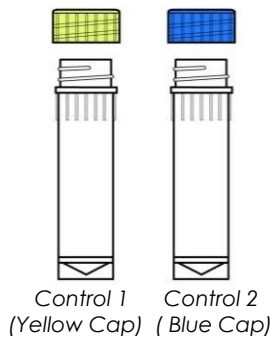
Intended Use

The FOB Controls 1 and 2 are designed to be used exclusively with Haemoglobin (FOB) detection kit (faecal occult blood) in human stool samples;

REF R3330000058 - Haemoglobin (FOB) detection kit – 100 test

KIT Components

The FOB control set is supplied ready to use with colour coded caps;



- FOBQC1 Control 1 1x 1mL
- FOBQC2 Control 2 1x 1mL

Preparations

1. The FOB control set is liquid Ready to Use.
2. Allow FOB QC1 & QC2 to reach room temperature (15-30°C) prior to testing.
3. Extract/aliquot the volume necessary for the run into appropriate vials or tubes.
4. Recap the FOB controls and replace at 2 -8°C
5. Ensure the Instrument has been calibrated and run the extracted aliquots.
6. Discard the aliquots.

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.

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 control material is

recapped and returned to 2-8°C immediately after use.

Assigned Values

The controls have been tested in accordance with standardised procedures and conditions, the values have been calculated from multiple determinations and instruments.

The assigned ranges for this lot:

LOT	XXXXX		XXXX/XX
	Lower Limit	Target	Upper Limit
FOBQC1			
FOBQC2			

Instrument and Materials Required but no supplied

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

Reagents Required:

REF R3330000058	Haemoglobin (FOB) detection kit
REF R3330000064	Calibrator for FOB

Disposal of reagent

Disposal of reagents must be performed in accordance with local regulations.

Symbols on labels and packaging

- = In vitro diagnostic medical device
- = Catalog Number
- = Lot Number
- = Manufacturer
- = Expiration date
- = Temperature limitation
- = Instruction for use

