


CALPROTECTIN Calibrator Set				
REF	R3330000065			Instructions for Use
EN	CAL	A	1 x 1mL	Doc Control: IFU90054-B-00 Rev. B – 26/05/2022
	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	

### Intended Use

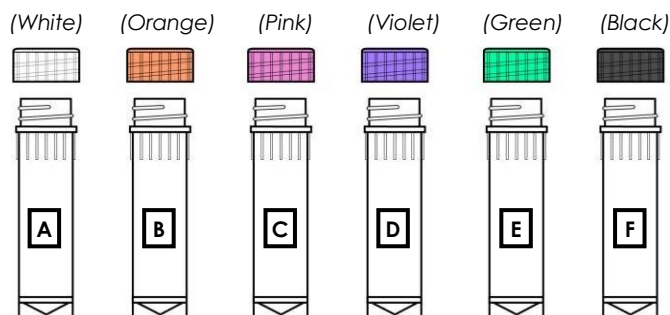
The Calprotectin Calibration Set is designed to be used exclusively with the ISE Calprotectin detection in human stool samples;

**REF** R3330000059 - Calprotectin detection kit – 100 test

### KIT Components

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

Calibrator Name	Assigned Value	Supplied Volume	Cap Colour
CAL A	0 µg/g	1x 1mL	White
CAL B	50 µg/g	1x 1mL	Orange
CAL C	100 µg/g	1x 1mL	Pink
CAL D	250 µg/g	1x 1mL	Violet
CAL E	750 µg/g	1x 1mL	Green
CAL F	1500 µg/g	1x 1mL	Black



### Instrument and Materials Required but not supplied

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

### Reagents Required:

<b>REF</b> R3330000059	CALPROTECTIN detection kit
<b>REF</b> R3330000069	CALPROTECTIN 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. Allow calprotectin calibrators to reach room temperature (15-30°C) prior to testing.
2. Extract/aliquot the volume necessary for the run into appropriate vials or tubes.
3. Recap the calprotectin calibrators and replace at 2 -8°C
4. Ensure the Instrument has been calibrated and run the extracted aliquots.
5. Discard the aliquots after use.

### Calibration Frequency

It is recommended to calibrate the Calprotectin 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

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

