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CALPROTECTIN Calibrator Set

REF R33300000065

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:R33300000065_v1.0.A.E

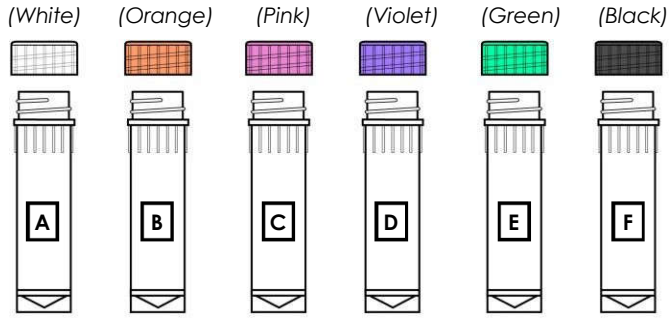
CE
IVD

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:

REF R3330000059	CALPROTECTIN detection kit
REF 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

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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