

ISE	Calprotectin Stool Extraction Tube		IVD
	REF R3330000062	Instructions for Use	
	100 x 2.4mL	Document Control:R3330000062_v1.0.A.E	

Intended Use

The Calprotectin Stool Extraction Tube (STET) is a single use tube for fecal sample collection. Each tube contains a buffer and measuring stick designed to ensure the same mass of material is collected. This product is intended to be used with the **Calprotectin detection kit** (Ref; R3330000059)

KIT Components

The kit R3330000062 comes supplied;

- 100 tubes (single use)
Each tube contains; 2.4mL buffer and <0.1% Sodium Azide as preservative.
- 100 caps (to close tubes after uses if required)

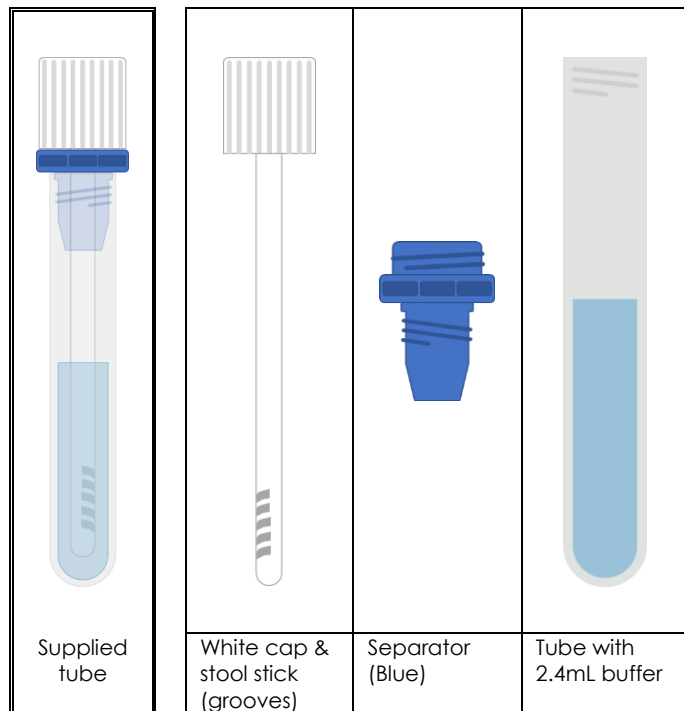
7. Safety data sheets are available.
8. All materials have been tested but should be handled as potentially hazardous and good laboratory practice should be followed.

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	R3330000059	Calprotectin detection kit
REF	R3330000065	Calibrator for Calprotectin



Specimen Collection

Stool collection

1. Stool samples should be collected in clean and dry containers (no preservatives or transport media)
2. Stool samples can be stored at 2-8°C for 3 days prior to testing
3. It is possible to freeze the samples at -20°C
4. Allow stools to reach room temperature prior to extraction (15 – 30°C)

Stool Extraction

1. Unscrew the white cap (anticlockwise) and remove the stick.
2. Dip the stick into the stool sample and rotate and make the sample as homogenous a possible.
3. Dip the stick into 4 zones around the stool and ensure the groves are filled.
4. Try to remove any excess stool before placing the stick back into the tube.
5. Fully insert the stick into the tube through the blue separator (this will remove excess faecal matter)
6. Screw tight the white cap
7. Vortex the Sample for approx. 60 seconds
8. See if the grooves are free of stool, if not repeat the vortex for another 60 seconds.
9. Allow the stool to stand for approx. 10 minutes.
10. Remove the screw cap (white) and the the separator (blue) by rotating the separator clockwise and dispose of the stick.
11. Load the sample onto the Instrument.

Storage and Stability

Store at 2 to 30 °C.
Do not freeze.

Unopened vial: stability is up to the expiration date on label when stored at 2 to 30 °C.

Extracted Sample: Extracted stools samples can be stored at 2-8°C for 7 days.

Precautions

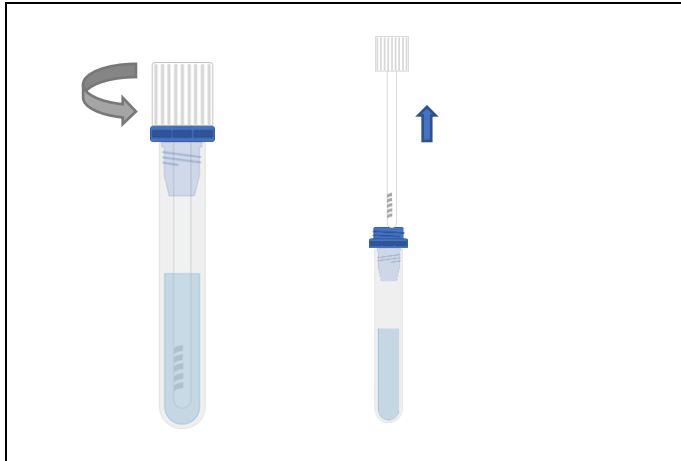
1. For *in vitro* diagnostic use only.
2. For professional use only.
3. For use only on the Miura / Hemo One instruments
4. Package Insert instructions must be read and understood prior to use of all instruments and kits.
5. Do not use beyond expiry date.
6. Do not mix materials from different lot numbers.

Notes.

1. If the buffer in the diluent has foam on the surface this may interfere with the liquid level detection system of the instrument and give erroneous results. Remove or repeat if foaming is evident.
2. If the sample has a lot of particulate matter in the diluent it may be necessary to centrifuge the sample (10 minutes 1000-3000x g)



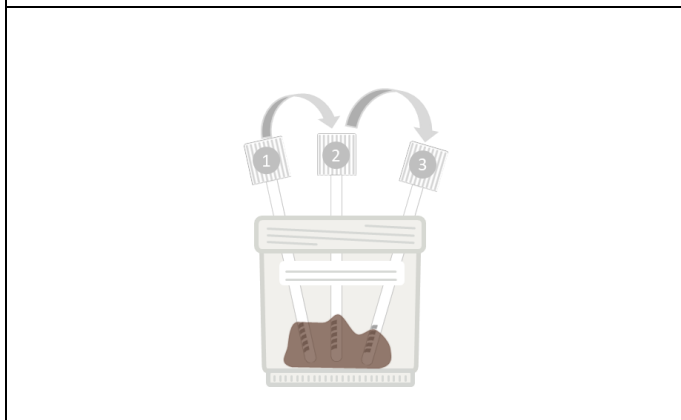
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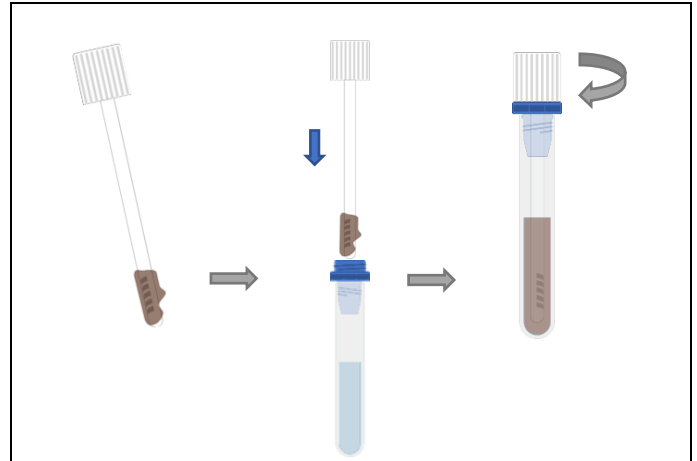
- Unscrew the white cap (anticlockwise) and remove the stick.



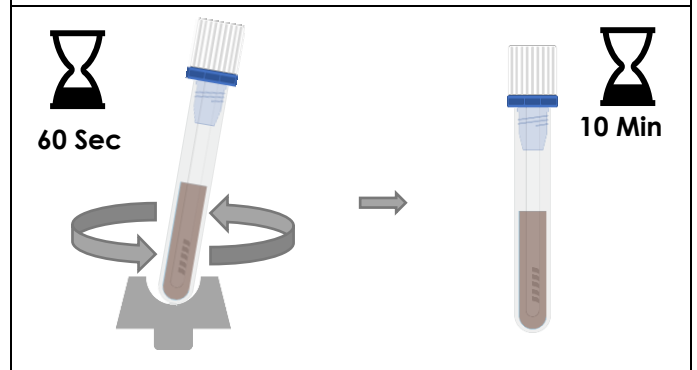
- Dip the stick into the stool sample and rotate and make the sample as homogenous a possible.



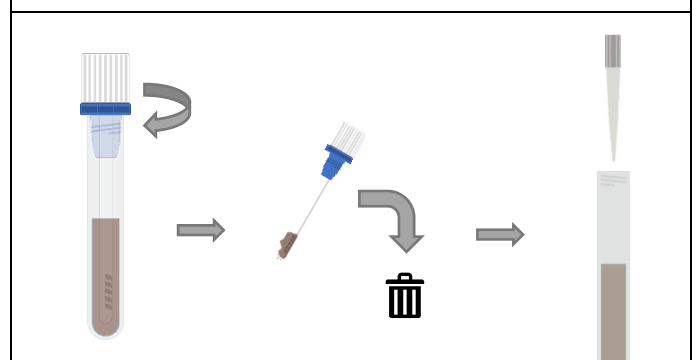
- Dip the stick into at least 3 zones around the stool and ensure the grooves are filled.



- Try to remove any excess stool before placing the stick back into the tube.
- Fully insert the stick into the tube through the blue separator (this will remove excess faecal matter)
- Screw tight the white cap (clockwise)



- Vortex the Sample for approx. 60 seconds
- Let Sample stand for 10 Minutes



- Remove the screw cap (white) and the the separator (blue) by rotating the separator clockwise and dispose of the stick.
- Sample is ready for pipetting

