

H.Pylori Calibrator Set			CE
EN	REF	R3330000066	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:R3330000066_v1.0.A.E

Intended Use

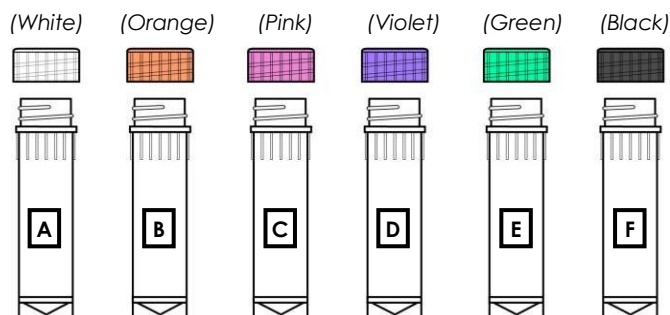
The H.Pylori Calibration Set is designed to be used exclusively with the ISE H.Pylori detection in human stool samples;

REF R3330000057 - H.Pylori detection kit – 100 test

KIT Components

The H.Pylori control set contains liquid calibrators containing recombinant human H.Pylori 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	2.5 ng/mL	1x 1mL	Orange
CAL C	5 ng/mL	1x 1mL	Pink
CAL D	10 ng/mL	1x 1mL	Violet
CAL E	20 ng/mL	1x 1mL	Green
CAL F	40 ng/mL	1x 1mL	Black



Instrument and Materials Required but not supplied

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

Reagents Required:

REF R3330000057	H.PYLORI detection kit
REF R3330000070	H.PYLORI 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 H.Pylori 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 H.Pylori 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 H.Pylori 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

H.Pylori Calibrator Set			REF	R33300000066	Instructions for Use	Control:R33300000066_v1.0.A.E	CE	IVD
EN	CAL	A						
	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					

