

<b>ISE</b>	<b>H.Pylori Control Set</b>		<b>CE</b>
	<b>REF</b> R3330000070	<b>Instructions for Use</b>	
	CTRL 1 1x 1mL		<b>IVD</b>
	CTRL 2 1x 1mL	Document Control:R3330000070_v1.0.A.F	

<b>LOT</b>	<b>H015</b>		<b>2020/07</b>
------------	-------------	---	----------------

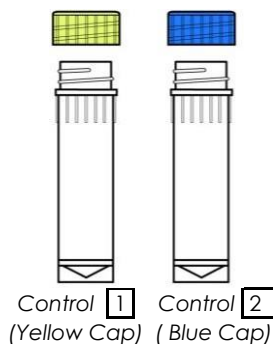
### Intended Use

The H.Pylori Controls 1 and 2 are 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 is supplied ready to use with colour coded caps;



- **CTRL 1** Control 1 1x 1mL
- **CTRL 2** Control 2 1x 1mL

### Instrument and Materials Required but no supplied

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

### Reagents Required:

<b>REF</b> R3330000057	H.Pylori detection kit
<b>REF</b> R3330000066	Calibrator for H.PYLORI

### 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.

### 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".

### Preparation

1. Allow H.Pylori QC1 & QC2 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 controls and replace at 2-8°C
4. Ensure the Instrument has been calibrated and run the extracted aliquots.
5. Discard the aliquots after use.


### 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.





### 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:

<b>LOT</b>	<b>H015</b>		<b>2020 / 07</b>
<b>ng/mL</b>			
	Lower Limit	<b>Target</b>	Upper Limit
<b>CTRL 1</b>	10	<b>14</b>	18
<b>CTRL 2</b>	20	<b>29</b>	38

### 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

