H. pylori Control Set

INTENDED USE

The H. pylori Control Set is intended for *in vitro* diagnostic use as an unassayed quality control for the determination of Immunoglobulin G (IgG) antibodies to *Helicobacter pylori*. This product should only be used to estimate the precision and monitor the performance of the OSOM® H. pylori Test. The set contains external positive and negative serum controls for qualitative use.

SUMMARY AND PRINCIPLE

The H. pylori Control Set uses a specially formulated matrix to provide satisfactory results when used with the OSOM® H. pylori Test. Although this product does not have assigned values, positive and negative controls are provided to facilitate monitoring in the expected clinical range.

MATERIALS PROVIDED

- 1 Positive control vial - 2 mL (contains 0.1% sodium azide)
- 1 Negative control vial - 2 mL (contains 0.1% sodium azide)

The control set is provided in liquid form, and is made from processed human serum to which preservatives, stabilizers, biochemicals and chemicals have been added.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage and disposal of samples or reagents.
- Handle all controls and materials used in testing as biohazards in the same manner as patient specimens.
- The human serum used to make this product was tested by currently approved methods and found non-reactive for hepatitis B surface antigens (HbsAg), HIV1, HIV2 and HCV antibodies. Currently there is no test method that can assure that human blood used in this product will not transmit infectious agents.
- The Control set contains sodium azide as a preservative. If control solution comes in contact with the skin or eyes, flush with ample volumes of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.

STORAGE AND STABILITY

- The H. pylori Control vials should be kept tightly closed after opening to avoid evaporation.
- Store vials upright at 2°-8°C (36°- 46°F).
- Do not freeze.
- The H. pylori Controls are stable until the expiration date printed on the vial label.

PROCEDURE

Use the H. pylori Controls as you would a patient sample in accordance with the procedure for the OSOM H. pylori Test. Read the procedural instructions from the OSOM H. pylori product.

1. Allow the H. pylori Controls to reach room temperature prior to use.
2. Gently invert the vial 5-10 times to assure complete mixing.
3. Positive Control - Remove the cap from the positive control vial. Dispense 1 drop of positive control material into the device sample. Replace the cap.
4. Negative Control - Remove the cap from the negative control vial. Dispense 1 drop of negative control material into another device sample well. Replace the cap.
5. Follow the test procedure as directed in the OSOM H. pylori package insert.

LIMITATIONS

1. DO NOT use the Controls beyond the expiration date printed on the label.
2. If the handling or recommended storage conditions are not followed, the controls may not perform as expected.
3. Do not use if there is evidence of microbial contamination or excessive turbidity.
4. Satisfactory results may not be obtained if procedural directions for the reagents are not followed.

EXPECTED RESULTS

The Negative Control should yield a negative result and the Positive Control shall yield a positive result as described in the Interpretation of Test Results section of the OSOM H. pylori test product insert.

ASSISTANCE

For assistance in the U.S., please contact Sekisui Diagnostics Technical Assistance at (800) 332-1042.

RE-ORDER

No. 175- OSOM® H. pylori Test (25 tests)
No. 176- H. pylori Control Set

Manufactured for:
LifeSign LLC 85 Orchard Road Skillman, NJ 08558 USA

KEY TO COMPONENT LABELING

IVD	In vitro diagnostic medical device
LOT	Batch Code
	Use by YYYY-MM
	Temperature Limitation
REF	Catalog Number
	Manufacturer
MFG | FOR	Manufactured For
	Consult Instructions for Use
CONTROL +	Positive Control
CONTROL –	Negative Control