KENLOR
Liquid H.Pylori Human IgG Antibody Serum Control
(Unassayed)

CATALOG NUMBER 150303

KIT CONTENT: H. Pylori stabilized Liquid IgG Antibody Serum Control.

INTENDED USE:
The Kenlor Liquid H.pylori IgG antibody serum controls are intended for use as unassayed precision control reagents. These controls are to be used with in vitro immunoassay procedures for the qualitative determination of H. pylori IgG antibody in human serum assays. The controls are designed for routine use to provide a means of estimating precision and monitoring system performance. The controls are not intended to replace reagent controls furnished with the commercial kit used.

SUMMARY AND EXPLANATION:
The usefulness of Quality Control materials for monitoring the accuracy and precision of clinical testing is well documented. The Kenlor Liquid H. pylori Serum Control is designed specifically to be used in qualitative analysis of H. pylori IgG antibody assay in serum. The control should be used like a patient sample to assist in the assessment of the analytical procedures and routinely used for the day to day quality control of the assay system. Kenlor Liquid H.pylori IgG serum for antibody assay is liquid, stable for two years at a refrigerated temperature of 2º-8º C.

REAGENTS:
The Kenlor H. pylori IgG antibody negative control serum is prepared by mixing appropriate amount of H. pylori negative human serum with other serum until desired concentration of H. pylori IgG antibodies are obtained. The Kenlor H. pylori IgG antibody positive control serum is prepared by mixing appropriate amount of H.pylori positive human serum with other serum until desire concentration of H. pylori IgG antibodies are obtained. All sera were preserved with a mixture of 0.1% EDTA, 0.05% Benzamide and 0.1% Sodium azide as preservatives. The volume of H. pylori negative and H. pylori positive human sera to be used in the preparation was determined by analysis of H. pylori IgG antibodies concentration in these sera by EIA with available commercial kit. Follow the manufacturer's recommended protocol in assaying Kenlor Liquid H.pylori IgG antibody control.

WARNINGS AND PRECAUTIONS:

* FOR IN VITRO DIAGNOSTIC USE ONLY

* **BIOHAZARD Caution:** Human source material used in the preparation has been found non-reactive for HBsAg when tested by RIA, and also negative for HIV-1 antibody when tested by ELISA. However, no known test method can assure that a product derived from human source does not contain hepatitis or HIV-1 viruses.
* If particulate matter is observed in the product, discard the product.
* **WASTE DISPOSAL METHOD:** The above product contains 0.1% **sodium azide** as preservative. Best disposal method for biological material containing sodium azide is to wash it down the sewer with large excess of water. Disposal should be made in accordance with existing disposal practices. Observe all Federal, State and Local laws.
* HANDLE AS IF CAPABLE OF TRANSMITTING HEPATITIS
* NOT FOR INTERNAL USE BY HUMANS OR ANIMALS.

STORAGE AND STABILITY

STORE AT 2º-8º C.

The product is stable up to the expiration date printed on the label if kept at 2º-8º C. and 6month at room temp. Once opened it is stable for 60 days.

This product is warranted to perform as described in its labeling and in the product literature. Kenlor Industries, Inc. disclaims any implied warranty, merchantability or fitness for any other purpose, and in no event shall be liable for any consequential damages arising out of the aforesaid expressed warranty.

PROCEDURE:
The Kenlor Liquid H. pylori IgG antibody Serum Control should be used like a patient sample to assist in the assessment of the analytical procedures and routinely used for the day to day quality control of the assay system. Carefully follow the test procedures of the manufacturer of the test kit including bringing the controls to room temperature if so indicated, for the analysis of the Kenlor Liquid H. pylori IgG antibody serum controls. The LIQUID CONTROL is specially designed and packaged to be stable in liquid state for two years. Once open, the Controls stable for 60 days. The stable LIQUID CONTROL eliminates errors arising from lyophilization, pipeting errors and discrepancies due to uneven lyophilization or improper mixing.

QUALITY CONTROL

SPECIFIC PERFORMANCE CHARACTERISTICS:
KENLOR LIQUID H. PYLORI IgG ANTIBODY SERUM CONTROL is formulated to give consistent result for use in clinical quality control. It is recommended that each laboratory validate the use of each lot of reagents with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF THE RESULTS:
Once a laboratory has established the range of values for the Liquid H.pylori IgG antibody controls it can use those values for routine day to day quality control of clinical test. However, the values are method dependent and different laboratories may observe variations as a result of

differences in techniques, the instrument and/or reagent variation, method modifications and other systemic and random errors.

LIMITATION OF THE PROCEDURE:

The Kenlor H. pylori human IgG antibody Serum Controls are not intended to be used as calibrators and should not be used for calibration of the assays. The controls should be used only when testing serum specimens following protocol of the test kit manufacturer. Performance characteristic of the controls were determined for H.pylori human IgG antibody only. Control should be used only in test involving serum; it is not intended for use in test of plasma or other body fluid.

BIBLIOGRAPHY:

1. Druet, E.B, Denoyel, G.A., Bonde, M., Wallano, E., Andujar, M & DeMont-Clos, H.P., J. Clin. Microbiology, August 1991 , 1620-1624.
2. Sethi, P., Bannerjee, A.K., Jones, D.M., Eldridge, J & Hollanders, D., "Gastritis and Gastric Campylobacter like organisms in endoscopically normal patients", in Post Grad. Med. Journal 1987
3. Appleman, M.D., Chandrasoma, P., Velenzeuela, J.E., Cohen, H. & Pettross, C.W., "Campylobacter pylori; its relationship to peptic disease, gastric inflammation and other conditions" Gasteroenterology 1986
4. Marshall B.J., McGeehie, D.B., Francis, G.J. & Utley, P.J., "Pyloric Campylobacter Serology" Lancet 11:281, 1984
5. "Campylobacter pylori" in Gastritis and Peptic Ulcer Disease, Martin J. Blazer, Ikagu-Shoin, New York 1989
6. Buck, G.E., Gourley, W.K., Subramanyam, K., Latimer, J.M. & DiNuzzo, A.R., "Relationship of Campylobacter pyloridis to gastritis and peptic ulcer." J. Infectious Diseases, 1986
7. Paterson, W. L., "Helicobacter pylori and Peptic Ulcer Disease" New England Journal of Medicine, 1991.
8. Marshall, B.J. & Warren, J.R., "Unidentified curved bacillus on gastric epithelium in active chronic gastritis" Lancet 1983.

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