K964014

510(K) SUMMARY

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Submittal's Name : Kenlor Industries, Inc.

Address: 1560 E. Edinger Ave., Suite A-1, Santa Ana, CA 92705, USA

Tel. No. : 714-647-0770

Fax No. : 714-647-0593

Contact Person : Dr. Kamales Som

Classification Name : Serum Control

Common Name : Serum Control

Proprietary Name : Kenlor Liquid H. pylori IgG antibody Serum Control (Unassayed)

Legally marketed Device to which equivalence is claimed : Commercial Serum Controls for H. pylori Antibody marketed with H. pylori antibody test kit by BioAmerica and Elias corporation.

Description of the Device : Ready to use stabilized, Liquid Serum Control for qualitative determination of Helicobacter pylori IgG antibody in human serum assays. The controls contain 0.05% Sodium azide as preservative. The human source material is from human Serum and protein fractions of human serum.

Intended Use : KENLOR H. pylori Serum Control is designed to provide unassayed precision control reagents. The controls are to be used with the in vitro immunoassay procedures for the qualitative determination of Helicobacter 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 kits. The control should be used like a patient sample to assist in the assessment of the listed analytical procedures.

The usefulness of Quality Control materials for monitoring the accuracy and precision of clinical testing is well documented.

SUMMARY OF DATA: Stability of H. pylori antibody in Serum Control were studied by measuring it at a regular interval of time. The control were kept at 2° - 8° C for the shelf life study. The mean of the assigned value is derived from assay of 24 vials that are representative of the lot. Suggested target ranges for quantitative values represent 2 X Standard Deviation (S.D.) of the assayed values. The experimental values are the mean of three vials analyzed at the time period. Studies on closed vial stability conducted over a period of one year at 2° - 8° C indicates that the antibody remains within the assigned range for the duration and condition of the study. An accelerated shelf life stability study was conducted at 37 C for two months.. Based on these studies a stability of two years is assigned for closed vials at refrigerated temperatures (2° - 8° C). Opened vials when used as directed and stored at 2°- 8° C are stable up to two months (sixty days).