

2. 510(k) SUMMARY

K961276

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[as required by Section 807.92 (c)]

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PRODUCT INFORMATION

Common/usual or classification name: Gastrin Enzyme Immunoassay Kit

Trade or proprietary name: Gastrin EIA

K961276

Device to which Substantial Equivalence is claimed: Gastrin (I¹²⁵) Radioimmunoassay Kit.
K821175

Description of Gastrin EIA:

Gastrin EIA is an in vitro enzyme immunoassay for the quantitative measurement of gastrin in human serum. Gastrin in serum is assayed by a competition reaction using an antibody raised against a gastrin immunogen. Gastrin in standards and samples compete with immobilised Gastrin in binding the anti-gastrin antibody. The extent of antibody binding to the solid phase is inversely related to the concentration of Gastrin in the standard or patient sample.

Intended Use:

The intended use of the Gastrin EIA is for quantitative measurement of Gastrin in human serum. Gastrin is a polypeptide hormone produced and secreted by the G cells of the gastric antral mucosa. It occurs in the circulation in several different forms, among those Gastrin-17 and Gastrin-34, sulphated and non-sulphated. The determination of serum gastrin can be used as an aid in the diagnosis of Zollinger-Ellison Syndrome, gastric cancers, achlorhydia (with or without pernicious anaemia), G-cell hyperplasia and duodenal ulcer. In all of these clinical conditions the serum gastrin concentration is elevated. Normal fasting serum gastrin concentrations are below 100 pg/ml, while fasting serum levels in the above conditions are significantly higher. Measurement of serum gastrin may also be used to monitor patients with previous gastric surgery. Treatment with histamine H₂ receptor antagonists and with antisecretory drugs may cause a rise in the serum gastrin concentration. Quantification of serum gastrin can then be used to monitor treatment with these drugs.

Comparison of Technological Characteristics of EIA and RIA:

Both are designed to quantify gastrin in a patient's serum sample by means of a competition reaction.

Both use a multi-specific antiserum generated against a gastrin immunogen.

The RIA utilizes a radioactive tracer as its means of detection while the EIA uses a an antibody-enzyme conjugate and chromogenic substrate both of which are non-hazardous and non-carcinogenic.

The EIA expands on the RIA standard curve facilitating easier measurement of very high patient samples.

Unlike the RIA, the EIA does not use any extracted human components in its standards.

The EIA kit size and smaller RIA kit size are similar, but the EIA can be used for up to 4 separate assays.

Assessment of Clinical Performance Data:

Patient samples were analysed by both EIA and RIA and results subjected to a linear regression analysis. Results obtained showed that there was no statistical difference between the two tests.

Conclusions:

Comparison of the technological characteristics of the EIA and RIA in conjunction with the Clinical performance data show that the Gastrin EIA is substantially equivalent to the RIA K821175.