

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K033067

B. Analyte:

Helicobacter pylori

C. Type of Test:

Enzyme-Linked Immunosorbent Assay

D. Applicant:

Trinity Biotech USA

E. Proprietary and Established Names:

Trinity Biotech Captia *H. pylori* IgG Enzyme-Linked Immunosorbent Assay

F. Regulatory Information:

1. Regulation section:
866.3110
2. Classification:
Class I
3. Product Code:
LYR
4. Panel:
83

G. Intended Use:

1. Intended use(s):
The Trinity Biotech Captia *H. pylori* IgG Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the qualitative detection of IgG antibodies to *Helicobacter pylori* in human serum. This assay is intended for use as an aid in the diagnosis of *H. pylori* infection in persons with gastrointestinal symptoms.
2. Indication(s) for use:
The Pylori IgG ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative determination of IgG antibodies in human serum to *Helicobacter pylori*, as an aid in the diagnosis of *H. Pylori* infection in adult patients with clinical signs and symptoms of gastrointestinal disease, and is not intended for use in asymptomatic patients.
3. Special condition for use statement(s):
Not Applicable

4. Special instrument Requirements:

Single or dual wavelength microplate reader with 450 nm filter

H. Device Description:

This is an ELISA kit that contains H. pylori (strain ATCC 43504) antigen coated microassay plate in a 96 well configuration, serum diluent, cutoff calibrator, a high positive, low positive, and negative control, horseradish-peroxidase conjugate, Chromogen/substrate solution, wash buffer and stop solution. It can be purchased with enough supplies for one or five plates.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Pylori IG ELISA Test System
2. Predicate K number(s):
K961221
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Detect H. pylori IgG antibodies in human serum	Detect H. pylori IgG antibodies in human serum
Reagents	Tris BSA Serum Diluent Tris Tween Wash Buffer Goat anti-human IgG (Fc)	Tris BSA Serum Diluent Tris Tween Wash Buffer Goat anti-human IgG (Fc)
Technology	ELISA	ELISA
Reagents	Horseradish Peroxidase Conjugate TMB enzyme substrate Sulfuric Acid Stop	Horseradish Peroxidase Conjugate TMB enzyme substrate Sulfuric Acid Stop
Procedure	Serum incubation-20 min Conjugate incubation-20min Substrate incubation-10min Stop-add 100µl of stop solution Read at 450nm	Serum incubation-20 min Conjugate incubation-20min Substrate incubation-10min Stop-add 100µl of stop solution Read at 450nm
Calculations	1 cutoff calibrator, high, low, and negative controls Multiply cutoff calibrator by correction factor	1 cutoff calibrator, high, low, and negative controls Multiply cutoff calibrator by correction factor
Differences		
Item	Device	Predicate
None	None	None

J. Standard/Guidance Document Referenced (if applicable):

Not Applicable

K. Test Principle:

Enzyme-Linked Immunosorbent Assays (ELISA) rely on the ability of biological materials, (i.e. antigens) to adsorb to plastic surfaces such as polystyrene (solid phase). When antigens bound to the solid phase are brought into contact with a patient's serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen-antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgG conjugated with horseradish peroxidase which then binds to the antibody-antigen complexes. The excess conjugate is removed by washing, followed by the addition of Chromogen/Substrate Tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient's serum, a blue color develops. When the enzymatic reaction is stopped with 1N H₂SO₄, the contents of the wells turn yellow. The color, which is proportional to the concentration of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not Applicable. This is a change in the name of distributor only.
Performance characteristics were established in K961221.
 - b. *Linearity/assay reportable range:*
Not Applicable
 - c. *Traceability (controls, calibrators, or method):*
Not Applicable
 - d. *Detection limit:*
Not Applicable
 - e. *Analytical specificity:*
Not Applicable
 - f. *Assay cut-off:*
Not Applicable
2. Comparison studies:
 - a. *Method comparison with predicate device:*
Not Applicable
 - b. *Matrix comparison:*
Not Applicable
3. Clinical studies:
 - a. *Clinical sensitivity:*
Not Applicable
 - b. *Clinical specificity:*
Not Applicable
 - c. *Other clinical supportive data (when a and b are not applicable):*
Not Applicable
4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:
Not Applicable

M. Conclusion:

The Trinity Biotech Captia *H. pylori* IgG ELISA is substantially equivalent in performance to the predicate device and to biopsy for the identification of *H. pylori* in human serum.