

K954996

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Summary of 510(k) Safety and Effectiveness information.
Trade / Proprietary Name: TREND Amebiasis (*Entamoeba histolytica*)
Serological ELISA Test System.

DESCRIPTION and INTENDED USE of the DEVICE:

The intended use of the device is for the qualitative and/ or quantitative determination of serum IgG antibodies to *Entamoeba histolytica* using an Enzyme-Linked Immunosorbent Assay (ELISA) technique.

Entamoeba histolytica is a protozoan parasite responsible for the disease state of amebiasis. This parasite is endemic in developing countries but is rare in most industrial nations. An infection with the organism originates in the intestine, but the organism may become invasive and may result in amebic liver abscesses. When tissues are invaded, antibodies are often formed.

Appropriate laboratory sites of use for this device would include laboratories in endemic third world countries and immigration centers in industrialized countries. The intended use for the device is as a supportive test kit in the differential diagnosis of symptomatic patients. When used as a supportive test, a serological test is useful not only to detect the presence of these antibodies but also to exclude amebiasis as the diagnosis. Since the kit detects IgG antibodies, a positive test may not indicate an active infection since the IgG antibodies exist for years.

SCIENTIFIC PRINCIPLES:

The device is an Enzyme Linked Immunosorbent Assay (ELISA). The antigen capture takes place in microwells. During the first incubation, antibodies in the patient's serum binds to antigen attached to the test wells. After washing the excess antibodies away, an enzyme complex binds to the antigen-antibody complex. After washings that remove unbound enzyme, a substrate is added which develops a blue color in the presence of the enzyme complex and peroxide. The stop solution ends the reaction and turns the blue color to yellow. The results may be read spectrophotometrically with a microplate reader or visually.

TECHNOLOGY:

The modifications of the submitted device do not affect the technological characteristics of the predicate device.

The modifications include: (1) changing the test sample preparation to facilitate ease of use, (2) changing to a 1-component combined TMB substrate system vs. a 2-component TMB substrate system with corresponding appropriate stop solution, (3) reducing the number of repetitive washes after each incubation step, (4) using a powder packet of PBS with a surfactant vs. a liquid concentrate, and (5) using more than one antigen source on the microwell plates.

PERFORMANCE TESTING:

Clinical Laboratory Bench Studies were performed to validate **SUBSTANTIAL EQUIVALENCE** to the original predicate kit.

Sensitivity/ Specificity Testing:

Serum samples confirmed as positive or negative for antibodies to *E. histolytica* were tested by the device. Sensitivity and specificity values were calculated and compared with sensitivity/ specificity values for the original 510(k) kit. Substantial equivalency was validated by the testing.

Performance Sensitivity/ Specificity Data:

Original 510(k) Test Kit ASM Abstract C 38 Data:			Modified Test Kit Comparison Data for Bench Study:					
Pos. / Neg.			TREND ELISA Pos. / Neg.			Competitor ELISA Pos. / Neg.		
Pos. { 64 }	6	13	Pos. { 8 }	8	0	7	0 (1 N.D.)	
Neg. { 104 }	3	101	Neg. { 49 }	4	45	5	43 (1 N.D.)	
168			57					
Sensitivity = 95%			Sensitivity = 100%			100%		
Specificity = 97%			Specificity = 92%			90%		

Additional Testing:

Further bench studies validated substantial equivalency in the following identified parameters:

- Testing for "visual" interpretation was performed.
- Testing for Intra-assay (With-in) Run Precision was performed.
- Testing for Run-to-Run Precision was performed.
- Testing for Cross-reactivity

SUBSTANTIALLY EQUIVALENCY CONCLUSIONS:

The above provided information validates that the modified kit presented is substantially equivalent to the original 510(k) kit.

- The Intended Use of the kit has not been changed.
- Scientific Principle / Technology has not been changed.
- Performance Data, as presented, validates that the performance sensitivity and specificity is equivalent.

Prepared by: Sylvia W. Mills Title: Immunology Manager
 Sylvia W. Mills Date: 7/24/96