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Schistosoma IgG

REF

Catalog No.E21-181

IVD

FOR IN VITRO DIAHNOTICS USE

Stop Solution	One (1) bottle containing 11 ml of 1 M phosphoric acid.
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MATERIALS REQUIRED BUT NOT PROVIDED

Pipettes
 Squeeze bottle for washing strips
 DI water
 ELISA plate reader with a 450/620-650 nm filter (optionally, results can be read visually)
 Tubes for serum dilutions

STORAGE CONDITION

Reagents, strips and bottled components:
 Store between 2-8 °C.
 Squeeze bottle containing diluted wash buffer may be stored at room temperature.

SPECIMEN COLLECTION AND HANDLING

Coagulate blood and remove serum. Freeze sample at -20 °C or lower if not used immediately.
 Do not heat inactivate serum.
 Avoid repeated freezing and thawing of samples.

PREPARATION FOR ASSAY

Wash Buffer - Remove cap and add contents of bottle to 475 ml DI water. Place diluted wash buffer into a squeeze bottle.
Note: Washings consist of filling to the top of each well, shaking out the contents and refilling.
 Avoid generating bubbles in the wells during the washing steps.
Test samples: Make a 1:40 dilution of patients' sera using the dilution buffer.

ASSAY PROCEDURE

- Break off number of wells needed (two for controls plus number of samples) and place in strip holder.
- Add 100 µl of negative control to well #1, 100 µl of positive control to well #2, and 100 µl of the diluted (1:40) test samples to the remaining wells.
Note: Negative and positive controls are supplied as prediluted. Do not dilute.
- Incubate at room temperature (15 °C to 25 °C) for 10 minutes.
- Shake out contents and wash 3 times with diluted wash buffer.*
- Add 2 drops of enzyme conjugate to each well.
- Incubate at room temperature for 10 minutes.
- Shake out contents and wash 3 times with wash buffer.
- Add 2 drops of Chromogen to every well.
- Incubate at room temperature for 5 minutes.
- Add 2 drops of stop solution.
- Zero ELISA reader on air, read wells at 450 nm with a reference filter at 620-650 nm or read results visually.

* Washings consist of using the diluted wash buffer to fill to the top of each well, shaking out the contents and refilling the wells for a total of 3 times.

Avoid generating bubbles in the wells during the washing steps.

Controls must be included each time the kit is run.

QUALITY CONTROL

The use of a positive and negative control allows easy validation of kit stability. For a valid test, the positive control must be over 0.5 OD units and the negative control must be under 0.2 units. Should the values fall outside these ranges, the kit should not be used.

INTERPRETATION OF RESULTS

Spectrophotometer:

Zero ELISA reader on air. Read all wells using a bichromatic reading with filters at 450 nm and 620-650 nm.

Positive - Absorbance reading greater or equal to 0.2 OD units.

Negative - Absorbance reading less than 0.2 OD units.

INTENDED USE

For the qualitative determination of serum antibodies in humans, primarily IgG, to *Schistosoma* spp. using the ELISA technique.

PRINCIPAL OF THE ASSAY

During the first incubation, the antibodies in the patients' serum bind to the antigens in the test well. The next incubation allows the enzyme complex to bind to the antigen-antibody complex. After a few washings to remove unbound enzymes, a substrate is added that develops a blue color in the presence of the enzyme complex and peroxide. The stop solution ends the reaction, turning the blue assay color to yellow.

WARNING AND PRECAUTION

Do not use solutions if they precipitate or become cloudy.
 Wash concentrate may show crystallization upon storage at 4 °C. Crystallization will disappear after diluting to working strength.
 Do not use serum that may have supported microbial growth, or is cloudy due to high lipid content. Samples high in lipids should be clarified before use.
 Do not add azides to the samples or any of the reagents.
 Controls and some reagents contain Thimerosal as a preservative.
 Treat all sera as if capable of being infectious.
 The negative control has been tested and found negative for Hepatitis B surface antigen and for the antibody to HIV by required test methods. Since no test can offer complete assurance that infectious agents are not present, this product should be used under appropriate safety conditions that would be used for any potentially infectious agent.

MATERIALS PROVIDED

Test Strips	Microwells containing <i>Schistosoma</i> SEA antigens - 96 test wells in a test strip holder.
Enzyme Conjugate	One (1) bottle containing 11 ml of Protein A Peroxidase (HRP) in a stabilizing buffer with Thimerosal.
Positive Control	One (1) vial containing 2 ml of diluted rabbit <i>Schistosoma</i> -positive sera in buffer with Thimerosal.
Negative Control	One (1) vial containing 2 ml of diluted <i>Schistosoma</i> -negative human sera in buffer with Thimerosal.
Chromogen	One (1) bottle containing 11 ml of the chromogen tetramethylbenzidine (TMB).
Wash Concentrate (20X)	One (1) bottle containing 25 ml of concentrated buffer and surfactant with Thimerosal.
Dilution Buffer	Two (2) bottles containing 30 ml of buffered protein solution with Thimerosal.

Visual

A sample should be interpreted as positive if the degree of color development is obvious and significant.

TEST LIMITATION

Serological results should be used as an aid in diagnosis and should not be interpreted as diagnostic by themselves.

PERFORMANCE DATA

		Reference Method*	
		+	-
Immunospec	+	12	6
	-	0	34

TROUBLESHOOTING

Problem: Negative control has substantial color development.

Correction: Inadequate washings. Rerun test with more vigorous washings.



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Revision A

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