Overview

Useful For
Detection of antibodies to *Schistosoma* species

Highlights
This assay can be used as a screening test for detection of antibodies to *Schistosoma* species.

Positive results should be interpreted alongside clinical findings and suitable exposure history.

A single negative result should not be used to rule-out *Schistosoma* infection.

False-positive results may occur in individuals with other helminth infections.

Method Name
Enzyme Immunoassay (EIA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 1 mL

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Heat inactivated</td>
<td>Reject</td>
</tr>
</tbody>
</table>

Specimen Stability Information
Test Definition: BILHA
Schistosoma Ab, IgG, S

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>30 days</td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information

*Schistosoma* species (class Trematoda) are flukes, characterized by their flat, leaf-like morphology as adults, and use of gastropod molluscs (eg, snails) as an intermediate host. The schistosomes are also referred to as the “blood flukes,” of which there are 5 species known to infect humans: *S mansoni*, *S japonicum*, *S haematobium*, *S mekongi*, and *S intercalatum*. Among these *S mansoni*, *S japonicum* and *S haematobium* are most common.

These species have a defined geographic distribution, with *S mansoni* occurring throughout sub-Saharan Africa, the Middle East, and islands in the Caribbean; *S haematobium* found in much of the African continent and the Middle East; and *S japonicum* localized to China, Indonesia, and the Philippines.

Humans are definitive hosts for all of the *Schistosoma* species except for *S japonicum*, and infection begins with skin penetration of cercariae in contaminated water sources. The cercariae shed their bifurcated tails, becoming schistosomulae and migrate through the vascular system to the lungs, heart, and the portal venous system in the liver. There they mature to adults, pair off and migrate to the mesenteric venules of the bowel and rectum (*S mansoni*, *S japonicum*) or venus plexus of the bladder (*S haematobium*). Females will shed eggs, which are moved progressively towards the lumen of the intestine (*S mansoni*, *S japonicum*) and bladder (*S haematobium*) and are eliminated in the feces or urine, respectively. These eggs will hatch under ideal conditions, releasing miracidia, which penetrate specific snail (mollusc) intermediate hosts and develop into cercariae, continuing the life cycle.

While many infections are asymptomatic, acute schistosomiasis (Katayama fever) due to *S mansoni* or *S japonicum*, may occur weeks after initial infection. Symptoms include fever, cough, abdominal pain, diarrhea, hepatosplenomegaly, and eosinophilia. Central nervous system infection is uncommon; however, cerebral granulomatous disease may be caused by migration of *Schistosoma* eggs into the brain or spinal cord. Cystitis and ureteritis with haematuria are associated with *S haematobium* infection, and can progress to bladder cancer.

Diagnosis of schistosomiasis can be made by detection of eggs in fecal or urine samples as appropriate for each species. Antibody detection can be useful for patients who reside in nonendemic areas but have recently traveled to regions where *Schistosoma* species are found, and in whom eggs cannot be identified in fecal or urine examinations.

Reference Values

Negative

Interpretation

Negative: No IgG antibodies to *Schistosoma* species detected.

Equivocal: Recommend follow-up testing in 10 to 14 days if clinically indicated.

Positive: IgG antibody to *Schistosoma* species detected. Differentiation between *Schistosoma* species is not possible by this assay. Serologic cross-reactivity may occur in individuals with other helminth infections, including with *Echinococcus* or *Taenia* species.

Cautions
This assay is designed to specifically detect IgG-class antibodies to *Schistosoma mansoni*, which are likely cross-reactive to other *Schistosoma* species.

Sensitivity for detection of antibodies to each of the *Schistosoma* species has not been evaluated for this assay.

Patients may remain seropositive by this assay following appropriate treatment and clearance of the infection.

Positive results should be confirmed with other laboratory findings (eg, ova and parasite examination), clinical symptoms, and suitable exposure history.

**Supportive Data**

The Mayo Infectious Disease Serology laboratory evaluated the accuracy of the NovaTec *Schistosoma mansoni* IgG ELISA (as performed in our laboratory) using 64 serum samples that were previously tested by a fluorescent microsphere immunoassay at Focus Diagnostics. A comparison of the results is shown in Table 1 below.

<table>
<thead>
<tr>
<th>NovaTec ELISA</th>
<th>Focus Diagnostics FMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>31</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
</tr>
<tr>
<td>Equivocal</td>
<td>5</td>
</tr>
</tbody>
</table>

Positive agreement (95% CI): 83.8% (68.5-92.6%)

Negative agreement (95% CI): 96.3% (80.2-100%)

Overall agreement (95% CI): 89.1% (82.6-97%)

The Mayo Infectious Disease Serology laboratory also evaluated the analytic specificity of the NovaTec *S mansoni* IgG ELISA using 36 serum samples positive for antibodies to other helminth and protozoa. The results are shown in Table 2 below.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>No. of specimens tested</th>
<th>No. of sera positive or equivocal by the <em>S. mansoni</em> IgG ELISA</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Entamoeba histolytica</em> IgG Ab</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td><em>Echinococcus</em> species IgG Ab</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td><em>Strongyloides ratti</em> IgG Ab</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td><em>Taenia solium</em> IgG Ab</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td><em>Trichinella spiralis</em> IgG Ab</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td><em>Trypanosoma cruzi</em> IgG Ab</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>

The reference range for the NovaTec *S mansoni* IgG ELISA was established by testing serum from 50 normal donors; 47/50 (94%) of healthy individuals were negative by this ELISA.
Clinical Reference

Performance

Method Description
The qualitative immunoenzymatic determination of IgG-class antibodies against *Schistosoma mansoni* is based on the ELISA technique.

Microtiter strip wells are precoated with *Schistosoma mansoni* antigens to bind corresponding antibodies of the specimen. After washing the wells to remove all unbound sample material, horseradish peroxidase (HRP)-labelled Protein A conjugate is added. This conjugate binds to antigen-antibody complexes. The immune complex formed by the bound conjugate is visualized by adding tetramethylbenzidine (TMB) substrate, which gives a blue reaction product.

The intensity of this product is proportional to the amount of *Schistosoma*-specific IgG antibodies in the specimen. Sulphuric acid is added to stop the reaction. This produces a yellow endpoint colour. Absorbance at 450 nm is read using an ELISA microwell plate reader. (Package insert: NovaLisa Schistosoma mansoni, NovaTec Immundiagnostica GmbH, Dietzenbach, Germany; 05/2017)

PDF Report
No

Day(s) and Time(s) Test Performed
Tuesday, Thursday; 9 a.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
5 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.
Test Definition: BILHA
Schistosoma Ab, IgG, S

Test Classification
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
86682

LOINC® Information

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>BILHA</td>
<td>Schistosoma Ab, IgG, S</td>
<td>33317-9</td>
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</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
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