Overview

Useful For
Screening for the presence of IgG-class antibodies to *Strongyloides*

This test is **not useful** for monitoring patient response to therapy as IgG-class antibodies to *Strongyloides* may remain detectable following resolution of infection.

Highlights
This assay detects IgG-class antibodies only.

Testing Algorithm
See [Parasitic Investigation of Stool Specimens Algorithm](#) in Special Instructions.

Special Instructions
- [Parasitic Investigation of Stool Specimens Algorithm](#)

Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

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

Specimen Minimum Volume
0.4 mL

Reject Due To

<table>
<thead>
<tr>
<th>Rejection Reason</th>
<th>Rejection Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
</tbody>
</table>
Clinical and Interpretive

Clinical Information

Strongyloidiasis is caused by Strongyloides stercoralis, a nematode endemic to tropical and subtropical regions worldwide. S. stercoralis is also prominent in the southeastern United States, including in rural areas of Kentucky, Tennessee, Virginia, and North Carolina. A small series of epidemiological studies in the United States identified that 0% to 6.1% of individuals sampled had antibodies to S. stercoralis.

S. stercoralis has a complex lifecycle that begins with maturation to the infective filariform larva in warm, moist soil. The larvae subsequently penetrate exposed skin and migrate hematogenously to the lungs, from where they ascend the bronchial tree and are swallowed. Once in the small intestine, filariform larvae mature into the adult worms that burrow into the mucosa. Gravid female worms produce eggs that develop into noninfectious rhabditiform larvae in the gastrointestinal tract and are eventually released in the stool. The time from dermal penetration to appearance of Strongyloides in stool samples is approximately 3 to 4 weeks.

The most common manifestations of infection are mild and may include epigastric pain, mild diarrhea, nausea, and vomiting. At the site of filariform penetration, skin may be inflamed and itchy—this is referred to as “ground itch.” Migration of the larva through the lungs and up the trachea can produce a dry cough, wheezing, and mild hemoptysis. Eosinophilia, though common among patients with strongyloidiasis, is not a universal finding and the absence of eosinophilia cannot be used to rule-out infection.

In some patients, particularly those with a depressed immune system, the rhabditiform larvae may mature into the infectious filariform larvae in the gastrointestinal tract and lead to autoinfection. The filariform larvae subsequently penetrate the gastrointestinal mucosa, migrate to the lungs, and can complete their lifecycle. Low-level autoinfection can maintain the nematode in the host for years to decades. Among patients who become severely immunocompromised, however, autoinfection may lead to hyperinfection and fatal disseminated disease. Hyperinfection has also been associated with underlying human T-cell lymphotropic virus type 1 (HTLV-1) infection. Uncontrolled, the larvae can disseminate to the lungs, heart, liver, and central nervous system. Septicemia and meningitis are common in cases of Strongyloides hyperinfection due to seeding of the bloodstream and central nervous system with bacteria originating from the gastrointestinal tract.

Reference Values

Negative

Reference values apply to all ages.

Interpretation

Positive:
IgG antibodies to *Strongyloides* were detected, suggesting current or past infection. False-positive results may occur with other helminth infections (eg, *Trichinella*, *Taenia solium*). Clinical correlation is required.

Negative:

No detectable levels of IgG antibodies to *Strongyloides*. Repeat testing in 10 to 14 days if clinically indicated.

**Cautions**

False-positive results may occur with other helminth infections, including prior exposure to *Entamoeba histolytica*, *Ascaris*, *Taenia solium*, *Fasciola* species, *Echinococcus* species, *Schistosoma* species, and *Toxocara* (per assay manufacturer).

This assay should not be used alone to establish a diagnosis of strongyloidiasis. Results should be correlated with other laboratory findings and through clinical evaluation.

False-negative results may occur during acute or localized infection. A single negative result should not be used to rule-out infection.

The seroprevalence of IgG-class antibodies to *Strongyloides stercoralis* ranges from 0% to 6.1% in the United States.

**Supportive Data**

**Accuracy:**

The Bordier *Strongyloides* enzyme immunoassay (EIA) was compared to the *Strongyloides* Luciferase Immunoprecipitation (LIPS) Assay as performed at the National Institutes of Health and to the SciMedix *Strongyloides* IgG enzyme-linked immunosorbent assay (ELISA) using 102 serum samples. Based on prior publications, the LIPS assay was considered the gold standard comparator for this evaluation.(1,2) The comparative data is shown below in Tables 1, 2, and 3:

<table>
<thead>
<tr>
<th>Table 1. Comparison of results between the Bordier and NIH LIPS assays (n=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NIH LIPS</strong></td>
</tr>
<tr>
<td>Positive</td>
</tr>
<tr>
<td>Negative</td>
</tr>
</tbody>
</table>

Positive Agreement: 96.2% (51/53); 95% Confidence Interval (CI): 86.5%-99.7%

Negative Agreement: 75.0% (36/48); 95% CI: 61.1%-85.2%

Overall Agreement: 85.3% (87/102); 95% CI: 77.0%-91.0%

<table>
<thead>
<tr>
<th>Table 2. Comparison of results between the Bordier and SciMedx assays (n=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SciMedx</strong></td>
</tr>
<tr>
<td>Positive</td>
</tr>
<tr>
<td>Negative</td>
</tr>
</tbody>
</table>
Positive Agreement: 84.9% (45/53); 95% CI: 72.7%-92.4%
Negative Agreement: 69.8% (30/43); 95% CI: 54.8%-81.5%
Overall Agreement: 73.5% (75/102); 95% CI: 64.2%-81.2%

<table>
<thead>
<tr>
<th>SciMedix</th>
<th>NIH LIPS</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>42</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>7</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>Equivocal*</td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

*Equivocal results were excluded from calculation of positive and negative agreement.

Positive Agreement: 85.7% (42/49); 95% CI: 73.0%-93.2%
Negative Agreement: 76.6% (36/47); 95% CI: 62.6%-86.6%
Overall Agreement: 76.5% (78/102); 95% CI: 67.3%-83.7%

Reference Range:
Evaluation was performed on 100 normal donor serum samples by the Bordier Strongyloides assay and 99% (99/100) were negative.

Clinical Reference

Performance

Method Description
The Bordier Strongyloides ratti IgG ELISA is an enzymatically amplified sandwich-type immunoassay. After a blocking step, diluted serum and controls are incubated in antigen-coated microtiter wells, then washed and
incubated with antihuman-IgG antibody labeled with protein A-alkaline phosphatase conjugate. After a washing step, 
the wells are incubated with phosphatase substrate. The reaction is halted by potassium phosphate stopping solution 
and the degree of enzymatic turnover is determined by absorbance measured at 405 nanometers with a reference 
filter of 590 to 650 nm. (Package insert: Strongyloides Ratti Enzyme immunoassay for the diagnosis of human 
Strongyloidosis. Bordier Affinity Products SA; 01/2018)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday, Wednesday, Friday; 2 p.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
4 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 Classification
This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per 
manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with 
CLIA requirements.

CPT Code Information
86682

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRNG</td>
<td>Strongyloides Ab, IgG, S</td>
<td>34376-4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRNG</td>
<td>Strongyloides Ab, IgG, S</td>
<td>80660-4</td>
</tr>
</tbody>
</table>