

# **Test Definition: STRNG**

Strongyloides Antibody, IgG, Serum

# 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.

# **Testing Algorithm**

For more information see Parasitic Investigation of Stool Specimens Algorithm.

# Special Instructions

• Parasitic Investigation of Stool Specimens Algorithm

# Highlights

This assay detects IgG-class antibodies only.

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 Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

# Forms

If not ordering electronically, complete, print, and send <u>Infectious Disease Serology Test Request</u> (T916) with the specimen.

# Specimen Minimum Volume

0.4 mL



Strongyloides Antibody, IgG, Serum

# Reject Due To

Gross	Reject
hemolysis	
Gross lipemia	Reject
Gross icterus	Reject
Heat	Reject
inactivated	
specimen	

# **Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	30 days	
	Frozen	30 days	

# **Clinical & 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 larva matures 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 infection. Uncontrolled,



Strongyloides Antibody, IgG, Serum

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 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 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 1. Comparison of results between the Bordier and NIH LIPS assays (n=102)

		NIH LIPS	
		Positiv	Negativ
		е	е
Bordier	Positive	51	12
	Negativ	3	36
	е		



# **Test Definition: STRNG**

Strongyloides Antibody, IgG, Serum

Positive Agreement: 96.2% (51/53); 95% 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 2. Comparison of results between the Bordier and SciMedx assays (n=102)

		SciMedx		
		Positiv	Negativ	Equivocal
		е	е	
Bordier	Positive	45	13	5
	Negativ	8	30	1
	е			

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 3. Comparison of results between the SciMedx and NIH LIPS assays (n=102)

		NIH LIPS	
		Positive	Negative
SciMedix	Positive	42	11
	Negative	7	36
	Equivocal	5	1
	*		

Г

\*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%



Strongyloides Antibody, IgG, Serum

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**

1. Ramanathan R, Burbelo PD, Groot S, et al: A luciferase immunoprecipitation systems assay enhances the sensitivity and specificity of diagnosis of *Strongyloides stercoralis* infection. J Infect Dis. 2008;198(3):444-451

2. Starr MC, Montgomery SP: Soil-transmitted Helminthiasis in the United States: a systematic review-1940-2010. Am J Trop Med Hyg. 2011;85(4):680-684

3. Krolewiecki AJ, Ramanathan R, Fink V, et al: Improved diagnosis of *Strongyloides stercoralis* using recombinant antigen-based serologies in a community-wide study in northern Argentina. Clin Vaccine Immunol. 2010;17(10):1624-1630

4. Centers for Disease Control and Prevention. Global Health. Division of Parasitic Diseases and Malaria:

Parasites-Strongyloides: Epidemiology and Risk Factors. CDC; Updated December 31, 2018. Accessed October 15, 2020. Available at www.cdc.gov/parasites/strongyloides/epi.html

# Performance

# **Method Description**

The Bordier *Strongyloides ratti* IgG enzyme-linked immunosorbent assay 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) Performed Monday, Wednesday, Thursday, Friday

**Report Available** Same day/1 to 4 days

Specimen Retention Time 14 days

Performing Laboratory Location

Rochester



# **Test Definition: STRNG**

Strongyloides Antibody, IgG, Serum

# Fees & Codes

#### Fees

- Authorized users can sign in to <u>Test Prices</u> for detailed fee information.
- Clients without access to Test Prices can contact <u>Customer Service</u> 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

#### **Test Classification**

This test has been cleared, approved, or is exempt by the US 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<sup>®</sup> Information

Test ID	Test Order Name	Order LOINC <sup>®</sup> Value
STRNG	Strongyloides Ab, IgG, S	34376-4

Result ID	Test Result Name	Result LOINC <sup>®</sup> Value
STRNG	Strongyloides Ab, IgG, S	80660-4