

## Overview

### Useful For

Evaluation of possible legionellosis (Legionnaires disease, Pontiac fever, extrapulmonary legionella infection caused by *Legionella pneumophila*)

### 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.

### Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Heat inactivated specimen	Reject

### Specimen Minimum Volume

0.4 mL

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	14 days	

**Clinical & Interpretive****Clinical Information**

*Legionella pneumophila* may cause pulmonary disease in both normal and immunocompetent hosts. The disease may occur sporadically in the form of community acquired pneumonia and in epidemics. Pneumonia (often referred to as Legionnaires disease) occurs more frequently in severely immunosuppressed individuals; a milder form of the illness, referred to as Pontiac fever, is more prevalent in normal hosts. Extrapulmonary infection with *L pneumophila* is rare. Legionnaires disease, Pontiac fever, and extrapulmonary infection have been collectively referred to as legionellosis.

Approximately 85% of the documented cases of legionellosis have been caused by *L pneumophila*. Serogroups 1 and 6 of *L pneumophila*, by themselves, account for up to 75% of cases of legionellosis.

The definitive diagnosis of *L pneumophila* is made by isolation of the organism on specialized culture medium (buffered charcoal yeast extract agar) or detection by a nucleic acid amplification test. In the absence of invasive procedures (eg, bronchial alveolar lavage), evaluation of patient urine samples for *L pneumophila* serotype 1 antigen may be useful. Testing for antibodies to *L pneumophila* may be helpful to establish prior exposure or infection, however, does not differentiate between acute and past infection.

**Reference Values**

Negative

Reference values apply to all ages.

**Interpretation**

A negative result indicates that IgG, IgA, and IgM antibodies to *Legionella pneumophila* serogroups 1-6 were not detected. Negative results do not exclude *Legionella* infection. It may require 4 to 8 weeks to develop a detectable antibody response; serum specimens taken early in the course of infection may not yet have significant antibody titers. Furthermore, antibody levels can fall to undetectable levels within a month of infection, early antibiotic therapy may suppress antibody response, and some individuals may not develop antibodies above detectable limits.

Some culture-positive cases of *Legionella* do not develop *Legionella* antibody.

Positive results are suggestive of *Legionella* infection. A positive result only indicates immunologic exposure at some point in time. It does not distinguish between previous or current infection. The level of antibody response may not be used to determine active infection. Other laboratory procedures or additional clinical information are necessary to establish a diagnosis.

Specimens with equivocal results are retested prior to reporting. Repeat testing on a second specimen should be considered in patients with equivocal results, if clinically indicated.

**Cautions**

A diagnosis should not be made on the basis of positive *Legionella* antibody results alone. Test results for *Legionella* antibodies should be interpreted in conjunction with the clinical evaluation and the results of other diagnostic procedures.

A positive result suggests infection with one or more of the groups 1-6 species; however, it is not possible to distinguish between species with the results of this enzyme-linked immunosorbent assay (ELISA) test alone.

Use of serogroups 1-6 for assessing antibody responses to different *Legionella* species and serogroups has not been established.

Cross-reactivity may occur in sera with infections due to other *Legionella* species.

Positive results may be due to cross-reactivity with antibody generated as a result of non-*Legionella* infection. Serologic cross-reactions have been reported with *Pseudomonas aeruginosa*, several *Rickettsia* species, *Coxiella burnetii*, enteric gram-negative rods, *Bacteroides* species, *Haemophilus* species, *Citrobacter freundii*, and *Campylobacter jejuni*. Additionally, some reports indicate that a number of apparently healthy individuals may carry antibodies to legionellae; however, a positive result, along with clinical signs and symptoms may indicate possible *Legionella* infection. Additional testing to directly detect the organism, either through culture or nucleic acid amplification tests is recommended to make a diagnosis of current infection.

The assay performance characteristics have not been established for matrices other than sera.

Although the conjugate is designed to detect human IgG, IgM, and IgA, it is not possible to determine which antibody is

present with this assay.

The use of hemolytic, lipemic, bacterially contaminated, or heat-inactivated specimens should be avoided as erroneous results may occur.

**Clinical Reference**

1. Koneman EW, Allen SD, Janda WM, eds. Color Atlas and Textbook of Diagnostic Microbiology. 5th ed. Lippincott-Raven Publishers 1997
2. Edelstein PH, Roy CR: Legionnaires' disease and Pontiac fever. In: Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 9th ed. Elsevier; 2020

**Performance****Method Description**

The *Legionella* kit is designed to detect IgG-, IgA-, and IgM-class antibodies to *Legionella pneumophila* in human sera. The test procedure involves 3 incubation steps:

1. Test sera (properly diluted) are incubated in multiwells coated with an inactivated, solubilized cocktail of *L pneumophila* groups 1-6 bacteria (antigen). *Legionella* specific IgG, IgM, or IgA antibodies in the specimen will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.
2. Peroxidase-conjugated goat-antihuman IgG, IgA, and IgM is added to the wells and the plate is incubated. The conjugate will react with antibody immobilized on the solid phase in step 1. The wells are washed to remove unreacted conjugate.
3. The multiwells containing immobilized peroxidase conjugate are incubated with peroxidase substrate solution. Hydrolysis of the substrate by peroxidase produces a color change. After a period of time, the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution depends upon the antibody concentration in the test specimen. (Package insert: *L. pneumophila* IgG/IgM/IgA Test System. Zeus Scientific; Revision 12/19/2017)

**PDF Report**

No

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

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Rochester

**Fees & Codes****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 US Food and Drug Administration.

**CPT Code Information**

86713

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
SLEG	Legionella Pneumophila Ab, S	7947-5

Result ID	Reporting Name	LOINC®
SLEG	Legionella Pneumophila Ab, S	7947-5