Test Definition: LEPDT

Leptospira, IgM, Serum

Overview

Useful For

Aiding in the diagnosis of leptospirosis

This test is **not useful for** establishing cure or response to therapy.

Highlights

This test is intended to be used as an aid for the diagnosis of acute or recent leptospirosis due to infection with *Leptospira* species.

This is a qualitative immunodot test for detection of IgM-class antibodies to *Leptospira* species.

A negative result by this assay does not exclude the possibility of leptospirosis, and all results must be correlated with clinical presentation and exposure history.

Method Name

Enzyme-Linked Immunoassay Dot (Immunodot)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.3 mL Serum
Collection Instructions: Centrifuge and aliquot serum into plastic vial.
Additional Information: If acute and convalescent specimens are being obtained to determine seroconversion, they should be collected 2 or more weeks apart.

Forms

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

Specimen Minimum Volume

Serum 0.1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Leptospirosis is a zoonotic disease of worldwide prevalence, though the majority of infections occur in warm, tropical climates. Wild mammals, typically rodents, are the primary, natural reservoir for disease-causing strains of *Leptospira*; however, domestic animals (eg, dogs) also represent a major source of human infection. *Leptospira* are gram-negative spirochetes with at least 20 different species in the genus. Of these, at least 9 species are considered disease-causing, including the most common agent of leptospirosis, *Leptospira interrogans*.

Transmission occurs through indirect human contact (eg, via mucous membranes or abraded skin) with water, food, or soil contaminated with animal urine containing the *Leptospira* spirochetes. Following infection, the incubation period can range from 3 to 30 days, depending on the inoculum dose and immune status of the individual.

The clinical manifestations of leptospirosis can vary, ranging from a mild, flu-like illness (eg, headache, malaise, fever, arthralgia, fatigue) to fulminant disease with severe liver and kidney involvement. The latter manifestation was previously referred to as Weil disease. *Leptospira* organisms may be found in the blood at the onset of disease and can persist for approximately 1 week. Subsequently, spirochetes may be found in the urine and can persist for 2 to 3 months; however, shedding may be intermittent, and the number of organisms present may be low.

While *Leptospira* can be grown in culture, this is a fastidious organism that requires immediate transport to the laboratory. Additionally, detectable growth requires prolonged incubation (1-6 weeks), limiting the utility of culture for acute diagnosis. For this reason, serologic detection for antibodies to *Leptospira* remains the method of choice for rapid diagnosis. IgM-class antibodies to this spirochete are detectable by day 6 of illness and remain detectable for 2 to 3 months following symptom onset.

Reference Values

Negative

Interpretation

Positive:
IgM antibodies to *Leptospira* species detected, suggesting recent infection. Antibody presence alone cannot be used to definitively diagnose acute infection, as antibodies from a prior exposure or infection may remain detectable for a prolonged period.

Borderline:
Result should be interpreted with caution. Additional testing of a second, convalescent specimen is recommended. If the specimen remains borderline reactive, a second serological method should be considered if leptospirosis infection is still suspected.

Negative:
No IgM antibodies to *Leptospira* detected. Since antibodies may not be present or may be present at undetectable levels during early disease, repeat testing of a convalescent sample collected in 2 to 3 weeks is recommended.

Cautions

The temporal IgM immune response can vary among patients. Therefore, a single negative result by this assay should not be used to exclude diagnosis, especially in patients with symptoms suggestive of leptospirosis who have an appropriate exposure history.

This test does not distinguish between acute or past infection. Clinical correlation is required. Patients may remain seropositive for months to possibly years following resolution of disease; therefore, this test cannot be used to establish cure or response to therapy.

Clinical Reference

1. Saliba J, Vassallo C, Saliba J, Pace Bardon M. Leptospirosis: A clinical and diagnostic challenge. BMJ Case Rep. 2024;17(5):e256905. doi:10.1136/bcr-2023-256905
2. Lee N, Tanaka T, Koizumi N, et al. Leptospirosis-clinical review and updates on therapeutics. Lancet Infect Dis. Published online April 17, 2026. doi:10.1016/S1473-3099(26)00060-5

Performance

Method Description

The GenBio IgM ImmunoDOT *Leptosirosis* test utilizes an enzyme-linked immunoassay dot technique for the detection of IgM antibodies. *Leptospira biflexa*, serovar Patoc 1 strain antigens are dispensed as discrete dots onto a solid membrane. After adding the test specimen to a reaction cuvette, an assay strip is inserted, allowing patient antibodies reactive with the test antigens to bind to the strip's solid support member. Alkaline phosphatase conjugated goat antihuman IgM antibodies are allowed to react with bound patient antibodies. Finally, the strip is transferred to an enzyme substrate reagent, which reacts with bound alkaline phosphatase to produce an easily seen, distinct spot.(Package insert: ImmunoDOT Leptospira IgM. GenBio; 06/20/2022)

PDF Report

No

Day(s) Performed

Monday, Thursday

Report Available
Same day/1 to 5 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 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
86720

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
LEPDT	Leptospira, IgM, S	23201-7

Result ID	Test Result Name	Result LOINC® Value
65183	Leptospira, IgM, S	23201-7