

## Overview

### Useful For

Determining the current disease status and evaluating response to therapy for syphilis

This test should **not be used** as a primary diagnostic approach for syphilis.

This test is **not useful for** testing spinal fluid specimens.

This test is **not intended for** medical-legal use.

### Highlights

This assay provides a rapid plasma reagin (RPR) screen and can be used to monitor response to therapy in patients treated for syphilis infection.

### Reflex Tests

| Test ID | Reporting Name | Available Separately | Always Performed |
|---------|----------------|----------------------|------------------|
| RRPRQ   | RPR Titer, S   | No                   | No               |

### Testing Algorithm

If this test is positive, then the titer will be performed at an additional charge.

### Method Name

RPRRT: Multiplex Flow Immunoassay

RRPRQ: Flocculation/Agglutination

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

This test is for monitoring response to therapy in patients treated for a syphilis infection. To screen patients for an undiagnosed syphilis infection, order SYPHT / Syphilis Total Antibody with Reflex, 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 plastic vial.

### 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

|                           |        |
|---------------------------|--------|
| Gross hemolysis           | Reject |
| Gross lipemia             | Reject |
| Heat-inactivated specimen | Reject |

### Specimen Stability Information

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

## Clinical and Interpretive

### Clinical Information

Syphilis is a disease caused by infection with the spirochete *Treponema pallidum*. The infection is systemic, and the disease is characterized by periods of latency. These features, together with the fact that *T pallidum* cannot be isolated in culture, mean that serologic techniques play a major role in the diagnosis and follow-up of treatment for syphilis.

Patients with primary or secondary syphilis should be reexamined clinically and serologically 6 months and 12 months following treatment. Typically, rapid plasma reagin (RPR) titers decrease following successful treatment, but this may occur over a period of months to years.

Treatment response is generally indicated by a 4-fold (2-tube dilution) reduction in RPR titer (eg, from 1:32 to 1:8). For proper interpretation of RPR results, titers should be obtained using the same testing method, preferably at the same testing laboratory.

Failure of nontreponemal test titers to decline 4-fold within 6 months after therapy for primary or secondary syphilis may be indicative of treatment failure. Patients whose titers remain serofast should be reevaluated for HIV infection.

### Reference Values

Nonreactive

### Interpretation

Reactive:

Specimen reflexed to determine rapid plasma reagin (RPR) titer value.

Nonreactive

### Cautions

Biological false-positive reactions with cardiolipin-type antigens have been reported in disease such as infectious mononucleosis, leprosy, malaria, lupus erythematosus, vaccinia, and viral pneumonia. Pregnancy, autoimmune diseases, and narcotic addictions may give false-positive results. Pinta, yaws, bejel, and other treponemal diseases may also produce false-positive results with this test.

### Clinical Reference

1. Workowski KA, Berman S: Sexually transmitted diseases treatment guidelines. MMWR Morb Mortal Weekly Rep. 2006 Aug 4;(55);22-30
2. Miller JN: Value and limitations of nontreponemal and treponemal tests in the laboratory diagnosis of syphilis. Clin Obstet Gynecol. 1975 Mar 18;18(1);191-203. doi: 10.1097/00003081-197503000-00017
3. Morshed M, Singh AE: Recent trends in the serologic diagnosis of syphilis. Clin Vaccine Immunol. 2015 Feb;22(2):137-147. doi: 10.1128/CVI.00681-14

### Performance

#### Method Description

For the initial automated rapid plasma reagin (RPR) screen, cardiolipin antigen-coated fluoromagnetic beads with unique fluorescent signatures are used to identify nontreponemal reagin antibodies in human serum. Dyed microparticle beads are coated with cardiolipin antigen. The BioPlex 2200 System combines an aliquot of patient sample, sample diluent, and bead reagent into a reaction vessel. The mixture is incubated at 37 degrees C. After a wash cycle, antibodies conjugated to phycoerythrin (PE) are added to the dyed beads, and this mixture is incubated at 37 degrees C. The excess conjugate is removed in another wash cycle, and the beads are resuspended in wash buffer. The bead mixture then passes through the detector. The identity of the dyed beads is determined by the fluorescence of the dyes, and the amount of nontreponemal reagin antibodies captured by the reagin is determined by the fluorescence of the attached PE. Raw data is calculated in relative fluorescence intensity (RFI). (Package insert: BioPlex 2200 Syphilis Total and RPR. Bio-Rad; 06/2017)

If the RPR screen is reactive, an RPR titer test is performed reflexively using a manual method. The RPR titer test is a macroscopic screening assay done with unheated serum. Reagin reacts with non-treponemal antigen containing colloidal charcoal particles. This reaction results in a visual flocculation of the black particles against the white card background. The test yields a positive or negative result, and all positive samples are titered to determine the highest positive dilution. (Huber TW, Storms S, Young P, et al: Reactivity of microhemagglutination, fluorescent treponemal antibody absorption, Venereal Disease Research Laboratory, and rapid plasma reagin tests in primary syphilis. J Clin Microbiol. 1983 Mar;17[3]:405-409; Kaur G, Kaur P: Syphilis testing in blood donors: an update. Blood Transfus. 2015 Apr;13[2]:197-204. doi: 10.2450/2014.0146-14)

#### PDF Report

No

#### Day(s) Performed

Monday through Saturday

**Report Available**

Same day/1 to 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 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**

0065U (PLA Code)

86593-Rapid Plasma Reagin Titer (if appropriate)

**LOINC® Information**

| Test ID | Test Order Name                    | Order LOINC Value |
|---------|------------------------------------|-------------------|
| RPRRT   | RPR Screen, Response to Therapy, S | 47236-5           |

| Result ID | Test Result Name                   | Result LOINC Value |
|-----------|------------------------------------|--------------------|
| RPRRT     | RPR Screen, Response to Therapy, S | 20507-0            |