

# Syphilis

## Overview

### Clinical

Syphilis is a sexually transmitted infection caused by the bacterium *Treponema pallidum* (*T.pallidum*) that can cause severe health issues if not treated. Infection develops in stages (primary, secondary, latent and tertiary) with its own symptomatology.<sup>1</sup> Congenial syphilis is when the disease is transmitted from progenitor to child during pregnancy.

In clinical settings the measurement of anti *Treponema pallidum* antibodies (TPAb) can be used as an aid to evaluate patients with signs suggestive of syphilis early primary infection <sup>2</sup>

### Epidemiology

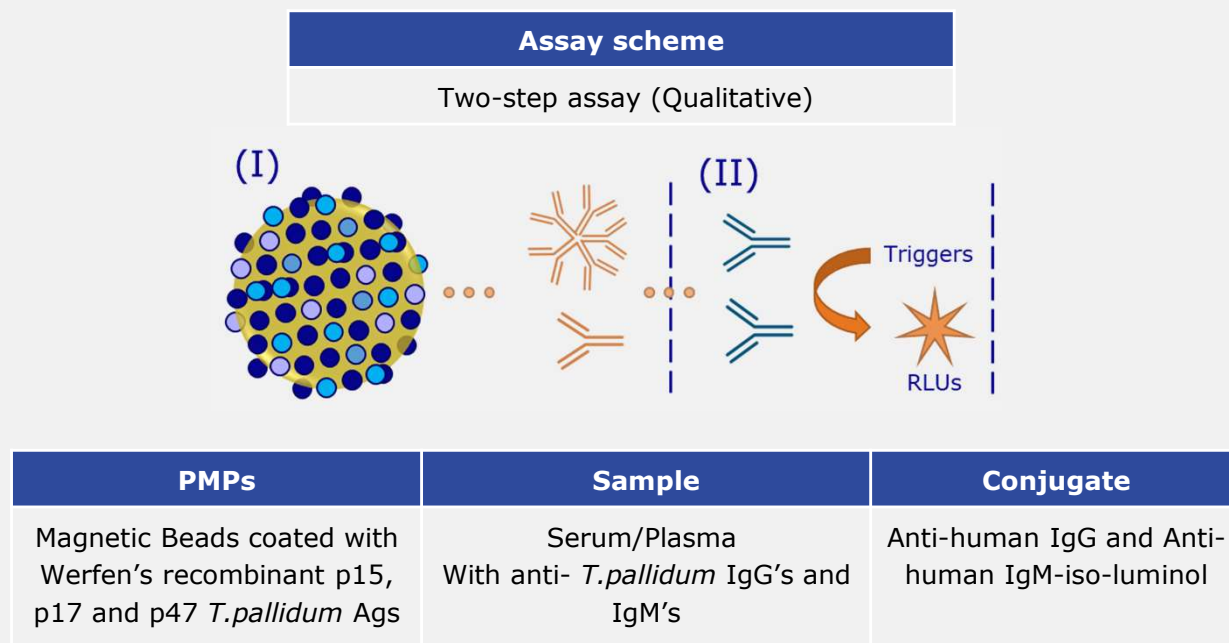
It is estimated that in 2022 8 million adults acquired syphilis globally. And it is estimated that in 2022 there were 700,000 cases of congenital syphilis globally.

Maternal syphilis cases in 2022 have led to an estimated 150,000 early fetal deaths and stillbirths, 70,000 neonatal deaths, 55,000 preterm/low weight births and 115,000 newborns diagnosed with congenial syphilis<sup>3</sup>.

## Syphilis CLIA

### Assay Scheme

Qualitative measurement of IgG and IgM antibodies to *Treponema pallidum* in human serum or plasma



1 CDC Factsheet on Syphilis. December 2023. Accessed July 2024 <https://www.cdc.gov/syphilis/about/index.html>

2. Papp J et al. CDC Laboratory Recommendations for Syphilis testing, United States. Feb 2024, Accessed July 2024 . <https://www.cdc.gov/mmwr/volumes/73/rr/rr7301a1.htm>

3. Syphilis Key Facts. WHO. May 2024. Accessed July 2024 <https://www.who.int/news-room/fact-sheets/detail/syphilis>

# Evaluation of Syphilis CLIA vs reference assay

Syphilis CLIA Assay	Algorithm Consensus		Total
	NEG	POS	
NEG	431	0	431
POS	0	65	65
Total	431	65	496

**Table 2:** External evaluations were performed in a clinical laboratory. Samples were characterized by a commercially available Syphilis CMIA Assay. Reactive samples were tested with RPR and TPHA in accordance with the algorithm followed in the laboratory

N	Resolved Sensitivity		Resolved Specificity		Resolved Overall Agreement	
	Value	95% CI	Value	95% CI	Value	95% CI
496	100%	95.4% to 100%	100.0%	99.1% to 100%	100%	99.3% to 100%

**Table 3:** Results on table 3 were obtained for relative sensitivity, specificity and overall agreement

## Cross-reactivity Test with Syphilis CLIA

Cross-reactivity	
Cross-reactant type	Agreement
anti-Toxoplasma ( <i>Toxoplasma gondii</i> )	3/3
anti-Rubella	3/3
anti-HIV (Human Immunodeficiency Virus)	3/3
anti-HSV-1 and HSV-2 (Herpes Simplex Virus 1&2)	6/6
Anti-HCV (Hepatitis C Virus)	3/3
anti-HAV (Hepatitis A Virus)	3/3
Anti-HTLV (Human T-lymphotropic virus)	3/3
<i>Chlamydia trachomatis</i>	3/3
anti-HEV (Hepatitis E Virus)	3/3
anti-EBV (Epstein-Barr Virus)	3/3
Anti-CMV (Cytomegalovirus)	3/3
anti-VZV (Varicella Zoster Virus)	3/3
<i>Neisseria gonorrhoeae</i>	3/3

**Table 4. Cross-reactant sample testing.** 42 specimens with potential cross-reactivity with the Syphilis CLIA assay were tested against a commercially available Syphilis assay. Table above is showing the agreement between methods

## Werfen's Biomaterial offering

### Recombinant p15 *Treponema pallidum* Ag

(ref 3000-5306 / 3000-5289)

Storage: -70 °C

Tag: GST

Source: *Escherichia coli*

Storage buffer: Tris-HCl, NaCl, pH 8.0

Purification method: Affinity

Chromatography

Protein concentration: 3-7 mg/mL

Preservative: None

### Recombinant p17 *Treponema pallidum* Ag

(ref 3000-5305 / 3000-5280)

Storage: -70 °C

Tag: GST

Source: *Escherichia coli*

Storage buffer: Tris-HCl, NaCl, pH 8.0

Purification method: Affinity

Chromatography

Protein concentration: 8-12 mg/mL

Preservative: None

### Recombinant p47 *Treponema pallidum* Ag

(ref 3000-5307 / 3000-5284)

Storage: -70 °C

Tag: GST

Source: *Escherichia coli*

Storage buffer: Tris-HCl, NaCl, pH 8.0

Purification method: Affinity

Chromatography

Protein concentration: 4-6 mg/mL

Preservative: None

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Contact [immunoassay@werfen.com](mailto:immunoassay@werfen.com) for further technical information and product availability

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