

# Syphilis Diagnostic Assay by Loop-Mediated Isothermal Amplification

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## What is the Problem?

The rapid and ongoing increase in syphilis infections in the United States have contributed to health disparities for racial/ethnic minorities and men who have sex with men. Syphilis cases are also associated with significant maternal-fetal mortality. Serologic assays are the current gold standard of syphilis diagnosis, but they require confirmation by stepwise, algorithmic testing for treponemal and non-treponemal antibodies, significantly increasing the time to diagnosis. As a result, there is a need to increase the speed and accuracy of laboratory diagnostics to disrupt the cycle of worsening infections by providing prompt treatment decision-making.

## What is the Solution?

The solution is a rapid assay that targets nucleic acids of the causative organism of syphilis, *Treponema pallidum*, to diagnose syphilis quickly and accurately. The technology is a loop-mediated amplification (LAMP) assay that detects *Treponema pallidum* nucleic acids with high-sensitivity and high-specificity and has been validated for clinical use. The test has 100% accuracy in clinical specimens known to contain *Treponema pallidum* DNA and 100% specificity in a panel of more than 100 species of bacteria.

## What is the Competitive Advantage?

The competitive advantage of this technology lies in its ability to provide fast and accurate diagnostic results for syphilis to enable prompt treatment decision-making. The assay can be used for direct testing of patient specimens, including swabs, cellular tissue, body fluids, and blood. It can be incorporated into point-of-care tests to improve patient outcomes. As the global syphilis testing market size was valued at \$1.1 billion in 2020 with an expected CAGR of 5.6%, there is a significant opportunity for this technology to advance the field of syphilis diagnostics.

**Technology ID**

BDP 8722

## Category

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## Authors

Joshua Lieberman

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