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

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Category

Selection of Available Technologies

Diagnostic

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