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Bio-Rad gets FDA approval for syphilis assay

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Clinical diagnostic products developer Bio-Rad Laboratories has obtained the US Food and Drug Administration (FDA) clearance for its BioPlex 2200 Syphilis Total and RPR assay designed to diagnose syphilis infection.

To enable effective monitoring of treatment, the BioPlex 2200 Syphilis features fully automated Treponemal/non-Treponemal dual assay that simultaneously detects Treponema pallidum (T. Pallidum) and reagin antibodies, as well as the level of antibody measured as RPR titer.

When compared to existing manual RPR card tests, the automation of examination is claimed to allow labour savings, objective result reporting, and improved workflow to laboratories.

The system facilitates quick process or multiplex of several individual tests that are usually processed separately.

The multiplex feature of the system aids in conserving patient sample volume and simplifies the workflow.

The addition of the BioPlex 2200 Syphilis Total and RPR assay broadens the company’s expanding BioPlex 2200 System infectious disease menu while offering laboratories a simplified approach to syphilis testing. It is adaptable to any testing algorithm used by a laboratory.