

Roche receives FDA nod for the cobas HSV 1 and 2 Test

05 June 2015 | News | By BioSpectrum Bureau

Roche receives FDA nod for the cobas HSV 1 and 2 Test



Roche has announced that the US Food and Drug Administration (US FDA) has provided 510(k) clearance for the cobas HSV 1 and 2 Test. The test is for the direct detection and differentiation of HSV-1 and HSV-2 DNA in anogenital specimens from symptomatic patients.

With dual target detection and automation, the cobas HSV 1 and 2 Test provides laboratories with the capability to report up to 94 results in significantly less time than traditional methods. It also provides a simplified workflow for sample handling in the laboratory.

"The addition of the cobas HSV 1 and 2 Test expands the menu for the cobas 4800 System, enabling labs to experience increased efficiency with innovative testing solutions. This highly sensitive and specific new test for the detection of herpes simplex virus delivers reliable results to physicians for optimal patient treatment and clinical management decisions," said Mr Paul Brown, head of Roche Molecular Diagnostics.

The cobas HSV 1 and 2 Test offers accurate and reliable results through the use of simple and reliable sample collection technology and automated processing.

The test is performed on the cobas 4800 System, currently the only FDA-cleared system which offers the flexibility to run sexually transmitted infection and healthcare-associated infection tests, in the same run, on a single platform.