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Roche's cobas TaqScreen MPX Test gains US FDA approval

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Roche has announced that the US Food and Drug Administration (US FDA) has approved the cobas TaqScreen MPX Test, v2.0 for use in the detection and identification of HIV, HCV, and HBV in donations of human whole blood and blood components including source plasma.

This latest version of the cobas TaqScreen MPX Test provides increased sensitivity and is the only FDA approved test to simultaneously detect and identify the most critical viral targets in one simple, ready-to-use assay.

The combination of viral target detection and identification steps on a fully automated system offers workflow advantages to blood and plasma testing centers by eliminating the need for consecutive rounds of testing, and facilitating earlier donor counseling in the event of a positive result.

"Since 1998, Roche has developed assays and systems designed to protect the blood and plasma supply on a global scale. By continually developing these innovative products we are striving for the highest level of safety for patients and efficiency for blood and plasma centers. This latest approval supports that commitment," said Mr Roland Diggelmann, COO, Roche Diagnostics.

Along with CE Mark and recent approvals in Canada, Brazil, China, and India, FDA approval of the cobas TaqScreen MPX Test, v2.0 supports safety standards of blood and plasma centers worldwide. By utilising real-time, multi-dye PCR technology, individual specimens are simultaneously detected and discriminated for HIV, HCV and HBV, reducing the sample volume required and the turnaround time for donor testing.