BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Roche receives US FDA approval for first molecular test to screen for malaria in blood donors

March 27, 2024 | News

Cobas Malaria test is the first FDA-approved molecular test to screen US blood donors for malaria



Swiss firm Roche has announced the US Food and Drug Administration (FDA) approval of the cobas® Malaria test for use on the cobas® 6800/8800 Systems. This approved test can aid healthcare professionals in reducing potential risks of patient infection from transfused blood products. The cobas Malaria test provides a highly sensitive and specific solution to help ensure that infected blood units are removed from the blood supply.

The cobas Malaria molecular test screens whole blood samples for the five main species of Plasmodium parasites that are known to cause human infection. The potential value of a molecular donor screening test for malaria is to improve both blood safety and availability. The test is intended for use in screening blood, organ and tissue donors.

The test will be available in the United States at the end of Q2 2024. Approval in CE-marked countries is anticipated later this year.

The cobas Malaria test, a qualitative in vitro nucleic acid screening test, allows for direct detection of Plasmodium RNA and DNA in whole blood samples from individual human donors. The test, which can be performed with other routine blood donor screening tests, is designed for use on the cobas 6800/8800 Systems in the US.