FDA approves automated hepatitis B test

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The U.S. Food and Drug Administration has approved the first automated product combining screening and confirmatory tests for hepatitis B surface antigen.

The Illinois-headquartered Abbott Laboratories' PRISM HBsAg assay was approved to test people who donate blood, blood components, and organs for the hepatitis B virus. The test also may be used to screen blood from cadavers for organ and tissue donation.

The FDA said the assay also was approved for the confirmation of samples it found to be reactive. Currently, screening and confirmatory tests are performed separately.

"This automated test system increases the efficiency and convenience of screening blood, tissue and organ donors for the hepatitis B virus," said Dr. Jesse Goodman, director of the FDA's Center for Biologics Evaluation and Research. "Improvements in blood donor screening and testing over the last few years have helped make the nation's blood supply safer from infectious diseases than it has been at any other time."

Hepatitis B, caused by a virus that infects the liver, can only be determined by a blood test.

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