FDA grants EUA for Chembio Ebola test

December 2018—Chembio Diagnostics announced FDA emergency use authorization for its DPP Ebola Antigen System for use with human capillary fingerstick whole blood, EDTA venous whole blood, and EDTA plasma. The test detects viral antigens and provides qualitative results in 15 to 20 minutes when used with the handheld, battery-operated DPP Micro Reader. The DPP Ebola Antigen System includes the DPP Ebola Assay and DPP Micro Reader and should only be run in laboratories and facilities, including treatment centers and public health clinics, that are adequately equipped, trained, and capable of such testing.

This is the second Ebola rapid antigen fingerstick test available under EUA; the FDA has authorized nine nucleic acid tests for emergency use.

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