FDA NEWS RELEASE

FDA alerts hospitals, laboratories and health care professionals about recall of Beckman Coulter blood test analyzers due to risk of inaccurate platelet analyzing results

Hematology analyzers help providers diagnose certain blood disorders and assess appropriate treatment options

For Immediate Release:

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The U.S. Food and Drug Administration is alerting (/medical-devices/medical-device-recalls/beckman-coulter-life-sciences-recalls-dxh800-and-dxh600-and-dxh-900-hematology-analyzers-due-risk) hospitals, laboratories and providers of a Class 1 recall of Beckman Coulter DxH 800, DxH 600 and DxH 900 hematology analyzers—devices that run blood tests to help providers diagnose diseases and conditions such as anemia (low red blood cell or hemoglobin count), infections, blood clotting problems, blood cancers and immune system disorders. This is an update to an urgent medical device correction letter first issued by the company in 2018, after the company received complaints of inaccurate blood platelet counts.

Hematology analyzers run diagnostic tests that count the number of different types of red and white blood cells, platelets, hemoglobin (oxygen levels) and hematocrit (volume of red blood cells in blood) levels in a blood sample. These diagnostic tests are often performed as part of routine patient check-ups and are commonly used as part of pre-surgical laboratory patient assessments to help providers assess if patients are suitable and healthy for surgery. They are also used to determine whether a patient with a very low platelet count needs platelet transfusion or to evaluate for potential bleeding and bruising disorders. Platelets help blood to clot, so a patient with a very low platelet count (severe thrombocytopenia) may be at an increased risk for life-threatening bleeding. The recall is related to the devices' platelet analyzing function. Beckman Coulter has not received complaints that this issue impacts other reported parameters, including white blood cell count, white blood cell differential, red blood count or hemoglobin tests.

"Inaccurate platelet counts may create serious health risks for patients," said Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health. "An inaccurate result may lead a provider

to conclude a patient is suitable for surgery, when they may not be, to withhold platelet transfusion in patients who may need it, or to delay or miss the diagnosis of serious blood disorders. Because this may cause serious injury, or even death, to a patient, we are urging health care professionals to be aware of the potential for inaccurate diagnostic results with these analyzers and to take appropriate actions including the use of alternative diagnostic testing or confirming analyzer results with manual scanning or estimate of platelets. We are working with the manufacturer to correct the problem with the devices as quickly as possible and will continue to communicate as more information becomes available."

Beckman Coulter first notified its customers in August 2018 that they had identified a trend of erroneously elevated platelet results that were occurring without error messages, or alerts, which should alert the laboratory operator of the test about a potential problem. Based on additional information provided by the company to the FDA in April 2019, the agency asked Beckman Coulter to provide a second urgent medical device correction letter to customers, as well as send a letter with recommended actions to physicians likely to have patients affected by inaccurate results to ensure both doctors and pathologists are aware of the recall and understand steps that should be taken to ensure accurate and appropriate patient assessments are conducted.

The FDA is communicating today to ensure hospitals, laboratories, health care professionals and patients have the appropriate information about the seriousness of the recall and recommended actions to take. The company has indicated to customers that a software update to the device may serve to alert laboratory personnel to any inaccurate results. However, the FDA has not evaluated the software and is working with the company to determine if the software update alone can adequately address the recall of this device.

The agency recommends laboratory personnel use backup analyzers, if available, to confirm platelet results or perform manual platelet estimate/screening and follow the instructions in the Urgent Medical Device Correction letter dated May 20, 2019 before reporting platelet counts out of the laboratory. The FDA will continue to investigate this issue and work with the company to implement appropriate patient safety mitigations. The FDA encourages laboratories to contact any affected ordering physicians to discuss whether retesting of recently tested patients is appropriate.

Health care providers who interpret these clinical results should discuss any concerns about the testing process with the clinical laboratory processing their samples and consider all available clinical information in their treatment decisions.

The FDA is aware of more than 2,000 laboratories in the U.S. that may be affected, in locations such as large medical centers and small community hospitals. The agency is unable to determine how many patient samples may have been impacted and has not received reports of serious adverse events linked directly to the hematology analyzers. The FDA encourages health care professionals and laboratory personnel to report adverse events or

quality problems experienced with the use of Beckman Coulter products to the FDA's MedWatch Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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