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Beckman Coulter Life Sciences Recalls DxH800 and DxH600 and DxH 900 Hematology Analyzers Due to Risk of Inaccurate Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

- **Recalled Product:** UniCel DxH 800 Coulter Cellular Analysis System, UniCel DxH 600 Coulter Cellular Analysis System, and UniCel DxH 900 Coulter Cellular Analysis System
- **Product Catalog/Reference Numbers (Part numbers for device models):** B23858, C11478, 629029, B24465, B24802, B68304, B66445, B63322
- **Distribution Dates:** January 2008 to present (DxH 800 and DxH 600); April 2018 to present (DxH 900)
- **Manufacturing Dates:** January 2008 to present (DxH 800 and DxH 600); April 2018 to present (DxH 900)
- **Devices Recalled in the U.S.:** 3428

Device Use

The DxH 800, DxH 600, and DxH 900 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 in clinical laboratory settings. These tests may help providers diagnose diseases and conditions such as anemia (low red blood cell or hemoglobin count), infections, clotting problems, blood cancers, and immune system disorders.

Reason for Recall

Beckman Coulter is recalling the DxH 800, DxH 600, and DxH 900 Hematology Analyzers due to sporadic erroneously elevated platelet count results without flags or system messages, meaning there is no way for the laboratory operator of the test

to recognize the error. Inaccurate platelet counts may cause serious adverse health consequences such as increased risk for life-threatening bleeding associated with withholding platelet transfusion or inappropriate decisions for surgeries or invasive procedures; delayed or missed diagnosis of serious medical conditions, including thrombotic microangiopathy and heparin induced thrombocytopenia (<https://medlineplus.gov/ency/article/000586.htm>).

The FDA is not aware of serious adverse events that have been directly linked to the hematology analyzers.

Who May be Affected

- Laboratory personnel who perform clinical testing using patient samples on the Hematology Analyzers
- Health care providers who interpret these clinical test results
- Patients being tested with the DxH800, DxH600, and DxH 900 Hematology Analyzers

What to Do

On May 20, 2019, Beckman Coulter notified customers of an updated Urgent Medical Device Recall letter which replaces the initial notification letter dated July 30, 2018. In this letter, customers are advised to:

- Share the letter with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have transferred any of the affected product(s) listed above to other laboratories, please provide them with a copy of the letter.
- Confirm receipt of letter to Beckman Coulter Customer Support within 10 days by:
 - Electronically, if you received this communication through email.
 - Manually, complete and return the Response Form.

Actions for Running Samples

- Run samples on an instrument not subject to this recall to confirm the platelet results
- If an alternative instrument is not available, use the following quality control measures to aid in identification of discrepant platelet results:

- Perform manual scanning or estimate of platelets on a peripheral smear and compare with instrument results. Note that this method will identify samples with marked to moderate thrombocytopenia but may not identify smaller discrepancies.
 - Repeat testing of samples in a workflow configuration may facilitate the identification of discrepancies. If an erroneous result is detected, review results from adjacent samples, such as those tested on the instrument both before and after the erroneous result.
 - Additional instrument or LIS features including reference ranges, XM (exponentially-weighted moving average) and delta checks may be informative.
 - Follow your laboratory's standard operating procedure to confirm unexpected results.
- Ongoing investigation indicates that sweep flow disruption may occur following the "Clear RBC Apertures" procedure. This potential root cause is currently under further investigation. Customers should discontinue using this procedure. If you suspect that your instrument has a clogged aperture that will not clear, discontinue use of the analyzer, contact Beckman Coulter Customer Support Center and request service.
 - Communicate to the ordering physicians the need to avoid patient treatment based solely on any single test result, and to interpret all results in the context of other clinical and laboratory features. Physicians should be vigilant when reviewing platelet count results, particularly in patients at risk for thrombocytopenia, such as those with leukemia, certain types of anemia, infection, alcohol abuse, autoimmune diseases, thrombotic microangiopathy, hypersplenism, pregnant patients, patients on chemotherapy, receiving heparin treatment or taking certain medication including quinine, anticonvulsants and sulfonamide antibiotics.
 - Consult with your Medical Director to determine if a retrospective review of results is warranted.
 - Report any unflagged erroneously elevated platelet counts experienced in your laboratory to Beckman Coulter and the FDA (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>).

Detecting Erroneously Elevated Platelets

To detect and flag erroneously elevated platelets due to temporary disturbance of the sweep flow, Beckman Coulter implemented an algorithm improvement. This algorithm improvement was implemented by way of one of the following:

1. Software upgrades, DxH 800 version 3.2.1 and above and DxH 600 version 1.3.1 and above
2. Customer-installable software patch made available in October 2018
3. Software version 1.0.0 and above for DxH 900

If your DxH 800 / DxH 600 system has not yet been upgraded with the improved algorithm, please contact your local Beckman Coulter representative. All fielded DxH 900 analyzers have the improved algorithm incorporated into their original software.

Beckman Coulter continues to investigate the unflagged elevated platelets issue and assess the “Clear RBC Apertures procedure” as well as other potential root and/or contributing causes. The algorithm improvement is currently being evaluated. Please continue to follow the instructions in this notification letter. This includes customers whose systems already have the updated software versions with the algorithm improvement.

Additional Information from the FDA:

Not all laboratories responded to Beckman Coulter’s initial letter. Based on additional information provided by the company to the FDA in April 2019, the FDA asked the company to provide a second urgent medical device correction letter to customers, detailed above, as well as sending a letter with recommended actions to health care providers likely to have patients affected by inaccurate results.

Beckman Coulter indicated to customers that a software update to the device may help reduce the risk inaccurate results. However, the FDA has not evaluated the software and is working with the company to determine if the software update alone can effectively alleviate concerns about the device.

Laboratories that use the recalled analyzers for Complete Blood Count (CBC) should report unflagged, erroneously high platelet count results to Beckman Coulter and the FDA. Health care providers who interpret these clinical results should discuss any concerns about the testing process with the clinical laboratory processing their samples and should consider all available clinical information in their treatment decisions. Patients should discuss any concerns with their health care provider.

Contact Information

Customers or distributors with questions regarding this recall may contact Beckman Coulter, Inc. by phone at 800-526-7694 in the United States and Canada or by website: <http://www.beckmancoulter.com> (<http://www.beckmancoulter.com>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>). Outside of United States and Canada, contact your local Beckman Coulter Representative.

Date Recall Initiated:

July 30, 2018

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX to 1-800-FDA-0178.