**URGENT MEDICAL DEVICE RECALL**

April 24,2017

UniCel DxH 800 Coulter Cellular Analysis System

|  |  |
| --- | --- |
| **ISSUE** | There is a possibility of a data acquisition disruption that may cause an unusual light scatter event pattern for the white blood cell differential that may not have a system flag and/or message. The events associated with the unusual light scatter pattern may be incorrectly removed from analysis which can result in an erroneous differential result.  In most cases, system flags and/or messages have accompanied the erroneous  results, indicating the need to review the |
| **IMPACT** | * An erroneous, automated White Blood Cell (WBC) differential result might be reported. The WBC count is correctly reported. * The most significant clinical impact might be an incorrect neutrophil count potentially leading to errors in patient management. |
| **ACTION** | * **Use all available features to assess patient results, including reference ranges, action and critical limits, instrument system flags, codes, messages, delta checks, and decision rules.** * **Follow all Instructions for Use pertaining to flow cell error and warning messages, and ensure daily Shutdown is performed.** * **Follow your laboratory’s standard operating procedure for confirming unexpected results.** * **Communicate to your Laboratory Medical Director 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.** * **Consult with your Medical Director to determine if a retrospective review of results is warranted.** |
| **RESOLUTION** | Beckman Coulter is working on a resolution to detect and flag these unexpected light scatter patterns. |