



Product Correction

Immediate Action Required

Date Issued

December 15, 2017

Product

Product Name: CELL-DYN Emerald 22
List Number: 09H59-01
UDI Number: N/A
Serial Numbers: All instrument with serial numbers below 000700

Explanation

Abbott Hematology has identified the following issue with the CELL-DYN Emerald 22 Analyzer Application Software v3.0.0 when the IUO (Information Use Only) reporting option is disabled:

- For the printout of the Levey-Jennings (L-J) graphs, the WBC Subpopulation differential labels do not match the L-J graphs. The labels are displayed in the following order: LYM%, MON%, NEU%, EOS% and BAS%, instead of NEU%, LYM%, MON%, EOS%, and BAS%. The graphs themselves are in the order of NEU%, LYM%, MON%, EOS%, and BAS%.

For clarity:

- LYM% label on the left displays with NEU% Graph;
- MON% label on the left displays with LYM% Graph;
- NEU% label on the left displays with MON% Graph;
- EOS% and BAS% are correct.
- The on-screen results as well as on-screen graphs are correct.
- All printed QC raw data results are correct.

Patient Impact

- Patient results are not impacted and there is no potential for delay in results.

Necessary Actions

- Your Abbott representative will begin scheduling software upgrades for CELL-DYN Emerald 22 Systems starting in January 2018. Until the software version 3.1.0 is installed on your system, do not use printouts of the Levey-Jennings (L-J) graphs. Instead use the QC results data printouts or on-screen display of the L-J graphs.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.