Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6081

DIAGNOSTICS

Product Correction

Immediate Action Required

Attn	Laboratory Manager
Cc	Chairman Medical Board and Relevant Head of Departments

Date Issued

November 16, 2017

Product

Product Name: CELL-DYN Ruby
List Number: 08H67-01; 08H67-03
Serial Numbers: All serial numbers below 70594BG
UDI: 00380740017170; 00380740099916

Explanation

The CELL-DYN Ruby allows the display of parameter results in USA, International System of Units (SI), modified International System of units (SI MOD), Unit Set 1 or Unit Set 2 per user configuration. Abbott has identified the following issue related to unit set selection for CELL-DYN Ruby analyzers using System Software Versions 2.2ML and lower:

- Standard Deviation (SD) values for select parameters (refer to Table A) in the QC Views only (QC-QCID Data View and QC-Levey Jennings) will be incorrectly displayed when unit sets other than the USA unit are selected on the CELL-DYN Ruby. These units are incorrectly converted from USA units to other unit sets for display purposes.
- Means, percent CV, and limit (upper and lower) information in QC Views are correct. In addition, instrument flagging, alerts, and results are correct for all unit sets.

Patient Impact

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

Necessary Actions

- Your Abbott representative will begin scheduling mandatory software upgrades for CELL-DYN Ruby Systems starting in November 2017. See Table A for necessary actions until software is installed on your system.
- 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. Custome please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a we Customers outside the U.S., please contact your local area Customer Service.

Table A

Unit Set	Parameter	Displayed SD Value in QC Views are….	Necessary Actions until mandatory upgrade is completed
SI	HGB	1/10th the value expected	Multiply incorrect HGB SD by 10
	HCT	100X the value expected	Multiply incorrect HCT SD by 0.01
	MCHC	1/10th the value expected	Multiply incorrect MCHC SD by 10
	PCT	1/10th the value expected	Multiply incorrect PCT SD by 10
SIMOD	HGB	1.6X the value expected	Multiply incorrect HGB SD by 0.6206
	HCT	100X the value expected	Multiply incorrect HCT SD by 0.01
	MCH	16.1X the value expected	Multiply incorrect MCH SD by 0.06206
	MCHC	1.6X the value expected	Multiply incorrect MCHC SD by 0.6206
	PCT	1/10th the value expected	Multiply incorrect PCT SD by 10
Set 1	HGB	1/10th the value expected	Multiply incorrect HGB SD by 10
	MCHC	1/10th the value expected	Multiply incorrect MCHC SD by 10
Set 2	WBC	1/10th the value expected	Multiply incorrect WBC SD by 10
	NOC	1/10th the value expected	Multiply incorrect NOC SD by 10
	RBC	1/100th the value expected	Multiply incorrect RBC SD by 100
	PLT	10X the value expected	Multiply incorrect PLT SD by 0.1
	RETC	10X the value expected	Multiply incorrect RETC SD by 0.1