



Product Correction

Immediate Action Required

Date Issued

March 3, 2011

Product

Product Name	List Number	Instrument Serial Numbers
ARCHITECT c4000	2P24-01	c460004 to c460014, c460016 to c460019
ARCHITECT c4000 (integrated)	2P24-40	c400069, c400071 to c400099, c400146, c400219
ARCHITECT c8000	1G06-11	c800307, c800742, c801237, c801462, c802378, c803060, c803061, c803062, c803063
ARCHITECT c16000	3L77-01	c1600284

Explanation

Abbott Diagnostics has received information from Toshiba, the supplier of the ICT Pre-Amp Board, indicating the board's photo couplers may degrade over time. Affected ARCHITECT cSystems will generate repeated calibration failures for the ICT analytes (sodium, potassium, and chloride).

Patient Impact

Falsely elevated patient results may occur only for samples whose recovery is below the low calibrator set points. This is mitigated by calibration that occurs every 24 hours and by controls that are run every 8 hours. There have been no reports of impact to patient results. The overall risk was assessed to be low.

Necessary Actions

No action is required of you at this time to replace your board. Abbott has identified the systems which may contain the affected boards, and will be making arrangements with you to replace the board at no charge. All replacements are expected to be completed within the next three months.

Follow the instructions in the reagent package inserts for ICT Sample Diluent (List Number 2P32). Ensure that calibration occurs every 24 hours, and controls are run every 8 hours.

If you receive repeated calibration failures for ICT analytes which are not resolved through normal troubleshooting, please contact your local area customer support. Reference this letter so that a service representative can be dispatched to replace the board.

Contact Information

We sincerely regret any inconvenience this may cause your laboratory. If you or any of your health care providers you serve have any questions regarding this information, U.S. customers should call Abbott Customer Service at 1-877-4ABBOTT. Customers outside the U.S. should contact your local area Customer Support.