



## Product Correction

Immediate Action Required

### Date Issued

January 25, 2016

### Product

Product Name	Sekisui List Number	Abbott List Number	Lot Number	Current Expiration Date	New Expiration Date
Acetaminophen Reagent	506-10	3R11-20	47677	SEP 2016	DEC 2015
			47694	SEP 2016	DEC 2015
			47649	DEC 2016	MAR 2016
			47650	DEC 2016	MAR 2016
			47662	DEC 2016	MAR 2016
			47663	DEC 2016	MAR 2016
			48253	JAN 2017	APR 2016
			48385	FEB 2017	MAY 2016
	506-30	N/A	48386	FEB 2017	MAY 2016
			47695	SEP 2016	DEC 2015
			48294	JAN 2017	APR 2016

### Explanation

Abbott Diagnostics has received the attached letter from Sekisui, the manufacturer of Acetaminophen reagent. Sekisui has investigated complaints related to the formation of crystals and or shift of controls. Abbott internal testing has shown that the crystal formation does not impact ARCHITECT cSystem instrument performance.

### Patient Impact

Please refer to the attached letter from Sekisui.

### Necessary Actions

- Please review the attached Sekisui letter carefully, follow the instructions, and retain a copy for your laboratory records.
- Complete the Customer Reply Form and return it.
- To implement the instructions in the attached letter, update your assay calibration interval to 24 hours. Reagent expiration and stability will need to be tracked manually. Contact Abbott customer service for assistance if needed.
- If you have forwarded any of the lots above to another laboratory, please provide a copy of this letter to them.

### 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 the information contained in the Field Correction, please contact Sekisui Diagnostics Technical Support at 1-800-565-0265 (U.S.) +44 1622 607800 (international). Hours when calls will be answered: Monday-Friday 7:00am to 5:00pm Eastern Standard Time (U.S. & Canada). After hours, please send email to: PEIDagnosticTechnical@sekisui-dx.com.

Please contact your local Abbott sales representative if you have questions regarding product replenishment.