SEKISUI DIAGNOSTICS

Date: 22-January-2016

IMPORTANT FIELD CORRECTION

Customer Notification

Sekisui Diagnostics Acetaminophen L3K® Assay

Catalog/List Number (LN)	Lot Number	Catalog/List Number (LN)	Lot Number
506-10	47677	506-30	47695
	47694		48294
	47649		
	47650		
	47662		
	47663		
	48253		
	48385		
	48386		

Dear Valued Customer:

This letter is to inform you that Sekisui Diagnostics has issued a Field Correction for the lots listed above (all distributed lots) for the Acetaminophen assay 506-10/30. This field correction will apply to these lots and all future lots.

Sekisui has investigated complaints related to the formation of crystals in the R2 reagent and/or shift of controls when left on board an automated analyzer. During the investigation, it was determined that when the R2 reagent is exposed to the atmosphere for prolonged periods of time, on board an automated analyzer, crystals may form. Sekisui has identified the crystals form from a standard component of the reagent. The amount of time to crystalize is dependent on reagent usage, temperature, and length of time on board the analyzer.

Sekisui does not currently have an on-board stability claim for the Acetaminophen 506 series. Customers will need to establish their own on board stability based on individual laboratory usage patterns.

Sekisui has made the decision to reduce the expiration date of the Acetaminophen L3K reagent, Catalogue numbers 506-10 and 506-30, to 9 months from 18 months due to the findings during the investigation. Any reagent with a current expiration date of 2016-09 must be discarded immediately. Please refer to the table below for new expiration dates for all current lots of Acetaminophen L3K reagent. Customers should update the expiration dates on all kits currently on hand. Going forward, all new lots of reagent will have the correct expiration date listed on the kit.

The Sekisui manufactured Acetaminophen reagent is for the in vitro quantitative measurement of acetaminophen in serum and plasma. As stated in the insert, the reagents should be clear. Turbidity would indicate deterioration. If crystals are observed, fresh reagent should be placed on board the instrument.

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Catalog/List Number (LN)	Lot Number	Current Expiration Date	NEW Expiration Date
506-10	47677	2016-09	2015-12
506-10	47694	2016-09	2015-12
506-30	47695	2016-09	2015-12
506-10	47649	2016-12	2016-03
506-10	47650	2016-12	2016-03
506-10	47662	2016-12	2016-03
506-10	47663	2016-12	2016-03
506-10	48253	2017-01	2016-04
506-30	48294	2017-01	2016-04
506-10	48385	2017-02	2016-05
506-10	48386	2017-02	2016-05

Patient Impact

- To date, no impact to patient results has been identified.
- A review of previously reported patient results is not required, however, if you chose to do so, we recommend following your standard laboratory protocol.

REQUIRED ACTIONS:

1. **Discard all reagent in house with a current expiration date of 2016-09.**
2. **Update the expiration on all remaining kits on hand with the new expiration dates provided in the table above.**
3. **When adding additional reagent to the analyzer, a new reagent wedge should be used.**
4. **If crystals are observed within reagent stored on-board, reagent should be discarded and replaced with fresh reagent.**
5. **Complete, sign and return the attached CONFIRMATION OF NOTIFICATION form by FAX to the number provided.** This will indicate receipt of this Field Correction, act as confirmation of compliance with the actions, and allow for issuance of replacement material for expired product on hand (lots 47677, 47694, 47695).

We apologize for any inconvenience or concern this action may cause. If you or any of the health care providers you serve have any questions regarding this information, please contact Technical Services at 1-800-565-0265 or via email at PEIDiagnosticTechnical@sekisui-dx.com.

Yours Sincerely,

Rachel Boone
Senior Regulatory Compliance Specialist

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SEKISUI DIAGNOSTICS

Date: 22-January-2016

Confirmation of Notification

IMPORTANT FIELD CORRECTION

Sekisui Diagnostics Acetaminophen L3K

Catalog/List Number (LN)	Lot Number	Current Expiration Date	NEW Expiration Date	Amount On Hand
506-10	47677	2016-09	2015-12	
506-10	47694	2016-09	2015-12	
506-30	47695	2016-09	2015-12	
506-10	47649	2016-12	2016-03	
506-10	47650	2016-12	2016-03	
506-10	47662	2016-12	2016-03	
506-10	47663	2016-12	2016-03	
506-10	48253	2017-01	2016-04	
506-30	48294	2017-01	2016-04	
506-10	48385	2017-02	2016-05	
506-10	48386	2017-02	2016-05	

Please complete and return to indicate your acknowledgement of receipt of this field correction, and to comply with FDA regulations. Please return this fax even if you currently have none of the affected product in inventory.

Check (√) the appropriate statement(s) below:

☐ I have read and understood these instructions, and have complied with the recommended actions.

☐ I have discarded material with a current expiration date of 2016-09, and require replacement product (lots 47677, 47694, 47695).

Please complete and return via FAX to: Attention Technical Services

Sekisui Diagnostics FAX #: (902) 628-6504 or EMAIL: PEIDiagnosticTechnical@sekisui-dx.com

Form Completed By:

Name (PRINT) & Title	Date
Signature	Phone#
Institution	Email
Address	City, State, Zip

If you have any questions, please call Sekisui Diagnostics Technical Service at (800) 565-0265 or email at PEIDiagnosticTechnical@sekisui-dx.com.