Date: 5-May-2015

IMPORTANT FIELD CORRECTION

Customer Notification

Sekisui Diagnostics Acetaminophen

Catalog/List Number (LN)	Lot Number	Expiration Date
2K99-20	45797UQ04	30-JUN-2015
	46121UQ07	30-SEP-2015
	46561UQ08	31-OCT-2015
	46207UQ09	30-NOV-2015
	46953UQ12	29-FEB-2016

Dear Valued Customer:

This letter is to inform you that Sekisui Diagnostics has issued a Field Correction for the lots listed above for the Acetaminophen assay LN 2K99-20, because the interference for N-acetylcysteine (NAC) has increased (resulting in a larger negative bias in Acetaminophen concentration), relative to the level reported in the reagent package insert.

The Sekisui manufactured Acetaminophen reagent is for the *in vitro* quantitative measurement of acetaminophen in serum and plasma. The current reagent package insert for Acetaminophen 2K99-20 contains the following statement:

> "Interference from N-acetylcysteine (NAC) was evaluated on a commercially available analyzer. Using a significance criterion of > 10% variance from control, acceptable results were obtained to a level of 800 mg/L N-acetylcysteine (NAC) in a 104 μg/mL (688 μmol/L) acetaminophen sample; this in vitro analysis was performed approximately two hours after the addition of NAC to a serum pool.
>
> NOTE: Significantly reduced Acetaminophen recovery has been demonstrated in situations where testing has been performed immediately after the introduction of NAC. It is recommended that laboratories review NAC treatment and monitoring protocols to determine the extent of the potential interference."

Based on testing performed by Sekisui Diagnostics on an ARCHITECT cSystems instrument, the concentration of NAC at which acceptable acetaminophen results were obtained was 200 mg/L NAC in values from a 109 μg/mL acetaminophen sample, tested two hours after the addition of NAC to a serum pool. The package insert will be updated accordingly based on these testing results.

Patient Impact

- Testing performed on patients who have not received NAC, such as those drawn initially to diagnose potential acetaminophen overdose, **are not impacted**.
- Testing performed on patients who have received NAC therapy **have the potential to be impacted**.
- Falsely depressed acetaminophen results could lead a healthcare provider to incorrectly believe that further treatment for acetaminophen toxicity is not necessary.

REQUIRED ACTIONS:

1. **Effective immediately, this communication will serve as temporary labeling for the updated interference level of the assay in the presence of N-acetylcysteine (NAC).**
2. **Please follow your internal procedures for notifying healthcare providers of this change to the interference level.**
3. **Please follow your laboratory protocol regarding the need for reviewing previously reported patient results.**

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, 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.

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