



May 2015

Dear Valued Abbott Customer:

Thank you for requesting data for N-acetylcysteine (NAC) interference related to the change communicated in FA05MAY2015 for Acetaminophen reagent, List Number 2K99-20.

Samples were tested at specified time points after the addition of NAC into a serum pool which was spiked to meet acetaminophen concentrations between 100-115 µg/mL. The NAC concentrations evaluated were from 100-800 mg/L as listed in Table 1.

Using a significance criterion of >10% variance from the control (an acetaminophen spiked sample without NAC), acceptable results were obtained at 200 mg/L two hours after the addition of NAC; therefore, the new interference claim is 200 mg/L effective immediately per FA05MAY2015.

**NOTE:** Per FA05MAY2015, 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. This data demonstrates a passing result at 300 mg/dL which allows for any variation in future lots while this issue is being investigated.

Table 1 contains representative data for the Acetaminophen lots listed in FA05MAY2015 shown below. All reagent lots tested show similar performance.

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



**Table 1: Acetaminophen Sample Recovery**

| NAC Concentration (in the sample) (mg/L) | 2 Hours after NAC Addition |                   |                      | 3 Hours after NAC Addition |                   |                      | 4 Hours after NAC Addition |                   |                      |
|--|----------------------------|-------------------|----------------------|----------------------------|-------------------|----------------------|----------------------------|-------------------|----------------------|
|  | Conv Units (µg/mL)         | SI Units (µmol/L) | % Recovery* (<= 10%) | Conv Units (µg/mL)         | SI Units (µmol/L) | % Recovery* (<= 10%) | Conv Units (µg/mL)         | SI Units (µmol/L) | % Recovery* (<= 10%) |
| 0 (Control)                              | 105.0                      | 695.1             | N/A                  | 104.8                      | 693.8             | N/A                  | 104.9                      | 694.4             | N/A                  |
| 100                                      | 103.9                      | 687.8             | -1%                  | 104.4                      | 691.1             | 0%                   | 104.6                      | 692.5             | 0%                   |
| 200                                      | 102.7                      | 679.9             | -2%                  | 104.3                      | 690.5             | 0%                   | 104.8                      | 693.8             | 0%                   |
| 300                                      | 99.5                       | 658.7             | -5%                  | 103.4                      | 684.5             | -1%                  | 104.7                      | 693.1             | 0%                   |
| 400                                      | 92.9                       | 615.0             | -12%                 | 100.7                      | 666.6             | -4%                  | 103.5                      | 685.2             | -1%                  |
| 500                                      | 85.1                       | 563.4             | -19%                 | 96.5                       | 638.8             | -8%                  | 101.5                      | 671.9             | -3%                  |
| 600                                      | 63.1                       | 417.7             | -40%                 | 79.1                       | 523.6             | -25%                 | 91.4                       | 605.1             | -13%                 |
| 700                                      | 54.2                       | 358.8             | -48%                 | 69.2                       | 458.1             | -34%                 | 82.5                       | 546.2             | -21%                 |
| 800                                      | 46.7                       | 309.2             | -56%                 | 59.8                       | 395.9             | -43%                 | 72.2                       | 478.0             | -31%                 |

\*The % differences were then calculated independently for Conventional and SI units, which may result in slightly dissimilar % difference values due to the rounding.

We sincerely regret any inconvenience this may cause your laboratory. Abbott is committed to providing you with the highest quality diagnostic products and support services to meet the needs of your laboratory and the providers and patients you serve. 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.

Sincerely,  
Abbott Diagnostics

