



8 September 2015

IMPORTANT PRODUCT NOTICE

Synchron Systems Enzymatic Creatinine (CR-E) and Uric Acid (URIC) Reagents

REF	LOT	
A60298 (CR-E)	All Lots	N/A
442785 (URIC)	All Lots	N/A

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter containing important product information regarding Enzymatic Creatinine (CR-E) and Uric Acid (URIC).

ISSUE:	<ul style="list-style-type: none">Beckman Coulter has confirmed that N-Acetyl Cysteine (NAC) used in the treatment of acetaminophen overdose may cause assay interference when administered in therapeutic concentrations.The anti-oxidant properties of NAC can interfere with assays employing the Trinder chemical pathways.The degree of NAC interference has been demonstrated to vary depending on the analyte. Of the Trinder chemical pathway assays, only Enzymatic Creatinine (CR-E) and Uric Acid (URIC) are affected.								
IMPACT:	NAC interference may lead to falsely low results for uric acid and creatinine in patients who are concurrently being treated for acetaminophen overdose with NAC.								
ACTION:	No action or retrospective review of results is required.								
RESOLUTION:	<p>NAC will be added to the INTERFERENCES section of the Chemistry Information Sheets (CIS) tables for Interferences:</p> <p><u>CR-E</u></p> <p>Table 4.0 Interferences</p> <table><tr><th>SUBSTANCE</th><th>SOURCE</th><th>LEVEL TESTED</th><th>OBSERVED EFFECT ON ANALYTE</th></tr><tr><td>N-Acetyl Cysteine</td><td>SIGMA</td><td>500 ug/mL</td><td>-6.3 %</td></tr></table>	SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT ON ANALYTE	N-Acetyl Cysteine	SIGMA	500 ug/mL	-6.3 %
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N-Acetyl Cysteine	SIGMA	500 ug/mL	-6.3 %						

<p><u>URIC</u></p> <p>Table 5.0 Interferences</p> <table> <tr> <th>SUBSTANCE</th><th>SOURCE</th><th>LEVEL TESTED</th><th>OBSERVED EFFECT</th></tr> <tr> <td>N-Acetyl Cysteine</td><td>SIGMA</td><td>500 ug/mL</td><td>-0.34 mg/dL</td></tr> </table> <p>This communication serves as temporary labeling until the CIS are updated. The updated CIS will be available on the Beckman Coulter website's Technical Documents section by October 2015.</p>				SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT	N-Acetyl Cysteine	SIGMA	500 ug/mL	-0.34 mg/dL
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N-Acetyl Cysteine	SIGMA	500 ug/mL	-0.34 mg/dL								

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected products listed above to another laboratory, please provide them a copy of this letter.

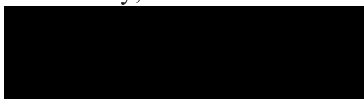
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via phone, call 1-800-854-3633 when in the United States and Canada
- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,



Noreen Galvin, PhD
Vice President Quality & Regulatory Affairs

Enclosure: Response Form