



April 18, 2017

### URGENT FIELD SAFETY NOTICE – FSN 29156

Synchron Systems Cholesterol, Creatinine, HDL Cholesterol, Lactate, Triglyceride, Uric Acid and Salicylate Reagents

REF	LOT	
467825 (CHOL)	<b>All Lots</b>	<b>NA</b>
A60298 (CR-E)		
A15625 (HDL)		
A95550 (LACT)		
445850 (TG and TG-B)		
442785 (URIC)		
378194 (SALY)		

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the products listed above. This letter contains important information that needs your immediate attention.

<b>ISSUE:</b>	<ul style="list-style-type: none"> <li>• Beckman Coulter has identified the following drugs as potential sources of interference:               <ul style="list-style-type: none"> <li>○ Metamizole (Dipyrone) – Analgesic/antispasmodic/antipyretic Note: No longer approved for sale in certain geographies, including the US and Canada.</li> <li>○ Sulfasalazine – Anti-inflammatory</li> <li>○ Sulfapyridine – Sulfonamide antibiotic</li> </ul> </li> </ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>• With the administration of these drugs, the effects to patient analytes are:               <ul style="list-style-type: none"> <li>○ Metamizole (Dipyrone) – may generate <b>false low</b> Cholesterol, Enzymatic Creatinine, HDL Cholesterol, Lactate, Triglycerides and Uric Acid results.</li> <li>○ Sulfasalazine – may generate <b>false high</b> Salicylate results.</li> <li>○ Sulfapyridine – may generate <b>false low</b> Salicylate results.</li> </ul> </li> </ul>
<b>ACTION:</b>	No action is required by your laboratory. No retrospective review of results is recommended.



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<b>RESOLUTION:</b>	<ul style="list-style-type: none"><li>• The following statement will be added to the respective INTERFERENCES sections of the CHOL, CR-E, HDL, LACT, TG, TG-B and URIC* Chemistry Information Sheets (CIS): <i>Venipuncture immediately after or during the administration of Metamizole (Dipyrone) may lead to <b>false low</b> results for [analyte name*]. Venipuncture should be performed prior to the administration of Metamizole.</i></li><li>• The following statements will be added to the INTERFERENCES section of the SALY Chemistry Information Sheets (CIS): <i>Patients treated with Sulfasalazine may generate a <b>false high</b> result for Salicylate.</i>  <i>Patients treated with Sulfapyridine may generate a <b>false low</b> result for Salicylate.</i></li></ul> <p>This communication serves as temporary labeling until the Chemistry Information Sheets (CIS) are updated. CIS are available on the Beckman Coulter website's "Technical Documents" webpage: <a href="https://www.beckmancoulter.com/wsrportal/page/techdocSearch">https://www.beckmancoulter.com/wsrportal/page/techdocSearch</a></p>
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The national competent authority has been informed of this field safety corrective action.

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 product(s) 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 that we are assured you have received this important communication.**

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or [techsupportie@beckman.com](mailto:techsupportie@beckman.com).

We apologize for any inconvenience that this caused your laboratory.

Yours sincerely,



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Enclosed: Vigilance Response Form

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