



April 3, 2017

URGENT FIELD SAFETY NOTICE

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

REF	LOT	
467825 (CHOL)	All Lots	NA
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.

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

ACTION:	No action is required by your laboratory. No retrospective review of results is recommended.
RESOLUTION:	<ul style="list-style-type: none"> <li data-bbox="435 300 1421 420">• 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): <p data-bbox="532 436 1388 583"><i>Venipuncture immediately after or during the administration of Metamizole (Dipyrone) may lead to false low results for [analyte name*]. Venipuncture should be performed prior to the administration of Metamizole.</i></p> <li data-bbox="435 625 1421 903">• The following statements will be added to the INTERFERENCES section of the SALY Chemistry Information Sheets (CIS): <p data-bbox="532 724 1421 793"><i>Patients treated with Sulfasalazine may generate a false high result for Salicylate.</i></p> <p data-bbox="532 829 1421 898"><i>Patients treated with Sulfapyridine may generate a false low result for Salicylate.</i></p> <p data-bbox="435 934 1421 1081">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: https://www.beckmancoulter.com/wsrportal/page/techdocSearch</p>

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 we are assured you have received this important communication.

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

- From our website: <http://www.beckmancoulter.com/customersupport/support>
- Contact your local Beckman Coulter Representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

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Enclosure:
Response Form

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