



10 July 2017

FIELD ACTION NOTIFICATION

Synchron Systems Salicylate Reagent

REF	LOT	
378194	All Lots	N/A

Dear Beckman Coulter Customer,

Copy: Chairman Medical Board/Head of Departments of Affected consignees*
*Singapore only

Beckman Coulter is sending this letter regarding a newly identified drug interference with the product listed above.

ISSUE:	As a result of internal investigations, Beckman Coulter has identified temozolomide, an oral antineoplastic drug used to treat certain types of brain cancers, as a potential source of interference with Synchron Salicylate reagent (SALY).
IMPACT:	<ul style="list-style-type: none">• Temozolomide concentrations of 40 mg/L or greater may cause a negative bias in salicylate test results of up to -22%.• The half-life of temozolomide is approximately 1.8 hours, with the active half-life of the metabolite being slightly longer. The probability of an erroneous patient result will be dependent upon the times of administration and dosages of both drugs, salicylate and temozolomide. Longer intervals of time between administration of the drugs and the testing will reduce the probability and severity of harm. Lower doses of either drug will also reduce the severity of harm. The worst case scenario only occurs if a patient that is overdosed on salicylates is tested within a short period of time after receiving a high dose of temozolomide.
ACTION:	<ul style="list-style-type: none">• No action is required by your laboratory.• Beckman Coulter is not recommending a retrospective review of prior test results.
RESOLUTION:	<ul style="list-style-type: none">• The following statement will be added to the INTERFERENCES section of the SALY Chemistry Information Sheet (CIS): <i>Patients treated with temozolomide may generate a false low result for salicylate.</i>• This communication serves as temporary labeling until the Chemistry Information Sheet (CIS) is updated. CIS' are available on the Beckman Coulter website's "Technical Documents" webpage: https://www.beckmancoulter.com/wsrportal/page/techdocSearch

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.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

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

- From our website: <http://www.beckmancoulter.com>
- By phone: call 1-800-854-3633 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,



David Davis
Director, Quality & Regulatory Affairs

Enclosure: Response Form

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