April 7, 2021

**IMPORTANT PRODUCT NOTICE**

Access Sensitive Estradiol

| REF | LOT | |
|---|---|---|
| B84493 | All | N/A |

Dear Beckman Coulter Customer,

This letter addresses the potential for bi-directional interference in the Access Sensitive Estradiol due to the presence of elevated levels of Estrone and Estrone-3-Sulfate.

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| **ISSUE:** | • Beckman Coulter has identified the potential for bi-directional interference with the Access Sensitive Estradiol assay in samples containing elevated levels of Estrone and Estrone-3-Sulfate.<br>• Bi-directional interference can be a positive or negative bias, depending upon the analyte and interferent concentrations present in the sample.<br>• Estradiol supplements may elevate estrone and estrone-3-sulfate concentrations to levels that are higher than those observed under typical clinical conditions. |
| **IMPACT:** | • Access Sensitive Estradiol test results may be either falsely increased or falsely decreased if they are measured after a patient receives estradiol supplements.<br>• The magnitude of a falsely increased or decreased Access Sensitive Estradiol test result depends upon the concentrations of estrone, estrone-3-sulfate and estradiol that are present in the sample.<br>• Access Sensitive Estradiol results obtained from adults and adolescents with typical Estrone and Estrone-3-Sulfate levels are not impacted. |
| **ACTION:** | • Do not use the Access Sensitive Estradiol assay to monitor the effectiveness of estradiol supplements.<br>• Consider the patient's total clinical presentation when interpreting results. Use alternate testing methods if the results are not consistent with accompanying clinical evidence.<br>• Any retrospective review of patient results is left to the discretion of the Laboratory Medical Director. |
| **RESOLUTION:** | • Beckman Coulter will update the Access Sensitive Estradiol Instructions for Use (IFU) Limitations section with the following statement: "The Access Sensitive Estradiol assay results are not intended to be used to measure the effectiveness of exogeneous Estradiol supplementation, for example, when the patient is on |

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| | hormone replacement therapy. The presence of estradiol drug analogues and their metabolites could have an impact on estradiol recovery when using this assay."<br>• The updated IFU should be available on the Beckman Coulter website by mid-April 2021. Please download the updated IFU at your earliest convenience. |

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 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
- By phone: call 1-800-854-3633 in the United States.
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Annette Hellie
Director, Quality and Regulatory Affairs

Enclosure: Response Form