11 April 2017

URGENT FIELD SAFETY NOTICE

Access BR Monitor
For use with the Access Family of Immunoassay Systems*

REF	LOT	
387620	All Non-Expired Lots and Future Lots	Multiple

*The Access Family of Immunoassay Systems includes the Access 2, UniCel DxI 600 and UniCel DxI 800, UniCel DxC 600i and the UniCel DxC 660i, UniCel DxC 680i, UniCel DxC 860i, and UniCel DxC 880i systems.

Attention Beckman Coulter Customer,

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

ISSUE:	Following biases observed in the results of the French National Quality Controls, Beckman Coulter has been informed that a study completed by the French Competent Authority Agence nationale de sécurité du Medicament et des produits de santé (ANSM) showed diagnosed cancer patients in non-remission of their metastatic disease, may have results below the upper reference limit (URL) of 31.3 U/mL as stated in the Access BR Monitor instructions for use (IFU).
IMPACT:	• The ANSM's preliminary study demonstrated that 10 out of 27 patients diagnosed with cancer in non-remission had a result below the Access BR Monitor URL. • In this preliminary study, at the cutoff of 31.3 U/mL designated in the Access BR Monitor IFU, the assay achieved a sensitivity of 63% and a specificity of 100% for patients in non-remission. • Any changes to the cutoff of the Access BR Monitor assay may impact the sensitivity and specificity of the assay. • Reliance on a single numerical result with the Access BR Monitor may inappropriately influence clinical decisions.

ACTION:	Ensure your laboratory staff and clinicians are aware of the following limitations of the Access BR Monitor assay found in the IFU: • The Access BR Monitor Assay should not be used as a cancer screening tool. A value below the cutoff limit does not indicate the absence of breast cancer. • Serum or plasma CA 15-3 antigen concentrations should not be interpreted as absolute evidence for the presence or absence of cancer. • This device is indicated for use in the measurement of CA 15-3 antigen to aid in the management of breast cancer patients. Serial testing for CA 15-3 antigen concentrations using Access BR Monitor assay should be used in conjunction with other clinical methods for monitoring breast cancer. • The Access BR Monitor results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information. • Values obtained with different assay methods cannot be used interchangeably. The concentration of CA 15-3 antigen in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. • Each laboratory should establish its own reference ranges to assure proper representation of specific populations.
RESOLUTION:	Beckman Coulter is evaluating the Access BR Monitor cutoff. The conclusions of this evaluation are planned by the third Quarter of 2017.

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 Technical Support Center:

- From our website: http://www.beckmancoulter.com
- By phone: call 1-800-854-3633 in the United States and Canada
- Outside of the United States and Canada, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

[redacted]

Enclosure: Response Form