October 26, 2018

FIELD SAFETY CORRETIVE ACTION NOTIFICATION
Access hsTnI Reagent

REF	LOT	
B52699	All	Multiple

Dear Beckman Coulter Customer,
Copy: Chairman Medical Board/Head of Departments of Affected consignees

**Applicable to Affected consignees of Singapore only*

Beckman Coulter is sending this letter regarding Access hsTnI reagent. Test results are not affected.

ISSUE:	• The Cardiac Troponin T cross reactivity concentration of 253 ng/mL (253,000 pg/mL) previously listed in the Access hsTnI Instructions For Use (IFU) does not apply to samples with hsTnI concentrations less than 16 pg/mL (ng/L).

IMPACT:	• Samples containing Cardiac Troponin T concentrations > 125 ng/mL (125,000 pg/mL) may cross react with the Access hsTnI Assay.
	• In the presence of Cardiac Troponin T concentrations > 125 ng/mL (125,000 pg/mL):
	  ○ Access hsTnI results may change by more than 10% for hsTnI sample concentrations > 11.5 pg/mL (ng/L)
	  ○ Access hsTnI results may change by more than 2.30 pg/mL (ng/L) for hsTnI sample concentrations ≤ 11.5 pg/mL (ng/L).

ACTION:	• Obtain the most current Access hsTnI Assay IFU, document version C11140F or higher, from the Beckman Coulter website.

RESOLUTION:

- Beckman Coulter conducted additional verification testing and has updated the cross reactant concentration for Cardiac Troponin T in the Access hsTnI IFU from 253 ng/mL to 125 ng/mL.
- Additional updates included with IFU document version C11140F:
  - The cross reactant and interfering substance specifications were updated to state "The change in concentration between the controls and test samples was within ±10% for samples > 11.5 pg/mL (ng/L). For samples ≤ 11.5 pg/mL (ng/L) the change in concentration between controls and test samples was within 2SD, where 2SD is defined as 2.30 pg/mL (ng/L)."
  - The cross reactant concentrations were rounded, see table:

Substance	Concentration Added (ng/mL) in IFU C11140E	Concentration Added (ng/mL) in IFU C11140F
Actin	1,063	1,000
CK-MB	1,014	1,000
Myoglobin	1,003	1,000
Myosin	1,008	1,000
Cardiac Troponin C	266	250
Skeletal Troponin I	266	250
Tropomyosin	1,017	1,000

  - The interfering substance concentrations tested were increased from 4 mg/dL to 20 mg/dL for Bilirubin (unconjugated), and from 30 mg/dL to 65 mg/dL for Dopamine.

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

- Via our website, http://www.beckmancoulter.com/customersupport/support
- By phone: call 1-800-854-3633 in Canada.
- Contact your local Beckman Coulter Representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

[redacted]

David G. Davis
Senior Director, Regulatory Affairs

Enclosure: Response Form