Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution on this issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Winnie Hii Lin Lin
Regulatory Specialist

Contact person of this notification	...Har Zi Mei.....
Department	...Marketing.....
Telephone	...601 2982 6529.....
Fax	...603 7772 0551.....
E-mail	... ZHAR@beckman.com .....

Beckman Coulter Malaysia Sdn. Bhd. (861038-K)
No. 18, Jalan Tandang 51/205A,
Seksyen 51, 46050 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.

Tel : (603) 7772 8256
Fax : (603) 7772 0551
Website : www.beckmancoulter.com

May 27, 2021

FIELD SAFETY NOTICE

Access CEA

REF	Product Name	LOT	⌛
33200	Access CEA Reagent	195018 195019 195022 195023 195024 195025 195026 195027 195028 195029	2022-01-05 2022-01-11 2022-02-15 2022-02-22 2022-03-04 2022-03-11 2022-03-15 2022-04-01 2022-04-07 2022-04-12

Dear Beckman Coulter Customer,

This letter addresses duplicate lot numbers for current and expired Access CEA reagent packs. Test results are not affected.

ISSUE:	• Beckman Coulter has discovered 10 active Access CEA reagent pack (P/N 33200) lots that share the same lot number as expired Access CEA reagent packs. These shared lot numbers are listed in the table above. • The Access CEA reagent packs that initially used these lot numbers were manufactured in 2011. These reagent packs expired in 2012.
IMPACT:	• The Access Family of Immunoassay Systems retain reagent pack information in the system database. If an operator loads an active Access CEA reagent pack with one of the shared lot numbers listed above, the system will assign the 2012 expiration date.
ACTION:	• Review the expiration date for any Access CEA reagent pack that is loaded on the system: ○ F3 Supplies > F2 Reagent Supplies > Select reagent pack > F6 Details **OR** ○ F3 Supplies > F2 Reagent Supplies > F8 Reagent Inventory • No additional action is necessary if the system displays the correct Access CEA reagent pack expiration date when a pack is loaded. • Contact Customer Technical Support if the system displays an incorrect 2012 Access CEA reagent pack expiration date.
RESOLUTION:	• Beckman Coulter will improve the process controls for assigning reagent pack lot numbers to consistently ensure that future reagent pack lot numbers for all Access assays are unique.

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska MN 55318-1084 U.S.A

Telephone: (800) 854-3633
Internet: www.beckmancoulter.com

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