



Helping all people
live healthy lives

URGENT FIELD SAFETY NOTICE

July 15, 2015

Product Name	Cat. Number	Unit	Lot Number	Exp. Date
BD BBL™ CHROMagar™ MRSA II	257434/257435	20/120 ea	5142463	August 4, 2015
BD BBL™ CHROMagar™ MRSA II	257434/257435	20/120 ea	5147498	August 7, 2015
BD BBL™ CHROMagar™ MRSA II	257434/257435	20/120 ea	5148248	August 10, 2015
BD BBL™ CHROMagar™ MRSA II	257434/257435	20/120 ea	5153362	August 18, 2015
BD BBL™ CHROMagar™ MRSA II	257434/257435	20/120 ea	5160473	August 25, 2015
BD BBL™ CHROMagar™ Staph aureus / BBL™ CHROMagar™ MRSA II (Biplate)	257585	120 ea	5147466	August 12, 2015

Dear Valued Customer,

BD has determined through complaint investigation that the above referenced lots of product **may** exhibit breakthrough growth of methicillin-susceptible *S. aureus* (MSSA) strains. Growth of MSSA strains on BBL™ CHROMagar™ MRSA II could be observed as mauve colonies and subsequently lead to false positive declaration of MSSA strains. This would result in detection of MRSA for MRSA-negative patients.

BD has identified the root cause to be associated with a specific raw material batch used in the manufacture of the affected lots.

As noted in the BBL™ CHROMagar™ MRSA II instructions for use, it is recommended that user Quality Control be performed in accordance with applicable local, state, federal or country regulations, accreditation requirements, and/or your laboratory's standard quality control procedures.

Our records indicate you may have been shipped the above-referenced lot number(s) of product. Please discontinue use of these lot numbers and discard any remaining packages. If further assistance is needed, please contact your local BDDS representative

Only the above specified lots are affected by the described product issue. Newly released lots are not affected. BD will issue replacements for the discarded material.

Please complete the attached form **whether or not you have any inventory remaining** so that we may acknowledge your receipt of this notification. Simply complete and fax the form to:
Attention: XXXXXXXXXXXXXXXXXXXX Fax: XXXXXXXXXXXXXXXXXXXX.

Please accept our apology for any inconvenience this may cause. BD is committed to providing you with the highest quality products. Thank you for your continued support.

Ann Vanlandschoot, Ph.D.
RA Manager Post-Market
BD Biosciences & BD Diagnostic Systems

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Fax to: XXXXXX

Fax #: XXXXX

PLEASE RETURN THIS FORM SO THAT WE MAY ACKNOWLEDGE YOUR RECEIPT OF THIS NOTIFICATION

Please do not send multiple forms.

Facility: _____

Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ **State:** _____ **Zip:** _____

Contact Person: _____

Telephone No.: _____ **Fax No.:** _____

Total number of affected units on hand:

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