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Marko Maric

Biomax D.O.O

FIELD SAFETY NOTICE (FSN)
Cefepime ESBL ID Detection Set; D63C: Lot-520593, expiry 31/08/2025

Mast has identified a potential problem with the above lot of Cefepime ESBL ID Detection Set. An investigation revealed that when the above-named product is used to determine Extended Spectrum Beta Lactamase (ESBL) enzyme production in Group 2 Enterobacterales, a proportion of the paired discs have been observed to produce an increase in inhibition zone of less than 5mm with certain isolates that are confirmed to produce ESBLs. Thus, there is a possibility that use of the product may result in falsely negative ESBL results. ESBL detection and characterization is suggested for epidemiological purposes and the recommended strategy for the detection of ESBLs in Enterobacteriaceae is based on non-susceptibility to indicator oxyimino-cephalosporins in primary susceptibility testing followed by phenotypic confirmation discs testing. Non-susceptibility to therapy with, for instance, third-generation cephalosporins will have therefore been reported initially. Additionally routine monitoring of performance of antimicrobial susceptibility tests with appropriate control strains would detect any issue in test performance so it is unlikely that patient safety would be compromised as a result. It is recommended that use of this lot of discs within laboratories is discontinued immediately whether or not any unexpected results have been noted.

Mast records show that we despatched 5 packs to you on 24/10/2024, and 2 packs on 18/09/2024. Please check if you have any packs of this batch left in your inventory, and if so, would you please discard them. For any unused inventory, we will provide replacements free of charge as soon as possible.

Please confirm the action you have taken on the reconciliation table below and we kindly request that you return this form back to us within 48 hours of receipt. We request that you pass a copy of this FSN onto any relevant users or customers, and/or alert any organisation to which this particular batch of the device have been sent.

We thank you in advance for your support and patience whilst we resolve this matter. Please accept our sincere apologies for any inconvenience caused, if you would like to discuss this matter any further, please contact Mast Customer Services by telephone on + 44 (0) 151 472 1444 or by email at sales@mastgrp.com.

Yours sincerely,

Marian
Marian Rehak
Technical Director
09/12/2024

Cefepime ESBL ID Detection Set; D63C: Lot-520593, expiry 31/08/2025		
Number of packs we sent you	Number of packs destroyed	Number of packs already used
7	6	1
Comments:		
Contact name: <i>Ivo DOKO</i>	Signed: <i>Ivo Doko</i>	Date: <i>11.12.2024</i>

BIOMAX D.O.O
ZAGREB

