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Customer

16th February 2018

**Urgent FIELD SAFETY NOTICE (FSN)
AUGMENTIN 32mg/L PLATE, MPM-AUG32, Date of FSN: 15/02/18**

Dear Customer,

Mast is issuing Field Safety Notice (FSN). This has also been reported to the Medicines and Healthcare products Regulatory Agency (MHRA) for the reason detailed below.

Mast has become aware of a potential problem with AUGMENTIN 32mg/L PLATE with the lots listed below where plates are showing sporadic false susceptibility to amoxicillin-clavulanic acid. This product is used for determining susceptibility for uncomplicated urinary tract infections (UTI) caused by Enterobacteriaceae only, in accordance with European Committee on Antimicrobial Susceptibility Testing (EUCAST) Breakpoint tables for interpretation of MICs and zone diameters Version 8.0, valid from 2018-01-01.

While we continue our investigations, and as a temporary measure, we recommend that any susceptible results from MPM-AUG32 should be confirmed using alternative antimicrobial susceptibility testing methods such as EUCAST disc diffusion testing until further notification. Continued use of this product will give accurate resistant results.

According to NICE British National Formulary guidelines (<https://bnf.nice.org.uk/treatment-summary/urinary-tract-infections.html>), uncomplicated lower UTI often respond to trimethoprim or nitrofurantoin, or alternatively, amoxicillin, ampicillin or oral cephalosporin. When resistance to these antibiotics occurs, amoxicillin-clavulanic acid is used as an alternative treatment. A false susceptibility result to amoxicillin-clavulanic acid of a causative isolate of a UTI may mean that a patient is administered amoxicillin-clavulanic acid and will not respond to therapy. Normally UTI infections respond within a few days of treatment. If the infection persists an alternative antibiotic is normally prescribed. Thus the main impact to patient safety would be a possible delay in resolution of the infection.

AUGMENTIN 32mg/L PLATE from 13th November 2017 may be affected, including the following lot numbers:

Product name	Lot number	Expiry date
AUGMENTIN 32mg/L PLATE	398336	07/12/2017
AUGMENTIN 32mg/L PLATE	399021	21/12/2017
AUGMENTIN 32mg/L PLATE	399282	28/12/2017
AUGMENTIN 32mg/L PLATE	399685	05/01/2018
AUGMENTIN 32mg/L PLATE	399990	11/01/2018
AUGMENTIN 32mg/L PLATE	400172	18/01/2018
AUGMENTIN 32mg/L PLATE	400348	24/01/2018
AUGMENTIN 32mg/L PLATE	400617	02/02/2018
AUGMENTIN 32mg/L PLATE	401642	16/02/2018
AUGMENTIN 32mg/L PLATE	402193	01/03/2018
AUGMENTIN 32mg/L PLATE	402531	08/03/2018
AUGMENTIN 32mg/L PLATE	402863	15/03/2018

We recommend that data generated using these plates are reviewed for evidence of unexpected susceptibility to amoxicillin-clavulanic acid occurring in either patient isolates or control cultures and, where appropriate, retesting is undertaken.

Mast records show that we dispatched to you on the listed dates the following lots of MPM-AUG32 plates within the lots of the identified plate sets:

Lot number of MPM-AUG32	Expiry date of MPM-AUG32	Lot number of plate set	Number of MPM-AUG32	Date dispatched

We request that you pass a copy of this FSN on to any relevant users and or customers and or alert any organisation to whom incorrect test results arising from the use of this device have been sent.

We thank you in advance for your support in helping us to 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,

Howard Rose
Managing Director, Mast Diagnostics