

Salutation First name Last name
Address

Date dd/mm/yyyy



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Post FIELD SAFETY NOTICE (FSN) Follow-up
AUGMENTIN 32mg/L PLATE, MPM-AUG32, Date of FSN: 05/06/2018

Dear **Salutation First name Last name**,

MPM -AUG32 FSN investigation

First of all, thank you for your patience with us whilst we have been carrying out extensive studies on reformulation of the MPM- AUG32 plate.

This has been a long and complex study, the outcome of which is summarised below.

Investigations have shown that reduced stability of the clavulanic acid component within the plate is the root cause of the problem. This has been exacerbated by the original raw material component being withdrawn from the market by our suppliers and which in turn has resulted in us having to source an alternative form of clavulanic acid. Initially this appeared to be performing within the expected parameters using a previously defined set of standard test organisms. However, subsequently it has become apparent that there were sporadic incidences where the plate appeared not to be performing as expected. A study was then initiated using a much larger number of 'wild type' organisms with MICs clustered around the breakpoint concentration for this antibiotic. This is a 'worst-case' scenario and therefore may not be truly representative of what could be found during routine testing where a much wider range of MIC's would be expected. Nonetheless, we believe that we should report these findings and state the sensitivity and specificity of the MPM- AUG32 plate as found, which are as follows:



14 Days after manufacture:

Sensitivity 97.98%

Specificity 79.36%

We feel that this may be interpreted as a limitation of use with this plate, although you may find that in routine use, results are not affected. However, we recommend that you revalidate the plate before putting it into routine use.

The MPM -AUG32 plate in its new format will continue to be acceptable for reporting an organism as 'susceptible' but as stated above, following your revalidation of the plate, additional tests may be necessary to confirm an organism as 'resistant'.

In view of the stability of the clavulanic acid, we have made a decision to reduce the guaranteed minimum shelf life on this plate to **seven** days from receipt of your plate delivery. Whilst we also recognise that a seven-day shelf life is far from ideal, this is all we can guarantee at this stage. However, we have instigated a further development programme with the aim of achieving a longer shelf life and will update you if we find that we are able to extend the guaranteed minimum shelf life.

Because of this reduction in shelf life, MPM-AUG32 plates will no longer be included in your plate set and will be packaged separately. This change will take effect from deliveries received week commencing 22nd October 2018 onwards.

We understand that this may need you to amend your stock control and work flow processes so we appreciate that you will need time to discuss with your team how you would like to take this forward.

Your territory manager will be contacting you shortly to discuss implementation options.

Yours sincerely,

Howard Rose
Managing Director
Mast Diagnostics Division