



July 2012

PRODUCT INFORMATION VITEK® 2

Dear Valued bioMérieux Customer,

We are pleased to announce the re-formulation of Piperacillin/Tazobactam (Pip/Taz) has recently been **granted clearance by the US FDA**. This formulation has been released and is currently in use here in Canada, subsequent to Health Canada's licensing the antibiotic in early 2012.

FDA requirements often differ from other regulatory bodies that may have already approved the current formulation. The FDA limitations are now being applied on the VITEK® 2 Piperacillin/Tazobactam, which will appear in the package inserts starting later in 2012 or early 2013.

bioMérieux recommends that customers create Advanced Reporting rules per instructions in Chapter 13 of the VITEK® 2 Software User Manual to prevent reporting of results for organisms that have new limitations with the Piperacillin/Tazobactam. These limitations are as follows:

- Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

o **Piperacillin/Tazobactam: *Serratia marcescens***

- Perform an alternative method of testing prior to reporting of results when a **resistant** result is obtained with the following antibiotic/organism combination(s):

o **Piperacillin/Tazobactam: *Pseudomonas aeruginosa***

This notification applies to the following cards AST-GN (gram negative AST cards) that have the re-formulation of Piperacillin/Tazobactam:

413085 AST-N220
413083 AST-N222
413066 AST-N216
413062 AST-N208
413063 AST-N213

413082 AST-N219
413143 AST-N226
413710 AST-N251
414125 AST-N273

As a reminder, these VITEK® 2 gram negative AST cards will only run on the PC platform of the VITEK® 2. Also, the new VITEK® 2 GN AST cards will not work unless

the 5.04 update has been installed. If you are still using the AIX (CC computers) platform, please contact your local bioMérieux representative for information on how to upgrade to the new PC platform.

We look forward to maintaining our strong partnerships, and are appreciative for the opportunity to provide you innovative diagnostic solutions and services that improve public health and patient care. If you have any questions or need assistance, please contact your local bioMérieux representative or customer service at 800-361-7321.

Sincerely,

A handwritten signature in blue ink, appearing to read "Christine Collins".

Christine Collins
ID/AST Product Manager

bioMérieux's solution for microbiology also offers Etest® and LyfoCults® Plus

Used together, VITEK® 2 and **Etest®** meet all the susceptibility testing requirements of a routine clinical microbiology laboratory, providing MIC results for bacteria and yeast, including slow-growing, fastidious and anaerobic bacteria.

For the QC needs of the micro biology laboratory, bioMérieux offers **LyfoCults® Plus QC organisms**, a broad variety of quality control strains for VITEK® 2 and other commercial systems in the market such as prepared media, stains and reagents.

For more information about how the VITEK® 2 and Etest® synergy can benefit your laboratory, or how to order LyfoCults® Plus please contact your local bioMérieux representative.