SIEMENS

Urgent Field Safety Notice

May 2010

MicroScan® Microbiology Systems

Tigecycline Dilution Error with MicroScan® Gram Negative MIC Type 37 (B1016-147) Panels

Our records indicate that your facility received MicroScan® Neg MIC Type 37 panels, catalog number B1016-147. A Siemens Healthcare Diagnostics internal investigation has confirmed that the tigecycline dilutions contain one-half the stated concentration of antibiotic. The following lot numbers are affected: 2010-09-15, 2010-10-27, 2010-11-12, 2010-11-16, 2010-12-18, and 2011-02-08.

The tigecycline dilutions stated on this panel type are 1µg/ml, 2µg/ml, and 4µg/ml. **The effect would cause reporting of falsely elevated MICs (+1 doubling dilution) and potentially an increase in minor (e.g. susceptible to intermediate or intermediate to resistant) errors as compared to a frozen reference broth microdilution method.** Tigecycline interpretations follow EUCAST recommendations. No other antimicrobial results are affected.

Siemens is conducting a voluntary corrective action for MicroScan® Neg MIC Type 37 panel, catalog number B1016-147. We recommend that tigecycline MICs and interpretations be suppressed for intermediate or resistant (2 µg/ml and 4 µg/ml) MICs with the affected lots. Instructions for antimicrobial agent suppression may be found in the Defining Rules section of your LabPro™ Operator's Guide. Your Laboratory Information System (LIS) may also need to be modified to ensure full suppression of tigecycline results. Tigecycline MICs and interpretations of susceptible (≤ 1 µg/ml) can still be reported.

As stated in our product Instructions for Use, test results should be interpreted in conjunction with the patients' medical history, clinical presentation and other findings. We recommend discussing the content of this letter with your laboratory director regarding the need to review previous test results, conduct patient follow-up, and/or repeat testing for tigecycline. If critical to patient care and an intermediate or resistant result is obtained, retest tigecycline using another method.

We have identified the root cause and have instituted proper corrective actions. Panels with an expiration date of 2011-04-08 or later are acceptable for all tigecycline results and testing by another method is no longer required.

Please share this information with all personnel who use this product and with others to whom you may have distributed this product. We apologize for the inconvenience that this situation has caused and thank you for your continued support. If you have any questions regarding this information, please contact your local Siemens Technical Solutions Center.

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