

Field Correction Notice
MicroScan® LabPro Information Manager System
Software Versions 1.55, 1.91, and 2.01
Potential for Incorrect Interpretations When LabPro Clears Stored ESBL Results for Clinical Isolates

October 20, 2006

Dear Dade Behring Customer:

The purpose of this letter is to inform you of the potential for LabPro to report incorrect interpretations for Extended-Spectrum beta-Lactamase (ESBL) producing organisms and antimicrobial agents when MIC values are edited in Patient Review and Edit (PRE) after an ESBL confirmation result has been stored. The likelihood of this event occurring is low because a unique set of circumstances must take place prior to this happening.

1. The MicroScan® panel contains ESBL screening antimicrobial agents (e.g., ESBL-a, -b, Ceftazidime). Panels that contain ESBL confirmation agents (e.g., ceftazidime/clavulanic acid, cefotaxime/clavulanic acid) are not affected.
2. A positive ESBL result was stored in LabPro for the isolate.
3. An MIC value was subsequently edited in PRE which required LabPro to reprocess the panel results.

After reprocessing, LabPro will re-evaluate the ESBL result based on the panel ESBL screen results. For antimicrobial agents dependent on ESBL testing, LabPro does display some visual clues in PRE that interpretations have changed when an MIC value is edited and results processed:


- The positive ESBL result in the Isolate Details area clears and is now blank or displays "Suspected ESBL".
- Cephalosporins, penicillins, and aztreonam will display interpretations (S, I, R, EBL?) based on the MIC value. The original interpretations would have been R* when the ESBL result was positive.
- If the organism was an ESBL screen-positive organism, "Suspected ESBL" displays in the Alert area.

To avoid the potential for further problems, prior to editing MIC values in PRE, take note of the isolate ESBL result. After editing the MIC values and selecting the Process command, you should enter the correct ESBL value and then process the panel results. LabPro will then display the correct interpretations for cephalosporins, penicillins and aztreonam based on the ESBL result.

If your laboratory currently confirms suspected ESBL results and enters them into LabPro as positive or negative, you may want to query the database for any isolates with Suspected ESBL (Interpretation = EBL?) and review those results for current patients.

We are currently working on a software update that will be made available to you in the first half of 2007. Please share this information with all personnel who use the LabPro Information Manager System. If you have any further questions, please contact the MicroScan Technical Assistance Center, at 1-800-677-SCAN (7226) in the U.S. and Canada or your local Dade Behring Representative. We apologize for any inconvenience this may have caused you and thank you for your continued support.

Sincerely,


Software Product Manager