SIEMENS

Urgent Field Safety Notice

13-17

March 2013

MicroScan® Microbiology Systems

MicroScan MICroSTREP *plus*® Type 1 Panels (B1027-201), MICroSTREP *plus*® Type 5 Panels (B1016-95), MICroFAST® Type 5J Panels (J1016-83) and MICroFAST® Type 7J Panels (J1016-84)

Potential for False Skipped Wells and False Susceptible Misreads with Group B Streptococci (*Streptococcus agalactiae*) with the WalkAway® System

Our records indicate that your facility received MicroScan MICroSTREP *plus* Type 1 (MSP1, B1027-201, SMN# 10444757), MICroSTREP *plus* Type 5 (MSP5, B1016-95, SMN# 10444626), MICroFAST Type 5J (MF5J, J1016-83, SMN# 10371536) and/or MICroFAST 7J (MF7J, J1016-84, SMN# 10714211) Panels in the last twelve months.

A Siemens Healthcare Diagnostics investigation has confirmed the issue of false skipped wells and false susceptible misreads with *S. agalactiae* affecting multiple antimicrobial agents on MicroScan MSP1, MSP5, MF5J and MF7J panels processed in a WalkAway System. **The effect is the potential for false susceptible results for *S. agalactiae* if the WalkAway System reads are not verified.** This issue is not panel lot specific nor is it related to a particular model of WalkAway instrumentation. No other streptococcal species are affected.

Siemens is conducting a voluntary corrective action for WalkAway System reading for *S. agalactiae* on MicroScan MSP1, MSP5, MF5J and MF7J panels. Until a solution is implemented, we recommend you perform manual reads or confirm any WalkAway System reads manually for all *S. agalactiae* testing.

As stated in our product Instructions for Use, test results should be interpreted in conjunction with the patient's 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 testing conducted in the last twelve months.

Confirmation of receipt of this letter is required. Attached you will find a form indicating you have received and understood the information. We would greatly appreciate your assistance in notifying us that you have received the information by taking a moment to complete and return the form below.

If you require further information or assistance, please contact your local Siemens Healthcare Diagnostics Representative. Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support.

Siemens Healthcare Diagnostics Inc.

1584 Enterprise Blvd.
West Sacramento, CA 95691

1-800-677-7226 Option 1 (USA/Canada)
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

MicroScan MICroSTREP *plus*® Type 1 Panels (B1027-201), MICroSTREP plus® Type 5 Panels (B1016-95), MICroFAST® Type 5J Panels (J1016-83) and MICroFAST® Type 7J Panels (J1016-84)

Potential for False Skipped Wells and False Susceptible Misreads with Group B Streptococci (*Streptococcus agalactiae*) with the WalkAway® System

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated March 2013 regarding the potential for false skipped wells and false susceptible misreads with Group B streptococci (*Streptococcus agalactiae*) with the WalkAway System. Please read each question and indicate the appropriate answer. Please fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. Did we effectively communicate all necessary information? Yes ☐ No ☐
2. Do you now have any of the noted products on hand? (Please check inventories before answering.) Yes ☐ No ☐
3. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT 302-631-8467.