



July 17, 2015

URGENT MEDICAL DEVICE RECALL
MicroScan LabPro Information Manager System
Version 1.0 to Version 4.11

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	<p>Beckman Coulter has confirmed the following issues can be encountered when generating organism identifications in the MicroScan LabPro Information Manager System from Dried Overnight Gram Negative panels processed on MicroScan autoSCAN-4 Systems or read manually and entered into the LabPro System.</p> <p>The use of Dried Overnight Gram Negative panels and the LabPro software system on the WalkAway system is not affected.</p> <p>Some glucose non-fermenting organisms may display a color change (shade of yellow) in the GLU, SUC, and SOR at 48 hours. When this occurs:</p> <ul style="list-style-type: none">• LabPro software incorrectly allows the operator to manually edit the carbohydrate substrates (specifically GLU, SUC, and SOR) when manually reading dried overnight gram negative (conventional) panels with an ID Hold status.• LabPro software incorrectly overwrites the previously stored carbohydrate substrate results (specifically GLU, SUC, and SOR) when reading dried gram negative overnight (conventional) panels which have an ID Hold status on the autoSCAN-4 system.• LabPro software then incorrectly uses the fermenter identification substrates to calculate the biotype which may cause non-fermenters such as an <i>Acinetobacter</i> species to be incorrectly identified as fermenters, for example, a <i>Shigella</i> species.
IMPACT:	<ul style="list-style-type: none">• An incorrect microbial identification reported to the physician may result in treatment with an ineffective or inappropriate antibiotic.• Panels processed on a WalkAway instrument do not incorrectly overwrite carbohydrate reactions stored at the 16-18 hour initial read. This Customer Notification does not apply to panels processed on a WalkAway instrument.
ACTION:	<ul style="list-style-type: none">• When manually reading overnight gram negative panels and entering results in LabPro's Results Summary and Edit window, follow the Panel Procedural Manual when determining biochemical reactions:<ul style="list-style-type: none">○ After 16-24 hours incubation, if the GLU is a strong yellow, or SUC or SOR is positive when GLU is negative, then the organism is classified as a fermenter and only the fermenter test results will be used to generate the biotype. If the GLU, SUC, or SOR are all orange or red, the organism is classified as a non-fermenter.

	<ul style="list-style-type: none"> ○ Once it is determined that the isolate is a non-fermenter and does not meet the requirements to add reagents, read all the MIC wells and CET and incubate the panel for an additional 24 hours. The panel status is now ID Hold. All ID Hold isolates are treated as non-fermenters; therefore only the following identification substrates should be read at 48 hours: URE, H₂S, IND, LYS, ARG, ORN, TDA, ESC, VP, CIT, MAL, ONPG, TAR, ACE, OF/G, NIT, and OXI. These substrates along with the previously recorded MICs and CET reads are used to generate the biotype. • If a GLU, SUC, or SOR reaction on the panel changes to a positive at the 48 hour read, do not edit the previous negative result. These carbohydrates should not be evaluated at 48 hours. • If after 48 hours the autoSCAN-4 changes the ID to a <i>Shigella</i> species or other fermenter based on a positive GLU, SUC, or SOR, edit those carbohydrate results back to negative. See the “Additional Information” section below. • To be alerted to the most likely misidentification scenario of <i>Acinetobacter</i> species incorrectly identified as a <i>Shigella</i> species, create an AlertEX Rule for all <i>Shigella</i> species. See the “Additional Information” section below. • Panels processed on a WalkAway system do not overwrite carbohydrate results stored at the 16 – 18 hour read. No action is needed
RESOLUTION:	<ul style="list-style-type: none"> • The issue will be corrected in a future software version update.



Additional Information

If you would like to add an Alert Rule to your system for notification of *Shigella* identifications that may be a result of this issue, then follow the instructions below.

This would allow the user to review the panel and culture information to ensure the identification is correct.

Note: This rule will be triggered for all *Shigella* identifications regardless of read method or read time.

Instructions for implementing an AlertEX Rule for *Shigella* species

1. When this AlertEX Rule is triggered and an investigation of the processing of the panel indicates it was read manually or on the autoSCAN-4 at 48 hours (ID Hold), edit GLU, SUC, and/or SOR back to negative. Click **Process** to recalculate the identification. If satisfied with the panel results, click **Save**.

WARNING: Any identification with a fermenter biotype configuration is incorrect at the 48 hour read and should be reviewed!

2. Panels reporting *Shigella* species at 16-24 hours incubation are valid. Follow your usual laboratory procedures when this organism is isolated.
3. To be notified to check the panel ID results displayed in LabPro create this user-defined Comment AlertEX Rule.
 1. Access the **Alert System** from **Customization**.
 2. Click **Alert Comments**.
 3. Create the following AlertEX Comments to communicate this information:

Code AS4MAN

Description: This Alert does not apply to panels processed on the WalkAway instrumentation

Code: 48 HR GLU READ1

Description: Identification of *Shigella* species at the 48 hour read is invalid.

Code: 48 HR GLU READ2

Description: If 48 hour read, edit GLU, SUC, and SOR to negative and re-process ID

4. Click **Save** after creating each new Comment. Click **Alert Rules**.
5. Return to **Utilities** and click **Alert Rules**.
6. Click **Add**. Enter the Code, Description, Parameters, and Conditions displayed in Figure 1.
7. For the Test Group Group parameter, enter only the Overnight Gram Negative group (GN)
8. Click **Save**.



Figure 1. Creating an Alert Rule

Alert Rules - Add
X

Data

Code: 48 HR GLU READ Description: 48 hour read GLU, SUC, SOR, positive (AS4, manual) Medium Active

Action Parameters	Parameters			
Alert Comments	Attending Physician	Isolate Comments	Patient Ward Group	Ward of Isolation
Organism Identification	Attending Physician Group	Isolate Extra Tests	Requesting Physician	Ward of Isolation Group
Drug Group Interpretation	Biochemicals	MIC	Requesting Physician Group	
AST Interpretation	Biotype	MIC for Drug Group	Service	
AST Systemic Interpretation	Disease State	Organism	Source	
AST Urine Interpretation	Institution	Organism Group	Source Group	
	Institution Group	Patient	Specimen Comments	
	Interpretation	Patient Comments	Test Group	
	Interpretation for Drug Group	Patient Ward	Test Group Group	

Alert Comments

Alert rule DOES NOT apply to WalkAway processed panels.
 Identification of Shigella species at the 48 hour read is invalid.
 If 48 hour read, edit GLU, SUC, and SOR to negative and re-pr...

Organism Group
SHIG

Test Group Group
GN

WHEN

AND

Alert Comments

Selected Alert Comments List

Code	Description
48 HR GLU READ1	Identification of Shigella species at the 48 hour read is invalid.
48 HR GLU READ2	If 48 hour read, edit GLU, SUC, and SOR to negative and re-pro
AS4 MAN	Alert rule DOES NOT apply to WalkAway processed panels.



Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact your Customer Support Representative:

- From our website: <http://www.beckmancoulter.com>
- By phone: call 1- 800- 677 -7226 in the United States and Canada.
- Outside the United States and Canada, contact your local Beckman Coulter representative.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product

We apologize for the inconvenience that this caused your laboratory.

Sincerely,



Jose Untalan,
Director, Quality Systems and Compliance

Enclosure: Response Form