



March 28, 2021

**RE: Urgent FIELD SAFETY NOTICE for the Accelerate Pheno™ system**

Catalogue Numbers: 10401008, 10301008

FSCA Identifier: FA000030

FIELD SAFETY CORRECTIVE ACTION – Immediate Attention Required

Dear Customer,

We are writing to inform you that Accelerate Diagnostics has identified a potential risk of very major discrepancies, major discrepancies and/or essential agreement <90% with some organism-antimicrobial combinations as listed below, when using the Accelerate Pheno™ system with software versions 1.4.1 and later. The Accelerate Pheno™ system is intended to measure signal intensity of fluorescent probes bound to nucleic acid in target and non-target organisms and to take time-lapse dark-field images of immobilized growing bacterial cells when used with the Accelerate PhenoTest™ BC kit. The Accelerate Pheno™ system is intended for use as an *in vitro* diagnostic medical device.

Results from the following combinations may produce errors:

- Any result for *Pseudomonas aeruginosa* and Ceftazidime/Avibactam (CZA) and Ceftolozane/Tazobactam (TZC)
- Any result for Enterobacterales and TZC

Actions to be taken immediately by customers using EUCAST breakpoints:

- For *P. aeruginosa*, stop reporting CZA and TZC
- For Enterobacterales, stop reporting TZC
- Following your institutional policies and processes, recommend review of results pertaining to the above scenarios when the Accelerate Pheno™ system with software versions 1.4.1 and later was used. It should be noted these errors are not related to a specific lot.

Continued reporting of the above organism-antimicrobial combinations could lead to false-susceptible and/or false-resistant results and the potential for ineffective or delayed treatment for patients.

Accelerate Diagnostics is currently working on a software update to automate the described actions. An Accelerate representative will contact you when the software update is available. Accelerate Diagnostics will be evaluating further development of these organism-antimicrobial combinations.

Please pass this FIELD SAFETY NOTICE to all who need to be aware of it within your organization and maintain awareness until such time as the software update has been implemented. In the EEA, the relevant National Competent Authority has been advised, as well as applicable Regulatory Agencies for other geographies.

Please sign the attached acknowledgement form, scan and return to your local Accelerate distributor / representative.

Sincerely,



EMEA Customer Service & Technical Support (or contact your local Accelerate distributor)

France: +33 441 920 245  
 Germany: +49 800 181 3437  
 Italy: +39 069 480 2890  
 Netherlands: +31 718 080 145  
 Spain: +34 932 204 547  
 UK & Ireland: +44 800 291 257  
 Portugal: +35 122 028 0007

Email: [support.emea@axdx.com](mailto:support.emea@axdx.com)

**Figure 1:** Affected Gram-negative organism-antimicrobial combinations.

Gram-Negative	Identification	Ampicillin	Amoxicillin-Clavulanic acid	Piperacillin-Tazobactam	Cefazolin	Cefuroxime	Cefoxitin	Ceftriaxone	Ceftazidime	Cefepime	Ceftazidime-Avibactam	Ceftolozane-Tazobactam	Ertapenem	Meropenem	Gentamicin	Tobramycin	Amikacin	Aztreonam	Ciprofloxacin	Colistin	Trimethoprim-Sulfamethoxazole
<i>E. coli</i>	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
<i>Klebsiella spp.</i>	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
<i>Enterobacter spp.</i>	•			•				•	•	•	•	•	•	•	•	•	•	•	•	•	•
<i>Proteus spp.</i>	•		•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•		•
<i>Citrobacter spp.</i>	•		•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
<i>S.marcescens</i>	•			•				•	•	•	•	•	•	•	•	•	•	•	•		•
<i>P. aeruginosa</i>	•			•					•	•	•	•		•	•	•	•	•	•	•	
<i>A. baumannii</i>	•			•						•				•			•		•	•	•



Stop reporting



## FIELD SAFETY CORRECTIVE ACTION

### APPENDIX: Acknowledgement Form

Customer Account Number: \_\_\_\_\_

Organization Name: \_\_\_\_\_

#### Software versions affected

Product Name	Software #
Accelerate Pheno™ system software	1.4.1 and later

#### My signature below reflects that:

1. I have read the attached Field Safety Corrective Action regarding the Accelerate Pheno™ system software versions 1.4.1 and later.
2. I understand and have followed the instructions as indicated in this Field Safety Corrective Action. If not, please indicate the reasons in the Comment section below.
3. I will report any potential adverse events related to this event to Accelerate Diagnostics, Inc.

Comments:

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Once completed, please scan a copy and send to your local Accelerate distributor / representative.

Thank you!