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 susceptible result for Enterobacterales and TZC if ceftriaxone (CRO) or ceftazidime (CAZ) are resistant
- Minimum inhibitory concentrations reported as ≤0.5 µg/mL for Enterobacterales and TZC may be out of essential agreement when compared to a reference test method (e.g. broth microdilution)

Actions to be taken immediately by customers using CLSI breakpoints:

- For *P. aeruginosa*, stop reporting CZA and TZC
- For Enterobacterales with susceptible TZC results when a resistant CAZ or CRO result is reported, confirm TZC by an alternate method if critical to patient care
- For Enterobacterales with TZC, report MICs of ≤0.5 as ≤1
- 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,

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

Phone: +34 932 204 547
Email: support.emea@axdx.com

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

Gram-Negative	Identification	Ampicillin	Ampicillin-Sulbactam	Piperacillin-Tazobactam	Cefazolin	Cefuroxime	Ceftriaxone	Ceftazidime	Cefepime	Ceftazidime-Avibactam	Ceftolozane-Tazobactam	Ertapenem	Meropenem	Gentamicin	Tobramycin	Amikacin	Aztreonam	Ciprofloxacin	Colistin	Trimethoprim-Sulfamethoxazole
E. coli	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
***Klebsiella* spp.**	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
***Enterobacter* spp.**	•			•			•	•	•	•	•	•	•	•	•	•	•	•	•	•
***Proteus* spp.**	•		•	•		•	•	•	•	•	•	•	•	•	•	•	•	•		•
***Citrobacter* spp.**	•			•			•	•	•	•	•	•	•	•	•	•	•	•	•	•
S.marcescens	•			•			•	•	•	•	•	•	•	•	•	•	•	•		•
P. aeruginosa	•			•				•	•	•	•		•	•	•	•	•	•	•	
A. baumannii	•		•	•					•				•			•		•	•	•

• Reportable range truncation and limitation

• Stop reporting