

ID 32, rapid ID 32, rapid ATB, ATB strips recognition defect
KC1 – FCA N° 2005- 06
Customer Product Notification

APPENDIX 2

For the attention of
Laboratories managers,
Healthcare Chairmen,
Reactovigilance correspondents

Marcy l'Etoile, November 8, 2005

URGENT PRODUCTS INFORMATION	
STRIPS (see list in appendix)	ID 32 Rapid ID 32 Rapid ATB ATB

Dear Sir, Dear Madam,

Further to complaints, an investigation in our Quality Control Laboratories has identified some recognition defects cases of the ID 32, Rapid ID 32 and Rapid ATB identification strips and ATB antibiotic susceptibility testing strips by miniAPI and ATB Expression instruments (see list in appendix), which could lead to an erroneous result.

The identification of the strips is performed on these instruments by reading the strip code which is itself determined by reading the identification box on the middle part of each strip.

Complaints for recognition defect generate either an existing strip code different from the expected code, either an unknown code and can be explained by :

- A false detection of an identification box, this phenomenon could be linked either to the presence of condensing water droplets or culture medium on the strip, or a maintenance defect of the systems.
- The absence of detection of an identification box linked to the printing quality.

An investigation is in progress in order to identify the causes of the anomaly and to implement the corrective actions :

The risk analysis we performed led us to the following conclusions :

- in relation with the identification strips, the defects of strips recognition are always detectable (unknown code or strip name incoherent the type of strip to identify : gram, morphology...).
- in relation with antibiotic susceptibility testing strips: the detectability of the recognition defect of the strips is not sure and a risk falsely sensitive (S) result feedback is possible.

We wish to draw your attention on the particular case :

- For ATB STAPH 1 new formula strips (Ref. 14321) and ATB STAPH 5 (Ref. 14325), a risk of falsely S result is possible for the antibiotics tested.

As a precaution, we request you to :

- to study retrospectively, in the severe case of infections and therapeutic failures (meningitis, septicaemias, osteitis), the results gave by ATB STAPH 1 and ATB STAPH 5 since 1 month. This in order to check the coherence of the results, and if need be to re-examine the patient file and to warn the clinician.
- Perform at the strips reading time, a systematic checking of the adequation of the strip composition with the results given which are displayed on the screen of your instrument.

Moreover, we do remind you that to avoid any false detection of an identification box, it is essential to follow :

- The maintenance procedure recommendations of the user manual (miniAPI instrument Manuel - Ref 99709 - chapter 6 and ATB Expression instrument Manuel - Ref. 40400 - chapter 4).
- The technical sheet recommendations where it is indicated in the paragraph « READING AND INTERPRETATION » of each ATB and RAPID ATB sheet : *Prior to automatic reading, it is advisable to wipe the middle part of the strip to eliminate any possible droplets of liquid so that the reader can recognize the strip code.*

We are aware of the perturbations this situations may involve, our Technical Assistance Department remains at your disposal for any further information you may require :

☎: XXXXXXXXXXX

Your sincerely,
Customer Service

LIST OF THE STRIPS CONCERNED

ID 32 / Rapid ID 32		Rapid ATB	
<ul style="list-style-type: none"> • rapid ID 32 E • rapid ID 32 A • rapid ID 32 Strep • ID 32 E • ID 32 STAPH • ID 32 GN • ID 32 C 	<ul style="list-style-type: none"> • Ref. 32700 • Ref. 32300 • Ref. 32600 • Ref. 32400 • Ref. 32500 • Ref. 32100 • Ref. 32200 	<ul style="list-style-type: none"> • rapid ATB E • rapid ATB G- • rapid ATB STAPH • rapid ATB UR • rapid ATB E4 	<ul style="list-style-type: none"> • Ref. 14189 • Ref. 14119 • Ref. 14179 • Ref. 14139 • Ref. 14384
ATB			
<ul style="list-style-type: none"> • ATB ANA • ATB BLSE • ATB G- • ATB HAEMO • ATB PNEUMO • ATB PSE • ATB STAPH • ATB STREP • ATB UR 	<ul style="list-style-type: none"> • Ref. 14269 • Ref. 14109 • Ref. 14019 • Ref. 14299 • Ref. 14250 • Ref. 14049 • Ref. 14029 • Ref. 14050 • Ref. 14039 	<ul style="list-style-type: none"> • ATB VET • ATB PSE 5 • ATB FUNGUS 2 INT • ATB G- 5 • ATB UR 5 • ATB STAPH 5 • ATB STREP 5 • ATB ENTEROC 5 • ATB PSE 1 • ATB G- 1 • ATB STAPH 1 • ATB UR 1 • ATB ENTEROC 1 	<ul style="list-style-type: none"> • Ref. 14289 • Ref. 14345 • Ref. 14203 • Ref. 14315 • Ref. 14335 • Ref. 14325 • Ref. 14355 • Ref. 14365 • Ref. 14341 • Ref. 14311 • Ref. 14321 • Ref. 14331 • Ref. 14351