

Marnes-La-Coquette, September 17, 2018

Ref. letter FSCA 10-18 IDD / Follow-up

Urgent Field Safety Notice

This information is intended for the end user of this product.
If you are not the end user, please forward this information to the appropriate laboratory staff

Subject: Pastorex Meningitis, Ref. 61607

Dear Valued Customer,

You are a user of the Pastorex Meningitis assay and we thank you for it.

Recent customer complaints concerning unusual high rates of positive agglutination with the R4 reagent, *Streptococcus.pneumoniae* latex, not confirmed by another technique raised our concern on the product. Quality control tests performed showed that the reagent R4 has an unspecific agglutination with sterile physiological water. This is observed with the reagent R4 only. Performances of the other reagents of the kit are conforming to specifications.

If the quality control with sterile physiological water isn't performed, the defect may not be detected. Consequently clinical samples agglutination with R4 reagent may be wrongly interpreted as positive results.

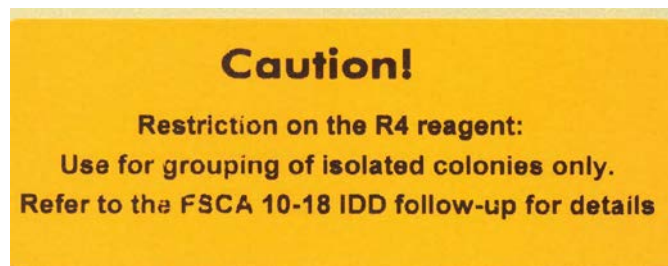
According to the first results of investigations performed, the impacted batches are listed below:

Reference	Name	Lot	Expiration date
61607	Pastorex Meningitis	64160551	2019-01-22
		64175493	2019-01-22
		64169521	2019-03-16

Additional investigations have shown that the following lot is also concerned:

Reference	Name	Lot	Expiration date
61607	Pastorex Meningitis	64186384	2019-05-27

As of today and until the defect is corrected, the Pastorex Meningitis kits will be released with the following label applied on each box:

**[Insert translation into local language]**

The latest investigations have demonstrated the following:

- Procedure for the grouping of bacterial strains isolated on agar: the R4 reagent agglutinates correctly the Quality Control strain *Streptococcus pneumoniae* within 2 minutes as expected; and does not agglutinate other Quality Control strains than this one. Therefore the R4 reagent (and all others reagents from the kit) can be used as usual.
- Procedures on CSF, serum, urine and on blood culture: an unspecific agglutination may be observed and wrongly interpreted as positive; therefore we do not recommend performing these procedures with the reagent R4.

Therefore, we ask you:

For the kits of the lots listed above remaining in stock and for kits with a different lot number but with the above warning label:

- For the procedure 'grouping of bacterial strains isolated on agar': the kit can be used as usual, as described in the package insert. For result interpretation, observe the appearance of any clear agglutination in less than **2 minutes**.
- For the procedures 'CSF, serum, urine' and 'blood cultures': **DO NOT USE the R4 latex reagent** (*Streptococcus pneumoniae* latex, green cap bottle).
The presumptive diagnosis of meningitis caused by *S. pneumoniae* has to be performed by another technique.
The other reagents of the kit can be used as usual.

Feel free to contact your local technical customer support for any assistance.

European competent authorities have been informed about this communication.

We apologize for the inconvenience caused by this issue.

Please forward to whomever it may concern.

Sincerely,



Sylvie FERNEZ

Regulatory Affairs Manager



CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Type: FSCA
Field Action Reference Number: 10-18 IDD / Follow-up
Bio-Rad Division: IDD

PRODUCT

Product Name:	Pastorex Meningitis	
Catalog No	61607	
Serial/ Lot No	Expiry Date	

CUSTOMER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address :	
Telephone Number / Fax :	
Customer Account Number :	

STATEMENT:

- I didn't received any of the affected lots
- I am aware of information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.

Number of affected kits: _____

Date:

Customer Stamp and Signature

Please return this form to: [enter local details]