Bio-Rad Laboratories

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Marnes La Coquette, August 22, 2018

Ref. letter FSCA 10-18 IDD

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 personnel

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.

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

Investigations are ongoing to identify the root cause of the defect.

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.

Therefore, we ask you:
For the concerned kits remaining in stock, perform a quality control on the R4 reagent (*Streptococcus pneumoniae* latex, green cap bottle) with sterile physiological water as described in the IFU of the kit.

- If there is no agglutination, the kit can be used as usual.
- If unspecific agglutination is observed, the R4 reagent cannot be used.
  The presumptive diagnosis of meningitis caused by *S. pneumoniae* has to be performed with another lot number of the Pastorex Meningitis assay and / or 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.

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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

Bio-Rad Laboratories

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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Type: FSCA
Field Action Reference Number: 10-18 IDD
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]