

To the attention of the Laboratory Manager

XXXX th, 2011

Important : Product Withdrawal

Our reference: FSCA 1148

Part number	Lot number	Expiry date
73112	1105104568	2012-03-06
73113	1105104545	2012-03-06

Dear Valued bioMérieux Customer,

You are using SLIDEX Staph-Kit Ref 73112 or 73113.

Further to complaints regarding the SLIDEX Staph-Kit reagent, investigations performed by our Quality Control Laboratory have detected a sensitivity problem with the R1 reagent (anti-*Staphylococcus aureus* latex) that could lead to false negative results with *Staphylococcus aureus* strains.

The risk of getting false negative results has been estimated as moderate because, as recommended in the package insert:

- After 18-24 hours of incubation at 33-37°C, suspect colonies should be tested with the classical methods of Gram stain, morphology and the catalase test, to confirm that they may be staphylococci.
- Quality control must be performed each time a new kit is opened using the strains *Staphylococcus aureus* ATCC 25923 and ATCC 51153: deterioration of reagents should be suspected if reagent R1 does not agglutinate with these strains.
- In the case of very weak agglutination with the anti-*Staphylococcus aureus* reagent, if the control reagent is agglutinated or if clumping occurs, further identification of the strain must be performed with the tube coagulase test or a biochemical range of tests.
- Sensitivity was shown to be 95.4% for MRSA strains (confidence interval 93.2-97%) and 100% for MSSA strains (confidence interval 99-100%).
- Interpretation of test results should be made taking into consideration the patient's history, the source of the specimen, colonial and microscopic morphology and, if necessary, the results of any other tests performed.

As a result, we ask that you stop using these batches of SLIDEX Staph-Kit.

If you are still in possession of these kits, we ask that you destroy them and return the Destruction Certificate to us by fax : xxxxxxxx.

We will send you a credit note or an exchange as soon as we receive this destruction certificate.

bioMérieux is committed to providing our customers with the highest quality products available. We sincerely apologize for any inconvenience that this matter has caused your laboratory.

Should you need additional information, feel free to contact our technical assistance department:
xxxxxxxxxx

Sincerely,
Customer Service

Attachment A: Destruction Certificate

Industry Customer Letter

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- After 18-24 hours of incubation at 33-37°C, suspect colonies should be tested with the classical methods of Gram stain, morphology and the catalase test, to confirm that they may be staphylococci.
- Quality control must be performed each time a new kit is opened using the strains *Staphylococcus aureus* ATCC 25923 and ATCC 51153: deterioration of reagents should be suspected if reagent R1 does not agglutinate with these strains.
- In the case of very weak agglutination with the anti-*Staphylococcus aureus* reagent, if the control reagent is agglutinated or if clumping occurs, further identification of the strain must be performed with the tube coagulase test or a biochemical range of tests.
- Sensitivity was shown to be 95.4% for MRSA strains (confidence interval 93.2-97%) and 100% for MSSA strains (confidence interval 99-100%).
- Interpretation of test results should be made taking into consideration the type and origin of product and if necessary, the results of any other tests performed.

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Attachment A: Destruction Certificate

ATTACHMENT A
DESTRUCTION CERTIFICATE

TO BE RETURNED TO YOUR CUSTOMER SERVICE
FAX : XXXXXXXX

Our reference: FSCA 1148

NAME OF THE LABORATORY:.....

CITY:

CUSTOMER NUMBER:

Products	Number of kits destroyed
73112 batch: 1105104568	
73113 batch: 1105104545	

We will send you a credit note or an exchange as soon as we receive this destruction certificate.

Date :

Signature :