

Marnes La Coquette, 2018 June 4th

Ref. letter FSCA 09-18 IDD / FSN 63757 63759

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

cc Chairman Medical Board and relevant Head of Departments

Subject: MRSASelect II agar, Ref. 63757 – 63759

Dear Valued Customer,

You are a user of the MRSASelect II chromogenic agar plates and we thank you for it.

Following reports concerning an abnormal coloration of certain agar plates and the growth of non-characteristic MRSA colonies, the first results of investigations performed, allow us to identify the valid batches which may present this risk of malfunction:

Code	Name	Lot	Expiration date
63757	MRSASelect II 20x90mm plates	64176319	2018/06/03
63757	MRSASelect II 20x90mm plates	64176665	2018/06/05
63757	MRSASelect II 20x90mm plates	64177987	2018/06/13
63757	MRSASelect II 20x90mm plates	64182549	2018/07/04
63757	MRSASelect II 20x90mm plates	64184389	2018/07/08
63757	MRSASelect II 20x90mm plates	64184619	2018/07/12
63757	MRSASelect II 20x90mm plates	64190128	2018/07/17
63757	MRSASelect II 20x90mm plates	64189124	2018/07/23
63757	MRSASelect II 20x90mm plates	64189214	2018/07/26

Code	Name	Lot	Expiration date
63759	MRSASelect II 100x90mm plates	64176352	2018/06/04
63759	MRSASelect II 100x90mm plates	64177995	2018/06/13
63759	MRSASelect II 100x90mm plates	64182547	2018/07/03
63759	MRSASelect II 100x90mm plates	64184619	2018/07/12
63759	MRSASelect II 100x90mm plates	64187554	2018/07/22
63759	MRSASelect II 100x90mm plates	64190805	2018/07/31

While investigations are still ongoing, we have identified the following:

- The origin of the problem seems to be related to certain raw materials.
- The observation of a non- characteristic coloration of agar and the observation of non-characteristic MRSA colonies, that is to say colonies without any pink color development, occur when the Petri dishes have been exposed to light during use and storage, for an exposure time greater than 4 hours.
- The coloration defect of the agar may be detected by the user before seeding the plate.

Impact Patient / User:

- If plates were exposed to light but none defects have been detected before use, then MRSA colonies may appear white to yellow instead of the pink characteristic color, or the growth may be delayed. As a result, there is a risk of misinterpretation of the result.

Therefore, we ask you:

- For the references and batches mentioned above, do not expose the boxes more than 4 h to light during the intermediate storage steps, including returning at room temperature, and during incubation until the reading step.
- Do not use a suspicious color agar. An example of agar with abnormal color is shown in the photo below:



Left: agar with normal color Right: agar with abnormal color, orange-pinkish shade

- As recommended in the package insert, if in doubt, confirm the identification of colonies by coagulase test or Pastorex™ Staph Plus.



**Bio-Rad
Laboratories**

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Télécopie : +33 (0) 1 47 41 91 33

European competent authorities have been informed about this communication.

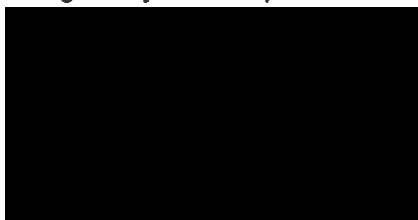
We apologize for the inconvenience, and remain at your disposal for any further information.

Please forward to whomever it may concern.

Sincerely,

Christine CHARPENTIER

Regulatory Affairs Specialist





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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Type: FSCA

Field Action Reference Number: 09-18 IDD

Bio-Rad Division: IDD

PRODUCT

Product Name:	MRSASelect II, 20x90mm plates	
Catalog No	63757	
Serial/ Lot No		Expiry Date

Product Name:	MRSASelect II, 100x90mm plates	
Catalog No	63759	
Serial/ Lot No		Expiry Date

CUSTOMER INFORMATION

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



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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]