

Marnes la Coquette, [date]

Ref. letter FSCA 06-18 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: Mueller Hinton Ref. 63824- lot 64153869 - Expiry date 2018/05/26

Dear Valued Customer,

Following reported cases for poor growth performances with some Staphylococci strains, we performed some investigations and we confirm this issue with the following product and lot:

Ref. **63824** Mueller Hinton 90 mm x 20 - **Lot 64153869** - Expiry date: 2018/05/26

A poor growth performance with some staphylococci strains can make the interpretation of the antimicrobial susceptibility testing more difficult and require additional tests.

As a consequence, we ask you to:

- Stop using Mueller-Hinton Petri dishes for this defective **lot 64153869**
- Destroy the products mentioned above (**lot 64153869**) that may remain in your local inventory
- Fill the attached form to attest of product destruction and send it to your local customer service to request kits replacement

The investigations to determine the root cause showed a failure during the manufacturing process of this lot and corrective actions have been implemented to minimize the occurrence of the event.

ANSM (National Security Agency of Medicines and Health Products) has 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



FSCA
06-18 IDD
Bio-Rad Infectious Disease Division

Form to return to your local customer service

INVOLVED PRODUCT/LOT

Product Name : Mueller Hinton 90 mm x 20	
Ref : 63824	Lot: 64153869 (Exp. date: 2018/05/26)

CUSTOMER INFORMATIONS

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

STATEMENT :

I have read information regarding the lot 64153869 of the device.

Number of concerned discarded kits to be exchanged : _____

Date:

Laboratory Stamp and Signature

Please return this form to: [enter local details]