



Marnes, Tuesday, December 08, 2015

IMPORTANT PRODUCT INFORMATION

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: Dengue NS1 Ag Strip (Ref. 70700) lots 5F0130, 5H0131, 5H1131& 5H2131.

Dear Valued Customer,

Following field complaints describing few negative results for supposedly positive patient samples, the quality of the following product has been investigated:

- Ref: 70700 – Dengue NS1 Ag STRIP
- Lots:
 - 5F0130 – Expiry date: 03/30/2016
 - 5H0131,5H1131,5H2131- Expiry dates : 04/30/2016 and 05/15/2016

Our quality control laboratory has confirmed the field results. A sudden and unusual of the sensitivity of these lots has been observed further to a punctual and isolated event. Despite deep analysis of root cause, this occurrence has not been clearly identified.

Nevertheless and as stated in the package insert, diagnosis of recent infection by dengue virus should only be established on the basis of a combination of clinical and biological data.

As a consequence, we ask you to:

- Destroy the kits that may remain in your local stock.
- Stop using kits from the 4 defective lots.
- Fill the attached form to attest of product destruction and fax it to your local technical support to request kits replacement.

NAMS has been informed about this communication.

May you have questions or need support on this subject, please do not hesitate to contact your local support.

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

Please forward whomever it may concern.

Sincerely,

Claude Giroud

Director Quality, Regulatory and Clinical Affairs



**Bio-Rad
Laboratories**

3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette France
Téléphone : +33 (0) 1 47 95 60 00
Fax : +33 (0) 1 47 41 91 33

PRODUCT REPLACEMENT

Form to return to your local customer service

INVOLVED PRODUCT/LOT

Product Name : Dengue NS1 Ag Strip	
Réf : 70700	Lots: 5F0130, 5H0131, 5H1131 & 5H2131

CUSTOMER INFORMATIONS

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

ACTIONS :

I have read information regarding the lots 5F0130,5H0131,5H1131 and 5H2131 of the device.

Number of kits to be exchanged: _____

Date:

Laboratory Stamp and Signature

For any other further information or support, please contact your local customer service.