Bio-Rad Laboratories, Inc.

Diagnostics Group
4000 Alfred Nobel Dr.
Hercules, CA 94547-1803
Telephone: 510 724-7000
Fax: 510 741-3954

URGENT: MEDICAL DEVICE CORRECTION

December 21, 2015

Dear Valued Customer:

This is to inform you of a D-10™ Rack Loader (Catalog No. 220-0600) product correction.

It has come to our attention that there is a potential to assign a patient result to an incorrect sample ID when running in the D-10 Rack Loader configuration. Although this is an unlikely occurrence, Bio-Rad wants you to be aware of the remote possibility.

While reviewing results, please verify that the number of results equals the total number of samples run. If there is a discrepancy, identify the rack with the missing result, rerun all samples from that rack, and check the laboratory information system (LIS) results.

We appreciate your patience as we actively investigate these customer reports and prepare a permanent solution. Bio-Rad Laboratories will release a follow-up communication providing a permanent solution upon completion of a thorough investigation. Please contact your regional Bio-Rad office if you have any questions.

Sincerely,

Bio-Rad CSD Regulatory Affairs Department

Bio-Rad
Laboratories, Inc.

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CUSTOMER FSCA RESPONSE FORM

FSCA / FN Reference Number: _____

Manufacturing Division: _____

PRODUCT

Product Name	Catalog No.	Serial / Lot No.	Expiry Date
D-10 Rack Loader	220-0600		

CUSTOMER INFORMATION

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

STATEMENT:

☐ I am aware of information about the field safety corrective action concerning the above referenced product and have proceeded according to the instructions issued by Bio-Rad.

Number of affected systems: _____

Date: _____ Customer Stamp and Signature: _____

PLEASE FAX COMPLETED RESPONSE FORM TO: (510) 741-3954, Attention: Bio-Rad CSD Regulatory Affairs Department.