



**Bio-Rad  
Laboratories, Inc.**

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

---

## PRODUCT QUALITY NOTIFICATION

### D-100 HEMOGLOBIN TESTING SYSTEM (290-1000) PERISTALTIC PUMP

August 24, 2018

Dear Customer:

Cc Chairman Medical Board and relevant Head of Departments

It has come to our attention that there is a potential for D-100 peristaltic pump failure resulting in a liquid waste leak. This liquid waste contains diluted patient samples. Although several instances of leaks have been reported to Bio-Rad, none have resulted in operator harm. This issue does not affect patient results.

Should a D-100 waste leak occur, please contact Bio-Rad Technical Service. Refer to your internal guidelines regarding biohazardous material handling. You may also refer to the D-100 Operation Manual (Section 7.2) which details cleaning up sample spills.

We have identified a replacement peristaltic pump and are actively working with the supplier to establish inventory for replacement worldwide. Bio-Rad Service will contact you shortly to schedule a visit to replace this part.

Please complete the attached “**FIELD ACTION RESPONSE FORM**” and fax or e-mail it to your regional Bio-Rad office.

We appreciate your patience as we actively source the replacement part. Please contact your regional Bio-Rad office if you have any questions.

Sincerely,

Bio-Rad CSD Regulatory Affairs Department



**Bio-Rad  
Laboratories, Inc.**

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

## CUSTOMER FIELD ACTION RESPONSE FORM

**Field Action Type: PQA**

**Field Action Reference Number: 2915274-08/15/2018-005**

**Bio-Rad Division: Clinical Systems Division (CSD)**

### PRODUCT

Product Name	Catalog No.	Serial No.	Expiry Date
D-100 Hemoglobin Testing System	290-1000		

### CUSTOMER INFORMATION

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

### STATEMENT:

- ☐ I am aware of information about the field 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.