August 31, 2005

URGENT

PRODUCT RECALL NOTICE

Product Name	Product Number	Unit	Lot Number
VeriCal® Calibrator Set	**252585**	**3 x VeriCal 1**	**161813**
		3 x VeriCal 2	**161907**
		3 x VeriCal 3	**161908**
			161909

ATTENTION: HEMOSTASIS/COAGULATION LABORATORY

Dear bioMérieux Customer:

bioMérieux Inc., Durham, North Carolina, U.S.A., is initiating a Voluntary Recall of the **VeriCal® Calibrator Set** (Product # 252585) for the lots noted above. This product is used to calibrate the Prothrombin Time (PT) and Activated Partial Thromboplastin Times (APTT) on bioMérieux instrument platforms. This recall only impacts INR determinations derived from Prothrombin Time (PT) results on the following instrument platforms: MDA, Coag-A-Mate® MTX and Coag-A-Mate® MAX.

The reason for the recall is the mis-assignment of ISI values associated with **VeriCal®** use. These calibrated ISI values are currently provided on Simplastin® HTF and Simplastin® L product labeling. The Verical labeling currently contains PT time in seconds and is being revised to include the ISI assignment for specified reagents.

There is currently only 1 **VeriCal® Calibrator Set** Lot in the field: Lot # 161909 as indicated in **Table A**. This lot expires October 31, 2005.

Table A

Product Name	Expiration Date	Product Name	Old ISI Assignment	New ISI Assignment
VeriCal® Calibrator Set Lot **# 161909**	Oct-31-2005	Simplastin® HTF	1.15	1.27
		Simplastin® L	2.00	2.14

Please replace the old ISI value with the new ISI value listed in the **Table A** above, if you have calibrated with **VeriCal®** lot 161909 and are using Simplastin® HTF and Simplastin® L on the identified instrument platforms. The bias for lot 161909 was determined to be greater than 0.3 INR but less than 0.5 INR at a 3.5 INR value. Therefore, this difference in ISI assignment **has no clinically significant impact within the INR therapeutic range**. There is no need for product replacement.

The **Simplastin® HTF** product, when used with the **VeriCal® Calibrator Set** lots listed in **Table B,** are also mislabeled. These **VeriCal®** lots have expired. The bias for the lots listed in Table B was determined to be greater than 0.3 INR but less than 0.5 INR at a 3.5 INR value. Therefore, this difference in ISI assignment **has no clinically significant impact within the INR therapeutic range**.

Table B

Product Name	Expiration Date	Product Name	Old ISI Assignment	New ISI Assignment
VeriCal® Calibrator Set Lot **# 161813**	Jan-31-2005	Simplastin® HTF	1.15	1.27
VeriCal® Calibrator Set Lot # **161907**	Apr-30-2005	Simplastin® HTF	1.15	1.27
VeriCal® Calibrator Set Lot **# 161908**	July 31, 2005	Simplastin® HTF	1.15	1.27

The Simplastin® L product, when used with **VeriCal® Calibrator Set** lots listed in **Table C,** are also mislabeled. These **VeriCal®** lots have also expired. The bias mislabeling of the ISI values for the lots identified in **Table C** could have resulted in discrepant INR results greater than 0.5 INR at the 3.5 INR value for patients who were receiving oral anticoagulant therapy. **The use of the discrepant ISI values on the identified instrument platforms are clinically significant and may have adversely impacted patient therapy.**

Table C

Product Name	Expiration Date	Product Name	Old ISI Assignment	New ISI Assignment
VeriCal® Calibrator Set Lot **# 161813**	Jan-31-2005	Simplastin® L	2.00	2.24
VeriCal® Calibrator Set Lot **# 161907**	Apr-30-2005	Simplastin® L	2.00	2.24

If your laboratory has used any of these lots with the corresponding instrument platforms, we recommend taking immediate action including providing notifications in accordance with your facility's policies and procedures in consultation with the appropriate medical personnel. However, if you have calibrated with any of the VeriCal lot numbers on the identified instrument platforms, please replace the old ISI value with the new ISI value immediately for the calculation of your INR results.

Finally, we request the following actions from you as soon as reasonable:

- Ensure this letter is distributed to all appropriate laboratory personnel within your organization.
- Fill out and return the acknowledgement in Attachment A by FAX to confirm receipt of the correction recall notice.

Please complete and return this form even if:

- There is no remaining inventory from the affected lots or
- The corresponding instrument platforms have not been used.

bioMérieux Inc. is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this has caused your laboratory. If you require additional assistance, please contact bioMérieux's Customer Support Center at **1-800-682-2666**, prompts 3, 2, and 1.

Sincerely,

John Cusack
Sr. Regulatory Affairs Specialist

Attachment

Attachment A

CUSTOMER ACKNOWLEDGEMENT FORM
URGENT
PRODUCT RECALL NOTICE

Product Name	Product Number	Unit Pack	Lot Number	Expiration Date	Number of Units In Inventory
Verical® Calibrator Set	252585	3 x VeriCal 1	**161813**	**Jan 05**	
		3 x VeriCal 2	**161907**	**April 05**	
		3 x VeriCal 3	**161908**	**July 05**	
			161909	**Oct 05**	

Contact Name: _____ Institution: _____

Street Address: _____

City, State, Postal Code: _____

Contact's Telephone Number: _____

Please complete the following:

- ❑ We received the notice of product recall on _____

Signature: _____ Date: _____

Please return this completed form to bioMérieux Regulatory Affairs:

Fax: (919) 620-2548

Mail: bioMérieux, Inc.
Attn: Regulatory Affairs
100 Rodolphe Street
Durham, NC 27712