Dealer Communication

Urgent Field Safety Notice

ProTime® 3 Cuvettes
Product Codes: PRO3-25 and PRO3-50
Reference Number IVD12.099 RAF 12-009
Return of Medical Device to the Supplier

Date

Attention: ProTime3 Cuvette Dealer

Details on affected devices:
Please refer to the attached list of affected ProTime3 cuvette lot numbers.

Description of the problem:
The purpose of this letter is to provide important information regarding certain lots of ProTime3 cuvettes. An essential part of ITC's quality system is continuous product performance surveillance. During this surveillance ITC has determined that some ProTime3 Test Cuvettes (PRO3-25 and PRO3-50) within the specified lot range may recover lower than expected Prothrombin Time/International Normalized Ratio (PT/INR) results. The company's investigation into the product's performance identified increased imprecision in addition to an increased negative bias, the combination of which may manifest as lower than expected PT/INR test results.

Management of warfarin (Coumadin®) therapy may have been affected for patients whose dosing regimen was determined solely using results from the affected cuvette lots. A low bias in patient PT/INR results with ProTime3 cuvettes that goes undetected by a laboratory may contribute to sub-optimal warfarin therapy, which may lead to a hemorraghic event and the potential for serious injury in some patients. Four adverse event reports have been received by ITC; the events occurred in the US and no permanent injuries or deaths were associated with these reports.

For patients tested with the affected ProTime3 lots, the PT/INR record should be reviewed and INR trends evaluated to determine if a repeat test is warranted. If a repeat test is required, ITC recommends that it be conducted either by using an ITC ProTime5 cuvette or a reference laboratory. It is advisable for you to conduct this review and follow up with your patients as soon as practicable. Please refer to the enclosed information for further information about the ProTime5 cuvettes.

ITC is implementing corrective actions to restore product performance.

ITC is conducting a voluntary medical device field safety corrective action for the affected lots which are listed on the attached table. This action does not involve the ProTime instrument or the ProTime 5 cuvettes. Distribution records indicate that at least one box of an affected lot of ProTime3 cuvettes was shipped to your facility.

Distributor Inventory:

1. Check your inventory to determine if you have any of the affected lots shipped to you as indicated on the attached affected lot list.
2. Immediately discontinue shipment of any affected product in inventory and place the product on "Hold." Forward this communication to all those who need to be aware within your organization.
3. IMPORTANT: Whether or not you have remaining inventory, complete the enclosed Dealer Account Tracking Form to provide the required information. ITC will review your response form and will contact you to replace all unused affected product in your inventory.
4. On a temporary basis, please order product code (PRO5-25) in place of (PRO3-25) for your inventory and to support your customers. Your cost will be the same for the PRO5 product as the PRO3 product until we resume shipment of PRO3 cuvettes. We have enclosed a letter explaining the difference between the cuvettes.
5. Complete the enclosed Dealer Account Tracking Form and confirm that you have notified your customers. Fax, e-mail, or mail the completed form to ITC using the contact information listed on the form.

Inventory Shipped to Customers and Replacements:

1. Send by traceable (certified or other) mail a copy of the enclosed customer communication to all customers who have been shipped the affected ProTime3 cuvettes.
2. Please inform your customers that they need to discontinue the use of affected lots. They must complete the enclosed response form and fax or e-mail it back to you. Please conduct check to ensure that all customers have received and responded to the notification.
3. Provide replacement product to your customers based on the quantity reported on the response forms they have returned to you, rounding up for partial boxes reported. Only unused, unopened cuvettes are eligible for replacement.
4. Arrange for the customers to return affected product to your facility.
5. On a weekly basis, fax or email a copy of your customers' response forms and the enclosed Distributor Periodic Summary Report, indicating the quantity of product that has been replaced to your customers in that timeframe. ITC will contact you to promptly arrange for replacement product to be shipped to you.

Handling Returned Affected Product:
Please contact ITC Tech Support to discuss the disposition of returned affected product.

Please contact ITC Technical Support (Telephone 1-732-548-5700 Extension 4707 or email ProTime@itcmed.com) immediately if you become aware of an adverse event due to the use of affected ProTime3 cuvettes.

ITC has notified the relevant National Competent Authorities of this FSCA. The Authorized Representative is MDSS GmbH (Telephone: +49 511 6262 8630) or email info@MDSS.com.

We apologize for any inconvenience that this matter may cause.

Questions and Contact Information	**If you have questions, please contact ITC Technical Support** **Telephone 1-732-548-5700 Extension 4707** **E-mail ProTime@itcmed.com** **FAX 1-732-635-0144**

20 Corporate Place South
Piscataway, NJ 08854 USA
Telephone +1-732-548-5700

Dealer Tracking Form

ProTime3 Cuvettes

IVD12.099 RAF# 12-009

Please complete and return this form:

Name _____

Address _____
Street

_____
City Country Postal Code

Contact Name _____

Contact Phone Number _____

Fax Number _____ E-Mail Address _____

Please select all that apply:

☐ I have read and understand the attached letter.

1. DISTRIBUTOR INVENTORY IN STOCK:

☐ I do not have any of the affected lots.

☐ My company has placed all inventory of affected product on "Hold."

☐ My company has the following amount of affected product:

Please circle the Item Number	Lot Number	Number of Boxes
ProTime3-25 or ProTime3-50		
ProTime3-25 or ProTime3-50		
ProTime3-25 or ProTime3-50		
ProTime3-25 or ProTime3-50		

INVENTORY SHIPPED TO CUSTOMERS:

☐ I have notified all customers who were shipped affected lots.

Enter the method you used to notify your customers _____

☐ I was not able to complete the actions provided in the letter because (please describe below):

_____

_____ _____

Signature Title

_____ _____

Name (Print) Date

FAX or E-MAIL to ITC Technical Support

FAX: 1-732-635-0144 E-MAIL: ProTime@itcmed.com