Accriva diagnostics

FIELD SAFETY CORRECTIVE ACTION

ATTENTION: Risk Management

January 27, 2016

Field Safety Corrective Action (RAF 16-001)
PROTIME InRhythm System
PT Test Cuvettes
Product Code: RHY-PT50 Lot Numbers:

K5PTD402-P1	**K5PTD403-P2**	**K5PTD404-P3**	**L5PTD405-P4**

An essential part of Accriva Diagnostics' quality system is continuous product performance surveillance. This surveillance program includes stability testing of product to verify that storage conditions and shelf-life claims continue to be met. During this surveillance testing program, Accriva has determined that four (4) lots of the InRhythm PT Test Cuvettes are exhibiting accelerated degradation during both refrigerated and room-temperature storage conditions. This degradation indicates the product will not meet claimed performance for its full labeled shelf-life and in the case of room-temperature storage for may lead to erroneous results or QC test failures.

No other lots of InRhythm Test Cuvettes are affected by this issue.

No adverse events have been reported due to this issue; however, the potential exists that when the product is stored at room-temperature for extended periods (up to the claimed 3 months), erroneous (high) results may be reported or in some cases the user will observe the "QC high" error message indicating the internal control channel has exceeded the control limits. Thus, we are recalling the subject lots from distribution. If product has been continuously refrigerated prior to use, it is expected that it is performing within claimed specifications up to this point in time. However, as an added precaution we are recalling the subject lots from distribution, even if stored at refrigerated temperature to avoid the need for any later communication and further user inconvenience. Distribution records indicate that at least one box of this lot has been shipped to your facility. Please take the following actions:

1. Forward this communication to all those within your organization who need to be aware of this matter.

2. Check your inventory to determine if you have any InRhythm PT Test Cuvettes, Lot Numbers K5PTD402-P1, K5PTD403-P2, K5PTD404-P3, L5PTD405-P4

3. If you have inventory of InRhythm PT Test Cuvettes, with the subject Lot Numbers please destroy the product and submit the attached Destruction Form along with your request for credit.

4. If you have inventory DO NOT SHIP TO CUSTOMERS any kits labeled with InRhythm PT Test Cuvettes and the subject Lot Numbers. If you have shipped this product to customers please inform them immediately to STOP using the product and request return of any unused product.

5. Please follow the instructions on the Distributor Field Corrective Action Form, complete the form and return it as instructed on the form.

6. If you have questions, please contact us directly using the contact information below.

Thank you!

Accriva Diagnostic, Attn: Regulatory Affairs
6260 Sequence Drive, San Diego, CA 92121, USA
Tel: 858.263.2347
Email: Fieldaction16-001@accriva.com

Distributor Field Safety Notice Form
PROTIME InRhythm System
PT Test Cuvettes
Product code: RHY-PT50, Lot Numbers:
K5PTD402-P1, K5PTD403-P2,
K5PTD404-P3, L5PTD405-P4
RAF 16-001

Please complete and return this form within 10 days from receipt.

Distributor name: _____ Country: _____

Business address: _____

Tel: _____ Fax: _____ Email: _____

Please select all that apply:

o I do not have inventory of InRhythm PT test Cuvettes, lot numbers .

o I have (enter # boxes) intact boxes of PROTIME InRhythm PT test Cuvettes, Lot numbers: K5PTD402-P1, K5PTD403-P2, K5PTD404-P3, L5PTD405-P4 in my inventory and I will destroy this product and forward a Destruction Form (attached) when complete.

o I shipped (enter # boxes) of the affected product to customers and I have instructed these customers to:

- NOT use the product any further
- To destroy any unused product (intact boxes and/or unused pouches) and I will submit another Destruction Form when complete.

o I was not able to complete the actions requested in the letter because (please state below):

_____

Please sign and date this form, then email or mail it to Accriva Diagnostics.

_____ _____
Signature Title

_____ _____
Name (print) Date

EMAIL or MAIL to: Accriva Diagnostics, Regulatory Affairs
6260 Sequence Drive, San Diego, CA USA
Email: Fieldaction16-001@accriva.com

*Please contact the above for Return instructions and/or Destruction Form

RAF 16-001

PROTIME InRythm PT Test Cuvettes

DEALER CONFIRMATI ON OF PRODUCT DESTRUCTION/DISPOSAL

Company Name _____

Company Address _____
Street

_____
City Country Postal Code

Contact Name _____

Contact Phone Number _____

Fax Number _____ E-Mail Address _____

Lot # (s)	Scrap Quantity (Number of Full or Partial Boxes)	Date of Destruction/Disposal

_____
Signature

_____
Title

_____
Name (Print)

_____
Date

Please return this form to: Fieldaction16-001@accriva.com