



URGENT FIELD SAFETY NOTICE
ROTEM ex-tem, PART No. 503-05,
LOT No. 42255701

July 22, 2019

Dear Valued ROTEM ex-tem Customer:

This notification is intended to advise your facility regarding a performance issue identified with the following product lot of ROTEM ex-tem:

Product Name	Part No.	Lot No.	Exp. Date
ROTEM ex-tem	503-05	42255701	3/31/2020

• **Issue Description and Impact**

We have received customer complaints on Lot No. **42255701** of ROTEM ex-tem, reporting prolonged clotting times (CT) with multiple lots of ROTROL N controls. To date, no complaints have reported erroneous patient results.

Internal testing has also demonstrated prolonged ex-tem CT results outside of the normal range for healthy donor whole blood samples. This could potentially result in patients being inappropriately treated.

Accordingly, we are removing Lot No. **42255701** of ROTEM delta ex-tem from the field.

• **Mandatory Customer Actions**

Based on the above, please take the following ***immediate*** actions:

- **Check** your inventory for **Lot No. 42255701** and **destroy** all remaining material.
- **Document** the destruction on the Customer Reply Form and **return** the completed and signed form to the fax number or e-mail address listed on the next page.

Our Passion.
Your Results.

- **Contact** your local representative for an alternative product lot of ROTEM ex-tem, Part No. 503-05.
- **Share** this information with your laboratory staff and follow your internal procedures.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

We appreciate your prompt attention to this Field Safety Notice.

Sincerely,

