

FIELD SAFETY NOTICE

Erba Prottime LS – extended clot time

Date: March 3th, 2023
ID: FSN 2023_01
Product: Erba Prottime LS
Cat. No.: EHL00024, EHL00046, EHL00047

Dear Sir. / Madam,

According to our internal records you have ordered and received one or several batches of Erba Prottime LS affected by this Field Safety Notification. See below the details of the defect that was detected in some batches of Erba Prottime LS.

List of affected lots:

Product	Cat. No.	Lot number	Expiration
Erba Prottime LS 10	EHL00024	2111028	31.07.2023
Erba Prottime LS 50	EHL00046	2111029	31.07.2023
Erba Prottime LS 50	EHL00046	2111030	31.07.2023
Erba Prottime LS 50	EHL00046	2111259	31.07.2023
Erba Prottime LS 100	EHL00047	2110020	31.07.2023
Erba Prottime LS 100	EHL00047	2110021	31.07.2023
Erba Prottime LS 100	EHL00047	2201121	31.07.2023
Erba Prottime LS 100	EHL00047	2203055	31.07.2023

Description:

Affected lots of Erba Prottime LS have **extended clot times** for Prothrombin Time (PT) tests, affecting controls and sample material. Clot times shift was detected within shelf life of these products compared to value assignment received with fresh product. The control results received with affected lots currently will not meet the defined reference range criteria therefore testing should be ceased, and an alternative lot should be used.

Current investigations are such that the issue is limited to above listed lots only, however, please enact the below advice to ensure the quality of result on any lot as standard practice. Clot time results received using affected lots before can be sued as correct until they meet defined reference range criteria.

Potential impact:

The risk to patient is a delay on patient result reporting as the controls will not meet the reference range criteria and therefore, an alternative lot should be used to mitigate the issue. Please ensure that adequate controls are in place to identify aberrant results, comprehensive analysis using Levy-Jennings rules should be performed to identify any developing trends or bias. This will identify any potential issue.

Actions to be taken:

If you have any of the lots of Erba Protime LS among those listed above, Erba will request you to:

- Identify, locate and discard the affected pieces of Erba Protime LS on your stock.
- If you have already shipped the affected lots to any customer, please immediately inform them about the discrepancy and instruct them to discard the entire quantity.
- Use other lots of Erba Protime LS in your stock until the affected lots can be replaced.
- New lots of Erba Protime LS are available and can be used without any risk.
- Also forward this notice to all those who need to be aware within your organization.
- We ask customers outside the EU to handle necessary announcements to authorities in their countries.
- Contact Erba as soon as possible in order to obtain without delay a lot exchange.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in, sign the attached confirmation, and communicate this information to all concerned customers. Please send back filled confirmation to Erba Lachema by e-mail until **March 31, 2023**.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Best regards,

Erba Lachema, s.r.o.

Radim Herrmann
Quality Manager



<mailto:r.herrmann@erba.com>

Confirmation of receipt

Please, confirm that the customer information below has been received by your facility.

ID: FSN 2023_01
Name: Erba Protime LS – extended clot time
Product: Erba Protime LS
Cat. No.: EHL00024, EHL00046, EHL00047

Herewith I confirm that we have received above mentioned customer notification and that all required actions have been implemented and all concerned parties have been informed about this Field Safety Notice. The use and further distribution of the affected products has been stopped.

Number of discarded pieces: boxes

Customer name:

Confirmed by:
(name and position)

Date and sign:

Please complete this form and send it back via email until **March 31, 2023**.

Thank you for your efforts.

Erba Lachema, s.r.o.

Radim Herrmann
Quality Manager
<mailto:r.herrmann@erba.com>

