

FIELD SAFETY NOTICE

ELite 3 HEM Control Normal – functional issue

Date: November 15th, 2022
ID: FSN 2022_01
Product: ELite 3 HEM Control Normal 3ML
Cat. No.: HEM00014

List of affected lots:

Product	Cat. No.	Lot number	Expiration
ELite 3 HEM Control Normal 3ML	HEM00014	B1122N	2023-02-10

Description:

This is to inform you that LOT B1122N, Normal Level may exhibit hemolysis or deterioration due to a microbial contamination.

MCV results measured with Normal level of ELite 3 HEM Control Normal 3ML, lot B1122N are discrepant from the values specified in the assay sheet. The values measured with the normal level control are about 20% higher than the specified 85fl. This alteration affects the calculated Hematocrit and MCHC parameters derived from the MCV values, too.

When control measurement is done using normal and low or high control, the analyser shows out of range result for MCV, HTC and MCHC while shows in range values for the same parameters in case of low and high controls.

Potential impact:

Microbiological contamination might cause contamination of the analyser and might cause cross contamination of any LOW or HIGH level control that was also tested in the same time.

The control is a process control used to monitor instrument performance and does not have any clinical impact.

Please note that the Low and High level controls are not affected and can be safely used for the daily QC of the analyzers. Daily QC measurements at only two levels are sufficient and will not affect the result values of the measured samples.

Actions to be taken:

- Locate and discard the affected ELite 3 HEM Control Normal 3ML on your stock.
- If you have already shipped the affected LOT to any customer, please immediately inform them about the discrepancy and instruct them to discard the entire quantity.
- If vials from LOT: B1122N normal control was used in any device, the device fluidics system shall be decontaminated as per the Elite 3 User Manual chapter 7.1 using Hard cleaning process with hypochloride solution.
- If any LOW or HIGH level control vials have been also used for testing at the same time, discard those control vials as well due to risk of microbiological cross contamination.
- If there is any unexpected trend visible with unaffected QC materials results and trend or/and discrepancies in results for patient samples, it is recommended to review the patient's history results to make sure the results are correct.
- New lot of Normal level control will be released to replace the affected Normal level vials.
- Please inform Erba if you have already shipped the affected LOT to any customer.
- 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.

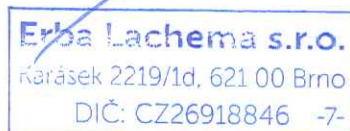
Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in, sign the attached confirmation, and communicate this information to all concerned customers. Please send it back to Erba Lachema by e-mail until **December 15, 2022**.

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@erbamannheim.com>

Confirmation of receipt

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

ID: FSN 2022_01
Name: ELite 3 HEM Control Normal – functional issue
Product: ELite 3 HEM Control Normal 3ML
Cat. No.: HEM00014

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.

Customer name:

Confirmed by:
(name and position)

Date and sign:

Please complete this form and send it back via email until **December 15, 2022**.

Thank you for your efforts.

Erba Lachema, s.r.o.

Radim Herrmann

Quality Manager

<mailto:r.herrmann@erbamannheim.com>

