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URGENT FIELD SAFETY NOTICE

Commercial name of medical device: *VACUTUBE K3E 2 ml*
Safety corrective action reference: *19.1.2023*
Type of action: *Product recall*

Datum: 19.1.2023

Subject: False low platelet count in K3E 2ml blood collection tubes

Information on affected medical devices:

In vitro medical devices, tubes for vacuum collection of venous blood with K3EDTA anticoagulant

Details of the affected medical device

Catalogue number	*Product name*	*LOT*	*Best before*
4.07.1.3	*VACUTUBE K3E 2 ml*	*3228*	*2024-05*

Description of the product problem:

Through complaint process we have received feedback that a falsely low platelet count was measured in a large number of VACUTUBE K3E 2 ml LOT number 3228. The number of platelets further decreases as the time since the blood collection increases. Blood count results for platelets can therefore be false. If you notice clumps of platelets in the blood plasma and the result shows a low platelet count at the same time, we suggest that you call the patient again for a blood sample and repeat the test.

Advice on action to be taken:

Due to the inconvenience this could cause to the laboratory and the patient, we are recalling the LOT number 3228 for preventive reasons. Please do not use this LOT number, notify the appropriate personnel and quarantine it. Please return the non-compliant tubes to us.

If your facility further distributes this product, please notify any additional affected customers.

If you have any questions or need additional information, please contact us by e-mail: info@lt-burnik.si.

We apologize for any inconvenience caused to your laboratory.

Reference person for contacts: Mateja Marolt

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The signature below confirms that the appropriate medical device authority has been notified of this notice.

Signature: