

April 16th, 2013

Ref#: FSN_2013_04-16

URGENT: FIELD SAFETY NOTICE
ABX DILUENT 20L LOT 130225H1* & 130311H1*

Dear Customer,

HORIBA Medical internal quality control process has confirmed an issue on some containers of ABX DILUENT 20L, ref. 0901020, a buffered isotonic solution intended for in vitro diagnostic use and designed for diluting, counting and differentiation of blood cells, and measurement of hematocrit on HORIBA Medical blood cell counters.

ISSUE:

During the use of some containers of ABX Diluent lot 130225H1* & 130311H1*, we observe some counting over $5 \times 10^3 / \text{mm}^3$ on the "platelet" parameter during blank cycle, causing "start-up" cycle failure.

IMPACT:

"Start-up" cycle failure does not allow use of the instrument.

ACTION/RESOLUTION:

We currently request the customer:

- When installing a new reagent, make sure that a start-up cycle is performed after priming.
- If the results of the start-up cycle are out of specifications, then stop using the concerned container and contact your HORIBA Medical representative.

Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation. It is mandatory for you to complete and return the enclosed reply form within 10 days so we may maintain our records.

If you have any questions regarding this Product Corrective Action, please contact us.

We sincerely apologize for any inconvenience that this may have caused to your laboratory.

Thank you for your continued support of HORIBA Medical products.

Yours sincerely,


Bruno LEMOINE

Director of Quality and Regulatory Affairs


Jean-Pierre BENEJNI

International Customer Service Manager

April 16th, 2013

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FAX ANSWER

Could you please return this document properly filled in and signed to us.



HORIBA ABX SAS

Parc Euromédecine - Rue du Caducée
BP 7290
34184 Montpellier Cedex 4, France
Fax : 04 67 14 18 75

ABX DILUENT 20L

During the use of some containers of ABX Diluent lot 130225H1* & 130311H1*, we observed some counting over $5 \times 10^3 / \text{mm}^3$ on the "platelet" parameter during blank cycle, causing "start-up" cycle failure

Could you please fill in the following sections:

Name of the Laboratory:

Address of the laboratory:

Telephone:

- I have received the quality information FSN_2013_04-16 concerning an issue on specific lot numbers of ABX DILUENT 20L reagent for use on HORIBA Medical blood cell counters.
- I have understood the recommendations of HORIBA Medical to prevent the issue on my analyzer(s).

Name:

Signature:

Title:

Date: