HORIBA
Medical

September, 19th 2018
Ref# FN_2018_09-19GBV02

cc Chairman Medical Board and relevant Head of Department

FIELD NOTICE
ABX DIFFTROL lot PX413H

Dear Horiba Medical Customer,

Horiba Medical internal quality control process has identified an issue on the ABX DIFFTROL lot PX413H regarding the target values.

ISSUE:

Internal measurements have shown that the target value for HCT and MCV parameter on Pentra 60 ranges, Pentra 80 ranges and Pentra 120 ranges has to be reassigned for ABX DIFFTROL lot PX413H.

IMPACT:

The current target value is overestimated on Pentra 60, Pentra 80 and Pentra 120 ranges. Consequently, it can generate HCt and MCV values below the tolerance interval.

This bias on the assay value is independent of the performances of your analyzer and does not affect the quality of patient results.

This issue concerns only HCT and MCV parameter, only for the level HIGH of lot PX413 on Pentra 60 range, Pentra 80 range and Pentra 120 range

ACTION/RESOLUTION:

The target values for HCT and MCV parameters were revised for the level H.
The updated target value sheet for lot PX413H will be available on the HORIBA Medical corporate website (http://toolkits.horiba-abx.com/documentation) on September, 19th 2018.
It is also attached with this communication.

The failure was recorded in our quality system in order to monitor the corrective actions we defined to avoid the re-occurrence of this issue.

Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation.

If you have any questions regarding this Product Corrective Action, please contact your local Horiba Medical representative.

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

Thank you for your continued trust in Horiba Medical products.

Yours sincerely,

Claire Mallié
Quality Assurance Manager