



Sysmex UK Ltd

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Date: Wednesday, August 15, 2018

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Ref: Field Safety Notice

Dear Valued Sysmex Customer,

We would like to inform you about observations of undetected eosinophils on XN series analysers. To alleviate any concerns you may have regarding the matter, please find below a summary of the background, clinical case assessment performed by Sysmex Europe GmbH and the software improvement scheduled by the manufacturer, Sysmex Corporation Japan.

In certain cases, on XN series analysers, eosinophils (EO) show an abnormal side scatter and/or fluorescence intensity based on the functional state of the cells such as activation or degranulation. This potentially interferes with the analysers' software to clearly classify the eosinophil population. Thus, resulting in a count of $EO = 0.00 \times 10^9/L$, whereas a microscopic evaluation of the sample revealed a count of $EO > 0.00 \times 10^9/L$.

Of the cases that were reported to Sysmex Europe with reference data for comparison, the majority had normal EO counts. Cases with an eosinophilia (count of $EO > 1.5 \times 10^9/L$), and hence of potential clinical relevance, were assessed by Sysmex Europe GmbH with the support of an external professional medical advisor.

This assessment concluded that all severe eosinophilia cases and most of the mild eosinophilia cases showed other abnormalities, indicated by quantitative or qualitative flags generated by the analyser.

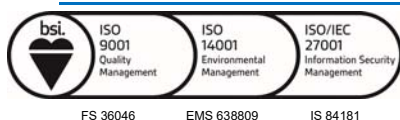
We would like to take this opportunity to remind you that, since the launch of the XN-Series many millions of samples have been measured on the XN-Series and we have received very few reports of isolated missed eosinophilia. The vast majority of which showed a mild eosinophilia with no implication for patient care. We therefore see no need to recommend smear reviews based on low eosinophilia counts.

Nevertheless, it is up to each laboratory to evaluate the need to set up a suitable follow-up for samples with $EO = 0.00 \times 10^9/L$ according to its standard procedure and the patients received.

A software revision is in development. We will contact you to arrange installation as soon as it is released.

Kind regards,

Adam Mellick
Haematology Product Manager



Registered Number 2598523

www.sysmex.co.uk



Acknowledgement of Receipt (AoR)

Incident: **XN-10, XN-20 false low Eosinophils measurement_648500000_vig_FR**

We hereby confirm, that SYSMEX has provided information regarding the above safety information.

For this, we acknowledge the receipt of the:

Field Safety Notice - XN-10, XN-20 false low Eosinophils measurement_648500000_vig_FR

— Please complete this form electronically from within the Legalsign application, if this is not possible print, sign and return this completed document to productmail@sysmex.co.uk

In order to comply with our regulatory obligations we kindly request that this AoR is completed and returned before the **27th August 2018**.

Date:

Company/Hospital:

Name:

Position:

Signature: