

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

## To whom it may concern

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Dear Valued Customer,

We would like to inform you about observations of undetected eosinophils on XN series analysers. To assuage your concerns regarding the matter, we provide you with 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 aforementioned cases reported to Sysmex Europe GmbH that included reference data for a comparison, the majority had physiological EO counts. Cases with a mild to extreme 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.

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.



Please be ensured that we take this issue very seriously and the legal manufacturer Sysmex Corporation Japan is working on an improvement with high priority. Sysmex Europe GmbH expects the release of the software version with the improved algorithm in 2018.

We request and thank you for your kind understanding and patience until the improved software is available.

Sincerely yours,

A handwritten signature in blue ink is written over the Sysmex logo and the company name. The signature is stylized and appears to be "S. Yaman".

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