

Urgent Field Safety Notice

FSCA-SEG/594900011

October 2013

XN-Series mixing issue and possible false high Hb values

Dear valued Sysmex customers,

Sysmex would like to inform you of the potential risk to health that could be caused by the possible reporting of falsely high Haemoglobin (Hb) values on the XN-Series analyser.

1. Details of affected devices:

Model	Serial number
Automated Hematology Analyser XN-10 & XN-20	all

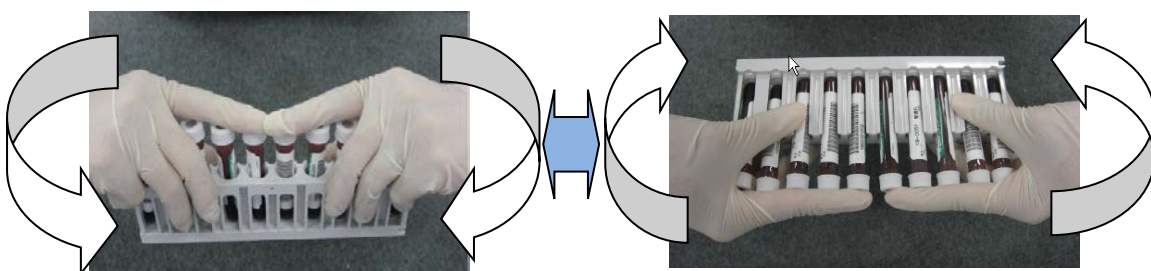
2. Description of the problem:

Sysmex was informed from the UK market that in very rare cases falsely high Hb values may occur, creating the potential risk of missed transfusions for patients with low Hb values.

As this does not occur in samples which were mixed correctly, we deduce that correct pre-analytical procedures and mixing can prevent this phenomenon.

In studies performed on the XN-Series analysers we have confirmed that the mixing function is effective for healthy volunteer samples which are measured less than 4 hours after the blood has been collected. However, for other samples with high viscosity or erythrocyte sedimentary rates (e.g. polymyalgia rheumatica, temporal arteritis or malignant lymphoma) or samples stored in the refrigerator, there is the possibility that the instruments standard mixing cycle may not be sufficient to suitably mix the sample. In this context please consider reviewing previous results that did not fit clinical expectations. In order to prevent this, we kindly ask you to check samples and pre-mix as follows:

Please **mix samples at least 10 times by inversion** as shown in the photos below before setting racks on the XN-sampler.





Note: If a sample tube is filled in excess of the specified volume, accurate analysis cannot be guaranteed as problems could be caused by inadequate anticoagulation and/or due to insufficient mixing. The tubes are designed such that the normal filling allows an air gap at the top of the tube. This air gap is crucial to mixing as without this the blood does not move when the tube is inverted. Therefore, please ensure that sample tubes are filled and used properly in accordance with its package insert and intended use.

While extensive testing has been done we cannot exclude with 100% certainty that an instrument issue may contribute to this phenomenon.

3. Immediate Corrective Action:

Please always assure that samples are **mixed sufficiently** before being placed on the analyser. This is especially important for samples from patients prone to high degrees of sedimentation or for cooled samples.

4. Permanent Corrective Action:

As the final root cause is still unclear, we will continue the investigation and act accordingly.

5. Contact reference:

Please contact your local Sysmex representative or distributors if you have any further questions regarding this matter.

Please distribute this information to all appropriate personnel in your laboratory and retain a copy on file.

We apologize for any inconvenience this may cause you and thank you for your kind understanding and continued support.

Yours sincerely

A handwritten signature in black ink, appearing to read "Kröger", with a long horizontal stroke extending to the right.

Thomas Kröger - Safety Officer - Sysmex Europe GmbH
Norderstedt, 09th October 2013