Urgent Field Safety Notice

2020-001

3rd March 2020

UF-5000, UF-4000: Potential wrong PMN/MN results in BF-mode

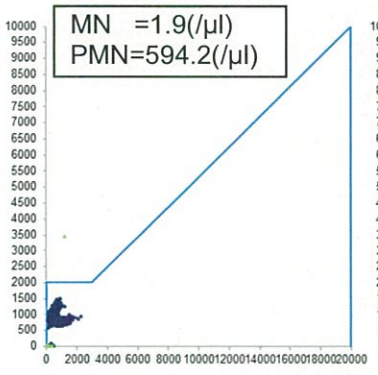
Product Name	UF-5000, UF-4000
Product Description	Fully Automated Urine Particle Analyzer
Device Identifier	n/a
Production Identifier (Lot No./Serial No.)	All serial numbers with software versions 00-21 or 00-22
FSCA-identifier :	2020-01 / 672100072
Type of Action	Advice given by manufacturer regarding use of the IVD

IMPORTANT NOTE: this FSN applies only to samples measured in Body Fluid mode!

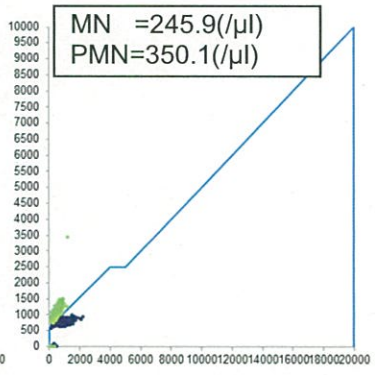
Description of Situation:

It is reported that Sysmex UF-5000/UF-4000 with software versions 00-21 or 00-22 generated false PMN / MN results (false low PMN with false high MN and vice versa) **in Body Fluid measurement mode**.

According to the investigation results, this phenomenon is caused by UF-5000/UF-4000 software version 00-21 and 00-22 that have an auto discriminator to separate MN and PMN cluster from each other. Please refer to the below scattergrams.



Version 00-21 and 00-22



Version 00-20 and before

Risk to Health:

When false high PMN in conjunction with false low MN is found, an unnecessary treatment with antibiotics may be administered.

When false low PMN in combination with false high MN is found, a serious infection (e.g. Meningitis) might be overlooked.

Actions taken by Sysmex:

The corrected software will be provided around May 2020. For an intermediate time, Sysmex will offer a downgrade of the software to version 00-18 if you measure the body fluid samples with UF-5000/UF-4000. In such case, the following software functionalities will not be available:

Version 00-20: Osmotic pressure conversion formula change and optional collection tube.
Version 00-21: Conductivity DP clogging countermeasure.
Change of BF WBC dilution ratio
Version 00-22: Additional RBC related parameters
All versions: Fix of software or technical related bugs according to the release notes

Actions to be taken by the customer:

Please take the following actions

1. In case the total WBC count is less 1,000/µl, please check the scattergram.
2. If the scattergram is same as above, please verify the WBC, MN, PMN results with another method such as manual microscopy or alternate devices (e.g. XN series).

Please note that with software version 00-18 positive WBC counts needs to be confirmed because the result of high amount of WBC in the sample might be incorrect!

Communication of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation.

Other information:

This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

To comply with regulatory requirements, we request that you complete the enclosed response form (AoR) and return to your authorised local Sysmex representative.

We deeply apologize for any inconvenience that this situation has caused and thank you for your patience and continued support.

Sincerely yours

Sysmex Corporation

H. Tauchi

Hidehiko Tauchi

Safety Officer