

Martillac, 06 December 2019

Subject : Security information n°R1916718 ANSM

Dear Madam, Dear Sir,

We hereby confirm that the Giemsa Solution lot I88021, lot I97523 and lot I63818 has a staining defect which could appear depending on the method used and result in stainings that may be either too dark or too pale.

These lots of Giemsa have been sold in 1 Litre bottles under the reference 75030SX1000 and are being recalled.

Therefore, all bottles that you have in stock must be withdrawn and destroyed.

You will find below a destruction certificate to be filled in and sent to your distributor. The products will be replaced as soon as possible.

The ANSM (French National Authority) has been informed of this communication.

Be assured of our total commitment in solving this problem and in the satisfaction of our clients.

Sandrine SAUVIGNON
Quality, Health, Safety and Environment Director



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Date :

Made by :

Society / department :

I declare, _____ to have destroyed the following products :

PRODUCTS	REFERENCES	QUANTITIES	LOTS

Signature and company stamp.

Document returned by fax +33 (0)557 960 405, by mail commercial@ral-diagnostics.fr or by letter.

Martillac, the 9th of december 2019

Object : Safety Information n°R1916718 ANSM

Madam, Sir,

Concerning Giemsa Solution lot I88021, lot I97523 and lot I63818 which have a staining defect, 3 cases may appear during the use depending on the dilution.

These batches of Giemsa have been sold in 1 liter bottles with the reference: 75030SX100.

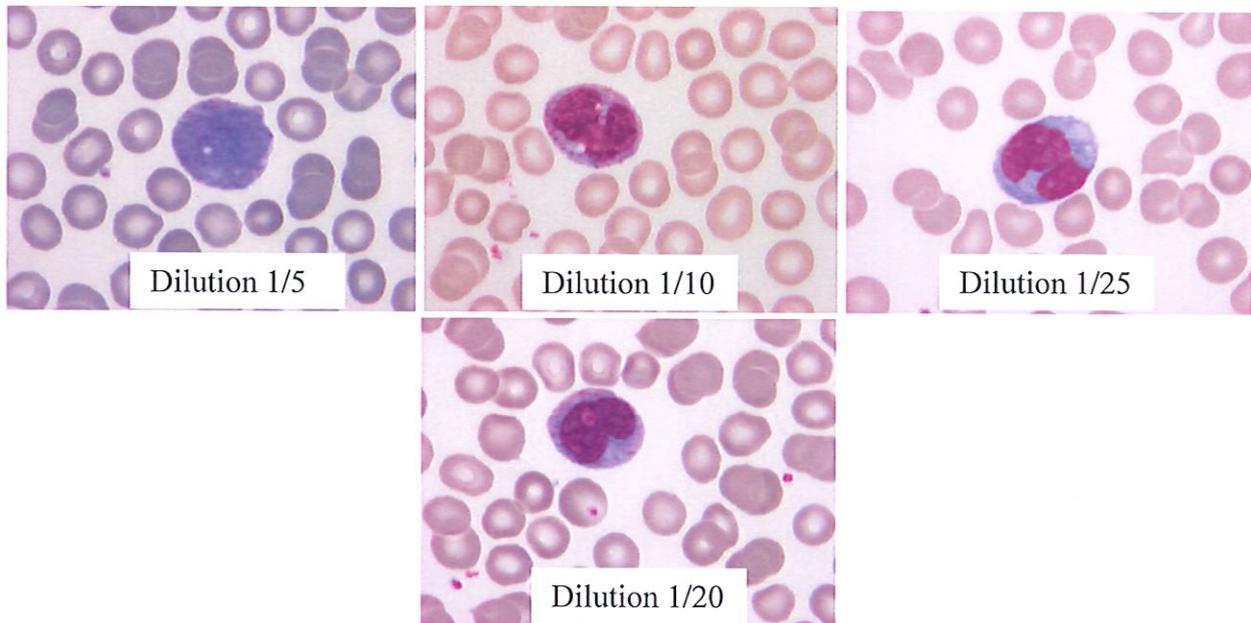
It has been observed that at 1/20 dilution (1 volume of Giemsa QS 20 volumes of buffer pH = 7.0) (example below), there is no color defect and the interpretation is normal.

For dilutions lower than 1/20 (example below 1/5 and 1/10), the staining is too pale.

For dilutions higher than 1/20 (example below 1/25): the staining is too dark.

The defect is noticeable on microscopic examination and concerns the sharpness of the cytoplasm and the nucleus of monocytes. The cytoplasmic shades are poorly revealed (too dark), the nuclei may be too pale.

If no defect has been detected when reading slides, there is no need for retrospective examinations.



Be assured of our total commitment in solving this issue and in the satisfaction of our customers.

Sandrine SAUVIGNON
Quality, Health, Safety and Environment Director