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FSCA Reference FSN20190221

For the attention of Site Director, local safety correspondant

Strasbourg, 11 march 2019

IMPORTANT: SECURITY INFORMATION: IFU UPDATE

Concerned Product	Designation : **Palutop +4 Optima** Legal manufacturer : Biosynex Reference : **5499**

Dear customer

This safety note is intended for users of the Biosynex Palutop +4 Optima test and is intended to inform you of a modification of the product's instructions for use.

Safety Problem description	PALUTOP®+4 OPTIMA is a simple and rapid test designed for the detection of the 4 Plasmodium (Plasmodium falciparum (Pf), Plasmodium vivax (Pv), Plasmodium. malariae (Pm), Plasmodium ovale (Po)) in whole blood and venous blood. This test detects the 4 Plasmodium species, differentiates the P. falciparum and the P. vivax malaria and helps monitoring successful anti-malaria! therapy. A laboratory obtained false positive results in Plasmodium vivax (C, PAN, Pf and Pv positive bands). The smear was positive for Plasmodium falciparum (controlled at CNR). As a precautionary measure, the instruction for use has been updated by mentioning that a false positive band in P. vivax due toa cross-reaction may appear in case of infection by another species of Plasmodium, especially if the antigenemia in panLDH is high.
Result	The possible consequence could be a false positive results that can lead to inadequate treatment.
Immediate Corrective action	For the next new batches distributed, the enclosed instructions for use will be modified and specify that: "A false positive band in P. vivax due toa cross-reaction may appear in case of infection by another Plasmodium species, especially if antigenemia in pan LDH is high. "described in the bibliography of van Dijk et al, 2009, Evaluation of the Palutop + 4 malaria rapid diagnostic test in a non-endemie setti ng. Malaria Journal 2009, 8: 293.

Biosynex SA - 22 Boulevard Sébastien Brant 67400 lllkirch Graffenstaden
Tel : 33(0)3 88 78 78 87- fax : 33 (0)3 88 78 76 78
SA au capital de 913 544,80 € - RCS: 481075 703 -APE: 2120Z- lieu de juridiction : Strasbourg

Recommended action to users	Users are asked to take this precaution into account immediately when interpreting the results. The updated notice (ref IFU_5499_EN_V04201903R01) is attached to this letter and includes this change in chapter *12. Limit and 14. Associated literature.*

The French Autority has been informed of this safety note.

We thank you for making sure that all your customers have read this safety notice and recommended actions.

Contact If you have any questions regarding this safety notice, do not hesitate to contact the technica! hotline service via customer@biosynex.com or 03 88 77 5752.

Attachments :
Palutop+4 Optima IFU and answer form on the last page of this letter.

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Acknowledgment FORM

FSCA Reference FSN20190221

Distributor : .....
Representant : .....
Adresse: .....
Order number : **N/** A.....

Product Designation	1	Reference number	Lot number
Palutop+4 Optima	1	5499	all

D We attest that we have read the Safety Notice and Corrective Action Recommendation for Palutop+4 Optima. This information has been sent to all relevant customers where the product concerned is used.

Signature **Date**

PLEASE SEND BV
FAX/ EMAIL/ POSTAL MAIL THIS AKNOWLEDGMENT FORM
at the following ELECTRONIC ADDRESS
TO ACCUSE RECEIPT OF THIS NOTICE

customer@biosynex .com **ou 33(0) 03 88 77 57 52.**

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