

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-malarial 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 to a 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 to a 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-endemic setting. Malaria Journal 2009, 8: 293.

**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 Authority 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 technical hotline service via customer@biosynex.com or 03 88 77 57 52 .

Attachments :

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

Best regards



Emmanuelle MARFING
Head of Quality and Regulatory department

Acknowledgment FORM

FSCA Reference FSN20190221

Distributor :

Representant :

Adresse:

Order number : N/A.....

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

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 BY
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.

