Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Address
City, Date

Reference: FSCA 4426

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VIKIA® Malaria Ag Pf/Pan ref 412499
lot 1006664060
Faint test line

Dear valued Customer,

You are a VIKIA® Malaria Ag Pf/Pan user and we thank you for your continued confidence. Our records indicate that your laboratory is using bioMerieux VIKIA Malaria Ag Pf/Pan (ref 412499) lot 1006664060, expiry date 30-JAN-2020.

This VIKIA® Malaria Ag Pf/Pan (ref 412499) is a rapid test for the qualitative detection of *Plasmodium sp* antigens in human blood specimens (venous blood or capillary blood).

This reagent is intended to be used as an aid in the diagnosis of malaria infections and the differential diagnosis of *Plasmodium falciparum* from other malarial infections.

This test is intended to be used by healthcare professionals in laboratories and for near-patient testing.
The VIKIA® Malaria Ag Pf/Pan rapid test is an immunochromatographic test in which monoclonal antibodies target:
- the HRP-II protein, antigen specific to *Plasmodium falciparum*.
- the Pan (Aldolase) antigen, common to all *Plasmodium* species.

Description of the issue:

Following Customers complaints, an investigation was initiated on false negative results or faint test line for *Plasmodium falciparum* obtained on patient's samples with lot 1006664060 VIKIA® Malaria Ag Pf/Pan (ref 412499).

The batch 1006664060 of VIKIA® Malaria Ag Pf/Pan (ref 412499), presents a lower intensity of the test line on internal samples compared to the other batches available.

As precautionary measure and to avoid any risk to the patients, we decided to ask you to no longer use the batch 1006664060 of VIKIA® Malaria Ag Pf/Pan (ref 412499).

The investigation and root cause analysis are still ongoing.

Impact to customer:

The associated risk is potential false negative results with *Plasmodium falciparum* on patient's samples.

Required actions:

We request you to take the following actions at this time:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Stop using the lot 1006664060 VIKIA® Malaria Ag Pf/Pan and destroy the remaining products.
- Discuss any concerns you may have regarding previously reported patient results obtained with your Laboratory Medical Director to determine the appropriate course of action. Results should be reviewed and interpreted in the context of the overall clinical picture.
- Contact your local customer service if you have observed the issue and if you have a doubt regarding your results.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible.
We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours faithfully,
Customer Service

Attachment A: Acknowledgement Form.

FIELD SAFETY NOTICE
VIKIA® Malaria Ag Pf/Pan (ref 412499) lot 1006664060

TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : +385 1 2396899
Email: igor.franic@aandb.hr

Name of the laboratory:

City:

❑ I acknowledge receipt of the bioMérieux letter regarding the "V**IKIA® Malaria Ag Pf/Pan (ref 412499) lot 1006664060"**

❑ I will implement the required actions as indicated in the Urgent Product Safety Correction Notice.

REF #	Product Name	Lot #	Quantity received	Quantity discarded
412499	V**IKIA® Malaria Ag Pf/Pan**	**1006664060**		

DATE ..... **SIGNATURE :** .....