Please distribute the attached customer letter

To the Laboratory Manager

To the attention of the Healthcare center Chairman

To the attention of the Reactovigilance correspondent

Address
City, Date

Our reference: FSCA 3860

IMPORTANT:

Urgent Field Safety notice

VIKIA® Malaria Ag Pf/Pan (Ref. 412499)

Dear valued bioMérieux Customer,

This letter is intended for all customers using VIKIA® Malaria Ag Pf/Pan (Ref. 412499) lot 1006150480. Our records indicate that your laboratory has received this concerned product.

Description of the issue

A raw material supplier informed bioMérieux that one lot of Anti-HRP-II PTL-3 used for the VIKIA® Malaria Ag Pf/Pan Test line has a quality issue due to the IgM content.

This raw material is expected to have an IgM level exceeding 90%. Our supplier informed us that the incorrect lot of Anti-HRP-II PTL-3 contains predominantly IgGs and only a small proportion of IgMs.

Anti-HRP-II antibody is used to detect HRPII antigen, specific from *Plasmodium falciparum*. Consequently, and according to the product design, the detection of other species (*Plasmodium vivax*, *Plasmodium ovale*, *Plasmodium malariae* and *Plasmodium knowlesi*) is not impacted.

The principle of the test is the following:

- VIKIA® Malaria Ag Pf/Pan rapid test is an immunochromatographic test in which monoclonal antibodies target HRP-II protein, an antigen specific from *P. falciparum* (*P.f.*) and Pan (Aldolase) antigen, common to all *Plasmodium* species.
- The blood specimen is dispensed in the specimen well, followed by the addition of the lysis and migration buffer in the buffer well, which releases the antigens. Then, the migration occurs on the membrane by capillary flow. If the sample contains *Plasmodium sp.* antigens, they will form Ag/Ab complexes with specific antibodies coupled to gold particles. These complexes will migrate along the membrane up to the *Pf* and/or Pan regions where they will be captured by antibodies immobilized on the membrane, resulting in the formation of one or two red test lines.

The current impacted lot predominantly contains IgGs which are expected to capture less target antigens than IgMs. According to design specifications, the anomaly may lead to a sensitive risk because a predominant IgG antibody level in Anti-HRP-II PTL-3 antibodies is not validated by the product design.

As a consequence, specific Anti HRP-II antibodies, expected to form complexes with *P.f* antigens may not capture these target antigens as expected, and the antigen/conjugate complex may not be fixed by the specific antibody. As a consequence, the immunochromatographic reaction may not occur properly, which could lead to false negative results, especially on borderline samples.

A precise and quantitative assumption of the impact of the anomaly on the sensitivity is not yet available. Investigation is ongoing to determine the impact of the anomaly on VIKIA® Malaria Ag Pf/Pan (Ref. 412499) lot 1006150480 sensitivity.

Impact to patient/customer:

As *P.f* test line may be affected. The anomaly is not detectable with the control line.
The potential hazard is to obtain false negative results.

Required actions:

We request that you take the following actions immediately:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy for your files, and forward this information to all parties that may use this product, including others to whom you may have transferred this product.
- Destroy the impacted lot: VIKIA® Malaria Ag Pf/Pan (Ref. 412499) lot 1006150480.
- Complete the attached Acknowledgement Form in Attachment A and return it to your local bioMérieux representative.
- If you wish to be supplied with a replacement Malaria rapid test, please call your bioMérieux local representative that will give your laboratory the appropriate support.

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.

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc. /SA

[Enter Local Contact]

Attachment A: Acknowledgement Form.

FIELD SAFETY NOTIFICATION NOTICE

FSCA 3860 – VIKIA® Malaria Ag Pf/Pan (Ref. 412499) – False negative results

TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE AT THE FOLLOWING

FAX NUMBER : XXXXXXXX
Name of the laboratory:

City:

Customer number:

❑ I acknowledge receipt of this bioMérieux Urgent Field Safety Notice regarding **VIKIA® Malaria Ag Pf/Pan (Ref. 412499) lot 1006150480** product issue.

Product : VIKIA® Malaria Ag Pf/Pan (Ref. 412499) lot 1006150480	
Number of kits received	
Number of kits destroyed	

❑ I have followed the instructions and implemented the actions as indicated in the Urgent Field Safety Notice.

Have you received reports of illness or injury related to the identified issue?
❑ Yes or ❑ No

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