

To the attention of Distributor

Neuville-sur-Oise, on September 17th, 2019

Internal ref: FSCA#18

FIELD SAFETY NOTICE

BIOPHEN[™] Normal Control Plasma - Ref 223201 - Lot F1801488

Fibrinogen Ag: Erroneous values on acceptance range printed on the flyer

Dear Customer,

Our traceability indicates that you have received the device listed below:

Product Name	Reference	Lot number
BIOPHEN [™] Normal Control Plasma	223201	F1801488

We inform you that an error has been identified on the acceptance range for the antigen fibrinogen measurement printed on the flyer.

<u>Erroneous</u> acceptance range for fibrinogen antigen	<u>Correct</u> acceptance range for fibrinogen antigen
2.26 g/L [1.81-2.71] g/L	2.83 g/L [2.26-3.40] g/L

▪ **Impact analysis**

There is an overlap between the erroneous acceptance range and the correct acceptance range : [2.26-2.71] g/L. Therefore, only values between [1.81-2.25] g/L (included in the erroneous acceptance range) are subject to impact analysis.

Underestimated results of maximum 20% can potentially be released during antigen fibrinogen measurement in the [1.81-2.25] g/L range.

The recommendations are to measure the BIOPHEN[™] Abnormal Control Plasma 223301 to validate the results obtained in the low part of the calibration curve.

A result obtained in the [1.5-2] g/L range is not considered as significantly low.

Consequently, this potential underestimation of the results is without incidence in terms of medical decision for the patient.

▪ **Corrective actions**

1. By the distributor

- Notify the Field Safety Notice to the end users with the corrected flyer dated 2019 September 9th (enclosed)
- Distribute the reagents in your stock with the corrected flyer
- Complete and return the Awareness Acknowledgment Form (AAF) to HYPHEN BioMed

2. By the end user

- Use the corrected flyer

All actions have been implemented in our Quality System to avoid any recurrence.

Our French competent authority, ANSM, has been informed about this communication.

We would like to apologize for any inconvenience this may cause and remain at your disposal.

For any question or information regarding this notification, please contact our Technical Support, by email at techsupport@hyphen-biomed.com

Sincerely yours,

Florence JOLY
Regulatory and Quality Assurance Director

Enclosure: corrected flyer dated September 9,2019

BIOPHEN™ Normal Control Plasma - Ref 223201 - Lot F1801488