To the attention of Distributor

Neuville-sur-Oise, December 9th, 2021

Internal reference: FSCA#23

URGENT FIELD SAFETY NOTICE

Product Recall

Dear Customer,

Our traceability indicates that you have received the device listed:

Product Name	Reference	Lot
HEMOCLOT™ Quanti. V-L	**CK065K**	**FA091617**

➢ Problem description

Following a customer complaint on tests performed on CS-5100 analyzer, overestimated concentration of Factor V Leiden has been observed for some patient samples expected as normal (from 10% to 20% FV-L instead of a specification < 10% FV-L).

Internal investigation has confirmed that this issue is related to lot FA091617 for assays on CS series analyzers.

Therefore, HYPHEN BioMed proceeds to a recall of lot FA091617 HEMOCLOT™ Quanti. V-L ref CK065K.

➢ Risk analysis and Impact

For normal samples, overestimated results from 10% to 20% FV-L are considered in “grey zone”.
This remains lower than usual expected value in true FV-L plasma, as:

- A heterozygous profile is usually not suspected below 25% FV-L
- The expected value in a plasma with R506Q mutation (FV-L) is usually around 50% FV-L

The risk identified for such “grey zone” results is to perform complementary investigation considering the clinical context and anamnesis of the patient.

Previously released patients’ results are expected to be managed as needed according to IFU recommendations (such as confirmation testing by means of FV clotting activity comparison, or molecular biology), and with regards to the clinical context and anamnesis.

TÜVRheinland CERTIFIED Management System ISO 13485:2016 www.tuv.com ID 0000043449

Adresse : 155 rue d’Eragny – 95000 Neuville-sur-Oise - France
Tél. : 01.34.40.65.10 ◆ **Fax :** 01.34.48.72.36 / 01.34.48.71.84 ◆ **Site Web** : http://www.hyphen-biomed.com
HYPHEN BioMed, SAS au Capital de 1 427 820 Euros
RCS Pontoise : B 421 645 979 - N° SIRET : 421 645 979 00038 - APE : 2120Z – TVA : FR 40 421 645 979

➢ **Actions to be implemented**

- Destroy the affected products in your stock.
- Notify the end users with the Field Safety Notice (FSN) and the Awareness Acknowledgment Form (AAF).
- Complete and return the AAF to HYPHEN BioMed.

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

➢ **Contact information:** VigilanceHBM@hyphen-biomed.com

- For replacement of destroyed products.
- For return of Awareness Acknowledgment Form (AAF).

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

Sincerely yours,

Florence JOLY
Regulatory Affairs and Quality Assurance Director

Management System ISO 13485:2016
TÜVRheinland CERTIFIED
www.tuv.com ID 0000043449

Adresse : 155 rue d'Eragny – 95000 Neuville-sur-Oise - France
Tél. : 01.34.40.65.10 ◆ **Fax :** 01.34.48.72.36 / 01.34.48.71.84 ◆ **Site Web** : http://www.hyphen-biomed.com
HYPHEN BioMed, SAS au Capital de 1 427 820 Euros
RCS Pontoise : B 421 645 979 - N° SIRET : 421 645 979 00038 - APE : 2120Z – TVA : FR 40 421 645 979

Internal reference: FSCA#23

URGENT FIELD SAFETY NOTICE

Product Recall

Product Name	Reference	Lot
HEMOCLOT™ Quanti. V-L	**CK065K**	**FA091617**

Awareness Acknowledgment Form for distributor

Please return completed and signed Form to HYPHEN BioMed:

VigilanceHBM@hyphen-biomed.com

Reference	Product name	Lot number	Number of kits in stock	Number of kits sold
CK065K	**HEMOCLOT™ Quanti VL**	**FA091617**		

☐ **I confirm implementation of actions listed.**

☐ **I confirm destruction of remaining kits in stock.**

Distributor	Name	Position	Signature	Date

Management System ISO 13485:2016 TÜVRheinland CERTIFIED www.tuv.com ID 0000043449

Adresse : 155 rue d'Eragny – 95000 Neuville-sur-Oise - France
Tél. : 01.34.40.65.10 ◆ **Fax :** 01.34.48.72.36 / 01.34.48.71.84 ◆ **Site Web** : http://www.hyphen-biomed.com
HYPHEN BioMed, SAS au Capital de 1 427 820 Euros
RCS Pontoise : B 421 645 979 - N° SIRET : 421 645 979 00038 - APE : 2120Z – TVA : FR 40 421 645 979