To the attention of Laboratory Manager,
and Vigilance Manager
For sharing to concerned departments

Neuville-sur-Oise, on xxxx, 2019

RECALL - FIELD SAFETY NOTICE

Product Identification

- ZYMUTEST™ Anti-VIII MonoStrip IgG ref # RK039A Lots F1800913 – F1701261
- ZYMUTEST™ HIA MonoStrip IGG ref # RK041A Lots F17010884 - F1900611
- ZYMUTEST™ HIA MonoStrip IGGAM ref # RK041D Lot F1701571

Internal reference: FSCA#17

Dear Customer

We inform you that HYPHEN BioMed proceed to a voluntary recall of several lots of ZYMUTEST MonoStrip products:

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

Reference	Product name	Lot number
RK039A	**ZYMUTEST™ Anti-VIII MonoStrip IgG**	
RK041A	**ZYMUTEST™ HIA MonoStrip IgG**	
RK041D	**ZYMUTEST™ HIA MonoStrip IGGAM**	

- **Problem Description**

Following customers complaints related to unusual aspect of the microplate (residual crystallization which could appear progressively in the time) and/or recurrent negative controls found out of range, internal investigations have confirmed that this issue impacts all ZYMUTEST MonoStrip products.

Investigations and root cause analysis are still on going.

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, SASU 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

- **Impact and risk evaluation**

  For kits **ZYMUTEST™ Anti-VIII MonoStrip IgG ref # RK039A**

  ZYMUTEST™ HIA MonoStrip IGGAM - ref # RK041D

  Due to residual crystallization, a nonspecific response could be obtained having as consequence two possibilities:

  - Negative control obtained out of validated range in terms of reactivity.
    The assay is not validated so no patient results could be released.
  - Negative control obtained is within the acceptance range in term of reactivity.
    The assay is validated but some negative patient samples could be obtained in the doubtful or positive zone. in this case additional testing is required, as stated in the IFUs.

  → No patient risk identified when respective IFU recommendations are followed.

  For kits **ZYMUTEST™ HIA MonoStrip IGG - ref # RK041A**,

  The residual crystallization has no impact on product performance.

- **Actions**

  - Destroy the affected kits lot in your stock and indicate the quantity in the Awareness Acknowledgment Form (AAF)
  - Complete, sign and return the AAF to your local distributor

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

- **Contact information**

  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 your local distributor:
  Email:
  Phone:

  Sincerely,

  Florence JOLY

  RA/QA Director

Internal reference: FSCA#17

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, SASU 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

RECALL - FIELD SAFETY NOTICE

AWARENESS ACKNOWLEDGMENT FORM FOR END-USER

Reference	Product name	Lot number	Number of kits destroyed
RK039A	ZYMUTEST™ Anti-VIII MonoStrip IgG		
RK041A	ZYMUTEST™ HIA MonoStrip IgG		
RK041D	ZYMUTEST™ HIA MonoStrip IGGAM		

☐ **I confirm the destruction of above listed devices**

End-User	Name	Position	Signature	Date

Please return completed and signed form to your local distributor:
By e-mail:

Company stamp:

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, SASU 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