



⚠ FIELD SAFETY NOTICE ⚠

Hyphen BioMed

BIOPHEN ARIXTRA[®] CONTROL PLASMA Ref 224001 – LOT #F1600528

Typographical error on the flyer:

Erroneous acceptance range for the C1 control

Dear customer,

Our traceability indicates that you have received this following product from Hyphen BioMed:

Product name	Product reference	Lot n°
BIOPHEN ARIXTRA [®] CONTROL PLASMA	224001	F1600528

We inform you that we have identified on the flyer, an error on the acceptance range of the C1 control:

Erroneous acceptance range of C1	<u>Correct</u> acceptance range of C1
0.3 – 0.56 µg/ml	<u>0.36</u> – 0.56 µg/ml

Potential consequence of the error

If the calibration curve is validated with a C1 control between 0.3 and 0.35 µg/ml, dosage values in the lower zone may be underestimated to 0.05 µg/ml.

Impact analysis

The maximum underestimation of 0.05µg/ml is not significant.

The potential risk does not affect the patient clinical setting.

Corrective actions

1. By the distributor (NODIA)

- Communicate the corrected flyer attached of 31.08.2017 to end users.
- Distribute the kits in stock with the new corrected flyer

2. By the end user

- Use the corrected flyer here enclosed

Cause and actions implemented

The internal investigation has identified a typographical error.

All measures are taken in Hyphen BioMed's Quality system to prevent any recurrence.

The French Competent Authority ANSM has been informed about this communication.

We would like to apologize for the inconvenience caused by this situation and remain at your disposal. For any question or information, do not hesitate to contact NODIA.

In order to meet regulatory requirements, can you please confirm receipt of this mail and provide

the enclosed corrected flyer to all concerned people in your laboratory?

Many thanks on beforehand.

Kind Regards,

6JG 01&+# - 6GCO

NODIA

Belgium/Luxembourg:

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B-2850 Boom
Belgium
Phone: +32 3 830 4644

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ENGLISH / FRANÇAIS



BIOPHEN® ARIXTRA® CONTROL

Control plasmas for the quality control of Arixtra® measurements with anti-Xa method /

Plasmas de contrôle surchargés et titrés pour le contrôle de qualité des dosages de l'Arixtra® par méthode chromogénique anti-Xa

REF 224001

For in vitro diagnostic use only / Pour diagnostic in vitro exclusivement

LOT F1600528

2018-11-24

Arixtra® Concentration [C] in the controls /
Concentration [C] en Arixtra® dans les contrôles

Control / Contrôle C1	LOT: F161100528
Target value / Valeur cible :	0.46 µg/mL
Acceptance range / Intervalle d'acceptation :	[0.36 – 0.56] µg/mL

Control / Contrôle C2	LOT: F161100528
Target value / Valeur cible :	1.24 µg/mL

Acceptance range / Intervalle d'acceptation

[1.08 - 1.40] J19(ml)

Standardization / Standardisation : NA

Approved Date / Date d'Approbation : 2017-08-31

Quality Control / Responsable Contrôle Qualité

F820-09/BI/4001 V3