De: Arnaud Favre <afavre@amplitech.net>

Envoyé: jeudi 31 octobre 2024 10:34

À:XXXXXX

Cc: Qualite <qualite@amplitech.net>; Pauline Puren <ppuren@amplitech.net>; Amplitech -

AMP Orders (EBP) <amp.orders@amplitech.net>

Objet: Retrait de produit Chromosome Medium M 100ml

Bonjour monsieur xxx,

Euroclone nous a informé d'un souci sur plusieurs bouteilles de Chromosome Medium M (ref EKAMTB100M, **lot MB1002405**).

Ci joint la déclaration qualité.

Vous en avez reçu 10 bouteilles de ce lot.

Je vous invite à isoler ces bouteilles et ne pas les utiliser.

Ces bouteilles seront remplacées par autre lot (je viens de découvrir ce matin la situation donc logistique encore à définir).

Nous nous excusons sincèrement pour la gêne occasionnée et vous tiendrons au courant de la procédure de remplacement.

Cordialement,





Directeur Commercial Génétique

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Ref. RAQ075_10/2024

TO WHOM IT MAY CONCERN

Pero, 30/10/2024

SUBJECT: Precautionary Recall of In Vitro Diagnostic Product EKAMTB100M, batch MB1002405

Dear Customer,

We wish to inform you of a precautionary recall concerning our in vitro diagnostic product, **code EKAMTB100M**, **batch MB1002405**.

During a routine check, it was found that a limited number of bottles in our warehouse were noncompliant.

Therefore, as a precaution, we have decided to recall the product.

We kindly ask you to:

- Refrain from using the specified batch of the product.
- Inform us of the quantities currently in your possession by emailing to <u>tsa@euroclone.it</u>, referencing this communication.

The reported quantities will be promptly replaced at no additional cost.

For organizational convenience, we prefer that the product be disposed of rather than returned to Euroclone.

We wish to reassure you that if the product has already been used, no adverse effects are expected.

Investigations are currently underway to determine the cause of the issue identified.

This recall is being conducted to ensure the highest standards of quality and safety. We thank you for your understanding and cooperation.

For further information or assistance, please do not hesitate to contact us via email at quality@euroclone.it.

Sincerely,



Maurizio Bianchi QA/RA Manager

RAQ075-10-2024 Recall EKAMTB100M_ENG