BioGX
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QUALITY HOLD & ACTION NOTIFICATION

400-057-C-MAX Viral Meningitis (HSV-1, HSV-2, VZV)
(Kit containing PCR Reagent Lot 0047-23-057XA)

March 10, 2023

Dear Valued Distributor Partner,

This notification is to inform you of a quality hold and action involving **400-057-C-MAX Viral Meningitis (HSV-1, HSV-2, VZV) with PCR Reagent Lot: 0047-23-057XA and Rehydration Buffer Lot: 023-010-0009.**

Issue identified:

A component packaging error for the above referenced lot where the package contents do not match its labeling is suspected that may result in false negative reporting. Based on our investigation, this is an isolated incident affecting only kits associated with PCR reagent lot 0047-23-057XA. As an abundance of caution, we are notifying our distributors to be aware of a possible issue with kits associated with this lot that were shipped on 02 March 2023.

Action Required:

1) Immediately quarantine any kits remaining of 400-057-C-MAX Viral Meningitis (HSV-1, HSV-2, VZV) associated with PCR reagent lot 0047-23-057XA. BioGX will provide a return shipping label to have quarantined kits returned to BioGX BV.
2) Replacement kits are now being processed for expedited shipment to replace the quantities shipped on 02 March 2023 within a week of this notification.
3) Immediately notify your Customers who may have received kits associated with lot 0047-23-057XA to quarantine their inventory and instruct them to preclude kits impacted from their original intended use.

BioGX is committed to providing the highest quality products. We have ensured that modes of controls are in place to mitigate and avoid any future occurrence of the rare packaging error. We sincerely apologize for any inconvenience this matter may have caused and thank you in advance for your cooperation. Please direct specific questions to BioGX BV's QRA Representative by email at **christopher.hughes@biogx.com**.

Chris Hughes, BioGX B.V. QRA Representative
Ref # 0308023-02

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05 May 2023

PEI Case Number: PEI0063/23
BioGX Reference Number: EU-031023-2

To Whom It May Concern:

Below is the information you requested regarding PEI Case Number: PEI0063/23.

(1) *Customers/distributors in Germany*

Axon Lab AG • axonlab.com
Täfernstrasse 15 • CH-5405 Baden-Dättwil
P +41 56 484 80 80 • F +41 56 484 80 99
info@axonlab.ch

(2) *Field Safety Notice in German and English* - Field Safety Notices in both English and German are attached in the email response provided.

(3) *A copy of the relevant risk analysis* - The updated Risk Analysis is attached in the email response provided.

(4) *A statement as to the planned corrective actions including a time schedule thereof* - The planned corrective action is stated below:

> A FSCA was submitted to each Distributor requiring the immediate quarantine of all kits having the lot number impacted as well as provided instructions for return & replacement. Inventory of kits on-hand associated with the lot impacted were immediately quarantined to preclude from their original intended use.

(5) *Information on the technical corrective measures taken to prevent recurrence of this product failure in the future* - The Reagent Pouching Document, MOP-008.20.F04 (r06), has been revised to include detailed pouching specifications and to require an independent review prior to release for distribution..

(6) *The current instructions for use and brochures on the product, including updates* - The current Instructions For Use (IFU) are attached in the email response provided.

(7) *If only certain lots are concerned, please explain for which reason you can restrict the corrective measures to these lot numbers* - As a result of our root cause analysis, it has been confirmed that only a single lot of 400-057-C-MAX was impacted. The single lot impacted is isolated to a single packaging event.

(8) *Please name the Authorised Representative in Europe, and the Notified Body responsible for the certifications which cleared the way for the CE marking*.

- EU Authorised Representative - BioGX B.V., Science Park 408, 1098 XH Amsterdam, Netherlands
- The risk class for this product is “IVD General” as defined under the IVDD and does not require Notified Body clearance.