



Unit 14 Carrowreagh Business Park
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E: info@biopanda.co.uk
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PRODUCT RECALL NOTICE

Product Name: Dengue Combo Rapid Test Cassette

Lot Numbers: DEC24110022 & DEC25030022

Recall Classification: Voluntary / Precautionary

Date of Recall Initiation: 21/11/2025

Dear Valued Customer,

We are writing to inform you of an important issue regarding one of our diagnostic products and to initiate an immediate product recall.

Product Affected:

- **Product Name:** Dengue Combo Rapid Test Cassette
- **Lot Numbers:** DEC24110022 & DEC25030022

Reason for Recall:

Although this lot passed our internal quality control procedures using validated positive and negative controls, we have been notified of instances where the product has produced **false negative results** when tested with **whole blood samples** by a customer.

At present, the root cause of the issue is not fully understood. However, our preliminary assessment suggests the possibility that **the affinity of the antibody used in the test may have changed between production batches**. This potential change was not detected by our routine QC of raw materials. We are actively investigating this with our antibody supplier to determine the exact cause and implement necessary corrective actions.

Potential Risk:

A false negative result may lead to missed or delayed diagnosis of dengue infection, which could have significant clinical consequences. Therefore, we are initiating this recall as a precautionary measure to ensure patient safety and diagnostic accuracy.

Immediate Actions Required by You:

1. **Stop Use Immediately:**
Please discontinue the use of any remaining inventory of **Lot DEC24110022 & DEC25030022** immediately.
2. **Product Quarantine:**
Isolate and clearly mark the affected inventory to prevent further use.



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3. Arrange Return:

Please arrange for the return of any remaining product from this lot to the following address and provide your Biopanda Sales Contact with the weights and dimensions of all packages to be returned. Shipping labels and documentation will be provided to enable to return of items:

Biopanda Reagents Ltd. Unit 14, Carrowreagh Business Park, Carrowreagh Road, Dundonald, Belfast, BT16 1QQ, Northern Ireland, United Kingdom

4. Confirmation Acknowledgement:

Complete and return the below **Recall Acknowledgment** to confirm receipt of this notice and the quantity of product to be returned.

We deeply regret any inconvenience this may cause and appreciate your cooperation and continued trust in our products. We are committed to resolving this matter quickly and transparently and will keep you updated on our investigation and findings.

Should you have any questions or require assistance, please do not hesitate to contact us directly at +44 (0)28 95438774 or info@biopanda.co.uk.

Sincerely,
Philip McKee
Sales Manager
Biopanda Reagents Ltd.

Recall Acknowledgment:

Details of Products to be returned:

- **Product Name:** Dengue Combo Rapid Test Cassette
- **Lot Numbers:** DEC24110022 & DEC25030022
- **Quantity:** _____

[Customer Name]
[Customer Position]
[Company Name]