



Abbott Diagnostic Health Sdn Bhd
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Product Recall Letter: BinaxNOW Nasopharyngeal Swab Pack

Date: 13 Jul 2022

Reference: QI-00056342

Details of the affected device:

- Product name: BinaxNOW Nasopharyngeal Swab Pack
- Product code: 400-065
- Lot No. 147380

Dear valued customer,

We, Abbott Diagnostic Health Sdn Bhd., would like to inform you that the aforementioned product lot supplied to you was missing the supplementary local label that Medical Device Authority(MDA) requires. The subject label contains the Name, Address, and the contact number of the Authorized Representative, and the MDA Registration Number.

There is no product quality , safety, or performance risk involved in using the product. However, as the product does not meet the Malaysian MDA supplementary labelling requirements, we would like to recall the subject affected lot.

Actions to be taken by the customers/users:

- A. Return the affected lot in full to your product distributor.
- B. Complete the reconciliation table below.

Reconciliation

- Product name: BinaxNOW Nasopharyngeal Swab Pack
- Product code: 400-065
- Lot No. 147380

User/Customer information	
Company name	
Name	
Address	
Telephone/Email	

Reconciliation status

Total quantity received	Quantity consumed	Quantity in stock
Kits	Kits	Kits

Confirmed by
(Name, Signature and Date)

For any further queries, please contact your product distributor.

Sincerely

Jayaprakash Jayachandran
Sr Manager Commercial Quality & Compliance, SEA
For Abbott Diagnostic Health Sdn Bhd