

## Field Safety Notice

Date: 24/05/2016

Dear Customers

Nipro Asia Pte Ltd, is initiating a voluntary Recall of a limited number of TRUEresult (GDH-FAD) Blood Glucose **Test Strip** lots including TRUEresult (GDH-FAD) Blood Glucose Test Kits.

**Remark:** TRUEresult (GDH-FAD) Blood Glucose Meter is NOT AFFECTED by this recall (only TRUEresult (GDH-FAD) Blood Glucose Test Strip is affected).

**Affected product:**

<u>Product Name</u>	<u>Item Code</u>	<u>Strip Lot Number (Affected)</u>	<u>Kit Lot Number (Meter included is not affected)</u>	<u>Imported Quantity</u>
TRUEresult Blood Glucose Test Strips (25ct)	K-E3I01-25FD	FR1286INT	---	2,160
TRUEresult Blood Glucose Test Strips (25ct)	K-E3I01-25FD	HS1019INT	---	8,640
TRUEresult Blood Glucose Test Strips (50ct)	K-E3I01-81FD	HS1014INT	---	2,880
TRUEresult Blood Glucose Test Strips (50ct)	K-E3I01-81FD	HS1015INT	---	2,880
			<b>TOTAL Vials:</b>	<b>16,560</b>

<u>Product Name</u>	<u>Item Code</u>	<u>Strip Lot Number (Affected)</u>	<u>Kit Lot Number (Meter included is not affected)</u>	<u>Imported Quantity</u>
TRUEresult Blood Glucose Monitoring System	K-E4I53-91FD	HS1020INT	KS1552	2,448
TRUEresult Blood Glucose Monitoring System	K-E4I53-91FD	HS1040INT	KS1939	948
			<b>TOTAL Kits:</b>	<b>3,396</b>

**Remark:** There may be other Lot Number that are affected globally.  
 User should contact Nipro Asia (Tel: +65-6836-0661 or +65-6836-2542,  
 Mon – Fri, 9am – 6pm) in the event TRUEresult Blood Glucose Monitoring  
 System / Test Strips is obtained from overseas.



**Advise on action to be taken by the user**

- (1) Check the Lot Number printed on the side of the test strip box and/ or on the test strip vial label.
- (2) Discontinue use of any blood glucose test strips with affected Lot Numbers.
- (3) Contact **Nipro Asia (Tel: +65-6836-0661 or +65-6836-2542, Mon – Fri, 9am – 6pm)** as soon as possible for return and replacement at no charge from the date of publication of this notice.

**Note: You may continue to test blood glucose using any other TRUEresult (GDH-FAD) blood glucose test strip lot that is not included in this voluntary Recall.**

**Problem description and potential risk:**

The Company has determined that during a packaging process that occurred at the Manufacturer's location during a specific period of time, a limited number of sealed test strip vial boxes from certain TRUEresult (GDH-FAD) blood glucose test strip lots may include an open test strip vial. Test strips contained within open vials are exposed to the outside environment, which can affect strip performance. In particular, test strips exposed to the environment may provide incorrect low blood glucose results.

Inaccurate low blood glucose results may lead to undetected hyperglycemia (high blood glucose) and result in improper treatment; action based on inaccurate low results may raise blood glucose levels further, resulting in hyperglycemia that may require medical intervention.

We apologize for any inconvenience that this Recall may create and appreciate your cooperation with our request.

Should you have any inquiries please do not hesitate to contact us.

Thank you for your attention and cooperation.

Sincerely,

**Nipro Asia Pte Ltd, QA/RA section**

**Email: [niproasia@nipro.com.sg](mailto:niproasia@nipro.com.sg)**

**Tel: +65-6836-0661 or +65-6836-2542**

**Mon – Fri, 9am – 6pm**