URGENT
MEDICAL DEVICE VOLUNTARY FIELD SAFETY CORRECTIVE ACTION / RECALL
TRUEresult (GDH-PQQ) BLOOD GLUCOSE TEST STRIP
LOT NUMBER PS2407IGB

18th July, 2016

Dear Pharmacist,

The purpose of this letter is to inform you that Nipro Diagnostics are announcing a voluntary product Field Safety Corrective Action/Recall of an individual **TRUE**result (GDH-PQQ) Blood Glucose Test Strip LOT PS2407IGB. This recall is going to patient level. The affected lot was distributed since 23rd November 2015.

Please note, there are no incident reports to date.

Nipro Diagnostics 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 **TRUE**result (GDH-PQQ) blood glucose test strip LOT numbers may include an open test strip vial. Test strips contained within strip vials that remain open for long periods are exposed to the outside environment, which can affect strip performance. If a user does not notice an open test strip vial upon opening the sealed test strip vial box, and then uses the test strips to measure blood glucose, the meter 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.

Note, you may continue to test blood glucose using any other **TRUE**result (GDH-PQQ) blood glucose test strip LOT number that is not included in this voluntary Recall. Please read all product packaging and inserts carefully to ensure you are using a blood glucose meter intended for use with the **TRUE**result (GDH-PQQ) blood glucose test strips.

Replacement **TRUE**result (GDH-PQQ) blood glucose test strips are available at no charge by following the instructions provided.

Actions for Pharmacists:

1. Determine whether you have any affected T**RUE**result (GDH-PQQ), blood glucose test strips by examining the LOT number printed on the side of test strip box and/ or on the

test strip vial label. Please quarantine this stock for return to Clonmel Healthcare (**Distributor**) as below.

2. Patients who were dispensed **TRUE**result (GDH-PQQ), blood glucose test strips during this time period should be contacted and requested to determine if they have any of the affected LOT number.
3. Should a patient be in possession of the affected lot number they should be advised to discontinue use of any blood glucose test strips with the affected LOT number. They should be requested to return them to the pharmacy for replacement with an unaffected LOT.
4. Please collect all the affected LOTs and complete the return form detailed below. Return all affected LOTs with the completed form to Clonmel Healthcare using the enclosed freepost label prior to 8th August 2016.

Patient safety is our top priority, and we apologise for any inconvenience this recall may cause you.

Yours sincerely
NIPRO Diagnostics

MEDICAL DEVICE VOLUNTARY RECALL RETURN RESPONSE
TRUEresult (GDH-PQQ) BLOOD GLUCOSE TEST STRIP
LOT PS2407IGB

I have read and understand the recall instructions provided in the letter. Yes ___ No___

☐ I have identified and notified my customers

Any adverse events associated with recalled product? Yes ___ No___
If yes, please explain:

Quantity of Lot PS2407IGB: _____
Signature of Receipt _____

Name/Title	
Company	
Telephone	
Email address	
Address	

If you have any queries please contact Clonmel Healthcare at 052 6177714.