HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

TRUEresult Blood Glucose Test Strips (GDH-PQQ)

Priority 2 – Warning

HPRA Safety Notice: SN2016(21) **Issue Date: 21 July 2016**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Nipro Diagnostics	V27790

ISSUE
Nipro Diagnostics issued a Field Safety Notice (FSN) in July 2016, advising of an issue, whereby some strip vials within certain lots of TRUEresult blood glucose test strips (GDH-PQQ) may not be sealed correctly, which can affect strip performance. The manufacturer has informed the HPRA that TRUEresult blood glucose test strips (GDH-PQQ), item number E3124-81, lot number PS2407IGB has been placed on the Irish market. The affected test strips were distributed from the 23rd of November 2015. The HPRA is concerned that all users of these devices may not be aware of the FSN and is issuing this safety notice to raise awareness of the issue.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Refer to the accompanying FSN and follow the instructions provided.
2 Discontinue use of the affected lot of blood glucose test strips.
3 Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

The HPRA advises that healthcare professionals;

4 Please withdraw from use all affected product identified at your facility as soon as possible.
5 Identify patients who use TRUEresult and TRUEresult Twist blood glucose meters.
6 Inform all patients of the issue outlined in the accompanying FSN and to discontinue use of the affected lot.
7 Forward a copy of this Safety Notice and the FSN to all relevant personnel.
8 Forward a copy of this Safety Notice and the FSN to any other persons/organisations where these devices have been transferred.
9 Report any adverse events / incidents associated with this device to the manufacturer and the HPRA.

TARGET GROUPS

Accident & Emergency Departments
All Nursing Home staff
Carers
Clinical Nurse Managers
Community Nurses
Diabetes clinics / outpatients
Diabetic Nurse Specialists
Endocrinology Units
Endocrinology Consultants
General Practitioners
Laboratory Managers
Paediatric wards
Paramedics
Hospital Pharmacists
Community Pharmacists
Paramedics
Purchasing / Procurement / Material Managers
Risk Managers
General Public

BACKGROUND

TRUEresult blood glucose test strips (GDH-PQQ) are for use with the TRUEresult and TRUEresult Twist blood glucose meters.

Nipro Diagnostics has determined that during a packaging process that occurred at the manufacturer's location during a specified period of time, a limited number of sealed test strip vial boxes from certain blood glucose test strip lots may include an open test strip vial.

The manufacturer has advised that test strips contained within strip vials that remain open for long periods are exposed to the outside environment, which can affect strip performance.

Nipro Diagnostics has advised the HPRA that 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: Recipients of this safety notice are advised to note that test strips distributed by Clonmel Healthcare may also have been supplied to end customers by other wholesalers.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **authorised representative** should be addressed to:

Nipro Europe NV,
Weihoek 3H,
1930 Zaventem,
Belgium.

Telephone: +32-2-714 89 37
Fax:
E-mail: Vanessa.Windscheid@nipro-europe.com
Website: www.nipro-europe.com

Enquiries to the **distributor** should be addressed to:

Clonmel Healthcare Ltd.,
Customer Service Department,
Waterford Road,
Clonmel,
Co. Tipperary.

Telephone: +353-52-6177714
Fax: +353-52-6177700
E-mail: homemarketorders@clonmel-health.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie