

Press release

Medical devices regulator issues alert on faulty glucose test strips

From: [Medicines and Healthcare products Regulatory Agency](#)
First published: 10 August 2016

People with diabetes who use particular blood glucose test strips should stop using them and seek an alternative as soon as possible says the Medicines and Healthcare products Regulatory Agency (MHRA). This follows a manufacturing fault which could lead to a risk of them giving false low blood glucose results.



The manufacturer, Nipro Diagnostics, found an issue with the packaging meaning that test strips in specific lots are not sealed properly. This can affect how the strips measure blood glucose levels and could lead to undetected high blood glucose (hyperglycaemia) which can have serious health implications.

People using these test strips, which are used in TRUEresult, TRUEresult twist, and TRUEtrack blood glucose meters, are asked to check if they use affected blood glucose test strips with the lot numbers below.

Product name	Item number	Lot number	Exp. Date
TRUEresult PQQ	E3I24 81 OTC	PS2190IGB	31 Dec 17
TRUEresult PQQ	E3I24 81 OTC	PS2319IGB	18 May 18
TRUEresult PQQ	E3I24 81 OTC	PS2322IGB	19 May 18
TRUEresult PQQ	E3I24 81	PS2190IGB	31 Dec 17
TRUEresult PQQ	E3I24 81	PS2319IGB	18 May 18
TRUEresult PQQ	E3I24 81	PS2322IGB	19 May 18
TRUEresult PQQ	E3I24 81	PS2407IGB	16 Jul 18
TRUEtrack	A3I24 81	RS4645IGB	30 Sep 17

Product name	Item number	Kit lot number	Exp. Date
TRUEresult PQQ	E4I24 81	KS1228	31 Mar 18
TRUEresult PQQ	E4I24 81	KS1229	31 Mar 18
TRUEresult PQQ	E4I24 81	KS1230	31 Mar 18

TRUEresult PQQ	E4I24 81	KS1241	31 Mar 18
-------------------	----------	--------	-----------

MHRA has issued a Medical Device Alert (MDA) to healthcare professionals.

John Wilkinson, MHRA's Director of Medical Devices said

“ It's important that you check your test strips. Stop using them if they are in the affected lots and, if necessary, seek alternatives as soon as possible. You can contact the manufacturer on 0800 08 588 08 to return affected strips.

“ If you have any questions about your blood glucose readings you should speak with your diabetes care team.

“ We continue to encourage people to report any issues involving medical devices to MHRA via our Yellow Card Scheme.”

Simon O'Neill, Director of Health Intelligence at Diabetes UK said:

“ Ensuring the correct level of blood sugar is vitally important in the management of diabetes.

“ We welcome this action taken by MHRA to ensure people can be sure of correctly testing their blood glucose.

“ People using these test strips should return them to the manufacturer. If they have any concerns about their blood sugar levels they should talk to their diabetes care team.”

Background

1. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks. MHRA

is a centre of the Medicines and Healthcare products Regulatory Agency which also includes NIBSC and CPRD. The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health.

2. [Please see link to Yellow Card Scheme](#) 
3. [Please see link to Medical Device Alert](#)

Media enquiries

News centre
MHRA
151 Buckingham Palace Road
Victoria
London
SW1W 9SZ

Email

newscentre@mhra.gsi.gov.uk

During office hours:

020 3080 7651 (08:30 - 17:00)

Out of office hours:

07770 446 189 (17:00 - 08:30)

Office hours are Monday to Friday, 8:30am to 5pm. For real-time updates including the latest press releases and news statements, see our Twitter channel at <https://www.twitter.com/mhrapress>

Share this page



Facebook



Twitter

Published:

10 August 2016

From:

Medicines and Healthcare products Regulatory Agency

[Is there anything wrong with this page?](#)

Services and information

[Benefits](#)

[Births, deaths, marriages and care](#)

[Business and self-employed](#)

[Childcare and parenting](#)

[Citizenship and living in the UK](#)

[Crime, justice and the law](#)

[Disabled people](#)

[Driving and transport](#)

[Education and learning](#)

[Employing people](#)

[Environment and countryside](#)

[Housing and local services](#)

[Money and tax](#)

[Passports, travel and living abroad](#)

[Visas and immigration](#)

[Working, jobs and pensions](#)

Departments and policy

[How government works](#)

[Departments](#)

[Worldwide](#)

[Policies](#)

[Publications](#)

[Announcements](#)

[Help](#) [Cookies](#) [Contact](#) [Terms and conditions](#)

[Rhestr o Wasanaethau Cymraeg](#) Built by the [Government Digital Service](#)

OGI All content is available under the [Open Government Licence v3.0](#), except where otherwise stated



© Crown copyright