

SINGAPORE, 27 MAY 2016

HSA UPDATES

“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.

HSA UPDATES NO 2/2016

HSA ALERTS PUBLIC ON NIPRO DIAGNOSTICS’ VOLUNTARY RECALL OF TRUE RESULT BLOOD GLUCOSE TEST STRIPS DUE TO INCORRECT LOW GLUCOSE RESULTS

The Health Sciences Authority (HSA) is overseeing the voluntary market recall of TRUEresult Blood Glucose Test Strips by Nipro Asia Pte Ltd due to incorrect low glucose results provided by the test strips. Please refer to **Annex 1** for the list of affected item codes and lot numbers.

2 The affected TRUEresult Blood Glucose Test Strips may give inaccurate results to diabetic patients, showing readings that are lower than their actual blood sugar level. This could lead to patients failing to control and manage their actual blood glucose adequately due to the inaccurate reading.

3 The TRUEresult Blood Glucose Meter is not affected by this recall.

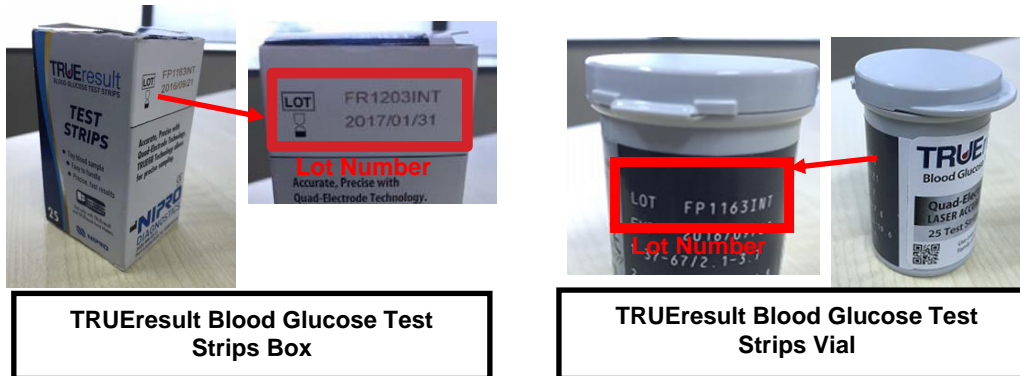
4 This global recall affects other lots of TRUEresult Blood Glucose Test Strips sold in other countries as well (refer to **Annex 2**). Affected lots that are being recalled overseas may be different from the ones recalled in Singapore. As such, patients should contact Nipro Asia (Tel: +65-6836-0661) if they had obtained their TRUEresult Blood Glucose Monitoring System / Test Strips from overseas. Only the lots listed in **Annex 1** have been imported and supplied in Singapore by Nipro Asia Pte Ltd and Aeras Medical Ptd Ltd.

5 Based on the investigations by Nipro Diagnostics Inc, the inaccurate readings were related to a packaging issue, whereby some of the test strip vials were not properly closed during packaging. The exposed test strips may potentially produce a blood glucose reading which is lower than the actual level.

6 In Singapore, Nipro Asia Pte Ltd will replace the affected test strips with new unaffected lots. The company has informed that replacement stock will be available from week of 30th May 2016 onwards.

HSA's Advisory to Consumers and Healthcare Professionals

7 For guidance on how to identify the affected lot number information on the device packaging, consumers and healthcare professionals may refer to the pictorial description provided below:



8 HSA advises that:

- i. Patients should stop using the affected TRUEresult Blood Glucose Test Strips. Patients should return the affected test strips to Nipro Asia Pte Ltd, who will provide replacement test strips.
- ii. Patients who have purchased their strips overseas, to check with Nipro Asia Pte Ltd if the test strips are affected.
- iii. Patients who have used the affected test strips should consult a doctor as soon as possible if they feel unwell or are experiencing symptoms of high or low blood sugar.
- iv. Patients should contact their healthcare provider to determine other testing options especially if they need to adjust their insulin therapy or oral diabetic medications.

9 For return of the affected test strips and other additional information, patients are advised to contact Nipro Asia Pte Ltd, at Tel: +65-6836-0661 or +65-6836-2542 (Mon – Fri, 9.00am – 6.00pm), or **email to niproasia@nipro.com.sg**

10 HSA will continue to monitor the situation closely and will take all appropriate actions to protect public health and safety.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
27 MAY 2016**

▪ About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety.

HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

▪ **About HSA Updates**

The “HSA Updates” seeks to provide current information, in a consistent and accurate manner, on topics of public interest. For all issues of HSA Updates, please visit www.hsa.gov.sg, click “News”, and select “HSA Updates”.

Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.

**HSA ALERTS PUBLIC ON NIPRO DIAGNOSTICS' VOLUNTARY
RECALL OF TRUERESULT BLOOD GLUCOSE TEST STRIPS DUE
TO INCORRECT LOW GLUCOSE RESULTS**

Item Codes and Lot Numbers of Affected Test Strips in Singapore

Product Name	Item Code	Test Strip Lot Number (Affected)
TRUEresult Blood Glucose Test Strip (25ct)	K-E3I01-25FD	FR1286INT
		HS1019INT
TRUEresult Blood Glucose Test Strip (50ct)	K-E3I01-81FD	HS1014INT
		HS1015INT
TRUEresult Blood Glucose Monitoring System (meter included in this system is not affected)	K-E4I53-91FD	HS1020INT
		HS1040INT

HSA ALERTS PUBLIC ON NIPRO DIAGNOSTICS' VOLUNTARY RECALL OF TRUERESULT BLOOD GLUCOSE TEST STRIPS DUE TO INCORRECT LOW GLUCOSE RESULTS

Item Numbers and Lot Numbers of Affected Test Strips Globally, other than Singapore

TRUEResult (GDH-FAD) Blood Glucose Test Strip Global Recall Lot	
Item Number	Lot number
E3163-25FD	FR1285IES
E3101-25FD	FR1285INT
E3101-25FD	FR1286INT
E3156-81FD	FS1309IDE
E3190-82FD	FS1309IGR
E3156-81FD	FS1310IDE
E3168-82FDL	HLS1024GBY
E3160-82FDL	HLS1024ISE
E415E70FDL-24	HLS1024ISE
E3157-82FDL	HLS1031INT
E3168-82FDL	HLS1032GBY
E3157-82FDL	HLS1032INT
E3168-82FDL	HLS1033GBY
E3157-82FDL	HLS1033INT
E3168-82FDL	HLS1036GBY
E3168-82FDL	HLS1037GBY
E4GBY70FDL-24	HLS1037GBY
E3142-80FD	HS1012IIN
E3142-80FD	HS1013IIN
E3163-82FD	HS1014IES
E3142-80FD	HS1014IIN
E3142-82FD	HS1014IIN
E3101-80FD	HS1014INT
E3101-81FD	HS1014INT
E3112-82FD	HS1014IRK
E3156-81FD	HS1015IDE
E3101-81FD	HS1015INT
E3112-82FD	HS1015IRK
E3137-82FD	HS1015ISA
E3163-82FD	HS1016IES
E3112-82FD	HS1016IRK
E3156-81FD	HS1017IDE
E3156-81FD	HS1018IDE
E3163-25FD	HS1019IES
E3163-82FD	HS1019IES
E3101-25FD	HS1019INT
E3112-82FD	HS1019IRK
E41IN70FD-24	HS1020IIN
E3112-82FD	HS1020IRK
E3163-82FD	HS1021IES
E3112-82FD	HS1021IRK
E3163-82FD	HS1022IES
E3163-82FD	HS1023IES
E3163-82FD	HS1025IES
E3101-80FD	HS1025INT
E3112-82FD	HS1025IRK
E3163-82FD	HS1026IES
E3163-82FD	HS1027IES
E3163-82FD	HS1034IES
E3163-82FD	HS1035IES
E3150-82FD	HS1040IBG
E3172-82FD	HS1040IID
E3101-81FD	HS1040INT
E3101-81FD	HS1040INT
E3134-82FD	HS1040IUA
E3163-82FD	HS1041IES
E3163-82FD	HS1042IES
E3168-82FDL	LS1303GBY
E3168-82FDL	LS1304GBY

TRUEResult (GDH-FAD) Blood Glucose Test Kit Global Recall Lot	
Item Number	Lot number
E4112-91FD	KS0936
E4170-91FD	KS0973
E4101-91FD	KS0982
E4137-81FD	KS1059
E4163-81FD	KS1180
E4163-81FD	KS1181
E4168-81FDL	KS1222
E4168-81FDL	KS1223
E4163-81FD	KS1354
E4163-81FD	KS1375
E4163-81FD	KS1377
E4163-81FD	KS1378
E4163-81FD	KS1379
E4163-81FD	KS1400
E4163-81FD	KS1410
E4171-81FD	KS1420
E4171-81FD	KS1421
E4163-81FD	KS1428
E4160-91FDL	KS1515
E4160-91FDL	KS1519
E4153-91FD	KS1552
E4137-81FD	KS1556
E4137-81FD	KS1565
E4168-81FDL	KS1570
E4168-81FDL	KS1575
E4157-81FDL	KS1592
E4157-81FDL	KS1596
E4163-81FD	KS1605
E4163-81FD	KS1606
E4163-81FD	KS1607
E4156-81FD	KS1619
E4156-81FD	KS1620
E4156-81FD	KS1621
E4156-81FD	KS1622
E4150-91FD	KS1623IBG
E4101-81FD	KS1645
E4135-91FD	KS1698IBD
E4157-81FDL	KS1712
E4156-91FD	KS1720
E4108-81FD	KS1741
E4168-81FDL	KS1784
E4168-81FDL	KS1785
E4163-81FD	KS1922
E4163-81FD	KS1923
E4153-91FD	KS1939
E4101-91FD	KS1952
E4101-81FD	KS1955
E4150-91FD	KTO155IBG