

UPDATE

URGENT: MEDICAL DEVICE VOLUNTARY RECALL

CERTAIN LOTS of TRUEread®, TRUEbalance®, TRUEtrack® and TRUEtest® BLOOD GLUCOSE TEST STRIPS

September 29, 2016

Dear Valued Customer:

The purpose of this letter is to provide additional information related to a voluntary product recall announced June 28, 2016 by Trividia Health, Inc., formerly Nipro Diagnostics, for a limited number of TRUEread®, TRUEbalance®, TRUEtrack® and TRUEtest® blood glucose test strip lots distributed in the United States.

The company has determined that certain isolated TRUEread, TRUEbalance, TRUEtrack and TRUEtest blood glucose test strip lots packaged during a specific timeframe, may include open test strip vials within the sealed test strip boxes. Test strips contained within strip vials that remain open for long periods are exposed to the outside environment, which can affect test 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.

There are 6 affected TRUEread vial lots, 56 TRUEtrack lots, 30 TRUEbalance lots and 160 TRUEtest lots that were packaged from April 16, 2015 thru July 30, 2015 for sale in the United States.

We have not received any reports of patient injuries related to this voluntary recall.

ATTENTION:

Concurrently, all TRUEresult and TRUE2go meters and TRUEtest test strips have been DISCONTINUED as of June 1, 2016. GDH-PQQ enzyme-based meter systems are known to have the potential for inaccurate results due to interference. Trividia Health has discontinued these meter systems in the United States and US Territories due to this potential for inaccurate results. All users and patients who use the TRUEresult and TRUE2go meters and TRUEtest strips should discontinue use immediately. For healthcare professionals, pharmacists/DME providers, and distributors, please ask your patients and customers to discontinue use of their TRUEresult meters, TRUE2go meters and TRUEtest test strips immediately.

Please refer to the following webpage for more important safety information regarding these products:

http://www.trividiahealth.com/global/important_safety_info.aspx

All patients and users should call Stericycle toll-free at 1-888-835-2723. Stericycle will arrange return of your TRUEtest strips, and if you have not yet received your upgrade to one of the NEW TRUE METRIX® Blood Glucose Systems through your retailer or diabetes supply provider, Stericycle will UPGRADE you for FREE to the NEW TRUE METRIX® Blood Glucose System or the new TRUE METRIX® AIR Blood Glucose System with Bluetooth Smart® Technology so that you can continue your usual testing routine.


TRUE METRIX® Systems are brought to you by Trividia Health, the same manufacturer of your TRUEresult® and TRUE2go® Systems. Featuring TRIPLE SENSE TECHNOLOGY®, the TRUE METRIX® portfolio of blood glucose systems provides proven accuracy and confidence in results and offers advanced performance testing features to help you more confidently monitor and manage your diabetes.

For the TRUEread, TRUEtrack or TRUEbalance systems, replacement test strips are available at no charge by following the instructions provided below:

- People with Diabetes: **If you are using a TRUEread, TRUEtrack or TRUEbalance System**, determine whether you have any affected lots by obtaining the test strip lot number printed on the side of the test strip box or on the test strip vial label or by obtaining the meter kit lot number printed on the side of the TRUEread, TRUEtrack or TRUEbalance kit box. Then visit www.trividiahealth.com/product-notice or call **Stericycle toll-free at 1-888-835-2723** to determine if you have affected product. If you have any affected product, please call Stericycle to verify the lot number and expedite return and replacement of test strips at no charge to you. You may continue to use test strips under the TRUEread, TRUEtrack or TRUEbalance brands for lots not included in this voluntary recall. Only use test strips that are intended for use with your meter.
- Health Care Professionals: Determine whether you have any affected TRUEread, TRUEtrack, TRUEbalance or TRUEtest lots in inventory by examining the test strip lot number printed on the test strip outer case/shipper label, on the side of the test strip box or on the test strip vial label. Examine your meter kit lot numbers printed on the meter outer case/shipper label or on the side of the meter kit box. The affected lot numbers are provided in the attached Appendix. If you have product with these lot numbers please return the product immediately. Please contact **Stericycle toll-free at 1-888-835-2723** to expedite return and replacement. Please advise any patients with recalled product to contact **Stericycle toll-free at 1-888-835-2723**.

Patients who use TRUEread, TRUEtrack or TRUEbalance products may continue to test blood glucose using any lots not included in this voluntary recall. Patients should only use test strips that are intended for use with their meter.

- Pharmacists/DME Providers: Determine whether you have any affected TRUEread, TRUEtrack, TRUEbalance or TRUEtest lots in inventory by examining the test strip lot number printed on the test strip outer case/shipper label or on the side of the test strip box. Examine your meter



kit/prepack lot numbers printed on the meter/prepack outer case/shipper label or on the side of the meter kit box. The affected lot numbers are provided in the attached Appendix. If you have any product with these lot numbers, return the product per your normal return procedures. Please advise any patients with recalled product to contact **Stericycle toll-free at 1-888-835-2723**.

Patients who use TRUEread, TRUEtrack or TRUEbalance products may continue to test blood glucose using any lots not included in this voluntary recall. Patients should only use test strips that are intended for use with their meter.

If you receive inquiries from healthcare professionals or users of TRUEread, TRUEtrack, TRUEbalance or TRUEtest test strips, please have them call **Stericycle toll-free at 1-888-835-2723**.

- **Distributors:** Determine whether you have any affected lots of TRUEread, TRUEtrack, TRUEbalance or TRUEtest test strips in inventory by examining the test strip lot number printed on the test strip outer case/shipper label or on the side of the test strip box. Examine your meter kit/prepack lot numbers printed on the meter/prepack outer case/shipper label or on the side of the meter kit box. The affected lot numbers are provided in the attached Appendix. In addition, please notify your customers of this voluntary product recall. Request that they return TRUEread, TRUEtrack and TRUEbalance products with lot numbers identified in this voluntary recall and use your normal return procedures. Once you have received all affected product to be returned, please call **Stericycle at 1-888-835-2723** to obtain prepaid return labels.

The voluntary recall and product discontinuation are being conducted with the knowledge of the Food and Drug Administration. Please complete and return the enclosed response form as soon as possible via fax at **1-888-237-5582** or email to **trividia4766@stericycle.com**. If you have any questions, please call **Stericycle toll-free at 1-888-835-2723**.

Patient safety is a top priority at Trividia Health and we apologize for any inconvenience this voluntary recall may cause you.

Sincerely,

Gregg Johnson
Senior Vice President, North America



MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form – Response Required
CERTAIN LOTS of TRUEread®, TRUEbalance®, TRUEtrack® and
TRUEtest® BLOOD GLUCOSE TEST STRIPS

I have read and understand the recall instructions provided in the June 28, 2016 letter.

Yes ___ No___

Any adverse events associated with recalled product? Yes ___ No___

If yes, please explain:

TEST STRIP LOTS*:

Product/Brand Names	Manufacturer's Product /Catalog Number	Lot Number shipped to Customer	Quantity in inventory	Quantity returned
TRUEread test strips				
TRUEtrack test strips				
TRUEbalance test strips				
TRUEtest test strips				

METER KIT LOTS*:

Product/Brand Names	Manufacturer's Product /Catalog Number	Lot Number shipped to Customer	Quantity in inventory	Quantity returned
TRUEtrack meter kits				
TRUEbalance meter kits				
TRUE2go meter kits				
TRUEresult meter kits				



PREPACK LOTS*:

Product/Brand Names	Manufacturer's Product /Catalog Number	Lot Number shipped to Customer	Quantity in inventory	Quantity returned
TRUResult prepacks				
TRUTrack prepacks				

* Please return any product with these lot numbers through the normal channels that you sourced the affected product and per your normal return process. Return labels are intended for use only by Health Care Professionals, Pharmacists or DME Providers that do not have a means to return product as outlined in the Customer Letter.

Return Response Box:

Please provide any additional information, if applicable.



Distributors:

I have checked my stock and have quarantined inventory consisting of _____ <select one: units, cases, etc.>.

I have identified and notified my customers who were shipped or may have been shipped this product by (**specify date _____ and method of notification _____**);

<or>

Attached is a list of customers (provide in Microsoft Excel) who received/may have received this product. Please notify my customers.

Questions: (when applicable)

Please have Customer Service contact me.

Signature of Receipt _____

Name (Printed)	
Title	
Telephone	
Email address	

PLEASE FAX COMPLETED RESPONSE FORM TO: 1-888-237-5582, ATTN: EVENT 4766 or e-mail to trividia4766@stericycle.com.



Appendix:

AFFECTED TEST STRIP LOTS

TRUEtest					TRUEtrack		TRUEbalance	TRUEread
Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #	Lot #
PS2265	PS2190	PS2326	PS2354	PS2391	RS4646	RS4688	BS4643	DR4559
PS2283	PS2189	PS2328	PS2371	PS2401	RS4631	RS4673	BS4640	DS4648
PS2285	PS2290	PS2334	PS2360	PS2402	RS4649	RS4667	BS4650	DS4624
PS2281	PS2298	PS2329	PS2366	PS2408	RS4645	RS4678	BS4668	DS4658
PS2278	PS2303	PS2331	PS2364	PS2388	RS4652	RS4680	BS4661	DS4579
PS2276	PS2289	PS2332	PS2370	PS2386	RS4641	RS4686	BS4588	DS4672
PS2275	PS2294	PS2336	PS2355SER	PS2387	RS4653	RS4677	BS4651	
PS2215	PS2295	PS2335	PS2358	PS2390	RS4638	RS4679	BS4621	
PS2271	PS2300	PS2340	PS2363	PS2385	RS4612	RS4695	BS4664	
PS2279	PS2304	PS2345	PS2319	PS2399	RS4644	RS4699	BS4615	
PS2209	PS2325	PS2308	PS2365	PS2396	RS4655	RS4703	BS4675	
PS2299	PS2312	PS2341	PS2361	PS2406	RS4669	RS4689	BS4666	
PS2273	PS2311	PS2339	PS2368	PS2398	RS4567	RS4704	BS4629	
PS2274	PS2305	PS2307	PS2372	PS2409	RS4639	RS4692	BS4687	
PS2280	PS2306	PS2343	PS2381	PS2337	RS4605	RS4694	BS4681	
PS2219	PS2315	PS2353	PS2369	PS2397	RS4659	RS4698	BS4696	
PS2277	PS2301	PS2352	PS2377	PS2404	RS4654	RS4663	BS4700	
PS2268	PS2314	PS2338	PS2392	PS2403	RS4657	RS4705	BS4707	
PS2282	PS2310	PS2348	PS2380	PS2322	RS4608	RS4708	BS4693	
PS2296	PS2347	PS2342	PS2374	PS2412	RS4660	RS4719	BS4671	
PS2288	PS2309	PS2355	PS2375	PS2416	RS4662	RS4710	BS4690	
PS2284	PS2318	PS2344	PS2373	PS2417	RS4634	RS4715	BS4697	
PS2291	PS2395	PS2359	PS2378	PS2419	RS4676	RS4717	BS4701	
PS2287	PS2320	PS2362	PS2379	PS2418	RS4670	RS4714	BS4706	
PS2286	PS2321	PS2357	PS2382	PS2420	RS4665	RS4723	BS4709	
PS2297	PS2316	PS2349	PS2380SER	PS2405	RS4544	RR4521	BS4713	
PS2252	PS2317	PS2376	PS2383	PS2413	RS4674	RS4716	BS4720	
PS2293	PS2330	PS2356	PS2389	PS2414	RS4607	RS4724	BS4682	
PS2302	PS2327	PS2350	PR2068	PS2394			BS4683	
PS2292	PS2324	PS2367	PS2393	PS2411			BS4721	
PS2313	PS2323	PS2351	PS2384	PS2415				
PS2270	PS2333	PS2346	PS2400	PS2421				



AFFECTED METER KIT LOTS

TRUEresult		
Kit Lot #	Kit Lot #	Kit Lot #
KS0967	KS1417	KS1339
KS1022	KS1488	KS0988
KS1214	KS1730	KS1268
KS1312	KS1732	KS1445
KS1154	KS1496	ks1045
KS1688	KS1650	KS1447
KS1631	KS1469	KS1362
KS1301	KS2235	KS1545
ks1133	KS1501	KS1725
KS1341	KS1736	KS1692
KS1063	KS1531	ks1434
KS1109	KS1107	KS2217
KS0968	KS1580	KS1543
ks1449	KS1021	KS1031
KS1340	KS1267	KS1047
KS1032	KS1051	KS1295
KS1266	KS1646	KS2260
KS1714	KS1483	KS1764
KS1910	KS1363	KS1189
KS1473	KS1925	KS1726
KS1546	KS1659	KS1510
KS1524	KS0994	KS1278
KS1759	KS1028	KS2415
KS1152	KS1369	KS1258
ks1108	KS1627	KS1748
KS1153	KS1049	KS0996
KS1243	KS1389	KS1734
KS1790	KS1701	KS1121
KS1763	KS1053	KS1724
KS1132	KS1048	KS1187
KS1306	KS1444	KS1574
KS0981	KS1176	KS1422
ks1323	KS1364	KS2324
KS1175	KS0980	KS1365
KS1909	KS1147	KS1023
KS1426	KS1797	KS1594
KS1215	KS1957	KS1525
KS1687	KS1459	KS2373
KS1533	KS1497	KS1303
KS1300	KS1767	KS1448
KS1643	KS1311	KS2449
KS1360	KS1700	KS1534
KS1779	KS1474	ks1188
KS1671	KS1276	ks1443
KS1933	KS1532	KS1661
KS1943	KS1792	KS1930
KS1597	KS1542	KS2437
KS1020	KS1366	

TRUE2go	
Kit Lot #	Kit Lot #
KS1941	KS1487
KS1796	KS1697
KS1954	KS1940
KS1190	KS1762
KS1281	KS2414
KS1559	KS1465
KS1489	KS1917
KS1737	KS2417
KS1927	KS1468
KS1326	KS1143
KS1560	KS1089
KS1528	KS2418
KS1000	KS1116
KS1162	KS1500
KS1453	KS1006
KS1942	KS1535
KS0993	KS1704
KS1145	KS1071
KS1944	KS1288
KS1751	KS1626
KS1320	KS1628
KS0995	KS2323
KS1441	KS1070
KS1747	KS1115
KS1277	KS1446
KS1052	KS0992
KS1599	KS1573
KS1752	KS0999
KS1217	KS1705
KS1731	KS1750
KS1013	KS1221
KS1302	KS1127
KS1553	KS1567
KS1928	KS1527
KS1186	KS1557
KS1395	KS2453
KS1144	KS2971
KS1544	KS1406

TRUEtrack	
Kit Lot #	Kit Lot #
KS1009TI	KS1359TI
KS1404TI	KS1721TI
KS2028TI	KS1001TI
KS1349TI	KS1427TI
KS2073TI	KS1151TI
KS1170TI	KS1216TI
KS1583TI	KS1530TI
KS1761TI	KS1093TI
KS1638TI	KS1252TI
KS1977TI	KS0954TI
KS1125TI	KS1242TI
KS1644TI	KS1305TI
KS0972TI	KS1097TI
KS1368TI	KS1098ti
KS1517TI	KS1046TI
KS1695TI	KS1029TI
KS2002TI	KS1997TI
KS0971TI	KS1766TI
KS1956TI	KS1438TI
KS1263TI	KS1405TI
KS1614TI	KS1676TI
KS2005TI	KS2184TI
KS2052TI	KS1129TI
KS1668TI	KS2119TI
KS1637TI	ks1996ti
KS1191TI	KS1265TI
KS1675TI	KS1370TI
KS1259TI	KS1467TI
KS1921TI	KS1374TI
KS1529TI	KS1287TI
KS1463TI	KS1304TI
KS1169TI	KS1019TI
KS1324TI	KS2185TI
KS1677TI	

TRUEbalance
Kit Lot #
KS1684TI
KS1683TI
KS1786TI
KS1298TI
KS1042TI
KS1526TI
KS1988TI
KS1297TI
KS1787TI
KS1036TI
KS1041TI
KS1604TI
KS1177TI
KS1432TI
KS1603TI
KS2051TI
KS1135TI
KS1130TI

AFFECTED PREPACK LOTS

TRUEresult	
PrePack Lot #	PrePack Lot #
KS1236	KS1201
KS0889	KS1582
KS1670	KS1794
KS1932	KS1197
KS1456	KS1330
KS1709	KS1294
KS1250	KS0986
KS1329	KS1309
KS0896	KS1505
KS1578	KS0975
KS0948	KS1477
KS1387	KS1262
KS1648	KS1079
ks1667	KS1458
KS1736	KS1630
KS1914	KS0891
KS0900	KS1174
KS1067	KS1203
KS1665	KS1506
KS0899	KS1663
KS1076	KS1744
KS1916	KS0850
KS0946	

TRUEtrack
PrePack Lot #
KS1452TI
KS1018TI
KS1635TI
KS1138TI
KS0933TI
KS1165TI
KS1352TI
KS1521TI
KS1540TI
KS1508TI
KS1912TI
KS1260TI
KS1008TI
KS0837TI
KS1248TI
KS1055TI
KS1746TI
KS1234TI
KS1247TI
KS0984TI
KS1233TI
KS1139TI
KS1149TI
KS1148TI