

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

PBM-2016-04

JULY 12, 2016

ITEM: Trividia Health - # 21200/21194/2196/21201/21202/21203- Various Diabetic Test Strips: Recall

SPECIFIC INCIDENT(S): Trividia Health, is voluntarily recalling various item(s)/lot(s) due to certain test strip lots packaged during a specific timeframe that may include open test strip vials within the sealed test vial boxes.

GENERAL INFORMATION:

- The company has received reports that the open bottles may give faulty readings.
- Affected product started shipping April 16, 2015, and includes those listed in Table 1 on pages 3-4.
- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 10926** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should continue to report any adverse reactions with diabetic test strips by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

ACTIONS: **PROVIDER NOTIFICATION:**

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, endocrinology staff, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 7/25/2016):
 - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Sites may not have lot number information available locally, so in the case that the lot number data is not available, sites will need to call all patients that received the product and ask them to

check the lot numbers.

- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
 - Identify the patient(s).
 - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
 - A sample letter can be found at:
<https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template.doc>.
 - This template can be altered according to site-specific needs.
 - Provide patient(s) in possession of the recalled product with instructions on the following:
 - How to return the product being recalled to the pharmacy.
 - How to obtain a new supply of product.
 - Patients should not continue to use the product until they obtain replacement product.
 - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
- Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website:
<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>.

SOURCE: Manufacturer.

REFERENCE(S): McKesson Important Notice: Urgent Recall. RC 16-101. July 5, 2016.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.

Table 1. Affected Products.

Description	Lot # Exp Date	NDC	UPC	Econo #
GIANT/E TRUE TRCK TST STRP 100	RS4544 04/22/17; RS4654 10/16/17;	56151081001	3003405548	1864305
GIANT/E TRUE TRCK TST/STRP 50	RS4667 10/29/17; RS4717 12/29/17;	56151085050	3003405549	1863463
HEB TRUE TEST STRIPS 50CT	PS2287 04/19/18; PS2315 05/13/18; PS2334 05/27/18; PS2381 6/30/18; PS2416 07/21/18;	56151103050	41220649402	2730950
HM TRTST MMPPK 4NC MTR 12STRP@	KS0889 04/14/18; KS1236 05/14/18; KS1670 05/31/18; KS1709 6/30/18; KS1932 07/22/18;		52569138465	2732907
HM TRUE TEST MEDI MEDI STR 50@	PS2278 04/14/18; PS2288 04/20/18; PS2313 05/14/18; PS2314 5/14/18; PS2338 05/29/18; PS2341 05/29/18; PS2357 05/31/18; PS2359 5/31/18; PS2368 06/13/18; PS239706/30/18; PS2399 07/13/18;	56151181350	5256913240	1279181
HM TRUE TRACK GLUC TST/STR 100	RS4654 10/16/17; RS4704 11/30/17;	56151081001	5256913241	1279892
HM TRUE TRACK GLUC TST/STRP 50	RS4657 10/18/17; RS4695 11/30/17; RS4708 12/16/17;	56151085050	5256913242	1280338
HM TRUE TRACK MEDI MEDI ST 50@	RS4652 10/14/17; RS4655 10/17/17; RS4677 10/31/17; RS4679 0/31/17; RS4717 12/29/17;	56151081350	5256913239	1278894
HM TRUE/T GLUC MTR KT A4089 81	KS0972TI 07/31/17; KS1614TI 09/20/17; KS1668TI 07/31/17; KS2002TI 07/31/17;	56151088880	5256913246	1281633
HM TRUERESULT METER E4089 81	KS1049 03/31/18; KS1107 04/30/18; KS1763 05/31/18; KS2235 6/30/18;	56151124001	5256913245	1280866
HM TRUETEST STRIP E3089 81 50	PS2297 04/30/18; PS2313 05/14/18; PS2357 05/31/18; PS2388 06/30/18;	56151103050	5256913243	1280486
HM TRUETEST STRIP E3089 80 100	PS2304 04/30/18; PS2359 05/31/18;	56151103001	5256913244	1280684
SHOPKO TRUE RESULT STRIP 50	PS2289 04/21/18; PS2311 04/30/18; PS2381 06/30/18; PS2400 07/13/18;	56151103050	40011456852	2170991
SM TRTST MMPPK 4 NC MTR12STRP@	KS1250 05/21/18; KS1648 06/30/18; KS1914 07/22/18; KS1916 07/22/18;		2129200659	2733095
SM TRUE TEST MEDI MEDI STR 50@	PS2288 04/20/18; PS2297 04/30/18; PS2313 05/14/18; PS2327 05/21/18; PS2385 06/30/18; PS2393 06/30/18; PS2417 07/20/18; PS2421 07/22/18;	56151181350	1093924144	3269701
SM TRUE TRACK GLUC TST/STR 100	RS4641 09/27/17; RS4659 10/22/17; RS4704 11/30/17; RS4710 12/18/17;	56151081001	1093975733	1134428
SM TRUE TRACK GLUC TST/STRP 50	RS4645 09/30/17; RS4657 10/18/17; RS4695 11/30/17; RS4715 12/24/17;	56151085050	1093975633	1134311
SM TRUE TRACK MEDI MEDI ST 50@	RS4607 07/31/17; RS4639 09/30/17; RS4645 09/30/17; RS4657 10/18/17; RS4695 11/30/17; RS4715 12/24/17;	56151081350	1093922444	3269651
SM TRUE TRACK TEST STRIP 25	RS4657 10/18/17;	56151082525	1093926444	1338755

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

Table 1. Affected Products (continued)

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

Description	Lot # Exp Date	NDC	UPC	Econo #
SM TRUE/T GLUC MTR KT A4054 81	KS0971TI 07/31/17; KS1368TI 09/20/17; KS1644TI 07/31/17; KS1977TI 07/31/17;	56151088880	1093975533	1134436
SM TRUE2GO GLU METER F4054 81	KS1144 04/30/18; KS1762 05/31/18;	56151134001	1093922344	3269669
SM TRUERESULT GLU METR E405481	KS1028 03/31/18; KS1132 04/30/18; KS1303 04/30/18; KS1671 05/31/18;	56151124001	1093922044	3269677
SM TRUETEST STRIP E3054 25 25	PS2209 10/31/17; PS2215 01/31/18;	56151103025	1093926344	1350354
SM TRUETEST STRIP E3054.81 50	PS2278 04/14/18; PS2288 04/20/18; PS2297 04/30/18; PS2313 05/14/18; PS2340 05/28/18; PS2389 06/30/18;	56151103050	1093922244	3269644
SM TRUETEST STRIP E3054.80 100	PS2280 04/14/18; PS2296 04/30/18; PS2310 04/30/18; PS2359 05/31/18; PS2396 06/30/18; PS2418 07/21/18;	56151103001	1093922144	3269636
TRUE BALANCE TEST STRIP 50	BS4640 09/26/17; BS4661 10/23/17; BS4683 11/15/17; BS4706 12/13/17; BS4713 12/22/17;	56151002150	21292003128	2069029
TRUE TEST STRIP (NFRS) 50	PS2290 04/23/18; PS2294 04/30/18; PS2301 04/30/18; PS2371 06/16/18; PS2388 06/30/18; PS2416 07/21/18; PS2420 07/22/18;	56151108950	2129200266	1136779
TRUE TRACK MTR STR KT A4H01 81	KS1001TI 07/31/17; KS1009TI 07/31/17; KS1170TI 09/20/17; KS1638TI 07/31/17; KS1677TI 07/31/17; KS1761TI 07/31/17; KS1921TI 07/31/17;	56151088880	2129200101	1733997
TRUE TRACK TEST STR (NFRS) 50	RS4652 10/14/17; RS4663 10/25/17; RS4673 10/31/17; RS4686 11/18/17;	56151085150	2129200195	1134808
TRUE TRACK TEST STRIPS 50	RS4645 09/30/17; RS4655 10/17/17; RS4662 10/24/17; RS4667 10/29/17; RS4669 10/31/17; RS4686 11/18/17; RS4692 11/28/17; RS4719 12/31/17; RS4723 12/31/17;	56151085050	2129200103	2212140
TRUE TRACK TEST STRIPS 100	RS4567 05/31/17; RS4649 09/30/17; RS4654 10/16/17; RS4676 10/31/17; RS4678 10/31/17; RS4704 11/30/17; RS4705 11/30/17; RS4714 12/23/17;	56151081001	2129200104	1734029
TRUE2GO METER F4H01 81	KS1013 03/31/18;	56151134001	2129200259	3242146
TRUEREAD GLUC TEST STRIPS 50	DR4559 11/18/16; DS4672 04/30/17;	56151001150	2129200206	1332634
TRUERESULT METER E4H01 81	KS0967 03/31/18; KS0968 03/31/18; KS1021 03/31/18; KS1022 03/31/18; KS1108 04/30/18; KS1109 04/30/18; KS1133 04/30/18; KS1154 04/30/18; KS1175 04/30/18; KS1176 04/30/18; KS1214 04/30/18; KS1301 04/30/18; KS1312 04/30/18; KS1323 04/30/18; KS1341 04/30/18;	56151124001	2129200260	3242138
TRUETEST STRIP E3H01 25 25	PS2215 01/31/18; PS2219 01/31/18;	56151103025	2129200472	2070597
TRUETEST STRIP HB E3H01.80 100	PS2265 03/30/18; PS2268 03/30/18; PS2293 04/23/18; PS2300 04/30/18; PS2314 05/14/18; PS2331 05/26/18; PS2335 05/27/18; PS2350 05/31/18; PS2356 05/31/18; PS2401 07/13/18; PS2418 07/21/18;	56151103001	2129200271	3219714
TRUETEST STRIP HB E3H01.81 50	PS2275 03/31/18; PS2287 04/19/18; PS2290 04/23/18; PS2299 04/30/18; PS2312 04/30/18; PS2317 05/15/18; PS2329 05/22/18; PS2330 05/22/18; PS2339 05/28/18; PS2367 06/15/18; PS2369 06/15/18; PS2388 06/30/18; PS2390 06/30/18; PS2391 06/30/18 PS2419 07/22/18;	56151103050	2129200270	3219722
TRUETEST STRIP HN E3H01 89 50	PS2292 04/20/18; PS2311 04/30/18; PS2330 05/22/18; PS2355 05/31/18; PS2398 06/30/18; PS2400 07/13/18;	56151107150	2129200598	2070191
WEGMANS TRUE TEST STRIP 50	PS2278 04/14/18; PS2379 06/30/18;	56151103050	7789023139	1381565
WEGMANS TRUE TEST STRIP 100	PS2365 05/31/18; PS2394 06/30/18;	56151103001	7789023141	1384791
WEGMANS TRUE2 GO MTR F.4087 81	KS1557 01/05/18	56151134001	7789023138	1378785