



URGENT MEDICAL DEVICE RECALL

Dear Valued Customer:

EDI drugs of abuse tests are calibrated to a single compound for each class of drugs targeted. For the Benzodiazepine (BZO) class of drugs, the test has been calibrated to Oxazepam, as stated in the Intended Use section of the product insert. Reactivity to additional compounds in the BZO family is reported in the Specificity section of the product insert.

Affected lots of EDI's Drugs of Abuse Tests have shown reduced reactivity for up to three (3) of the nineteen (19) Benzodiazepine (BZO) compounds for which specificity information is provided in the product insert. The specific BZO compounds for which there may be reduced reactivity include Clonazepam, Nordiazepam and Lorazepam. Only the BZO test is affected. The test continues to perform as expected for the other drugs.

The purpose of this letter is to inform you that Express Diagnostic Int'l (EDI) is initiating a voluntary recall of the following products that you have received:

Part Number	Lot Number	Expiration Date	Invoice Number	Quantity Shipped	Invoice Date
31202-5	PD-01132	05/2015	10-04-67045	100	01/21/14
31281-A	PD-01243	05/2015	10-04-69104	500	02/28/14
70940-5	PD-03374	08/2015	10-04-72848	100	04/30/14
70940-5 BLK	PD-01022	08/2015	10-04-67915	1,000	02/07/14
70601	PD-03130	10/2015	10-04-71439	400	04/07/14
70601	PD-03130	10/2015	10-04-71440	200	04/07/14
30650 BLK	PC-12255	10/2015	10-04-67046	3,600	01/21/14
30650 BLK	PD-01203	10/2015	10-04-67912	4,200	02/07/14
30650 BLK	PD-01203	10/2015	10-04-67913	4,200	02/01/14
70600	PD-02195	11/2015	10-04-68960	200	02/26/14
30650 BLK	PD-03255	12/2015	10-04-70676	2,400	03/26/14
71020	PE-03173	01/2016	10-04-91583	200	05/08/15
30650 BLK	PD-02254	01/2016	10-04-71007	8,400	04/01/14
30650 BLK	PD-03369	01/2016	10-04-71400	12,000	04/04/14
31202-5	PE-03034	06/2016	10-04-90972	225	04/13/15
30650	PE-02100	07/2016	10-04-89975	525	03/03/15

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30650	PE-02100	07/2016	10-04-89977	500	03/03/15
31202-5	PE-04118	07/2016	10-04-92142	1,000	06/03/15
61281-5A	PD-12013	07/2016	10-04-88416	375	01/16/15
61281-5A BLK	PD-12014	07/2016	10-04-88426	1,000	01/19/15
61281-5A BLK	PE-02027	07/2016	10-04-89823	2,000	02/25/15
61281-5A BLK	PE-02045	07/2016	10-04-90993	1,000	04/14/15
61281-5A BLK	PE-02045	07/2016	10-04-90994	2,000	04/14/15
70550-5	PD-12017	07/2016	10-04-86725	200	12/09/14
70940-5	PD-12018	07/2016	10-04-87916	500	01/07/15
70940-5	PE-03218	07/2016	10-04-91294	500	04/28/15
30650	PE-01019	08/2016	10-04-88772	475	01/22/15
30650	PE-01019	08/2016	10-04-89491	225	02/10/15
60640	PE-03028	10/2016	10-04-90240	200	03/12/15
70600	PD-12189	11/2016	10-04-88574	200	01/19/15
30418	PE-02111	12/2016	10-04-89977	200	03/03/15
30418	PE-02111	12/2016	10-04-89978	275	03/03/15
30418	PE-02111	12/2016	10-04-89979	375	03/03/15
30650	PE-02258	12/2016	10-04-90627	1,250	03/31/15
30650	PE-02258	12/2016	10-04-90628	375	03/31/15
30650	PE-02258	12/2016	10-04-90629	225	03/31/15
30650	PE-02258	12/2016	10-04-90630	200	03/31/15
30650	PE-02258	12/2016	10-04-90631	350	03/31/15
30650	PE-03092	12/2016	10-04-90629	1,525	03/31/15
30650	PE-03092	12/2016	10-04-90653	300	03/31/15
30650	PE-03092	12/2016	10-04-90674	350	04/01/15
30650	PE-03092	12/2016	10-04-91233	600	04/24/15
30650	PE-03092	12/2016	10-04-93931	25	08/19/15
61281-5A BLK	PE-04220	12/2016	10-04-92003	4,000	05/29/15
30418	PE-04015	01/2017	10-04-91455	250	05/05/15

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30418	PE-04015	01/2017	10-04-91456	200	05/05/15
30418	PE-04015	01/2017	10-04-91457	325	05/05/15
30418	PE-04015	01/2017	10-04-91458	200	05/05/15
30418	PE-04015	01/2017	10-04-91459	125	05/05/15
30418	PE-04015	01/2017	10-04-91460	100	05/05/15
30418	PE-04015	01/2017	10-04-91461	200	05/05/15
30418	PE-04015	01/2017	10-04-91463	550	05/05/15
30650 BLK	PE-03033	01/2017	10-04-91001	1,800	04/15/15
30650 BLK	PE-03126	01/2017	10-04-91007	3,600	04/15/15
30650 BLK	PE-03199	01/2017	10-04-91310	2,400	04/28/15
30650 BLK	PE-03199	01/2017	10-04-91311	1,200	04/28/15
61056-5	PE-07113	02/2017	10-04-93655	300	08/06/15
60640	PE-05172	03/2017	10-04-92211	200	06/10/15
30650 BLK	PE-03172	03/2017	10-04-91333	9,000	04/29/15
30650 BLK	PE-04281	03/2017	10-04-91671	12,600	05/13/15
30650 BLK	PE-04281	03/2017	10-04-92319	625	06/10/15
30650 BLK	PE-04281	03/2017	10-04-91583	3,600	05/08/15