AMEDITECH, INC.

Ameditech, Inc.
9940 Mesa Rim Road
San Diego, CA 92121
Ameditech7340@stericycle.com

URGENT MEDICAL DEVICE RECALL NOTIFICATION

Dear Valued Customer:

The purpose of this notice is to inform you that Ameditech is initiating a voluntary medical device recall due to a product performance issue affecting its visually read drug screening products including First Check. This issue was identified through in-process testing, monitoring and complaint investigations. You are receiving this letter because our records indicate that you have received one or more of the affected products as found in Attachment #A. *You are requested to immediately quarantine affected products in your possession and discontinue their use and/or sale.*

Background:
Affected products are used to screen for the presence of up to 14 primary drugs of interest (**calibrator** drugs) in the sample. In addition to the calibrator drugs, professional product labelling includes the levels at which some **secondary** cross-reactant compounds are detected. While not representative of an assay decision point, the secondary compound information may be consulted by healthcare professionals to interpret laboratory confirmation testing. In accordance with product instructions for use, all positive samples are to be sent to a drug testing lab in order to confirm the initial screening result. Negative results do not require additional testing.

Affected products do not consistently detect all calibrator and secondary compounds at the levels stated in the labeling. Drug-free samples or samples containing drugs below the levels stated in labelling may incorrectly produce a positive test result. Alternatively, samples with drug present above the level stated in the labelling may incorrectly produce a negative test result.

No injuries or adverse events associated with the use of these products have been reported. A health hazard assessment concluded that these performance issues present a low risk of harm; while incorrect screening results could lead to further diagnostic tests or delay in diagnosis, they are unlikely to change any necessary emergency treatment if required. Risks are further reduced for positive results which, per product labelling, require confirmation through further laboratory testing.

Recommended Actions:
Return all non-expired product in your possession by promptly taking the following actions.

<u>Customer Action Requested within 10 Days of this Notification:</u>

1) Determine whether you have affected products in your possession by consulting Attachment A
2) If you have affected products in your possession, immediately quarantine and discontinue use and/or sale of affected lots AND
3) Contact us at Phone: 888-480-2864, FAX: 888-548-8521 or email: Ameditech7340@stericycle.com or contact your Ameditech support services representative. This event # is: 7340.
4) The manufacturer or its service provider will provide a return kit.
5) Return the affected product in your inventory using the provided prepaid UPS return label.
6) Retain this record of notification.
7) Consumer Users: Consult with your physician if there are concerns about this notification.
8) Credits for returned product will be provided upon receipt of the product.

Additional Information:
If you have any questions regarding this information, please contact us at Phone: 888-480-2864, FAX: 888-548-8521 or email: Ameditech7340@stericycle.com or contact your Ameditech support services representative. This event is #: 7340.

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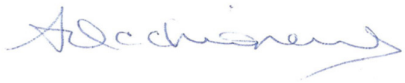
While Ameditech has taken corrective measures to address the identified product performance issues, all products in Attachment #A have been discontinued at this time. We sincerely regret the impact this action has on you and your customers, and appreciate your cooperation in this matter.

Sincerely,



Angela Occhionero
Sr. Director US Manufacturing Quality Assurance
9940 Mesa Rim Road
San Diego, CA 92121

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Attachment A: List of Affected Products

All unexpired lots of the following products:

FirstCheck Finished Goods Product Number	Description
962200	First Check 1 Panel Drug Cup (THC)
971001	First Check 4 Panel Drug Cup: (COC/MET1000/OPI2000/THC)
971002	First Check 7 Panel Drug Cup (AMP/COC/MDMA/MET/OPI/PCP/THC)
971004	First Check 4 Panel Drug Cup: (COC/MET1000/OPI2000/THC)
971005	First Check 14 Panel Drug Cup
971007	First Check 14 Panel Drug Cup
971020	First Check 7 Panel Drug Cup (AMP/COC/MDMA/MET/OPI/PCP/THC)
980100	First Check 1 Panel Drug Cup (THC)
980101	First Check 2 Panel Drug Cup (THC/COC)
980106	First Check 1 Panel Drug Cup (THC)
980112	First Check 1 Panel Drug Cup (THC)
WMT9105	First Check 4 Panel Drug Cup: (COC/MET1000/OPI2000/THC)
WMT9218	First Check 1 Panel Drug Cup (THC)