



URGENT FIELD SAFETY NOTICE

**Re: Innovacon, SureStep, and Instalert Drug of Abuse Tests
Product Insert - French Language Version**

Date: December 4, 2012

Dear Valued Customer,

The purpose of this letter is to inform you that Innovacon, Inc. is initiating a field correction of the following products:

- All Innovacon, SureStep, and Instalert One Step Drug Screen Test Strips (DXX-1x1) with French instructions for use
- All Innovacon, SureStep, and Instalert One Step Drug Screen Test Cassettes (DXX-1x2) with French instructions for use

Our records indicate that you have received one or more of the aforementioned kits from Innovacon under the Innovacon, SureStep, and/or Instalert brands.

It has come to our attention that the French product insert has incorrect instructions for use. Please be advised that the section below denotes the correction of the interpretation of results. We request that you reference the below correction when performing the test:

CORRECT	INCORRECT
POSITIF: Une bande colorée dans la zone de contrôle (C) et une absence de ligne colorée dans la zone test (T) indiquent un résultat positif. Un résultat positif indique que la concentration de drogue est supérieure au seuil de détection.	POSITIF: Une bande colorée dans la zone de contrôle (C) et une absence de ligne colorée dans la zone test (T) indiquent un résultat positif. Un résultat négatif indique que la concentration de drogue est supérieure au seuil de détection.

Based on a health hazard evaluation of the incorrect labeling, it was determined that labeling error (French language) could be expected to yield an increased frequency of false negative result interpretations. The new product insert with the correct changes is attached to this notice. If you question any previously reported results, we recommend you consult with your resident clinical expert or physician in the setting where the test was performed. All relevant National Competent Authorities have been advised of this FSCA

CUSTOMER REQUIRED ACTION

- Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice.
- Please ensure that all users of the device have received a copy of the Urgent Field Safety Notice.



DISTRIBUTOR REQUIRED ACTION

- Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice.
- Please ensure that all users of the device have received a copy of the Urgent Field Safety Notice.
- Monitor the effectiveness of the communication by receipt of the Verification Form.
- Once the Verification Forms have been received from your customers, please notify Innovacon, Inc. that the notification of your customers is complete.


If you should have any questions about the information contained in this notification, please contact:

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Sincerely,


Senior Manager, Regulatory Affairs
Innovacon, Inc.