



## URGENT FIELD SAFETY NOTICE

June 18, 2013

**Re: Innovacon Multi-Drug Multi-Line Twist Screen Test Device Saliva Collector**

Dear Valued Customer:

Innovacon, Inc. is issuing a Field Safety Notice for the Saliva Collector that is an accessory in the Innovacon Multi-Drug Multi-Line Twist Screen Test Device. In certain lots, the sponge may become dislodged from the Saliva Collector handle prior to or during the oral fluid sample collection process. If the sponge becomes dislodged during the specimen collection process, the donor may inadvertently swallow the sponge which could present a choking risk. Our investigation indicates that the sponge may become dislodged on approximately 5% of the Saliva Collectors from affected lots.

**Saliva Collector Inspection Process:**

**Before using the Saliva Collectors for the lots specified below, gently pull the sponge while it is in the wrapper to ensure it remains firmly attached to the handle. Immediately discard any Saliva Collectors if the sponge detaches from the handle. Alternatively, contact your sales representative at Innovacon to receive replacement product.**

The attached tables show the affected products and lot numbers.

### CUSTOMER REQUIRED ACTIONS

- Immediately implement the recommended inspection step of gently pulling the sponge before using the Saliva Collector.
- Discard all Saliva Collectors where the sponge detaches from the handle after gently pulling it.
- If you prefer to receive replacement product, rather than performing the inspection step above, please contact your sales representative at Innovacon.
- Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice. (Please return the form even if you have no remaining inventory or do not have any involved product in order to confirm receipt of this notification).
- Please ensure that all users of the device have received a copy of this Urgent Field Safety Notice

Innovacon, Inc.

9975 Summers Ridge Rd • San Diego, CA 92121 • USA • T +1 877 441 7440 • F +858.695.7100



Please note that the relevant National Competent Authorities have been advised of this Field Safety Corrective Action. Should you have any questions about the information contained in this notification, please contact:

Innovacon, Inc.  
9975 Summers Ridge Road  
San Diego, CA 92121  
U.S.A.  
Phone: +1 877 308 8289  
FAX: +1 858 805 8457  
E-mail: [InnovaconComplaints@alere.com](mailto:InnovaconComplaints@alere.com)

In Germany, please contact our European Representative:

MDSS GmbH  
Schiffgraben 41  
30175 Hannover  
Germany  
Tel.: +49 511 6262 8630  
Fax: +49 511 6262 8633

Sincerely yours,

Keith McLain  
Vice President, Quality Assurance and Compliance  
Innovacon, Inc.



**Attachments: Tables of Affected Products**

**Table I. Innovacon Multi-Drug Multi-Line Twist Screen Test Device PN DSF-765-011 (Alere PN 4508589004)**

| <b>Kit Lot No.</b> | <b>Saliva Collector Lot No.</b> |
|--------------------|---------------------------------|
| DOA3030217         | B130101                         |
| DOA3030706         | B130101                         |
| DOA3040066         | B130101                         |

**Table II. Innovacon Multi-Drug Multi-Line Twist Screen Test Device PN DSF-765-031 (Alere PN 4511109004)**

| <b>Kit Lot No.</b> | <b>Saliva Collector Lot No.</b> |
|--------------------|---------------------------------|
| DOA3010588         | B130101                         |
| DOA3010639         | B130101                         |
| DOA3020241         | B130101                         |

**Table III. Innovacon Multi-Drug Multi-Line Twist Screen Test Device PN DSF-765-041 (Alere PN 4515949004)**

| <b>Kit Lot No.</b> | <b>Saliva Collector Lot No.</b> |
|--------------------|---------------------------------|
| DOA3020212         | B130101                         |



## VERIFICATION FORM

Please complete this form and **FAX BACK** to Technical Services at Fax Number: 1-858-805-8457.

### Innovacon Multi-Drug Multi-Line Twist Screen Test Device Saliva Collector

1. I have read and understood the Urgent Field Safety Notice regarding the **Innovacon Multi-Drug Multi-Line Twist Screen Test Device Saliva Collector** issued by Innovacon, Inc. on June 18, 2013.
2. I confirm that all areas where the product could be located have been checked.
3. **SELECT ALL STATEMENTS THAT APPLY, SIGN THIS FORM** and **FAX** to 1-858-805-8457.

- We do not have any affected product.
- Product was redistributed to another facility; we forwarded a copy of this Urgent Field Safety Notice to that facility.
- We have the affected product. We have read and understand the instructions in the Urgent Field Safety Notice.

|                |           |
|----------------|-----------|
| Signature*:    | Title*:   |
| Printed Name*: | Date*:    |
| Telephone*:    | E-mail:   |
| Institution*:  | Address*: |

Please complete and return this form within 10 business days of receipt

\* Denotes **MANDATORY** Field

Innovacon, Inc.

9975 Summers Ridge Rd • San Diego, CA 92121 • USA • T +1 877 441 7440 • F +858.695.7100