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URGENT MEDICAL DEVICE RECALL

August 29, 2008

Re: Prostate Specific Antigen (PSA) Semi-Quantitative Rapid Test (Whole Blood/Serum/Plasma) and Prostate Specific Antigen (PSA) Semi-Quantitative Ultra Rapid Test (Whole Blood/Serum/Plasma)

Dear Valued Customer,

The purpose of this letter is to inform you that Innovacon, Incorporated is initiating a voluntary recall of the following products:

- **TPS-401 Prostate Specific Antigen (PSA) Semi-Quantitative Rapid Strip (Whole Blood/Serum/Plasma)**
- **TPS-402 Prostate Specific Antigen (PSA) Semi-Quantitative Rapid Device (Whole Blood/Serum/Plasma)**
- **TPS-402H Prostate Specific Antigen (PSA) Semi-Quantitative Rapid Device (Whole Blood/Serum/Plasma)– single unit packaged with unitized buffer, lancet, product insert**
- **TPS-422 Prostate Specific Antigen (PSA) Semi-Quantitative Rapid Uncut Sheet (Whole Blood/Serum/Plasma) – semi-finished product component**
- **TPS-U402 Prostate Specific Antigen (PSA) Semi-Quantitative Ultra Rapid Device (Whole Blood/Serum/Plasma) – Ultra-Sensitivity**

These products were distributed under the *ACON, On-Call, Quik-Check, Innovacon,* and *InstAlert* brand names.

Immediately discontinue all use and discard all affected product in accordance with your local regulations.

Please note that this recall applies to all lots with an expiration dating starting at November 2008 or greater.

Recent studies have demonstrated that there has been a shift in stability since the initial development of the product. Results of the studies show that the current product is unable to meet performance requirements at the assigned 24 month shelf-life which may yield false negative PSA results at or near the limit of detection. A false negative result for PSA could lead to a misdiagnosis or delayed diagnosis of prostate cancer.

As a result we have made the decision to discontinue the use of these products. Therefore, immediately discontinue all use and discard all affected product in accordance with your local regulations.

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According to the package inserts, these products should be used to indicate the semi-quantitative level of PSA in the specimen and should not be used as the sole criteria for the diagnosis of Prostate Cancer, benign prostatic hyperplasia (BPH) or prostatitis. According to the ACS, patients with PSA level greater than 10.0 ng/ml are at an increased risk for prostate cancer (more than 67%). Levels between 4.0 ng/ml and 10.0 ng/ml are often referred to as the "grey zone" which may indicate prostate cancer (about 25% chance), benign prostatic hyperplasia (BPH) or prostatitis. As with all diagnostic tests, all results should have been interpreted together with other clinical information available to the physician. If you or your customers have any questions regarding previously reported results from any of the above tests, we recommend that you instruct your end users to consult their resident clinical expert or physician in the setting where the test was performed. End users should alert the recipient of the results obtained with the affect devices of this field safety notice.

END USER/CUSTOMER/ REQUIRED ACTION

- **Discontinue the use of all PSA Strip; PSA Device; PSA Device – single unit packaged with unitized buffer, lancet, product insert; PSA Uncut Sheet – semi-finished product component and PSA Device – Ultra-Sensitivity distributed under the brands of ACON, On-Call, Quik-Check, Innovacon and InstAlert.**
- **Discard in accordance with your local regulations all PSA Strip; PSA Device; PSA Device – single unit packaged with unitized buffer, lancet, product insert; PSA Uncut Sheet – semi-finished product component and PSA Device – Ultra-Sensitivity distributed under the brands of ACON, On-Call, Quik-Check, Innovacon and InstAlert.**
- **Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice and to indicate the number of devices discarded from your inventory.**
- **Contact your sales representative regarding reimbursement, *if applicable.***

We sincerely regret any inconvenience this product performance issue may have caused. Please note that the relevant National Competent Authorities have been advised of this Field Safety Corrective Action.

An update regarding the re-release of the Prostate Specific Antigen (PSA) Semi-Quantitative Rapid Test (Whole Blood/Serum/Plasma) and the Prostate Specific Antigen (PSA) Semi-Quantitative Ultra Rapid Test (Whole Blood/Serum/Plasma) will be forthcoming.

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Sollten Sie Fragen zum Inhalt dieser Benachrichtigung haben, wenden Sie sich außerhalb Deutschlands bitte an:

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Mit freundlichen Grüßen

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