Urgent Safety Information

DiaSys respons®910 analyzer

- **Incorrect finding of lipase test values**

Date: August 23, 2011

Products: respons®910 analyzer Cat. No.960500

Explanation: During a trial measurement with a respons®910 analyzer in a hospital in Germany, a patient sample was measured for lipase and came up with a value of 325 U/L. This value was accepted and not flagged. Lipase was measured again on a different analyzer and found at 11.000 U/L.

A manual re-run on respons®910 with diluted sample also showed significantly increased values for lipase.

The root cause for this failure was a discrepancy in between the application settings on the analyzer and the IFU (= instructions for use). The upper technical limit (measuring range) is set to 300 U/L in the IFU, whereas this value was incorrectly set to 340 U/L in the application setting. This lead to acceptance of a value that is higher than the defined measuring range.

Impact on patient safety: If a patient is diagnosed according to clinical guidelines (e.g. according to German Academy of Medical Sciences, AWMF), there is no risk with regard to patient safety since for an adequate diagnosis a single clinical value is not sufficient. In the case described above a lipase value of 325 U/L has to be considered as pathological. Therefore the result did not lead to a false negative diagnosis. The incorrect lower value solely may lead to a misinterpretation with regard to the severity of pancreatitis.

The following measures have been taken imperatively:

(1) Correction of the application data within the software.
(2) Release of upgraded software version for respons®910 with additional bug fixes to prevent reporting of false low values and correctly flagging samples that violate absorbance limits.

Please keep this product information in your records as a reference.

DiaSys has announced this incident of failure for the respons®910 application to the relevant authorities in the European Union.

If your business is located outside of the European Union, it is within your responsibility to inform the respective competent authority with the enclosed report form according Medical Device Vigilance System (MEDDEV 2.12/1 rev 5).

Please also inform all customers who have received respons®910 analyzer/s on the current situation and the upcoming software upgrade.

We would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all relevant customers and to the competent authorities (if required). Please send it back to us by fax or as scan until **September 09, 2011**.

DiaSys apologizes for all inconveniencies caused by this and hope for your understanding.

Sincerely yours,

DiaSys Diagnostic GmbH