

RDNZ Customer Bulletin

DATE: March 25th 2008

REFERENCE: CB 08/14

Adjustment of Sensitivity Limit for Tina-quant[®] D-Dimer on Cobas c501

Current Situation:

Internal investigations have revealed that the sensitivity limits (SENS) for D-Dimer on the Cobas c501 were set too narrowly, which has resulted in flagged calibrations in rare cases. As a result, the sensitivity limit has been adjusted for all reagent and calibrator lot combinations for both Tina-quant[®] D-Dimer applications; ACN 123 (citrate) and ACN 125 (heparin).

Actions Required:

To avoid loss of all calibration and QC data by complete reinstallation of the application, the sensitivity limit can be adjusted manually according to the table below:

Sensitivity limit for D-Dimer		ACN	old	<i>new</i>
Citrate plasma	D-DI	123	31-53	32 - 115
Heparin plasma	D-DIH	125	37-68	38 - 137

Please note that manually edited parameters will not be overwritten by subsequent e-barcode updates. Only a complete re-installation would override manually edited fields.

We apologise for any inconvenience. Please contact us on Techline if you would like to discuss this further, or require any additional information. .