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Improved Repeatability of a Vitamin D Assay in Plasma Samples Obtained from Mechanical Separator Tubes

TO THE EDITOR:

Medical laboratories using the Roche Elecsys Vitamin D total II assay in plasma samples reported nonreproducible and overestimated results *(1)*. This led to an urgent field safety notice by Roche in which the company suggested examining the preanalytical handling of samples, in particular, centrifugation conditions *(2)*. Performing the Vitamin D total II assay in serum is inevitable when the issues persist in plasma samples. Roche claims that in human serum the lowest measured repeatability is 0.88 ng/mL (2.2 nmol/L), expressed as the statistical SD *(3)*.

Cobas analyzers of the e 801 series were recently installed in the clinical chemistry laboratory at VieCuri Medical Center, meaning that stepping back to the Elecsys Vitamin D total I assay was not optional. In addition, BD Barricor lithium heparin plasma tubes (mechanical separator tubes; Becton Dickinson) are used for all routine chemical and immunochemical tests, making vitamin D analysis in serum undesirable. For these reasons, we decided to perform all vitamin D analyses in duplicate in the first month after installation. In this period, a total of 2772 vitamin D duplicate measurements were performed in Barricor lithium heparin plasma (centrifugation: 10 min at 2000*g*). The average SD hereby was shown to be 0.64 ng/mL (1.6 nmol/L), independent of the vitamin D plasma concentration (5.0–100 ng/mL or 13–250 nmol/L) and clearly lower than the manufacturer's claim *(3)*.

Whether the unexpectedly low repeatability could be attributed to the quality of the plasma sample obtained by the mechanical Barricor separator as opposed to gel separation was investigated by means of a tube comparison study. Lithium heparin plasma in routine Barricor tubes was collected from 50 patients; in addition, a lithium heparin plasma separation tube (PST) with gel separation and a serum separation tube with gel separator (all obtained from BD) from the same patients were used. The vitamin D concentration in all tubes was measured in duplicate with a Cobas e 801 analyzer using Elecsys Vitamin D total II reagent. Figure 1 represents the plot showing the repeatability expressed as the SD in ng/mL. The average SD

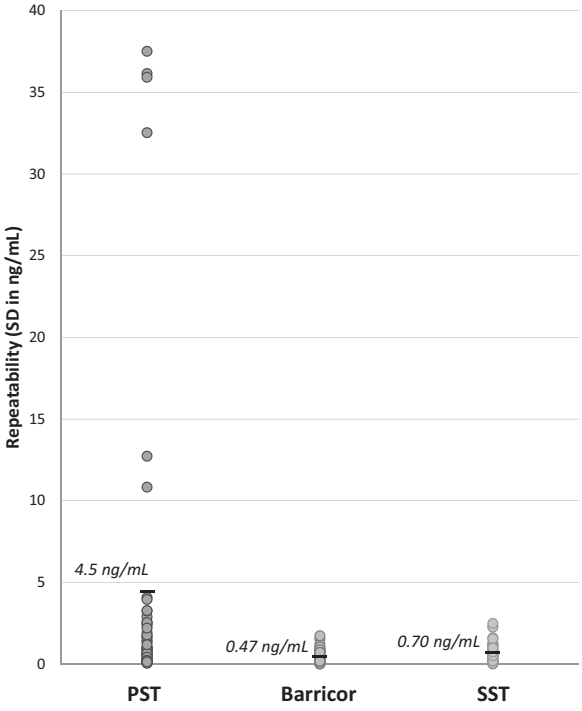

Fig. 1. Repeatability results of Elecsys Vitamin D total II measurements for samples collected from 50 patients using lithium heparin plasma gel tubes (PST), lithium heparin BD Barricor tubes, and serum gel tubes (SST). The average SDs per tube type are indicated by a line and annotated. PST, plasma separation tube; SST, serum separation tube.

calculated from the measurements in PST plasma (4.5 ng/L) clearly exceeded the SD described in the assay insert for measurements in serum (0.88 ng/mL). The SDs calculated from measurements in Barricor plasma and serum are 0.47 and 0.70 ng/mL, respectively—both well below the manufacturer's claim.

In conclusion, as stated in Roche's field safety notice, the preanalytical issues leading to nonreproducible and overestimated results of vitamin D seem to occur in plasma samples only *(1)*. The results described above show clear differences between duplicate measurements in lithium heparin plasma obtained with a gel separator and are in line with this statement. The experiments confirm that serum samples are not affected but also that duplicate measurements in Barricor plasma do follow the same trend. Based on this conclusion, the Elecsys Vitamin D total II assay is suitable for routine measurements in lithium heparin plasma obtained from Barricor tubes without additional sample preparation steps or duplicate measurements.

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