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Capillary Blood Compared to Venous Blood for Use with the Vitamin D Total II Assay on the Atellica IM Analyzer

A. Palladino,[1] B. Czap,[1] N. Carmosino,[1] J. Freeman,[1] C. DiPasquale,[2] E. G. Olson,[2] R. Barr,[2]
H. McKenzie,[2] J. W. Jacobson[2]
[1]Siemens Healthcare Diagnostics Inc., Tarrytown, NY, USA; [2]Babson Diagnostics, Inc., Austin, TX, USA

Background

Capillary blood collection is a convenient, less invasive alternative to venipuncture used in a wide range of clinical and ambulatory settings. Capillary blood produces accurate diagnostic results from small sample volumes and facilitates both point-of-care and core laboratory testing. It is an asset for testing geriatric and pediatric populations, as well as those with difficult venous access. The first study compared test results from adult capillary and venous serum using the Vitamin D Total II (VitDII) assay[1] on the Atellica IM Analyzer; the second study established capillary sample stability for the assay.

Material and Methods

Study Population

- Two IRB-approved clinical studies were performed at the Babson Diagnostics site with ambulatory adult subjects enrolled with informed consent.

Specimen equivalence

- The specimen equivalence study was designed according to CLSI EP35.[2] One hundred eighteen (118) matched set samples were collected: venous serum using Vacutainer SST (comparator) and capillary serum using Microtainer SST. A total of 108 native matched sets were assayed, and 10 contrived matched sets spiked with 25(OH)D_3 stock for concentrations across the measuring interval. Of the 118 sets, final analysis was performed on 113 due to loss of replicates including failed venipuncture attempts. Samples were collected on a rolling basis and assayed in duplicate within 4 hours (hr) of collection using one reagent lot on one Atellica IM Analyzer.
- Data were analyzed by Weighted Deming fit regression of the venous comparator (X-axis) versus capillary (Y-axis) samples, utilizing the first replicate from each sample to estimate slope, intercept, and correlation (r) for each parameter.

Repeatability

- Relative repeatability was estimated by pooled SD ratio with 95% Confidence Interval (95% CI).

Capillary sample stability

- For room temperature (20–25°C) sample stability, blood was drawn from a total of seven patients, with five patient sets used as native and two patient sample sets were contrived (spiked with 25(OH) VitD_3) to cover the assay range. A fresh microtainer was run at each of the following time-points: 0 hr, 4 hr, 8 hr, 24 hr. Samples were assayed in five replicates per time point on one Atellica IM Analyzer utilizing one lot of VitDII reagents. A single on-board calibration was used for the duration of the study. Quality control material in each run as defined on system.
- For refrigerated (2–8°C) sample stability, blood was drawn from a total of nine patients, with seven patient sets used as native and two patient sample sets were contrived (spiked with 25(OH) VitD_3) to cover the assay range. Samples were stored at 2–8°C until use. A fresh microtainer was run at each of the following time-points: 0 hr, 24 hr, 48 hr, 72 hr. Samples were assayed in four replicates per time point on one Atellica IM Analyzer utilizing one Lot of VitDII reagents. A single on-board calibration was used for the duration of the study. Quality control material in each run as defined on system.
- Aggregate sample stability was determined using trend analysis, with allowable drift of ≤10.0% concentration change, or absolute bias ≤3.20 ng/mL, whichever was greater. At each time-point, the mean dose recovery of each sample was compared to the fresh (0 hr) mean. The % of acceptance criteria was calculated for each sample by dividing the dose difference by each sample's allowable drift (either 10% or ±3.2 ng/mL from 0 hr mean; whichever was greater) for a percent 0–100. The aggregate performance was then determined by the average of all samples' % acceptance criteria at each time point. % acceptance criteria was then analyzed by trend analysis using Minitab 21 regression modelling, and the 95% CI for stability determined.

Results

Specimen Equivalency

Specimen equivalency of capillary versus venous serum (n=113) yielded the following equation: y=1.01x+0.10 (ng/mL) [y=1.01x+0.25 (nmol/L)] at a sample interval of 5.36–117.87 (ng/mL) [13.40–294.68 (nmol/L)], r=0.992, fulfilling requirements. Slope 95% CI was 0.97–1.06 and y-intercept 95% CI was -0.74–0.94 ng/mL [-1.85–2.35 nmol/L].

Table 1. Specimen equivalency of capillary versus venous serum for the Atellica IM VitDII assay.

Platform	Specimen Type	n	Slope	Slope 95% CI	Intercept	Intercept (95% CI)	r	Sample Interval
Atellica IM	Capillary SST (Gel-Barrier)	113	1.01	0.97–1.06	0.10 ng/mL (0.25 nmol/L)	-0.74-0.94 ng/mL (-1.85–2.35 nmol/L)	0.992	5.36–117.87 ng/mL (13.40–294.68 nmol/L)

[n]number of samples; [r]correlation coefficient.

The design requirements for specimen equivalency were met for capillary versus venous samples for the VitDII assay on the Atellica IM Analyzer. When analyzed by Weighted Deming regression, the capillary serum samples on the Atellica IM Analyzer recovered samples spanning the measuring interval, with a slope of 1.00±0.10, intercept ±3.20 ng/mL and a correlation coefficient (r) ≥0.950 compared to venous serum samples on the Atellica IM Analyzer.

Weighted Deming fit and percent difference plots on the Atellica IM Analyzer for the sample interval indicated in Table 1 are shown in Figure 1 for capillary versus venous serum samples.

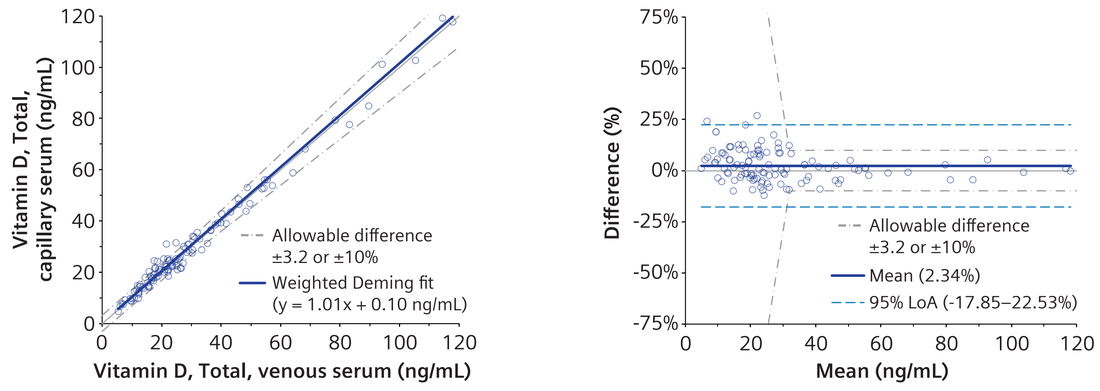


Figure 1. Weighted Deming regression and difference plot of the VitDII assay results for capillary serum compared to venous serum specimen equivalence on the Atellica IM Analyzer.

Repeatability

Full range repeatability SD was 1.818 for capillary serum and 1.681 for venous serum, with ratio 1.082, and ratio 95% CI 0.899–1.302.

Table 2. Repeatability by pooled SD ratio.

Full Range Repeatability	Variance (SD^2)	SD	n
Microtainer (MS) Capillary SST	3.306	1.818	113
Vacutainer (VSB) Venous Serum	2.826	1.681	113
Ratio (MS)/(VSB)	1.170	1.082	
Ratio 95% CI Lower Limit	0.807	0.899	
Ratio 95% CI Upper Limit	1.695	1.302	

Stability

Refrigerated (2–8°C)

Aggregate trend analysis of 2–8°C sample stability by % of acceptance criteria and time (hr) shows capillary sample stability of 75.6 hr.

With the latest time-point tested being 72 hr. Capillary sample stability at 2–8°C is set at 72 hr.

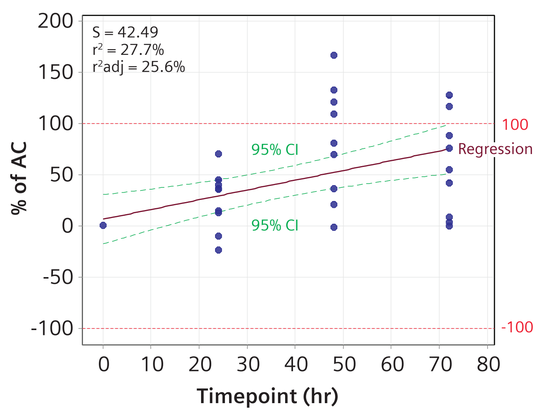


Figure 2. Aggregate trend analysis of 2–8°C sample stability by % of acceptance criteria (% of AC) and time (hr).

Room temperature (20–25°C)

Aggregate trend analysis of 20–25°C sample stability by % of acceptance criteria and time (hr) shows capillary sample stability > 24 hr.

With the latest time-point tested being 24 hr. Capillary sample stability at 20–25°C is set at 24 hr.

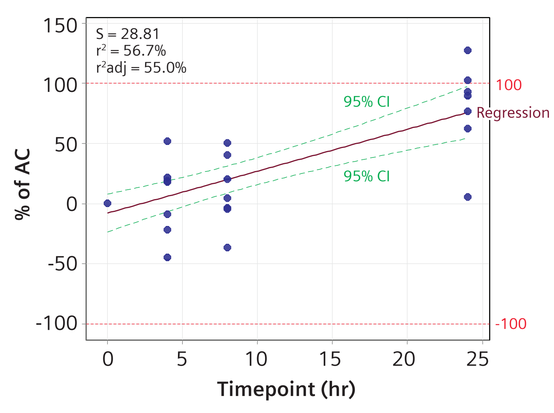


Figure 3. Aggregate trend analysis of 20–25°C sample stability by % of acceptance criteria (% of AC) and time (hr).

Vitamin D in capillary serum was stable at 2–8°C for 72 hr and at 20–25°C for 24 hr. The stability study fulfills acceptance criteria.

Conclusion

The studies verified that test results for the Atellica IM VitDII assay were equivalent between capillary and venous serum, and that vitamin D in capillary samples was stable for 72 hr at 2–8°C and 24 hr at 20–25°C.

References

1. *Vitamin DII (VitDII) assay. Atellica IM Analyzer. 11700182_EN Rev. 01, 2026-03.*
2. *CLSI. Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures. 1st ed. CLSI guideline EP35. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.*

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