Simoa® Dry Blood Extraction Kit

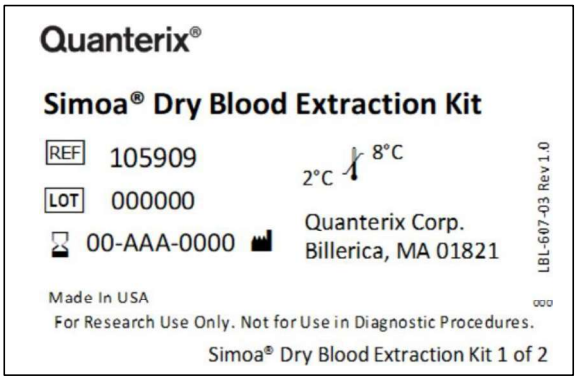
Introduction

The rapid evolution of blood-based biomarkers for disease research and therapeutic development has created an urgent need for scalable, accessible, and standardized sample collection methods. Traditional venous blood testing often requires phlebotomy support, immediate processing, and refrigerated transport, adding significant logistical complexity and cost especially for longitudinal studies, remote sampling, or large-scale clinical trials.

Dried Blood Spot (DBS) and Dried Plasma Spot (DPS) sampling offers a compelling alternative. These micro- sampling techniques enable capillary blood collection with minimal training, support ambient-temperature shipping, and eliminate the need for centrifugation or freezers.
However, challenges have persisted around analyte recovery, consistency across devices, and compatibility with high-sensitivity assay platforms.

To address this, Quanterix developed the Simoa® Dry Blood Extraction Kit, a semi-automated, harmonized solution to support DBS and DPS collection devices for extracting protein analytes to be analyzed on the Simoa platform.
Engineered for analytical rigor, this kit preserves femtogram- level sensitivity for Simoa® assays, enabling accurate detection of critical biomarkers from a single DBS collection device.

With demonstrated analytical performance and compatibility across devices, the Simoa Dry Blood Extraction Kit enables decentralized, high-resolution biomarker data generation. It is an enabling tool for investigators exploring disease progression, therapeutic response monitoring, and large-scale population health studies.



Methods

Venous whole blood was collected from 10 donors into EDTA tubes and used to prepare dried plasma spot (DPS) samples on Capitainer® and Telimmune™ collection devices. Both devices are designed to receive small volumes of whole blood, from which a plasma portion is separated onto a filter disc inside the device. Each Capitainer device was spotted with 70 µL of blood, yielding an estimated 10 µL of plasma. Each Telimmune device received 30 µL of blood per spot across two channels, yielding an estimated 3 µL plasma per channel and the two resulting filter discs were
pooled into a single well for extraction. A total of 20 samples (10 unspiked and 10 spiked) were prepared per device type, for sensitivity and precision analysis.

Spiked samples were generated by adding disease-state cerebrospinal fluid (CSF) containing elevated p-Tau 217 levels into donor blood at three target concentrations: 0.05, 0.1, and 0.2 pg/mL. The extraction protocol used was adapted from the University of Gothenburg's DROP- AD workflow, involving a semiautomated shaking and centrifugation process designed to recover low-volume plasma extracts while preserving protein integrity. All biomarker measurements were determined using the Simoa® ALZpath p-Tau 217 Advantage PLUS assay on the Simoa HD-X Analyzer®.

For precision evaluation, two devices spotted with the same blood sample were processed as biological replicates to assess inter-device reproducibility. In the unspiked and spiked sample groups, respectively, the percentage of the 10 sets of replicates with %CV values <20% was reported for each device type. Sensitivity was determined by the proportion of samples exceeding the assay's lower limit of detection (LOD) and lower limit of quantification (LLOQ). All results reported for the Capitainer and Telimmune devices were generated using spotted venous blood. While this mimics capillary-based workflows, additional validation using fingerstick-collected samples may further support the use of the Simoa Dry Blood Extraction kit with DBS/DPS samples collected in remote and at-home settings.

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Results

Sensitivity

The Simoa Dry Blood Extraction Kit demonstrates robust sensitivity and analytical precision in recovering low- abundance biomarkers from dry blood spot matrices using minimal sample volumes. Performance was evaluated across two commercially available collection devices: Capitainer® and Telimmune™, on the measurement of p-Tau 217 using both endogenous and spiked samples.

To evaluate recovery and quantification at biologically relevant levels, venous blood samples were spiked with CSF containing high p-Tau 217 levels at concentrations of 0.05, 0.1, and 0.2 pg/mL, mimicking disease-relevant conditions.

Detectability refers to samples with signals above the assay's LOD, while quantifiability indicates concentrations above the LLOQ for the Simoa® p-Tau 217 Advantage Plus assay

With the Capitainer device, 95% and 79% of non-spiked samples were measured with values above LOD and LLOQ, respectively. When samples were spiked with CSF, 100% were above LLOQ, confirming the kit's ability to detect biologically meaningful concentrations at femtogram levels even in matrix-limited conditions.

While the Telimmune device yields lower plasma volumes (~3 µL per filter disc or ~6 µL per device), the system still showed strong performance relative to its constraints, with lower detectability likely attributed to inherent sample volume limitations and device variability. These findings highlight the need for researchers to consider differences across collection devices and underscore the kit's flexibility and capability in supporting different collection platforms.

Precision

Precision was assessed through inter-device replicate analysis, simulating real-world biological replications by processing matched filter discs from independently spotted devices. In unspiked conditions, 50% of Capitainer- derived samples demonstrated inter-filter coefficients of variation (CVs) below 20%. This level of variability is not unexpected due to the proximity of endogenous p-Tau 217 concentrations to the assay LLOQ. Importantly, with spiked samples, where analyte concentrations were raised into the mid-analytical range, 89% of samples met the <20% CV threshold, confirming the ability of reproducible quantification when analyte levels are above the digital detection boundary.

Variability observed in the remaining samples can be attributable to both low input volume and potential inconsistencies in plasma separation efficiency across devices. Nevertheless, with spiked samples, measurements of p-Tau 217 from venous blood samples and DBS samples are highly correlated across for both devices, suggesting that the extraction protocol is reliable and reproducible when used under analytically relevant conditions.

Table 1. Analytical Sensitivity and Precision for DBS Extraction Across Two Collection Devices.

This table summarizes the detectability and inter-device precision performance for the Simoa Dry Blood Extraction Kit using Capitainer® and Telimmune™ devices, with and without spiked disease-state CSF. Performance is reported as the percentage of samples with concentration above LOD and LLOQ and the proportion of samples with inter-device %CV <20%, demonstrating strong detectability and reproducibility under constrained sample volumes.

	No Spike		CSF Spike	
Capitainer	Sensitivity	15/19 filters > LLOQ [79% detectability] 18/19 filters > LOD [95% detectability]	Sensitivity	19/19 filters > LLOQ [100% detectability]
	Precision	50% filters - filter-to-filter %CV < 20%	Precision	89% filters - filter-to-filter %CV < 20%
			%Recovery	Average %Recovery - 55%
Telimmune	Sensitivity	12/20 filters > LLOQ [60% detectability] 17/20 filters > LOD [85% detectability]	Sensitivity	19/19 filters > LLOQ [100% detectability]
	Precision	43% filters - filter-to-filter %CV < 20%	Precision	89% filters - filter-to-filter %CV < 20%
			%Recovery	Average %Recovery - 21%

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Figure 1. Venous vs. Capitainer Correlation with Spiked Samples

This figure illustrates the linear correlation between p-Tau 217 concentrations measured in spiked venous plasma samples and matching DBS-extracted plasma samples using Capitainer®. The strong agreement (R^2 > 0.85) confirms the extraction protocol's accuracy and supports its use in decentralized sampling workflows.

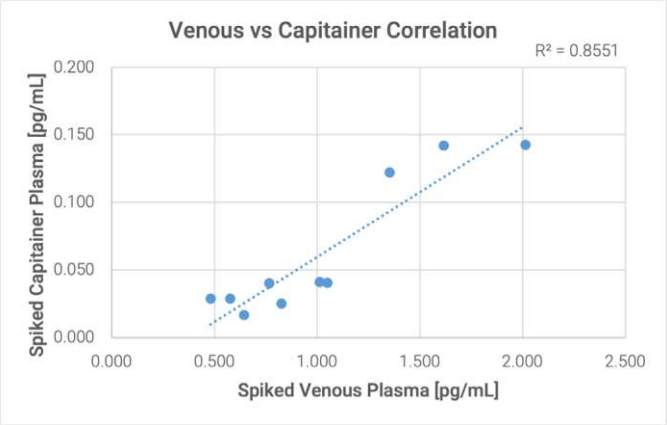
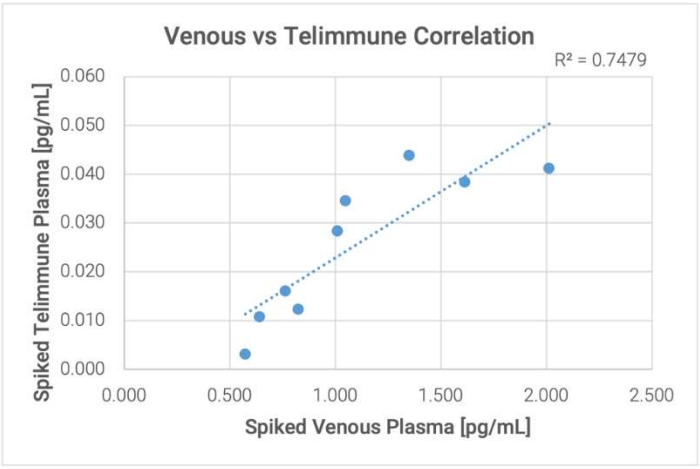


Figure 2. Venous vs. Telimmune Correlation with Spiked Samples

This figure shows the relationship between p-Tau 217 concentrations measured in spiked venous plasma samples and matching DBS-extracted plasma samples using Telimmune™. While slightly lower than Capitainer®, the correlation supports the use of Telimmune™ for research applications when adjusted for volume-related constraints.



*Note: Figures 1 & 2 display a subset of the samples shown in Table 1. Full datasets for precision are reported in Table 1.

Conclusion and Suggested Use

The Simoa Dry Blood Extraction Kit provides a verified, research-use-only (RUO) solution for extracting analytes from capillary-derived dried blood and plasma samples with demonstrated compatibility across multiple collection devices. The kit enables the detection of ultra-low levels of biomarkers using Simoa® technology, with robust detectability even at femtogram-level concentrations.

Performance data confirms strong device-to-device precision and high detectability rates for both endogenous and spiked samples. For example, using the Capitainer® device, 95% of non-spiked samples showed signal above the assay's limit of detection (LOD), and 100% of spiked samples exceeded the lower limit of quantification (LLOQ), supporting excellent analytical sensitivity. Precision was acceptable even in low-volume extracts (10 µL for Capitainer®; ~6 µL for Telimmune™), with 89% of spiked samples showing inter-filter CV% <20%. Differences in performance between devices were attributed primarily to sample volume differences and proprietary device manufacturing characteristics, further highlighting the need for a device- agnostic extraction solution.

Correlation analysis between venous plasma and DBS- extracted samples revealed strong agreement (R^2 = 0.85 for Capitainer), reinforcing the kit's suitability for decentralized collection in research studies where traditional phlebotomy, cold chain logistics, or laboratory infrastructure are limiting.

Finally, this kit achieves reliable performance from as little as 6-10 µL of plasma, well below standard venous draw volumes, expanding its utility for low-volume applications and vulnerable populations.

For guidance on assay performance or protocol design, contact TechSupport@Quanterix.com.

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