

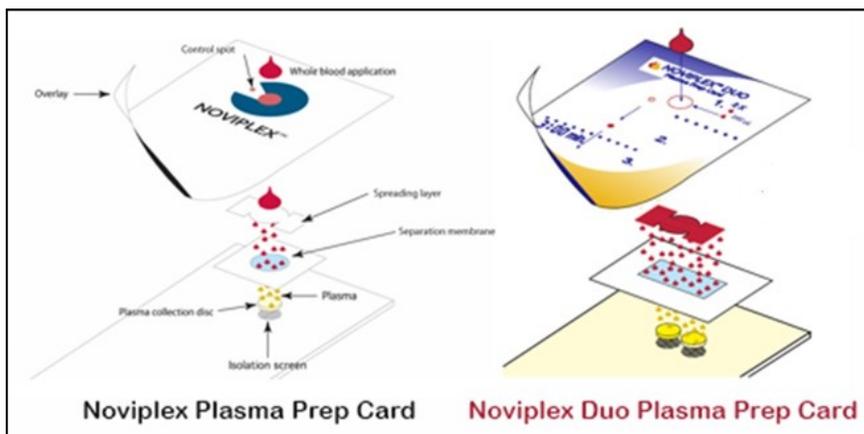
The Evaluation of Noviplex Plasma Prep Cards for Regulated Bioanalysis

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Presented at the 2016 AAPS Annual Meeting, Denver, CO

The purpose of this work is to determine if the Noviplex plasma prep cards produce the precision required to perform regulated bioanalysis. Sample collection cards are ideal for use in remote regions and when sample volume is limited such as during pediatric studies. Unlike dried blood spot cards, with Noviplex, plasma is extracted so there are no hematocrit effects, samples are more stable, and data is comparable with methods that use conventional plasma collection procedures.

Human whole blood was spiked with Indomethacin at three concentrations; 9.00, 70.0 and 1,200 ng/mL. Two different types of Noviplex cards at n=6 were then spotted with the whole blood: the original Noviplex (40 μ L blood volume per card) and the Noviplex DUO (60 μ L blood volume per card). Once spotted the cards were allowed to dry for at least 15 minutes. The cards are designed to remove red blood cells from whole blood using capillary action to pull the matrix through the card. The resulting plasma spreads out onto the plasma discs and dries. The plasma is split onto two separate plasma discs when the blood is processed on the DUO cards.



The plasma discs were then placed into a 96 DWP and extracted with methanol. The extracts were analyzed on an ABSciex 5500® QTRAP coupled with a Shimadzu HPLC system with a flowrate of 0.7 μ L/min. The column used for the binary gradient analysis was a Supelco HSC18 heated to 50°C (3 μ m, 50 mm X 2.1 mm). The data collected from the extracts was quantified against a calibration curve extracted from plasma with a dynamic range of 1-1500 ng/mL.

The data indicates that the plasma aliquot dried onto the disc, extracted and analyzed resulted in a CV that exceeds GLP specifications. The CV at 9.00, 70.0, and 1200 ng/mL was found to be 11.6, 7.4 and 5.8 respectively. The low concentration of 9.00 ng/mL accuracy was found to

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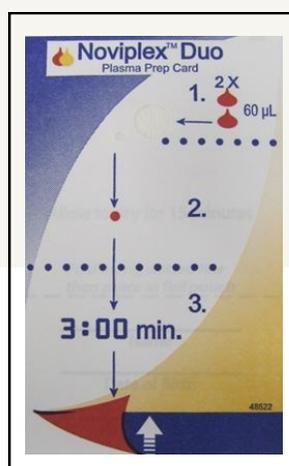
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be 27.8% bias from nominal which indicated that direct quantitation from a standard curve prepared from plasma will not provide the required accuracy at the lower limits of quantitation.

However, there is acceptable accuracy and precision at the LQC when both DUO collection discs are used. The standard curve must also be prepared on the cards in order to compensate for the difference in extraction efficiency or matrix effects that may be occurring at the lower concentrations.

The data generated from the Noviplex DUO card by extracting the left and right plasma spot separately indicates that the plasma distribution between the two spots are equivalent. The percent difference between the left and right spot for the 9.00, 70.0, and 1200 ng/mL was found to be 0.9%, 5.3%, and 0.6% respectively.

The Noviplex plasma prep cards provide precise plasma spot data that when extracted and analyzed may be used for regulated bioanalysis.

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