

Evaluation of Genomic DNA Purification from Human Whole Blood using the Maxwell[®] CSC Automated Nucleic Acid Extraction System and Maxwell[®] CSC Blood Reagents

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1. Introduction

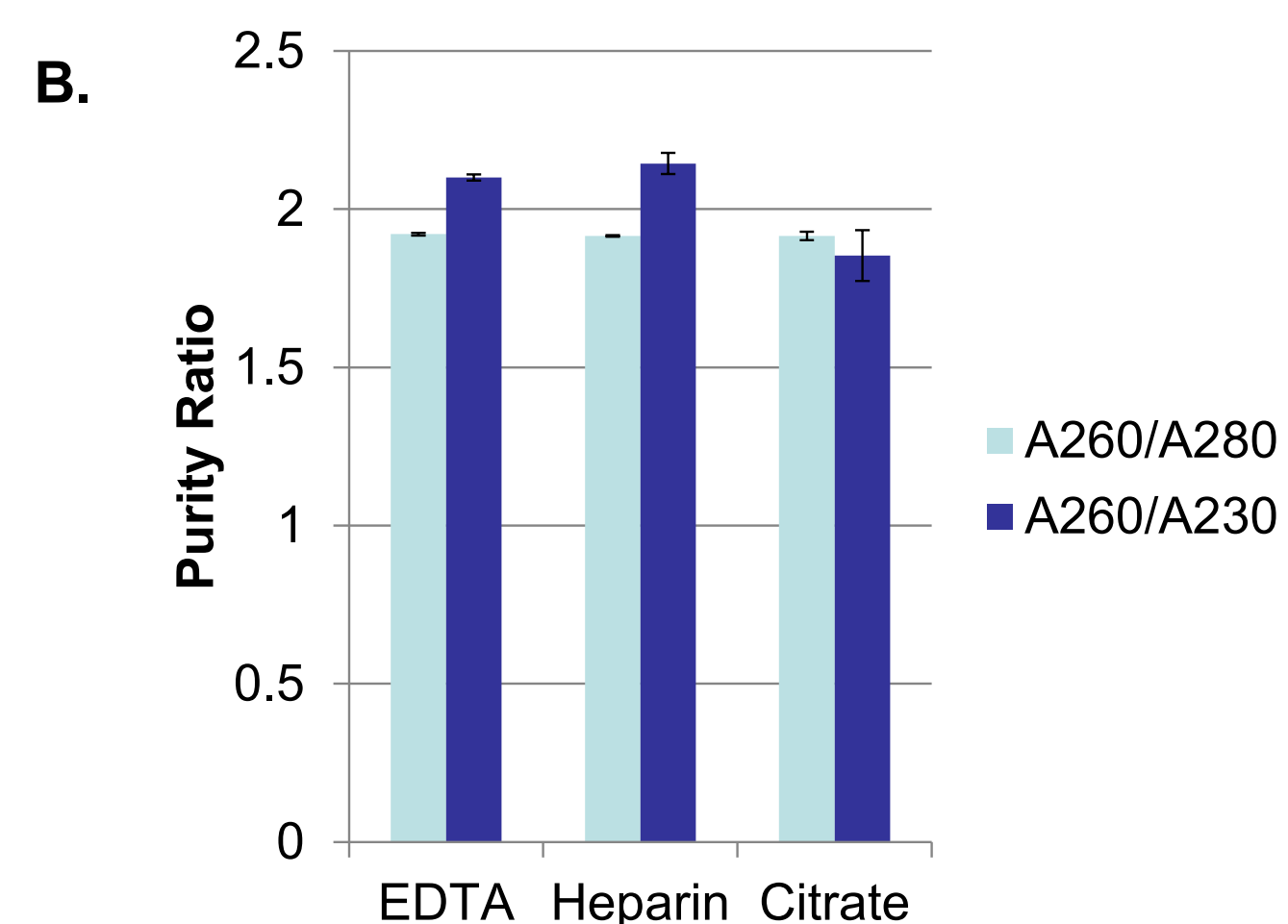
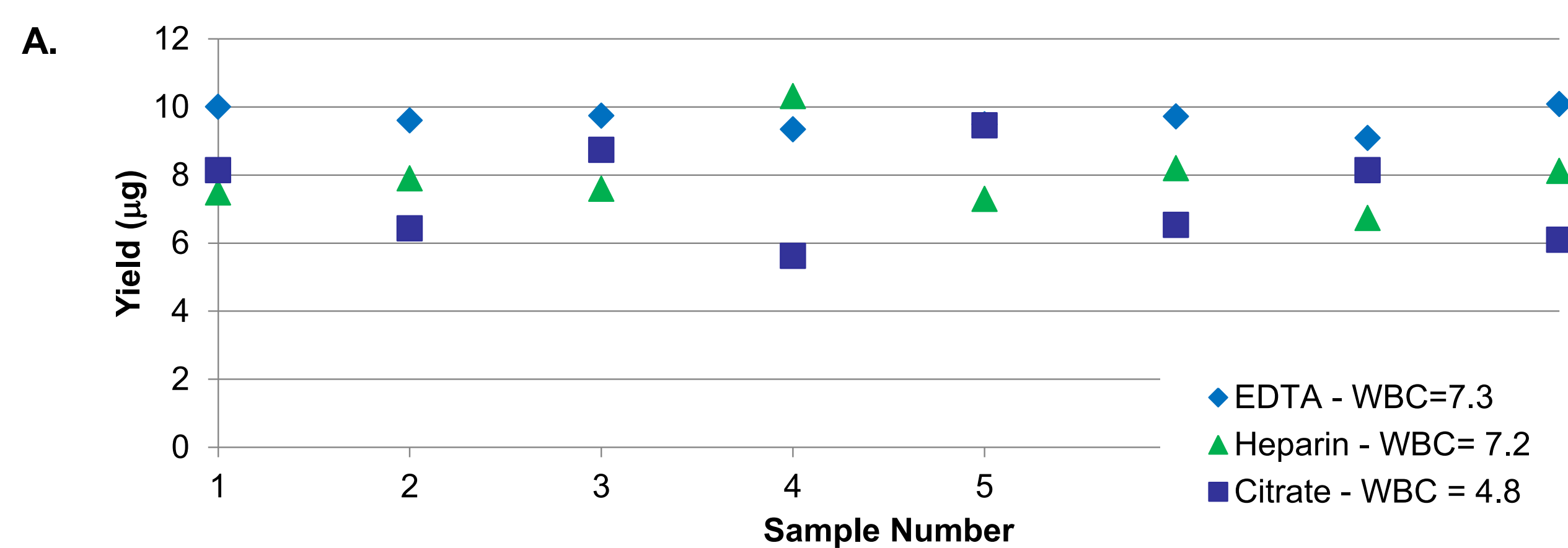
The Maxwell[®] CSC Blood DNA kit is Promega's first cGMP-manufactured nucleic acid purification kit developed for use with the Maxwell[®] CSC instrument specifically for the clinical diagnostic market. This product is only available in the US and is intended for in vitro diagnostic use as a clinical sample concentrator.

Based on Promega's proprietary Maxwell[®] 16 technology, the new Maxwell[®] CSC Blood DNA Kit has undergone extensive testing for functionality, reliability, reproducibility, cross-contamination, and amplification inhibitor carryover as part of its development. This product was designed to ensure reproducible, reliable performance with no cross-contamination introduced during processing. While the Maxwell[®] CSC Blood DNA kit is our first offering for the new Maxwell[®] CSC Instrument, we are currently working on additional nucleic acid extraction systems specifically designed to address the needs of the clinical laboratory.

Extensive design testing of the Maxwell[®] CSC Blood DNA Kit was performed in combination with the Maxwell[®] CSC Instrument. Typical results obtained from 300µl whole blood samples (WBC counts between 4x10⁶ and 10x10⁶ WBC/ml) eluted in 50µl showed nucleic acid concentrations ranging from 150ng/µl to 400ng/µl and purities in the range A₂₆₀/A₂₈₀ from 1.85-1.95 and A₂₆₀/A₂₃₀ from 1.9-2.2. These results demonstrate the superior performance of this chemistry with whole blood samples and provide assurance of the results you can obtain with this system when it is used in your laboratory.

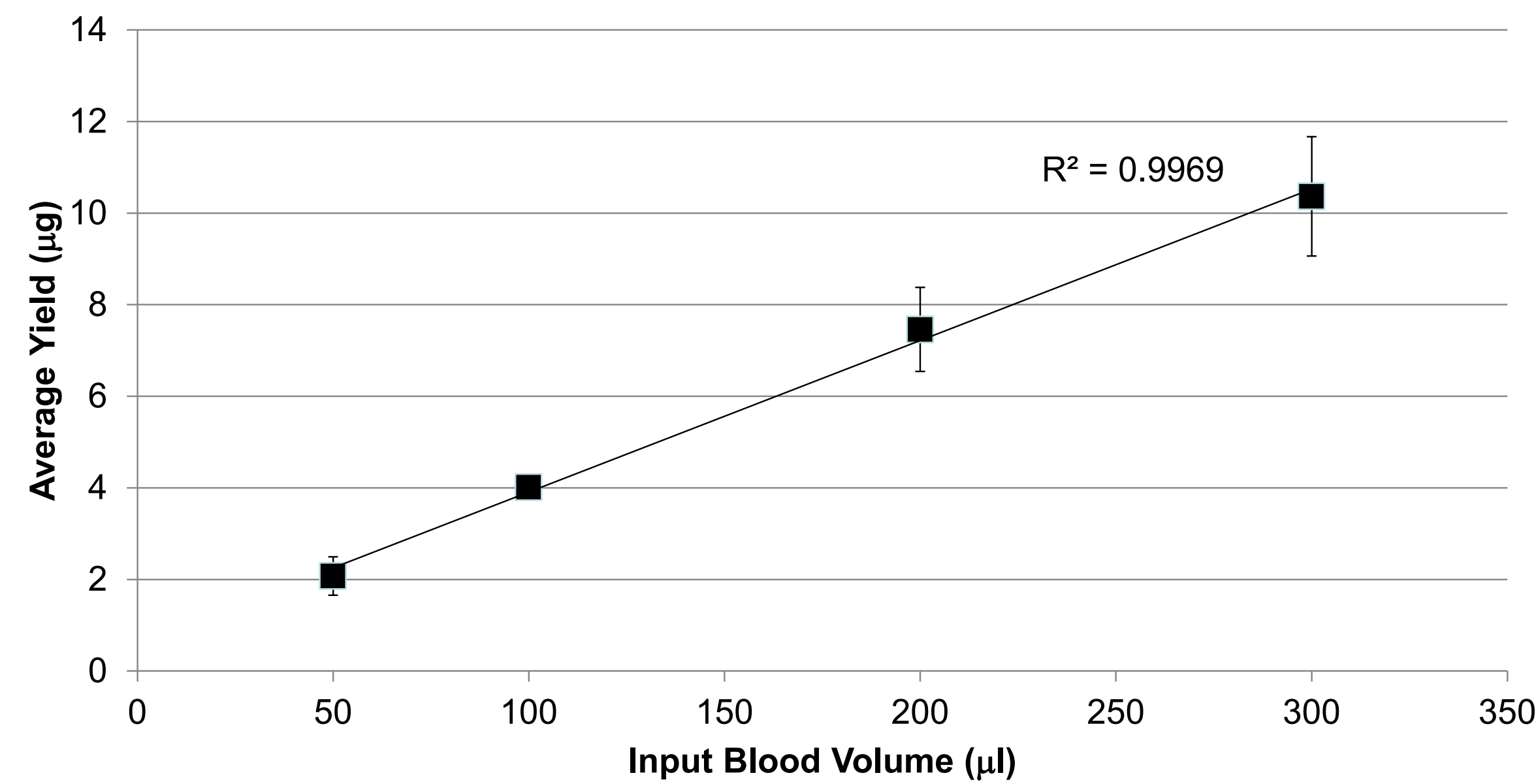
In this poster we describe a portion of the design verification and validation of this new system.

2. Anticoagulant type testing



Eight 300µl replicates from three single donors collected in three common anticoagulant tube types were processed using the Maxwell[®] CSC Blood DNA Kit on the Maxwell[®] CSC instrument. Yields for each purification are shown in panel A along with the white blood cell count for each anticoagulant tube type. Panel B displays the average A₂₆₀/A₂₈₀ and A₂₆₀/A₂₃₀ purity values for each of these sample sets.

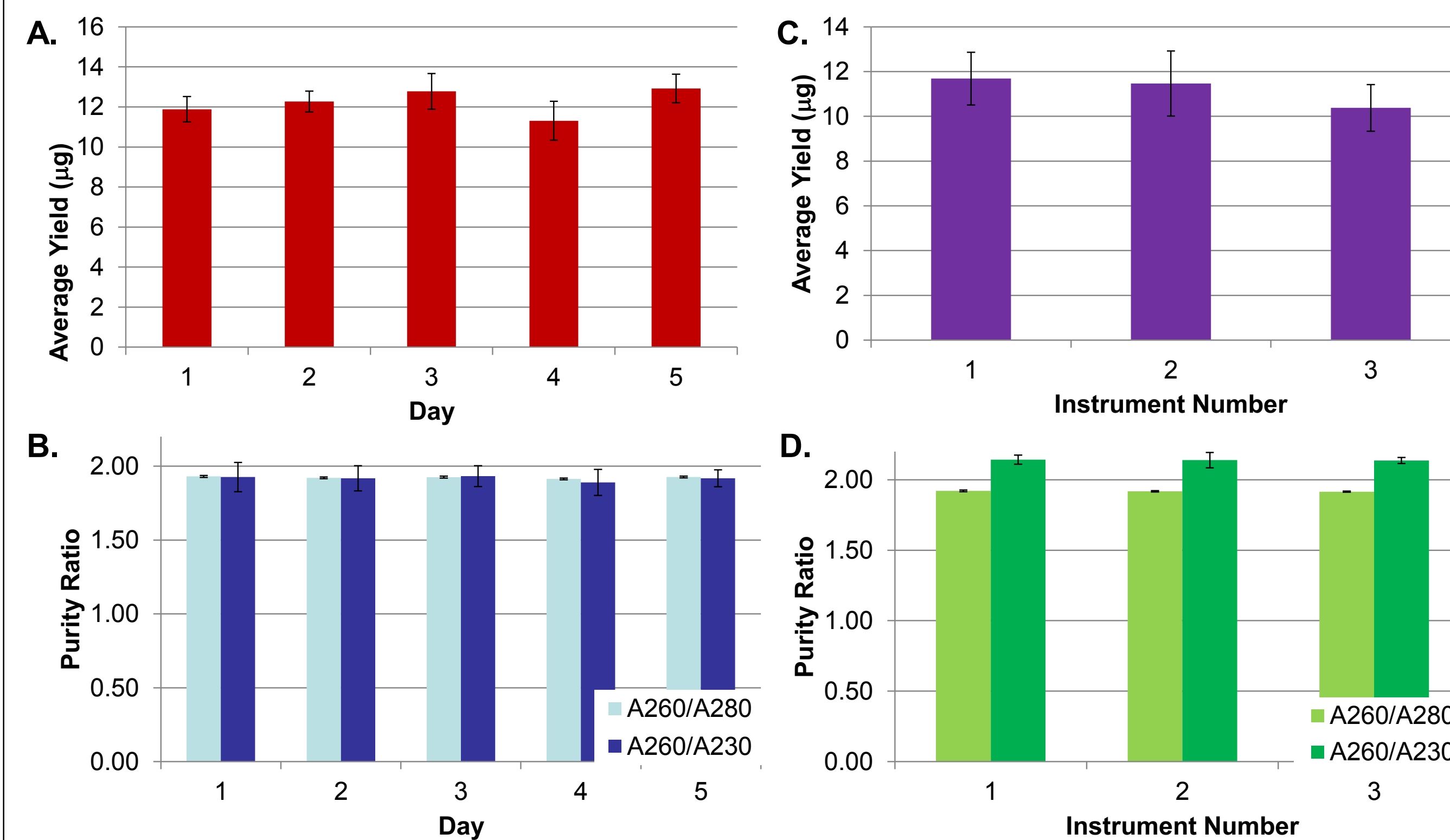
3. Sample volume and storage



A range of input blood volumes from 50µl to 300µl was tested with the Maxwell[®] CSC Blood DNA kit. Shown here are the average yields plotted against the input blood volume indicating the linearity of the purification across a range of input blood volumes. Blood frozen at -80°C was used for this purification.

Purification performance for blood samples stored under a variety of conditions was also tested during development. Blood was stored for up to 72 hours at room temperature, up to 7 days at 4°C, or frozen at -80°C and then processed. Results demonstrated that blood stored under any of these conditions produced comparable yields and purities when processed with the Maxwell[®] CSC Blood DNA kit (Data not shown).

4. Consistent performance



Consistency testing of the Maxwell[®] CSC Blood DNA kit. Panels A and B show replicate DNA purifications from the same human blood sample (300µl blood frozen at -80°C) on multiple days. Panels C and D show replicate DNA purifications from the same human blood sample (300µl sample frozen at -80°C) using three different Maxwell[®] CSC instruments. Both experiments show yield and purity is consistent across instruments and across multiple days.

5. Cross-contamination testing

Sample ID	C _t Value	Sample ID	C _t Value
Sample 1	23.3	Sample 5	24.0
Blank 1	No C _t	Blank 5	No C _t
Sample 2	23.9	Sample 6	23.9
Blank 2	No C _t	Blank 6	No C _t
Sample 3	24.2	Sample 7	24.2
Blank 3	No C _t	Blank 7	No C _t
Sample 4	23.6	Sample 8	23.7
Blank 4	No C _t	Blank 8	No C _t

Cross-contamination was assessed by processing cartridges containing alternating water and blood samples on the Maxwell[®] CSC Instrument and analyzing the eluates for human DNA using a real-time PCR method, which provides extremely sensitive quantitation of human genomic DNA in the pg range. Analysis of the eluates showed no human genomic DNA contamination of the eluates from the water samples occurred during processing on the Maxwell[®] CSC instrument.

6. Summary

Extensive testing of the Maxwell[®] CSC Blood DNA kit in combination with the Maxwell[®] CSC Instrument was performed during design and development. Blood from multiple donors, different anticoagulant tubes, and sample storage conditions was evaluated, as well as multiple lots of reagents.

Typical results obtained during testing with 300µl whole blood samples (WBC counts between 4x10⁶ and 10x10⁶ WBC/ml) and 50µl elution showed:

- Concentrations: 150ng/µl to 350ng/µl
- A₂₆₀/A₂₈₀: 1.85-1.95
- A₂₆₀/A₂₃₀: 1.90-2.20

These results demonstrate the superior performance of this chemistry with whole blood samples and provide assurance of the results you can obtain with this system when it is used in your laboratory.

Many additional experiments (not shown here) were performed during design and development of the Maxwell[®] CSC system. Data from these experiments confirm the robust, reproducible, consistent and reliable nature of both the Maxwell[®] CSC instrument and the Maxwell[®] CSC Blood DNA chemistry.