

Maxwell® CSC: cGMP-Compliant Automated DNA Extraction from Blood

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Presentation Agenda

- Maxwell® CSC Instrument/Kit Introduction
- Workflow/Interface
- Design Verification/Design Validation data

Maxwell CSC – Nucleic Acid Extraction for IVD use



This product is only available in the USA and is intended for in vitro diagnostic use.

Maxwell® CSC Instrument



- Manufactured under cGMP
- Clinical Sample Concentrator / IVD Medical Device
- IQ / OQ available
- Windows 7 Software: WiFi Capable / Data Ready

Maxwell[®] CSC Features



- New instrument design
- Improved consistency
- Integrated barcode reader
- UV light for sanitization
- Easy-to-use touchscreen interface
- 21 CFR Part 11 compliant software
- Advanced administrator-level options
- Method import – no need to revalidate existing methods



Maxwell® CSC Blood DNA Kit



Promega Maxwell® CSC Reagent Kits are ...



- Designed specifically for in vitro diagnostic (IVD) use
- Designed specifically to use with Maxwell® CSC instrument
- Manufactured under cGMP
- Expiration dated at kit and component level



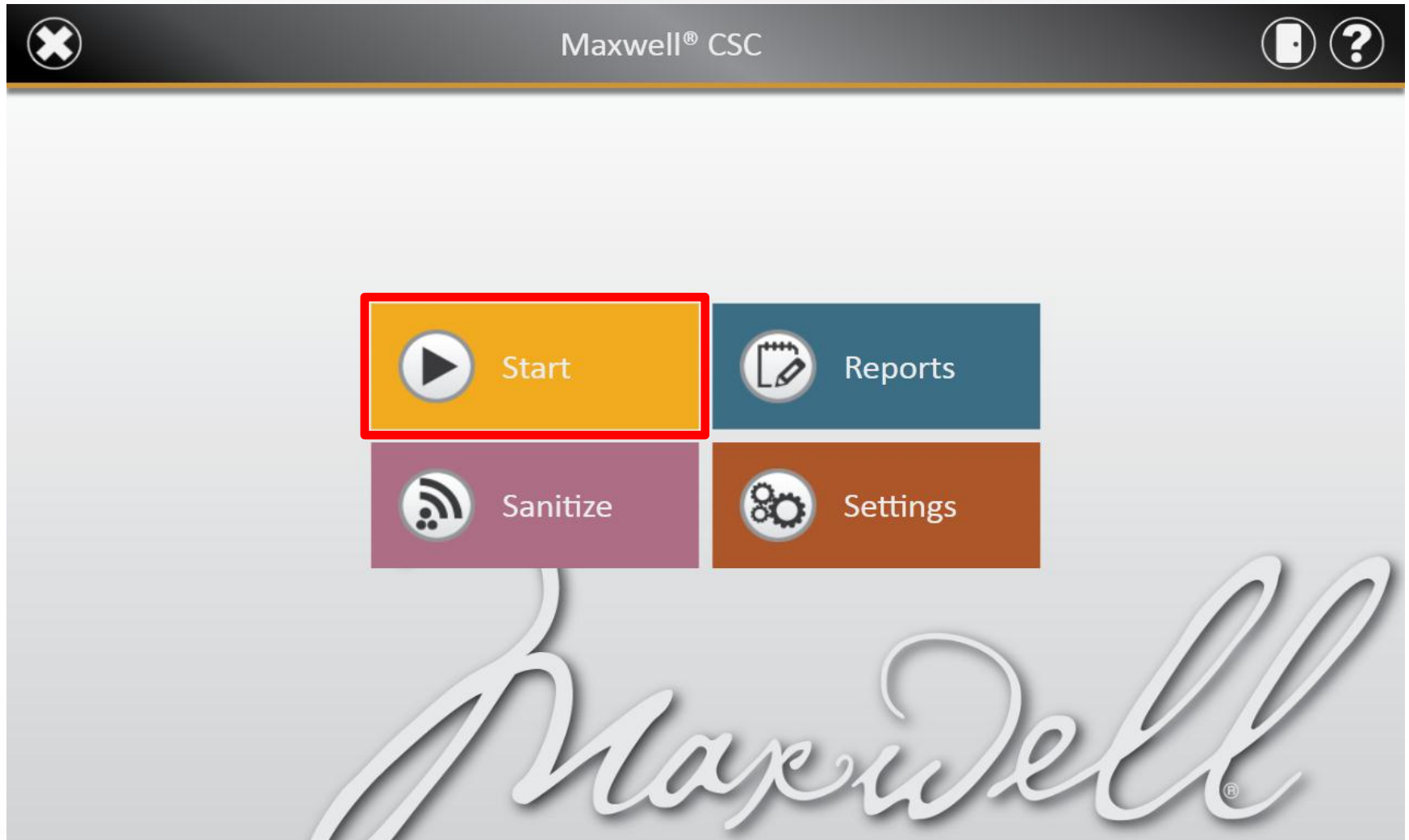
Extensive Testing:

- Reproducibility/repeatability
- Sample types/storage conditions
- PCR inhibition
- Cross-contamination

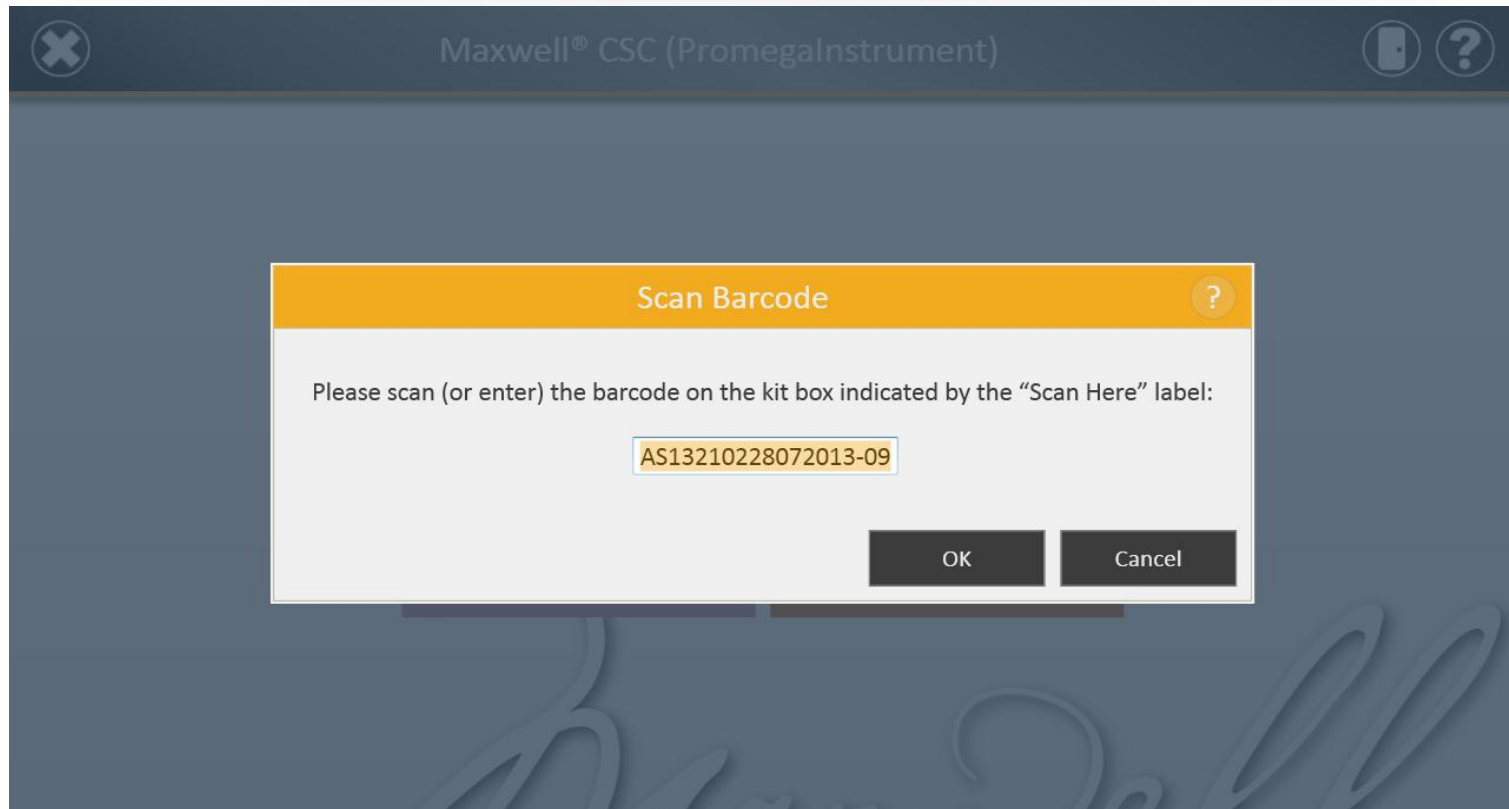
Workflow/Interface



Easy-to-use Graphical Touchscreen Interface



Method Selection Tied to Kit Barcode



- Scanned barcode selects method to run
- Kit lot number is included for traceability
- Checks kit expiration date

Sample Tracking



Cartridge Setup - Blood

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Sample 1, 021053	Sample 2, 021053	Sample 3, 021053		Sample 5, 021053	Sample 6, 021053		Sample 8, 021053	Sample 9, 021053		Sample 11, 021053	Sample 12, 021053		Sample 14, 021053	Sample 15, 021053	Sample 16, 021053

← Sample ID Kit Lot Number Cartridge ID Elution Tube ID Custom1 Custom2 →




Sample 9 021053

Proceed

- Select cartridge positions
- Sample ID required for all cartridges
- Multiple Kit Lots allowed*
- Administrator can choose additional fields
- All required fields must be entered

User confirmation of instrument setup




Cartridge Setup - Blood

Sample 1, 022807

1

Sample 16, 022807

16

Extraction Checklist

Confirm

Sample pre-processing is complete as per the Blood Technical Manual

Confirm

Deck tray has been prepared as follows and placed in the instrument:

- Cartridges with seals completely removed placed at positions 1-3,5,6,8,9,11,12,14-16
- Elution tubes placed at positions 1-3,5,6,8,9,11,12,14-16
- Appropriate volume of elution reagent has been added to each elution tube
- Plunger has been placed in well 8 of each cartridge

Confirm

Plungers are not present on instrument plunger bar

Start

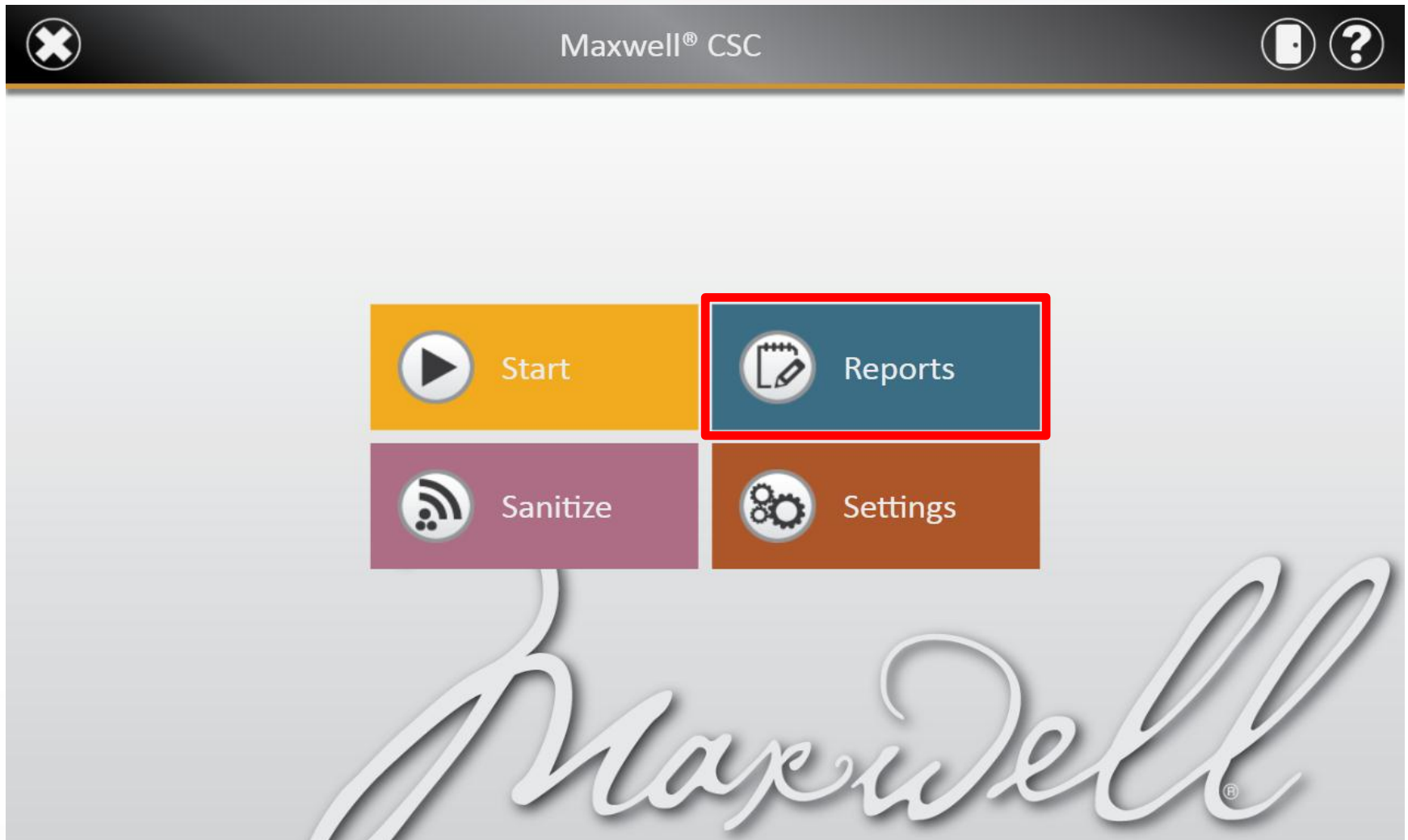
Cancel

Touch a number to enter lot specific information for a processing position

Touch multiple numbers to enter lot specific information common to multiple positions

Proceed

Database of run reports



Retrieve run reports



80 Reports					
Today	Date/Time ▼	Name	Type	By	
This Week	9/29/2012 9:45:54 AM	SelfTest	System	Promega-Maxwell\P...	View
This Month	9/27/2012 10:57:57 AM	SelfTest	System	Promega-Maxwell\P...	View
3 Months	9/26/2012 8:59:23 AM	...	Extraction	Promega-Maxwell\P...	View
6 Months	9/19/2012 1:41:35 PM	...	Extraction	Promega-Maxwell\P...	View
This Year	9/18/2012 2:51:15 PM	...	Extraction	Promega-Maxwell\P...	View
All	9/17/2012 11:48:55 AM	...	Extraction	Promega-Maxwell\P...	View
	9/17/2012 11:14:14 AM	...	Extraction	Promega-Maxwell\P...	View
	9/17/2012 8:32:57 AM	SelfTest	System	Promega-Maxwell\P...	View
	9/13/2012 6:24:50 PM	CleanUp	System	Promega-Maxwell\P...	View
	9/13/2012 6:14:25 PM	SelfTest	System	Promega-Maxwell\P...	View
	8/30/2012 8:44:17 AM	❗ Blood	Extraction	Promega-Maxwell\P...	View
Export All	8/30/2012 8:31:32 AM	SelfTest	System	Promega-Maxwell\P...	View

- Reports sortable by date, method, protocol type, and user
- Select record to retrieve and export data from any run

Sample tracking reports



Report View

Print
Zoom In
Zoom Out
Actual Size
Fit to Width
Whole Page
Export

Extraction Report

Protocol: Blood v0.9
Status: **Completed**
Started at: 6/21/2012 12:33:19 PM
Duration: 00:37:08
Operator: Promega-Maxwell/Promega

Software: Maxwell® CSC
Software Version: 1.1
Instrument Name: Klops
Serial Number: Beta4
Firmware Version: 3.26.0

Catalog Number: AS1290
User Confirmations:
Sample pre-processing is complete as per the Blood Technical Manual
Deck tray has been prepared as follows and placed in the instrument:
• Cartridges with seals completely removed placed at positions 7-10
• Elution tubes placed at positions 7-10
• Appropriate volume of elution reagent has been added to each elution
• Plunger has been placed in well 8 of each cartridge
Plungers are not present on instrument plunger bar

#	Sample ID	Lot Number	Exp. Month	Cartridge ID	Elution Tube ID	Custom1	Custom2
1							
2							
3							
4							
5							
6							
7	as127a-1	015240	06/2013				
8	as132a-1	015240	06/2013				
9	as127a-2	015240	06/2013				
10	as132a-2	015240	06/2013				
11							
12							
13							
14							
15							

Run details and system information

Kit # and user confirmations

Sample details

- Run reports stored for all runs
- Reports exportable in text delimited format for integration with LIMS

Design Verification / Design Validation data



Overview of experiments

Project Phase

Development

Design Verification

Design Validation

- **Reproducibility**
- **Sample Type**
- **Downstream**
- **Output Requirements**

Protocol



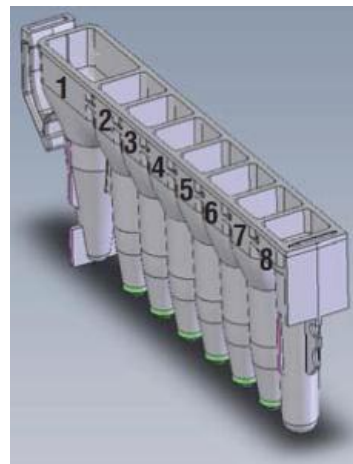
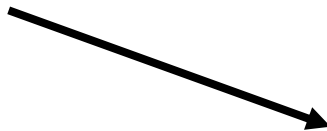
Whole Blood + Proteinase K
and Lysis Buffer



Vortex lysate



Incubate 20min.
at 56°C

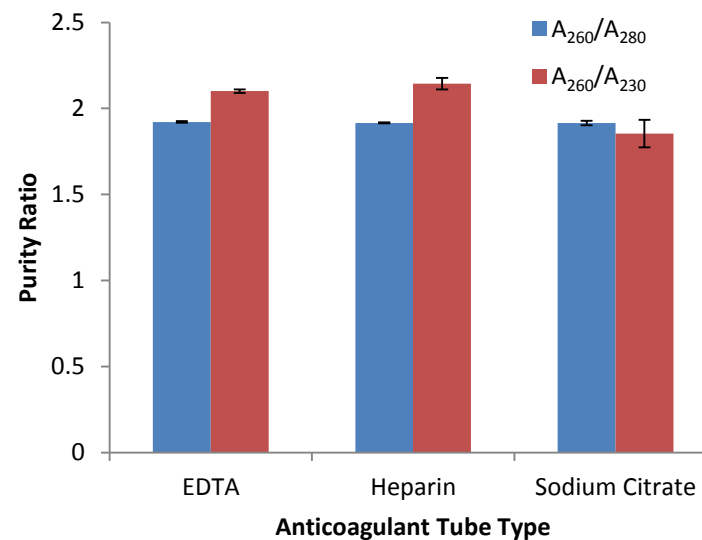
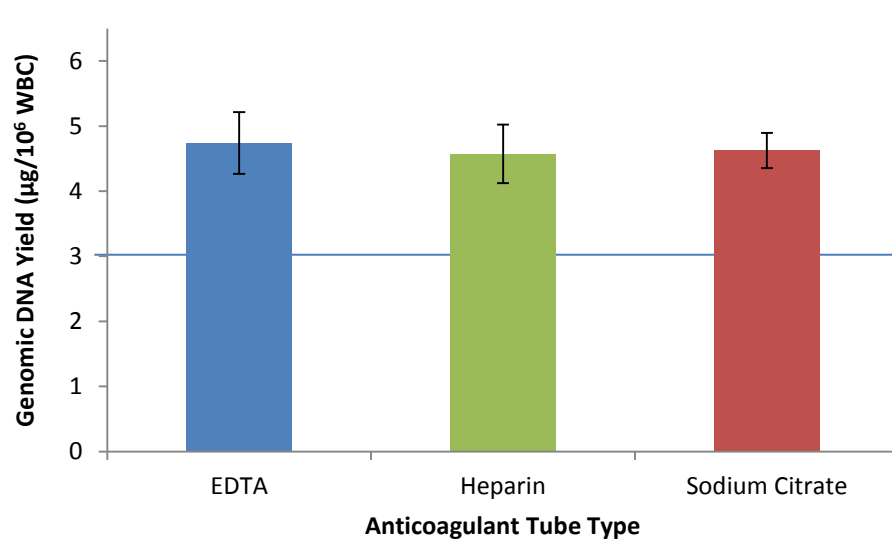


Load Cartridge



Run-time = 38 Minutes

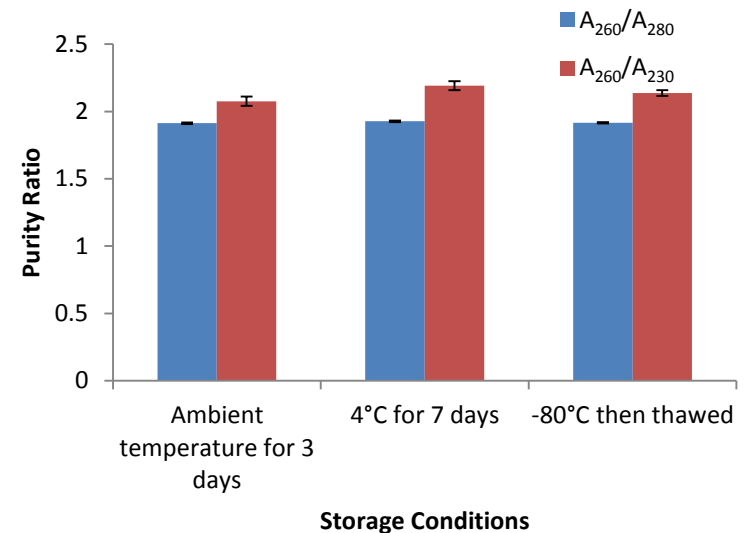
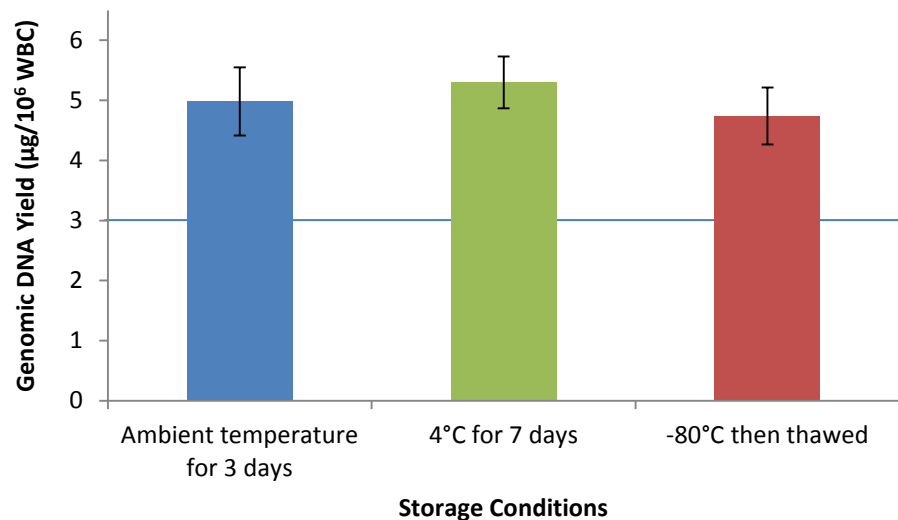
Collection Tube Compatibility



* n=8

→ Consistent performance regardless of anti-coagulant

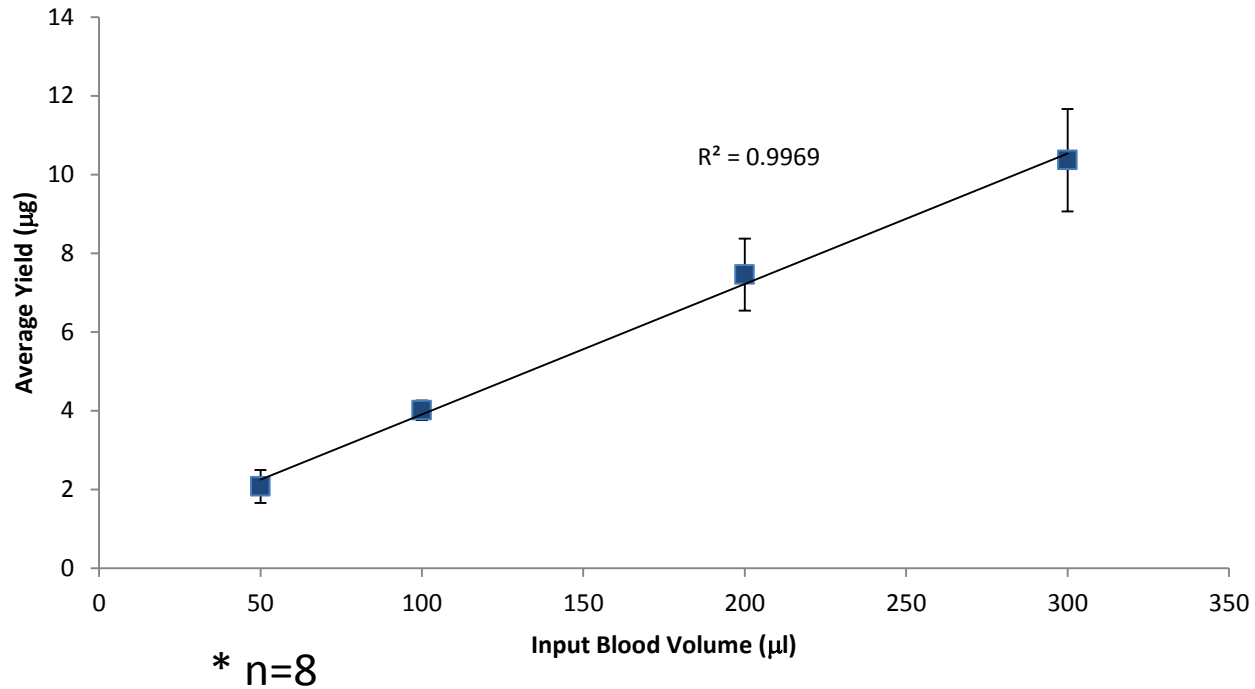
Sample Storage



* n=8

→ Ability to store sample in common conditions and still have robust yield and purity.

Linear DNA Yield

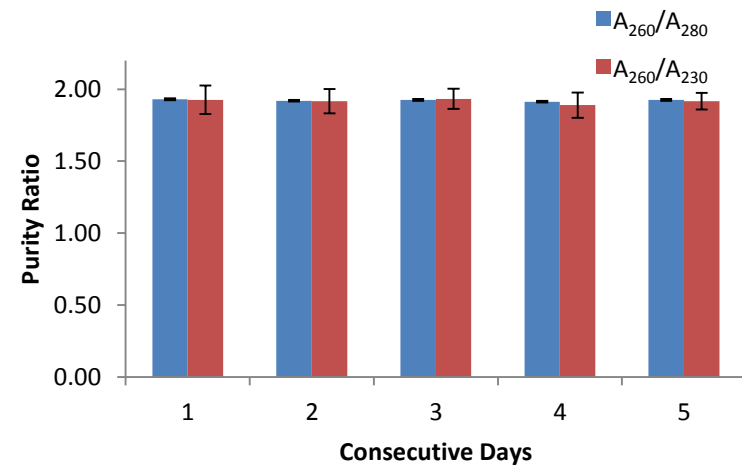
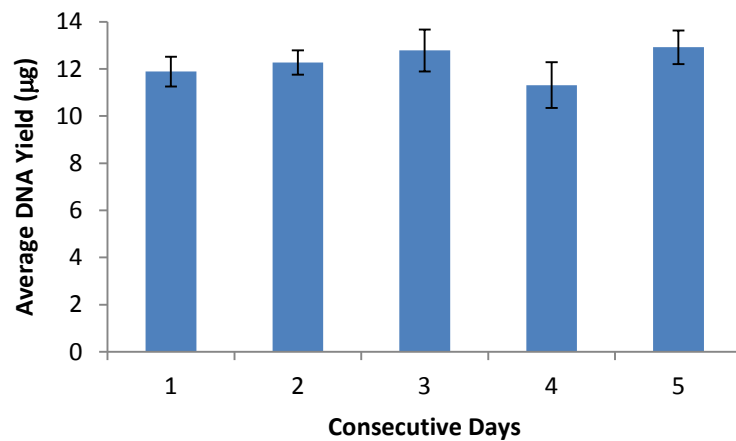


→ Flexibility to adjust input volume

Consistency



Day-to-day



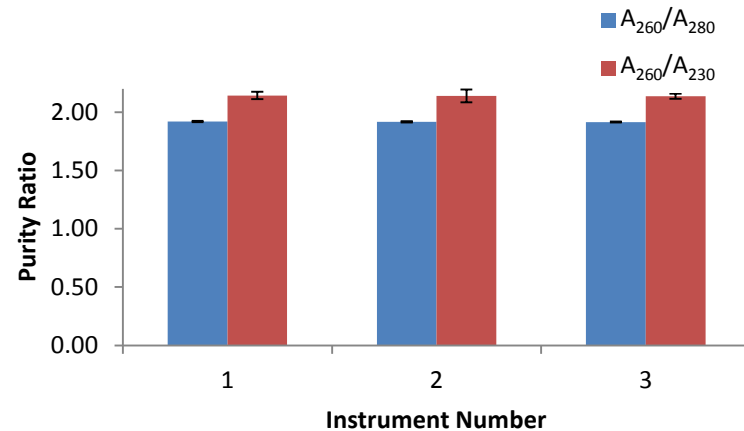
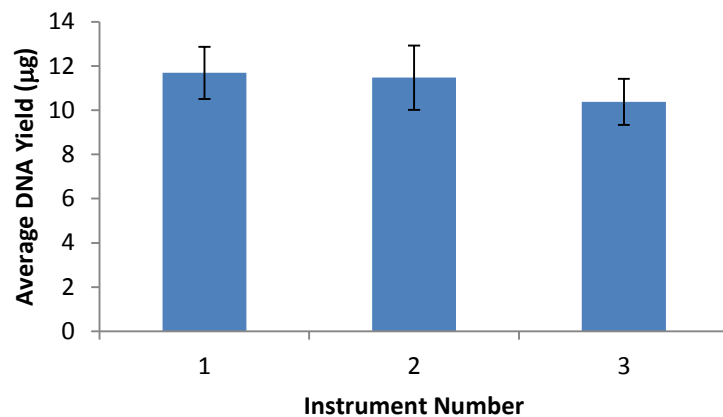
* n=8

→ Yield between 10-12µg over multiple days

Consistency



Unit-to-unit

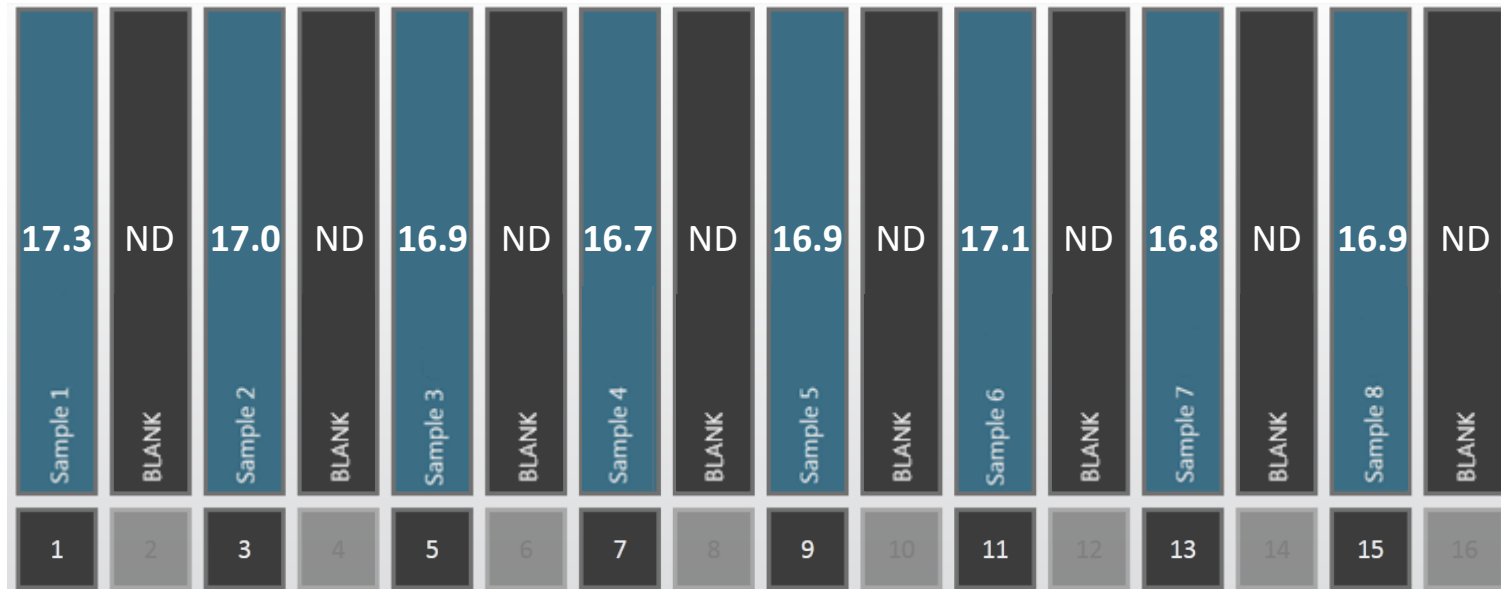


* n=8

→ Yield between 10-12µg with multiple units

Cross-Contamination

C_t :



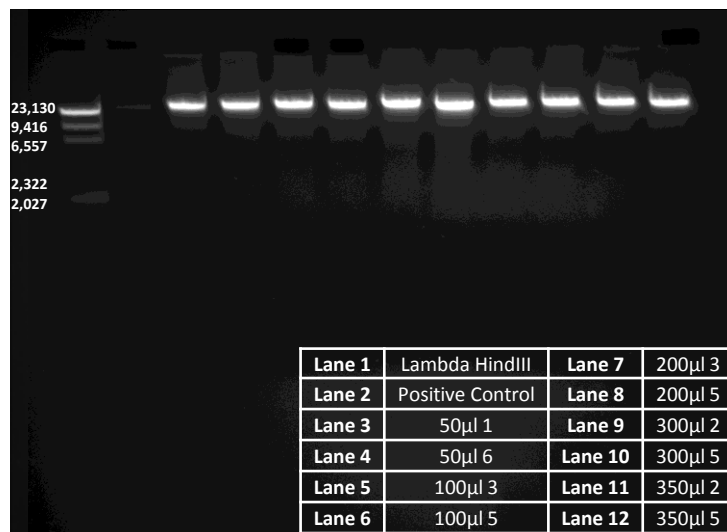
* ND = Not Detected

→ CSC does not contribute to cross-contamination

gDNA quality

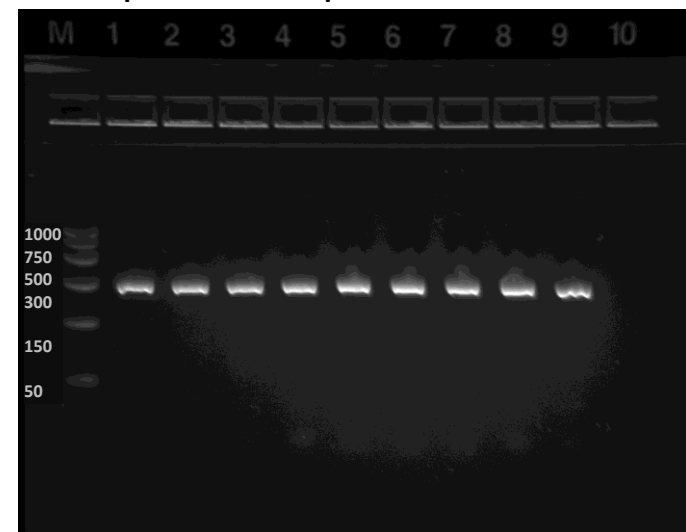
Agarose Gel Electrophoresis

CSC Eluates



- 2% gel
- normalized to 100ng

Endpoint PCR product



- 290 base pair CAPZA3 amplicon
- 1ul sample in 25ul reaction
- 2.5ul product on 2% gel

→ Purified gDNA is suitable for demanding downstream assays

Summary



- Instrument and Kit manufactured under cGMP
- Updated instrumentation for enhanced performance and consistency
- Improved workflow tailored to clinical laboratory
- Consistent, reliable, reproducible performance
- 38 minute instrument run time
- Additional reagent kits in development:
 - RNA from blood
 - DNA/RNA from FFPE sections
 - etc.

Maxwell CSC – Nucleic Acid Extraction for IVD use



Thank You!

