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DOCUMENT TITLE:	Quality Control on IQ200
DOCUMENT NOTES:	

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AUTHOR:		**PREVIOUS NUMBER:**	LUM 243
OWNER:		**CHANGE NUMBER:**	LAMC-CR-0134

Quality Control on IQ200

Purpose QC is performed on iQ200 to assure that the instrument is functioning as expected and that patient results are reported accurately

Scope To monitor the performance of iQ200, QC is performed on regular intervals

Policy Quality control must be processed and be acceptable every 24 hours before sample results can be released. Carryover check is part of quality control performed on iQ200, meaning that an acceptable Quality Control performed is an acceptable Carryover check.

QC will be run **once every 24 hours**. Running of QC will rotate every month and will be run at the beginning of the shift. 1st day of the month will have **2 runs** of Quality Control
(1 from previous shift and 1 from the next assigned shift).
Schedule for running of Quality Control by shift:

Day Shift: JANUARY, APRIL, JULY, OCTOBER
PM Shift: FEB, MAY, AUGUST, NOVEMBER
GY Shift: MARCH, JUNE, SEPTEMBER, DECEMBER

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Quality Control on IQ200

Workplace Safety

All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures.

- For standard precautions and safety practices in the laboratory; see **Safety Practices**, specifically, but not limited to, equipment safety, proper body mechanics, sharps exposure and proper use of personal protective equipment (PPE).
- For Universal Body Substance precautions, see **Universal Body Substance Precautions**, specifically, but not limited to, exposure to body fluids.
- For proper hand-washing, see **Hand washing Policy**, specifically, not limited to, proper hand-washing.
- For proper infection control, see **Infection Control**, specifically, but not limited to, proper use of gloves.
- For proper handling of regular and infectious waste, see **Handling of Regular and Infectious Waste**, specifically, but not limited to, proper disposal of regular and biohazardous waste.
- For proper cleaning of work area, see **Cleaning Work Areas**.
- For proper handling of chemicals and reagents, see the Chemical Hygiene Plan.

For proper storage and disposal of chemical hazardous waste, see **Storage & Disposal of Chemical Hazardous Waste**. All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures.

Reagents

Description	Vendor	Storage
IQ Control/Focus Set (REF 800-3104)	Beckman Coulter	Refrigerated

Control Storage

- Controls are stored at 2 to 8°
- Unopened controls are stable until expiration date listed on the bottle.
- Open stability is up to 15 days

Materials and supplies

- iQ Control Rack
- Test tubes

Quality control rejection

- If quality control fails. Failure must be documented and the corrective action policies for failed QC must be followed. QC follows a pass/fail system meaning no patient results can be reported until all QC levels are acceptable.

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Quality Control on IQ200

Carryover

Initial Carryover Study using iQ200 precision kit is only performed during installation of instrument by FSE. Carryover check on any major maintenance or repair of the pipetting assembly of the instrument is performed by running Quality Control on iQ200.

Carryover is assessed not only by FSE but also on daily basis by:

1.	Comparing Positive QC results to Negative QC results.
2.	Negative control must be run after Positive control and must read 0-20 uL
3.	Use of Carryover Pop-Up may give an indication of sample to sample possible carryover.

Note: If the instrument has any unacceptable carryover (based on the manufacturer's acceptance criteria), the *iQ200* microscopy controls will fail and the software will disable patient samples from being run. Acceptance criteria is that the negative control must read between 0-20 particles/uL

Step	Quality control frequency
1	Run IQ focus once every 24 hours before running the controls
2	IQ positive and negative controls are run once every 24 hours

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Quality Control on IQ200

Procedure: Perform Quality control on IQ200 following steps outlined in the table below

Step	Action
1	The IQ200 instrument. IQ Focus is suspensions offixed human red IQ Control/Focus Set (REF 800-3104) is used to focus and control blood cells in a particulate-free, buffered, isotonically balanced solution. Keep refrigerated and bring to room temperature before use. Once opened material can be kept at room temperature
2	IQ Positive Control (REF475-0046) is used as an abnormal control give five hard shakes followed by five gentle inversions. Let sit for about 1 minute until the air bubbles are dispersed. Place 3ml of IQ Positive control into the bar-coded tube, place tube into position 6 on the QC rack. See QC rack chart below
3	Do not shake negative control. Place barcode label on the tube and pour 3 ml of control into the tube. Place tube in the QC rack position 7. Note: Both positive and negative controls in positions 6 and 7 must be run at the same time
4	If range are provided with each product additional controls are run for a parallel, place the second set of QC.

Step	Handling of QC material
A	Shake the IQ Focus as follows. Hold the bottle upside down and give five hard sharp shakes followed by five gentle inversions. Let sit about 1 minute until the air bubbles are dispersed. Pour 6 ml of IQ focus into the bar-coded tube. Place into position 5 in the QC rack. See QC rack char below.
B	Shake IQ Positive Control bottle. Hold the bottle upside down and give five hard shakes followed by five gentle inversions. Let sit for about 1 minute until the air bubbles are dispersed. Place 3ml of IQ Positive control into the bar-coded tube, place tube into position 6 on the QC rack. See QC rack chart below
C	Do not shake negative control. Place barcode label on the tube and pour 3 ml of control into the tube. Place tube in the QC rack position 7. Note: Both positive and negative controls in positions 6 and 7 must be run at the same time
D	If additional controls are run for a parallel, place the second set of controls as follows, place second positive control into position 8 and the second IQ negative control in position 9 of the QC rack.

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Quality Control on IQ200

QC rack See table for correct loading of the QC rack

Position	Insert color	Vol	Contents	Function	Barcode
1	None	3m!	Iris system Cleanser	Cleans lines	No
2	Gray	3ml	Iris Diluent	Rinses Cleanser from lines	No
3	Gray	3 ml	Iris Diluent	Rinses Cleanser from lines	No
4	None		Empty		
5	Dark blue	6ml	IQ Focus	Focuses camera	Yes
6	Orange	3ml	IQ positive Control	Primary lot positive control	Yes
7	Light blue	3 ml	IQ negative control	Primary lot negative control	Yes
8	Orange	3 ml	Optional 2^{ml} lot IQ positive control	Secondary lot positive control for parallel	Yes
9	Light blue	3ml	Optional 2na Lot IQ Negative control	Secondary lot negative control in parallel	Yes
10	Gray	3 ml	Iris Diluent	Will initiate a shut down	No

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Quality Control on IQ200

Procedure, continued

Step	Action
6	The controls in positions 6 and 7 (and 8 and 9 if present) of the QC rack will automatically be processed.
7	If the results are within allowable range, the date and time of the QC will appear on the last QC field of the instrument screen. Then it is Ok to proceed with patient testing
8	If the QC results are out of range repeat the controls using fresh Aliquots of both IQ positive and IQ negative controls. If results are in proceed with patient testing.
9	If results are still out repeat using new bottles of controls. If results are in proceed with patient testing.
10	If results are still out notify supervisor and contact Iris Diagnostics Technical Service. Do not proceed with patient testing until problem is resolved.

Controlled Documents

The following controlled documents support this procedure.

Document Number	Document Name
LAMC-PPP-0123	Safety Practices
LAMC-PPP-0127	Infection Control
LAMC-PPP-0128	Universal Body Substance Precaution
LAMC-PPP-0129	Handling of Regular and Infectious Waste
LAMC-PPP-0130	Cleaning Work Areas
LAMC-PPP-0132	Hand-washing Policy
LAMC-PPP-0134	Storage and Disposal of Chemical Hazardous Waste

Non Controlled Documents

	Document Name
	IQ200 Operators manual

Author(s) Alvin Castillo

Signature Manifest

Document Number: LAMC-PPP-0150 **Revision:** 02
Title: Quality Control on IQ200

All dates and times are in Pacific Standard Time.

Quality Control on IQ200

Change Request

Name/Signature	Title	Date	Meaning/Reason
Alvin Castillo (B114810)	Area Lab Manager	17 Jun 2017, 12:02:32 PM	Approved

Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Jocelyn Javier (T684676)	Assist. ADA	21 Jun 2017, 08:00:01 AM	Approved

Operations Approval

Name/Signature	Title	Date	Meaning/Reason
Julie Toti (K084521)	DIR AREA LAB	27 Jun 2017, 12:12:29 PM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
Hedyeh Shafi (I086749)	Pathologist	03 Jul 2017, 08:20:08 AM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Alvin Castillo (B114810)	Area Lab Manager	18 Jul 2017, 09:44:37 AM	Approved

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DOCUMENT NUMBER:	LAMC-PPP-0158
DOCUMENT TITLE:	I-Chem Velocity Quality Manual
DOCUMENT NOTES:	

LOCATION:	LAMC-rel	**VERSION:**	03
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EFFECTIVE DATE:	31 Jul 2017	**NEXT REVIEW DATE:**	30 Jan 2019
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AUTHOR:		**PREVIOUS NUMBER:**	LUM 253
OWNER:		**CHANGE NUMBER:**	LAMC-CR-0133

Kaiser Permanente Medical Care Program California Division – South	SCPMG Laboratory System Los Angeles Procedure

iCHEM Velocity Quality Control

Purpose

QC is performed on iChem VELOCITY to assure that the instrument is functioning as expected and that patient results are reported accurately

Scope

To monitor the performance of iChem VELOCITY, QC is performed on regular intervals

Policy

Quality control must be processed and be acceptable every 24 hours before sample results can be released. Carryover check is part of quality control performed on iCHEM Velocity, meaning that an acceptable Quality Control performed is an acceptable Carryover check.

QC will be run **once every 24 hours**. Running of QC will rotate every month and will be run at the beginning of the shift. 1st day of the month will have **2 runs** of Quality Control

(1 from previous shift and 1 from the next assigned shift).

Schedule for running of Quality Control by shift:

Day Shift: JANUARY, APRIL, JULY, OCTOBER
PM Shift: FEB, MAY, AUGUST, NOVEMBER
GY Shift: MARCH, JUNE, SEPTEMBER, DECEMBER

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iCHEM Velocity Quality Control

Workplace Safety

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- For proper handling of regular and infectious waste, see **Handling of Regular and Infectious Waste**, specifically, but not limited to, proper disposal of regular and biohazardous waste.
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Reagents

Description	Vendor	Storage
iChem VELOCITY Urine Chemistry Strips	Beckman Coulter	Room temperature
iChem wash solution	Beckman Coulter	Room temperature
IRISSpec CA/CB/CC controls Ref 800-7702	Beckman Coulter	Refrigerated

Control Storage

- Controls are stored at 2 to 8°
- Unopened controls are stable until expiration date listed on the bottle.
- Open stability is up to 15 days

Materials and supplies

- Control Rack
- Test tubes

Continued on next page

Kaiser Permanente Medical Care Program California Division – South	SCPMG Laboratory System Los Angeles Procedure

iCHEM Velocity Quality Control

Quality control rejection

- If quality control fails. Failure must be documented and the corrective action policies for failed QC must be followed. QC follows a pass/fail system meaning no patient results can be reported until all QC levels are acceptable.

Carryover

Carryover is assessed not only by FSE but also on daily basis by performing QC on instrument.

Definitions

IChem VELOCITY utilizes wavelength reflectance and refractive index.

Procedure:

Follow instructions below for performing QC

Step	Action
1	Make sure that there are enough test strips in the test strip provider
2	Prepare control tubes according to the directions on the package insert.
3	Place the controls in the following positions onto the Control Rack:
4	Place the rack on the sampler.
5	Press the START button. The system detects the Control Rack and displays the position number.
6	When the control testing is completed, the results are printed and/or transmitted to the LIS depending on the set configuration (Consult QC settings). Document any outlier in the department corrective action log sheet. If the control testing is out, repeat the testing. If it is still not resolve, call for service.
	Note: If QC is not acceptable no patient samples can be processed until QC problem has been resolved and QC is acceptable.

Position	Insert color	Volume	Contents	Function	Barcode
5	Blue	3 ml	CA control	Primary control	No
6	Green	3ml	CB control	Primary control	No
7	Red	3ml	CC control	Primary control	No

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iCHEM Velocity Quality Control

Controlled Documents

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LAMC-PPP-0132	Hand-washing Policy
LAMC-PPP-0134	Storage and Disposal of Chemical Hazardous Waste
LAMC-PPP-0150	Quality Control on IQ200

Non Controlled Documents

	Document Name
	IChem VELOCITY Operator's Manual, 300-4449 English Rev E 10/2008

Author(s) Alvin Castillo

Signature Manifest

Document Number: LAMC-PPP-0158 **Revision:** 03
Title: I-Chem Velocity Quality Manual

All dates and times are in Pacific Standard Time.

IChem Velocity Quality Manual

Change Request

Name/Signature	Title	Date	Meaning/Reason
Alvin Castillo (B114810)	Area Lab Manager	17 Jun 2017, 12:02:11 PM	Approved

Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Jocelyn Javier (T684676)	Assist. ADA	21 Jun 2017, 07:58:54 AM	Approved

Operations Approval

Name/Signature	Title	Date	Meaning/Reason
Julie Toti (K084521)	DIR AREA LAB	27 Jun 2017, 12:11:27 PM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
Hedyeh Shafi (I086749)	Pathologist	03 Jul 2017, 08:20:57 AM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Alvin Castillo (B114810)	Area Lab Manager	18 Jul 2017, 09:43:56 AM	Approved