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

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

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| 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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| 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. |

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

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| 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
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| Materials and supplies | * iQ Control Rack
* Test tubes
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| **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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| 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:

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|  | Comparing Positive QC results to Negative QC results. |
|  | Negative control must be run after Positive control and must read 0-20 uL |
|  | 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 |
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| 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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| Procedure: | Perform Quality control on IQ200 following steps outlined in the table below

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| 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. |

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| 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 positions6 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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| QC rack | See table for correct loading of the QC rack |
| **Position** | **Insert** | **Vol** | **Contents** | **Function** | **Barcode** |
|  | **color**  |  |  |  |  |
| 1  | None  | 3m!  | Iris system  | Cleans lines  | No  |
|  |  |  | Cleanser  |  |  |
| 2  | Gray  | 3ml  | Iris Diluent  | Rinses  | No  |
|  |  |  |  | Cleanser  |  |
|  |  |  |  | from lines  |  |
| 3  | Gray  | 3 ml  | Iris Diluent  | Rinses  | No  |
|  |  |  |  | Cleanser  |  |
|  |  |  |  | from lines  |  |
| 4  | None  |  | Empty  |  |  |
| 5  | Dark blue  | 6ml  | IQ Focus  | Focuses  | Yes  |
|  |  |  |  | camera  |  |
| 6  | Orange  | 3ml  | IQ positive  | Primary lot  | Yes  |
|  |  |  | Control  | positive  |  |
|  |  |  |  | control  |  |
| 7  | Light blue  | 3 ml  | IQ negative  | Primary lot  | Yes  |
|  |  |  | control  | negative  |  |
|  |  |  |  | control  |  |
| 8  | Orange  | 3 ml  | Optional 2ml lot  | Secondary  | Yes  |
|  |  |  | IQ positive  | lot positive  |  |
|  |  |  | control  | control for  |  |
|  |  |  |  | parallel  |  |
| 9  | Light blue  | 3ml  | Optional 2na Lot  | Secondary  | Yes  |
|  |  |  | IQ Negative  | lot negative  |  |
|  |  |  | control  | control in  |  |
|  |  |  |  | parallel  |  |
| 10  | Gray  | 3 ml  | Iris Diluent  | Will initiate  | No  |
|  |  |  |  | a shut down  |  |

 **Procedure**, continued

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| 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 theQC will appear on the last QC field of the instrument screen. Thenit is Ok to proceed with patient testing |
| 8 | If the QC results are out of range repeat the controls using freshAliquots 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 DiagnosticsTechnical Service. Do not proceed with patient testing until problem is resolved. |

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| Controlled Documents | The following controlled documents support this procedure.

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| **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 |

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| Non Controlled Documents

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|  | Document Name |
| 1 | IChem VELOCITY Operator’s Manual, 300-4449 English Rev E 10/2008 |

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|  | **Document Name** |
|  | IQ200 Operators manual |

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| Author(s) | Alvin Castillo |