IQCP Demystified: Practical Considerations for a Blood Gas Individualized Quality Control Plan (IQCP)

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Objectives

1. Analyze the instances in which an IQCP is required for a blood gas analyzer

2. Discuss the process used to identify risk areas for blood gas testing

3. Review the pre and post analytic considerations when developing and IQCP
What is Risk?
History

• CLIA 88 requires 2 levels of QC each day of testing (3 levels for BG)!
• Newer lab devices offer internal and engineered control processes that make daily liquid QC duplicative and redundant.
• IQCP allows laboratories to develop a plan that optimizes the use of engineered, internal control processes on a device and balances the performance of external liquid QC without impacting safety!
• CLSI EP23 introduces industrial and ISO risk management principles to the clinical laboratory
• CMS adopted key risk management concepts to develop the IQCP option for quality control
• IQCP replaces 2003 EQC (Equivalent QC) options currently in place.
New IQCP

• Two levels of liquid QC required each day of testing (3 levels required for blood gas testing)

OR

• Laboratory develops an IQCP:
  • Balance internal control processes with external controls
  • Reduce frequency of liquid QC to minimum recommended by manufacturer
  • Maximize clinical outcome, available staff resources and cost effectiveness in the lab
Individualized Quality Control Plan

Quality Control Plan

Risk Assessment

Quality Assessment

Individualized Quality Control Plan
Is an IQCP Required?

- CLIA non-waived testing (CLIA mod/high complexity)
- CLIA will not set a minimum QC frequency for labs performing IQCP
- However...
  - Performing no QC is unacceptable
  - QC frequency can not be less than the manufacturer’s instructions
  - The RA & lab’s data must support the QC frequency
- Two levels of QC analyzed each day of testing or IQCP
  - CLIA for BG analysis – one QC sample q 8 hr, two levels q 24 hrs, one QC w/ each pt sample unless calibration every 30 mins
• Solution (reagent) pack contains three dedicated levels of NIST traceable QC solutions. They are not used at anytime for calibration.

• Aspiration of these QC solutions into the sensor cassette is through the same inlet probe as used to measure patient samples.

• QC is scheduled to be run every 8 hours.
ABL 90 FLEX On-Board Automatic Quality Management (AQM)

**System Cycle**
- **Pre-defined schedule**
  - Calibration:
    - Automatic 2-point calibration event every 2 hours based on a pre-defined parameter schedule
    - A comprehensive evaluation that ensures strict specifications are met and the calibrations are validated
    - A 1-point calibration is done before every sample measurement and QC
  - Quality control:
    - Separate aqueous solutions
    - Three levels (low, normal and high)
    - Spans a broad segment of reportable range
    - One level run at least every 8 hours
    - More frequent QC can be scheduled by the user

**System Check**
- **Daily**
  - System checks:
    - At start-up, once per day and at consumables replacement
    - Assess drift, sample path and all electronic functions

**Analysis Check**
- **Every sample**
  - Analysis checks:
    - Drift assessment (1-point cal) performed before, during and after every patient sample
    - Minimum every other hour if no samples are run in relation to calibrations and QC

**Verification Check**
- **Every new solution pack**
  - Verification check:
    - Automatically done at new solution pack installation for pack validation
AutoCheck System ABL800 FLEX

- Four levels of QC
- Temperature controlled
- User defined frequency
- Automatically mixed and sampled through the same inlet port used for patient specimens
AutoCheck System ABL800 FLEX

Ampoule is rotated 180°

Inlet probe

Ampoule breaker moves back

Bar code identified ampoules
An IQCP is Ultimately the Lab Director’s Choice

ABL80 FLEX Series

The ABL80 FLEX series of analyzers utilizes the QC³ system for quality management. This robust system provides a System Cycle which includes three levels of NIST traceable QC every 8 hours, a 30-minute System Check to further verify system performance and an Analysis Check with each patient sample to ensure accurate results. Because the QC3 system does not process the internal QC solutions through the sample probe used for patient specimens, Radiometer recommends that an IQCP plan should be developed for the ABL80 FLEX Series.

ABL800 FLEX Series

The ABL800 FLEX series of blood gas analyzers all use the AUTOCHECK system for quality control. AUTOCHECK was found to be substantially equivalent to the manual quality control process by the FDA in 510(k) 992859. Since the AUTOCHECK module treats the QC ampoules and sampling process exactly as if introduced manually, Radiometer recommends that an IQCP is NOT required for the ABL800 FLEX Series analyzer.

ABL90 FLEX

The ABL90 FLEX blood gas analyzer utilizes the AQM system for quality management. The heart of the system is three dedicated levels of NIST traceable quality control solutions contained in sealed pouches. During the QC measurement process the QC materials are treated in the same manner as a patient sample, including the inlet probe, completely challenging the entire analytic process as would be done with a manual external QC solution. Therefore, Radiometer recommends that an IQCP is NOT required for the ABL90 FLEX analyzer.
Risk in the Laboratory

• There is no “perfect” laboratory device, otherwise we would all be using it!
• Any device can and will fail under the right conditions
• A discussion of risk must start with what can go wrong with a test (errors or nonconformities)
• Lab tests are not fool-proof!
What Could Go Wrong?
Risk Mitigation

• Liquid quality control is historic means of detecting and preventing errors (nonconformities or incidents)!
  – Liquid controls detect systematic errors that affect every sample the same way (calibration errors, pipette errors, reagent degradation)
  – Liquid controls do a poor job at detecting random errors that affect a single sample uniquely (hemolysis, lipemia, clots, drug interferences)
  – For unit-use tests, liquid controls consume entire test and do not ensure performance of next test

• Newer devices have built-in electronic controls, and “on-board” chemical and biological controls.
Types of Quality Control

• QC is broader than liquid QC! It is any control process to ensure quality of test results!
• “On-Board” or Analyzer QC – built-in liquid QC or device controls and system checks
• Internal QC (laboratory enacted QC) – laboratory-analyzed surrogate sample controls – liquid QC
• External QC (external required controls) – blind proficiency survey samples
• Other types of QC – control processes either engineered by a manufacturer or enacted by a laboratory to ensure result reliability (barcoded expiration dates on reagent packs)
Laboratory-Manufacturer Partnership

- No single QC procedure can cover all devices, because the devices may differ.

- Newer devices have built-in electronic controls, and “on-board” chemical and biological controls.

- Developing a quality plan surrounding a laboratory device requires a partnership between the manufacturer and the laboratory.

- Some sources of error may be detected automatically by the device and prevented, while others may require the laboratory to take action, such as analyzing surrogate sample QC on receipt of new lots of reagents.

- Clear communication of potential sources of error and delineation of laboratory and manufacturer roles for how to detect and prevent those risks is necessary.

CLSI Document EP23

• Laboratory Quality Control Based on Risk Management; Approved Guideline (EP23-A™)

• James H. Nichols, PhD, DABCC, FACB, Chairholder of the document development committee

• EP23 describes good laboratory practice for developing a QCP based on the manufacturer’s risk mitigation information, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting.
EP23 Laboratory QC Based on Risk Management

Input Information
- Medical Requirements for Test Results
- Regulatory and Accreditation Requirements
- Test System Information: Provided by the manufacturer Obtained by the Laboratory
- Information about Health Care and Test-Site Setting

Process
- Risk Assessment

Output
- Laboratory Director’s QC Plan
- Post Implementation Monitoring

Continuous Improvement

CLSI EP23 Table
Collect Information about the System
On-Board Quality System Components – ABL80 QC³

**Calibration**
- Comprehensive evaluation that ensures linearity

**Quality Control**
- Aqueous solutions
- Three levels
- Spans a broad segment of the reportable range
- At least every 8 hours

**System Checks**
- Continual – every 30 minutes
- Assess drift and electronic functions

**Analysis System Checks**
- Drift assessment and other system checks performed with every patient sample
Solution pack – independent solutions

- The solution pack contains four pouches of precision tonometered, buffered solutions
  - Each pouch has a unique lot number
- Each pouch has different concentrations of analytes
  - Concentrations are NIST traceable
- Solutions are used for QC and calibrations
- Smart chip provides lot-specific information
  - Calibration values
  - Quality control acceptable ranges

<table>
<thead>
<tr>
<th></th>
<th>Solution 1</th>
<th>Solution 2</th>
<th>Solution 3</th>
<th>Solution 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7,38</td>
<td>7,04</td>
<td>7,70</td>
<td>6,69</td>
</tr>
<tr>
<td>$pCO_2$ (mmHg)</td>
<td>38</td>
<td>73</td>
<td>10</td>
<td>44</td>
</tr>
<tr>
<td>$pO_2$ (mmHg)</td>
<td>(157)</td>
<td>159</td>
<td>76</td>
<td>215</td>
</tr>
<tr>
<td>$cNa^+$ (mmol/L)</td>
<td>155</td>
<td>106</td>
<td>167</td>
<td></td>
</tr>
<tr>
<td>$cK^+$ (mmol/L)</td>
<td>4,1</td>
<td>8,1</td>
<td>2,3</td>
<td></td>
</tr>
<tr>
<td>$cCa^{2+}$ (mmol/L)</td>
<td>1,15</td>
<td>2,10</td>
<td>0,48</td>
<td></td>
</tr>
<tr>
<td>$cCl^-$ (mmol/L)</td>
<td>111</td>
<td>66</td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>$cGlu$ (mmol/L)</td>
<td>0,0</td>
<td>14,3</td>
<td>4,6</td>
<td></td>
</tr>
<tr>
<td>Hct (%)</td>
<td></td>
<td>12</td>
<td></td>
<td>63</td>
</tr>
</tbody>
</table>
ABL80's comprehensive On-Board quality system QC³

Calibration

- 2-pt. Cal
- Linearity Checks
  - For each parameter:
  - 3 QC levels (high, mid, low) measured on aqueous solutions

Quality Control

- Time
  - 24 hrs
  - 16 hrs
  - 8 hrs
  - 0 hrs
- Calibration Quality Control
- System Checks
  - Continual (every 30 mins.)
  - w/ every patient sample

0 hrs | 8 hrs | 16 hrs | 24 hrs

Time
Where is the Risk in Our Process?

Baseball Coach Loans Ferraris to Teenagers. What Could Possibly Go Wrong? *April 1, 2009*
EP23 Laboratory QC Based on Risk Management

Create a Process Map
(Preanalytic – Analytic – Postanalytic)

Identify Weaknesses in the Process

Define a Process that will Mitigate Risk

Summarize Processes and Actions in a QC Plan
Developing a Process Map

• All tests can benefit from mapping the process and identifying weaknesses – preanalytic, analytic and postanalytic

• Compile information. Look for weaknesses in each process step
Process Map: Blood Gas/Electrolytes - Finding the Failure Points

• Work from the current package insert
• Test order – electronic or hardcopy
• Test collection
  – Incorrect collection – bubbles, sample exposure to air
  – Wrong tube type – calcium titrated, heparinized BG tubes
  – Undermixing/overmixing – sample clots, hemolysis
  – Analytic delay – glucose, BG, pH, iCa, etc.
• Analysis
  – Wrong sample volume loaded
  – Incorrect procedure, timing, result interpretation
  – Expired reagent
  – Reagent exposure during shipment
  – Degradation during storage
• Infection Control
• Result reporting errors
Developing an Individualized Quality Control Plan (IQCP)

ABL80 FLEX analyzer
Risk Assessment

• Risk Assessment should consider at a minimum:
  – 3 phases of testing (preanalytic, analytic, postanalytic)
  – 5 common error sources (samples, operators, reagents, environment and analyzer)

<table>
<thead>
<tr>
<th>Preanalytical Phase</th>
<th>Process step</th>
<th>Area of Focus</th>
<th>Measuring System Feature</th>
<th>Recommendations &amp; References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering the Sample</td>
<td>Positive Patient Identification</td>
<td>N/A</td>
<td></td>
<td>Use two patient identifiers.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ensure that the sample has an ID label attached when you leave the patient.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Always enter patient ID into the analyzer.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prebarcoded arterial blood gas samplers are available from Radiometer.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Implement a positive patient ID system (e.g. prebarcoded sampler and ID data capture).</td>
</tr>
</tbody>
</table>
| Sampling Device | Anticoagulant Level | N/A | Use heparin in sufficient concentration. The recommended concentration depends on the sampling device and specific blood sample.  

Samplers with different heparin concentrations are available from Radiometer.  

*Operator’s Manual pp. 11-3, 13-11, 13-12* |
|---|---|---|---|
| Anticoagulant Type | N/A | Use heparin exclusively, as this is the only anticoagulant suitable for blood gas testing.  

Use electrolyte-balanced heparin when electrolytes are to be reported. Unbalanced heparin will cause bias on electrolytes, especially iCa^{2+}.  

Use preheparinized devices with dry heparin.  

Samplers preheparinized with electrolyte balanced / dry heparin are available from Radiometer.  

*Operator’s Manual pp. 11-3, 13-11, 13-12* |
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Drawing the Sample</td>
<td>Sample Integrity</td>
<td>N/A</td>
<td>Mix the sample thoroughly with heparin immediately after sampling.</td>
</tr>
<tr>
<td></td>
<td>(Mixing)</td>
<td></td>
<td><em>Operator’s Manual pp. 11-6, 11-7, 11-11</em></td>
</tr>
<tr>
<td></td>
<td>Sample Integrity</td>
<td>N/A</td>
<td>It is recommended to withdraw a volume equal to three to six times the “dead space” of the catheter.</td>
</tr>
<tr>
<td></td>
<td>(A-line Collection)</td>
<td></td>
<td><em>Operator’s Manual p. 11-5</em></td>
</tr>
<tr>
<td></td>
<td>Sample Integrity</td>
<td>N/A</td>
<td>Infusion solution can bias results on parameters. Stop infusion for a period of time prior to sampling or use another sampling site.</td>
</tr>
<tr>
<td></td>
<td>(A-line Collection)</td>
<td></td>
<td><em>Operator’s Manual p. 11-3</em></td>
</tr>
</tbody>
</table>
Collection technique (air, bubbles) and Operator Exposure to Blood Borne Pathogens

- Often overlooked first step before sample introduction

<p>| Sample Integrity (Air Bubbles) | N/A | Visually inspect the sample for air bubbles. Expel any air bubbles immediately after collection, without prior agitation. Arterial blood gas samplers with vented tip caps (&quot;safeTIPCAP&quot;) from Radiometer will allow you to expel air and seal the sampler with least possible contact with blood. Operator’s Manual pp. 11-6, 13-11 |</p>
<table>
<thead>
<tr>
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</table>
| Analyzer Management | Consumable Replacements | Consumable replacements must be performed as required by the analyzer based on consumable expiration dates, tests remaining and solutions remaining. The analyzer will not allow sample analysis when consumables are expired or exhausted. | Analyzer can be configured to provide a warning when consumable replacement will soon be required. 
*Operator’s Manual pp. 3-5, 8-2, 8-5, 9-42, 9-43* |
<p>| Environment - Humidity | N/A                     | Maintain an external monitoring system according to the specifications in the operator’s manual.   | <em>Operator’s Manual p. 12-9</em>                                                                 |
| Environment - Temperature | N/A                      | Maintain an external monitoring system according to the specifications in the operator’s manual.   | <em>Operator’s Manual p. 12-9</em>                                                                 |
| Environment - Altitude | Operating the analyzer above the maximum altitude specification can release dissolved air from the solutions which will result in air bubbles. The analyzer will flag any calibration, QC or sample results that are affected by air bubbles. The analyzer can be configured to suppress results that are flagged. | <em>Operator’s Manual pp. 9-73, 9-74, 10-47, 10-48, 10-63, 12-8, 12-9</em> |</p>
<table>
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<th>Recommendations &amp; References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Analysis</strong></td>
<td>Sample Volume</td>
<td>The proper sample volume is automatically aspirated into the analyzer during the sample analysis procedure. If there is insufficient sample volume, the sample will be flagged with “possible air in sample”. The analyzer can be configured to discard all patient sample results that include air warnings.</td>
<td><em>Operator’s Manual pp. 4-2, 9-74</em></td>
</tr>
<tr>
<td><strong>Analyzer Management</strong></td>
<td>Consumable Shipment / Storage Specifications</td>
<td>Ensure storage conditions meet all specifications as described in the operator’s manual. The analyzer will perform a verification check during solution pack installation and a System Cycle during installation of a sensor cassette and/or solution pack to verify the integrity of the consumables.</td>
<td><em>Operator’s Manual pp. 5-2, 8-2 through 8-6, 12-8, 12-9</em></td>
</tr>
<tr>
<td>Analyzer Security</td>
<td></td>
<td>Ensure all users are properly trained to perform all necessary interactions with the analyzer. The analyzer can be configured to require security access to all areas of the software. This feature can prevent untrained users from performing analyzer activities including sample analysis.</td>
<td><em>Operator’s Manual pp. 9-76 through 9-83</em></td>
</tr>
</tbody>
</table>
## Postanalytical Phase

<table>
<thead>
<tr>
<th>Process step</th>
<th>Area of Focus</th>
<th>Measuring System Feature</th>
<th>Recommendations &amp; References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Handling</td>
<td>Positive Patient Identification</td>
<td>N/A</td>
<td>Implement a positive patient ID system (e.g., prebarcoded sampler and ID data capture)</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
<td></td>
<td>Implement a bi-directional data management / transmission system (e.g., Radiometer’s AQUIRE data management system)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Operator’s Manual pp. 9-29 through 9-35</em></td>
</tr>
</tbody>
</table>

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### Sample & data registration

![Sample & data registration diagram](image)

### Sample mixing & analysis

![Sample mixing & analysis diagram](image)

### Result transmission

![Result transmission diagram](image)
Quality Control Plan Summary: Blood Gas

• Test order – electronic or hardcopy - *Training*
  • Test collection
    – Incorrect collection – bubbles, sample exposure to air – 1<sup>st</sup> *Automatic*
    – Wrong tube type – calcium titrated, heparinized BG tubes - 1<sup>st</sup> *Automatic*
    – Undermixing/overmixing – sample clots, hemolysis - 1<sup>st</sup> *Automatic*
    – Analytic delay – glucose, BG, pH, iCa, etc. - 1<sup>st</sup> *Automatic*

• Analysis
  – Wrong sample volume loaded - 1<sup>st</sup> *Automatic*
  – Incorrect procedure, timing, result interpretation – QC<sup>3</sup>/AQM- 1<sup>st</sup> *Automatic*
  – Expired reagent - QC<sup>3</sup>/AQM
  – Reagent exposure during shipment - QC<sup>3</sup>/AQM
  – Degradation during storage - QC<sup>3</sup>/AQM

• Infection Control - 1<sup>st</sup> *Automatic*
• Result reporting errors - 1<sup>st</sup> *Automatic*
• Training should include – checking test order, collection technique (mixing), temp monitoring, analyzer limitations and troubleshooting
Individualized Quality Control Plan
The “Right QC” is IQCP

- CMS has incorporated key EP-23 concepts into CLIA Interpretive Guidelines (IG) as an alternative QC policy called IQCP (Individualized QC Plans)
- Effective Jan 1, 2014, IQCP will be implemented
- 2 year phase-in and educational process – ends Jan 1, 2016
- Existing CLIA QC & quality system concepts won’t change
- No regulations will change!
- CMS’ survey process won’t change
- Accreditation agencies, CAP and Joint Commission have released updated checklists effective 2015.
The “Right QC” is IQCP

- Permits labs to develop an IQCP using many of their existing quality practices/information
- Is based on labs’ patient population, environment, test system, clinical uses, etc.
- Applies to CMS-certified non-waived labs
- IQCP is a choice & default is 2 external QC/day
- Labs must follow mfr’s. instructions if > CLIA
- Includes existing & new analytes/test systems
Don’t Be Discouraged—
Risk Management Is Documenting Much of What We Already Do!
Resources for Reducing Errors

- Clinical Chemistry book recently released!
- Focus on errors in the Chemistry Laboratory including POCT
- Discussion of real-world errors and what can be done to detect and prevent errors.
Blood gas preanalytics app available from Radiometer for iPhone and Android.

Preanalytical errors are said to be the reason for up to 62% of all errors in laboratory medicine.
Summary

• Risk management is something laboratories are already doing. EP23 and IQCP simply formalizes this.
• An IQCP assesses the medical need for test, performance requirements, and weaknesses in the testing process as well as actions to address those risks.
• Each IQCP is unique because the combination of device, setting, medical requirements and operators may differ between laboratories.
• An IQCP is the industry standard. It depends upon the extent to which the device’s features achieve their intended purpose in union with the laboratory’s expectation for ensuring quality results.
• Once implemented, the IQCP is monitored for effectiveness and modified as needed to maintain risk to a clinically acceptable level.
• Whether to develop an IQCP or use the default CLIA QC option is a choice of the laboratory medical director.
Questions?