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The Advantages of Automatic Quality Control (AQC) for Blood Gas Testing QC

White Paper

Answers for life.

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Introduction

For over 40 years, Siemens Healthcare Diagnostics has been developing, manufacturing and marketing critical care products, including blood gas analyzers that now incorporate the innovative Automatic Quality Control (AQC) systems. Our Quality Control (QC) products and services portfolio is designed to help laboratories monitor the reliability and performance of their instrumentation, measure the variability of tests performed, and evaluate the integrity of all results reported. Our commitment to consistency and stringent quality control helps laboratories around the world to excel in the face of ever-increasing regulatory demands and higher performance goals.

An overview of Quality Control

An analyzers QC system helps to ensure and verify that analytical processes are performing according to expectations, and more importantly, that all patient test results obtained are accurate. Any instrument QC program generally incorporates a variety of processes to help ensure performance quality. These processes include instrument calibration, calibration verification, system functionality checks, preventative maintenance, proficiency testing, and the routine analysis of materials of known concentration, referred to as controls.

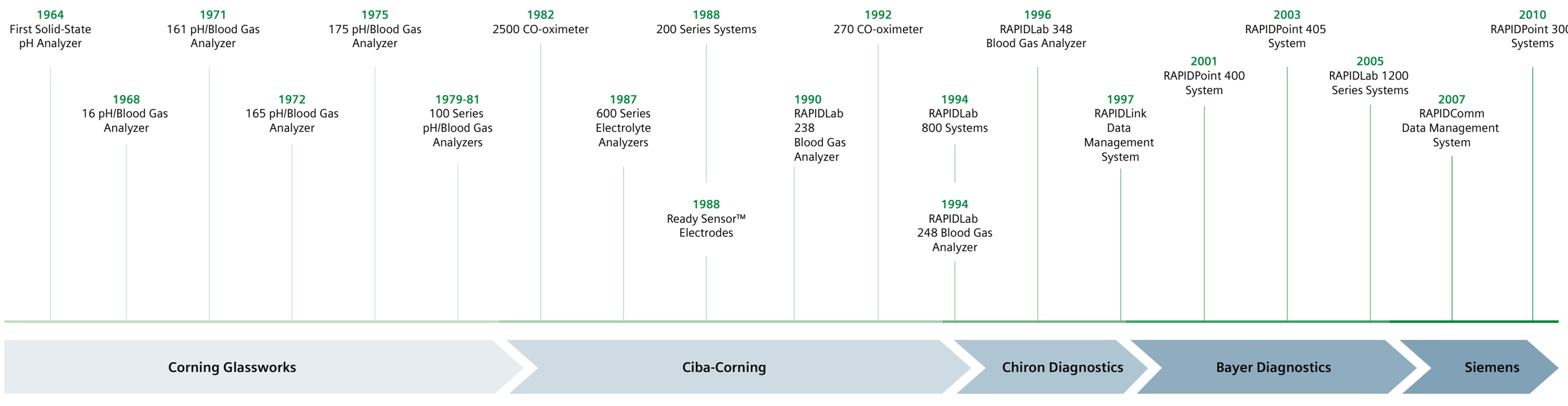

Figure 1: Siemens Blood Gas Testing Milestones

Why perform Quality Control?

There are three important reasons for test sites to run QC checks:

1. The measured values of control analytes will indicate to the operator if the analyzer is reporting results within "acceptable" limits.

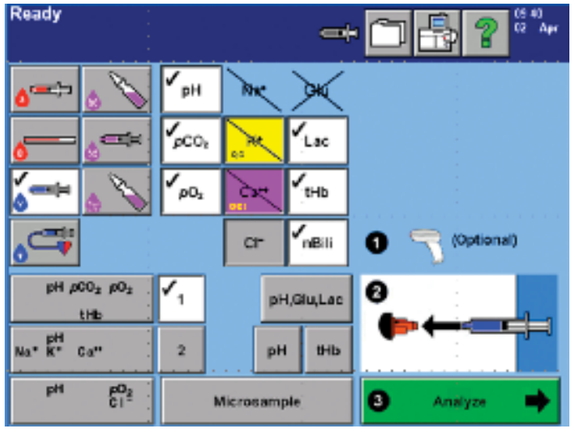

Figure 2. Siemens RAPIDLab 1200 and RAPIDPoint 400 Series analyzers automatically report acceptable and unacceptable QC results for multiple analytes

- ✓ Acceptable QC performance, parameter is ready
- Failed QC
- Parameter failed calibration: Parameter should be available after repeat calibration
- Parameter failed calibration: Parameter is unlikely to become available
- Required QC analysis was not performed when scheduled

Siemens RAPIDLab® 1200 and RAPIDPoint™ 400 Series blood gas analyzers feature fully automated QC routines that measure control samples and evaluate patient test results. If QC results (based on user-defined criteria) are acceptable, then patient values are reported. If a QC test result is "out of control", the analyzer will attempt to rectify the situation by automatically repeating the QC procedure. If the analyzer continues to be unsuccessful with the repeated QC procedure, the test channel will be shut down and operator intervention will be required.

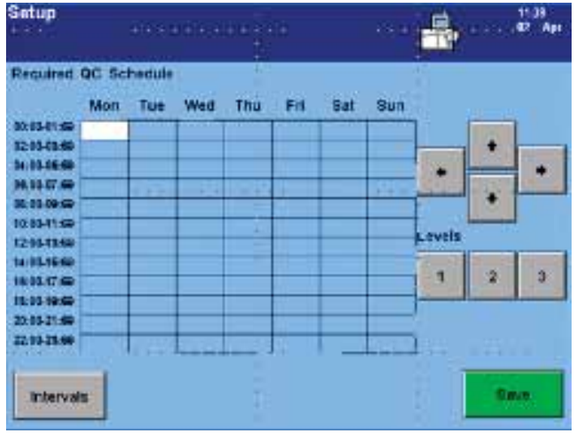

Figure 3. Siemens blood gas analyzers can be configured to meet user-defined QC schedules. Fully customizable QC schedules include selecting the day, time interval and level of QC.

2. To satisfy regulatory requirements that may be unique to certain regions of the world.

At the direction of the laboratory director or point-of-care supervisor, and/or according to established local protocols, both RAPIDLab 1200 and RAPIDPoint 400 Series analyzers automatically run the desired level of QC at a frequency that meets or exceeds regulatory requirements.

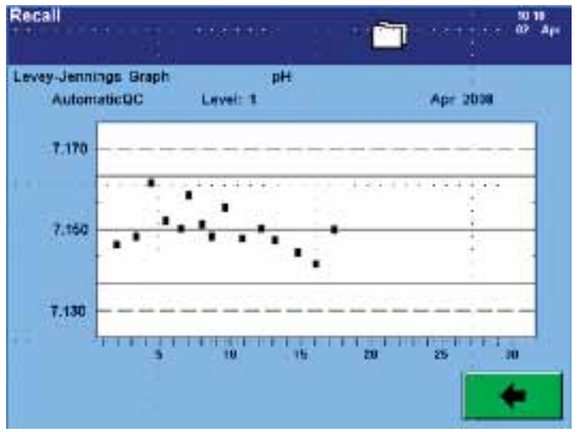

Figure 4: Levey-Jennings graph showing Level 1 AQC results for pH over time on a RAPIDLab 1200 system

3. To evaluate the operational performance of the analyzer over time.

Day-to-day and month-on-month performance of Siemens blood gas analyzers can be assessed by laboratory directors and point-of-care supervisors through tabulated reports of QC data, up-to-date QC statistics and software-generated Levey-Jennings graphs.

How has blood gas QC evolved over recent years?

Blood gas QC has evolved over time as new technologies and materials have become available. Previously, a blood gas control material was made of a buffer solution spiked with varying concentrations of electrolytes, metabolites and hemoglobin (and the hemoglobin fractions). The buffer was also equilibrated with a gas mixture containing oxygen, carbon dioxide and nitrogen. This procedure is known as tonometry. While this QC approach worked well, the procedure was a tedious one, and difficult to maintain at the laboratory level.

Recognizing the need for a commercially available blood gas QC product, manufacturers replaced the manual tonometry process with a blood gas QC product in a sealed glass ampule, impervious to the effects of room air.

Although easy to use, it is important that this type of control material be tested as soon as possible after opening, since control values can change upon exposure to room air.

The possibility of shifting control values due to room air exposure, coupled with the operator interaction required to run QC checks, led manufacturers to search for an alternative solution—

RAPIDQC™ Complete product, packaged 30 ampules per level, three unique levels

What is AQC?

AQC is an acronym for the Automatic Quality Control system used on Siemens RAPIDLab 1200 and RAPIDPoint 400 Series blood gas analyzers. This cartridge-based system provides QC in a standardized and unique manner that removes the need for operator intervention, and ensures the running of specific levels of QC at specified time intervals, as regulatory requirements dictate or according to individual hospital protocol.

Figure 6: On-board AQC requires no operator intervention during its 28-day cartridge life

RAPIDLab 1200 Blood Gas Series System

RAPIDPoint 400/405 Blood Gas Series System

The response from Siemens was the Automatic Quality Control (AQC) cartridge.

It is important to note that cartridge-based AQC is, just like ampuled QC, an external form of quality control. It is simply packaged differently, and is more convenient. The AQC cartridge is value assigned to a master lot, and is entirely external to the measurement system. The consistency of the manufacturing process allows the laboratory to consider their AQC as one long lot number with no expiration date.

The elimination of room air contamination allows the laboratory to consider using the data as one long shift on a day-to-day basis. This technology allows all laboratories to apply the same expected ranges over time for a given type of analyzer.

Figure 7: Actual reagent and QC manufacturing line for the cartridge-based products.

What does the AQC system consist of?

The AQC system is made up of the following components:

- **AQC Cartridge**—a single, self-contained cartridge that attaches to the side of the analyzer and remains viable for up to 28 days.
- **AQC Levels**—contained in three (Level 1, Level 2, Level 3) separate, sealed foil bags inside the cartridge. A buffer amount of QC is added to each one of the bags to account for repeats. The three levels of control material span the clinically significant ranges.
- **Data Manager**—this is built into the blood gas analyzer software, and includes a fully customizable, automatic schedule and decision rules that determines the availability and frequency for testing each parameter.

How does the AQC system work?

AQC fluidics is designed so that the AQC manifold provides a fluid path for QC materials to flow from the AQC cartridge to the patient sample entry port of the instrument reagent/measurement cartridge. In Figure 8, the red line represents the patient sample flow path and the blue line represents the QC flow path. Both the patient sample and QC materials follow the exact same sample path in the reagent/measurement cartridge (also see Figure 9).

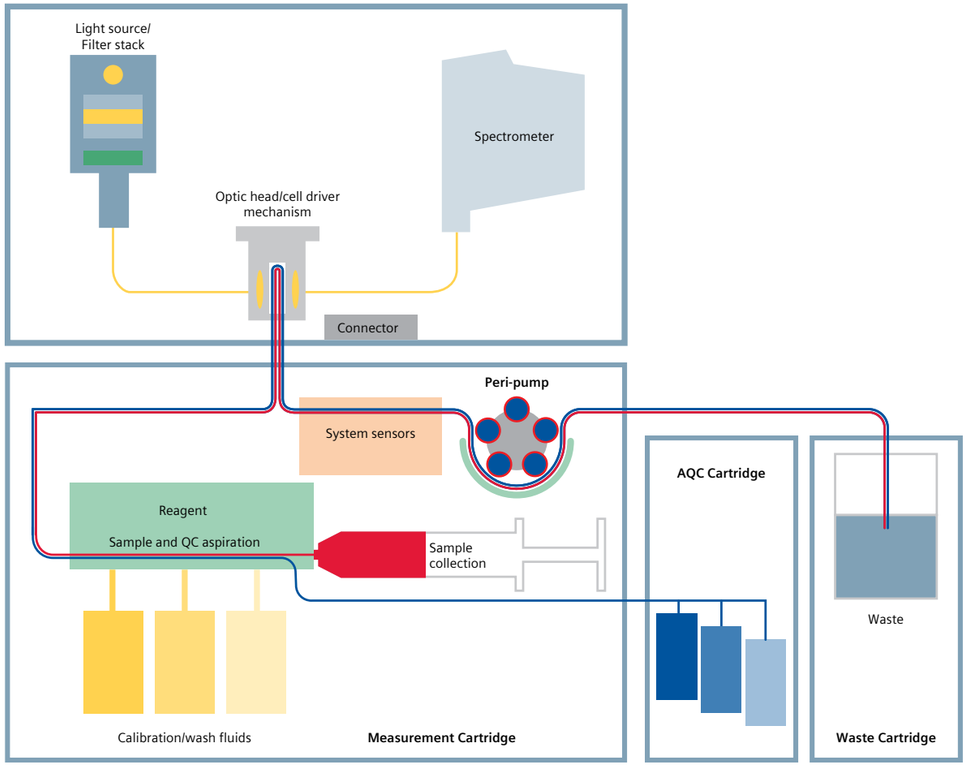

Figure 8: RAPIDLab 1200 system fluidics—both patient sample and AQC pathways

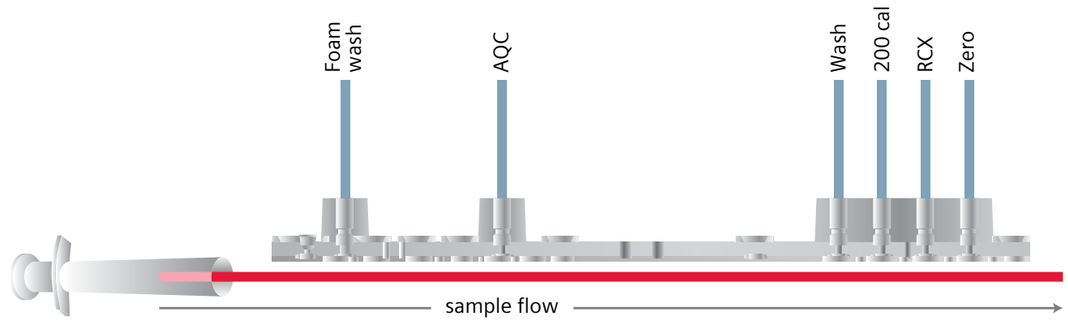

Figure 9: The AQC pathway is the same as the patient sample pathway

RAPIDPoint 400/405 System with AQC cartridge

QC statistical application

Siemens recommends the evaluation method of 3SD (Standard Deviations) Absolute Limits for RAPIDLab 1200 and RAPIDPoint 400 Series analyzers when using on-board AQC.

In simple terms, the QC recovery is either in or out of established default range limits. Since each reagent/measurement cartridge contains all new reagents, pump tubes, and fluidic pathways, when a changeover is implemented (every 28 days) it is generally accepted that there will be variability and shifts associated with the change.

A similar shift is seen when a sensor or reagent lot is changed on conventional blood gas analyzers (for example, the RAPIDLab 800 Series analyzers) every 6 - 12 months. However, the amount of change seen with RAPIDLab 1200 or RAPIDPoint 400 Series analyzer cartridges is minimal compared to that seen with more traditional blood gas systems.

	AQC Level 1		AQC Level 2		AQC Level 3	
	Target	Range (+/-)	Target	Range (+/-)	Target	Range (+/-)
pH	7.150	0.020	7.350	0.020	7.55	0.026
pCO_2 (mmHg)	70.0	6.4	40.0	5.0	22.0	3.0
pO_2 (mmHg)	150.0	11.0	100.0	7.8	65.0	9.2
Na^+ (mM)	115.0	5.0	135.0	5.0	155.0	7.0
K^+ (mM)	3.00	0.30	5.00	0.30	7.00	0.30
Ca^{++} (mM)	1.60	0.12	1.20	0.10	0.80	0.10
Cl^- (mM)	80.0	6.0	100.0	6.0	120.0	8.0
Glucose (mg/dL)	200	14	100	10	50	10
Lactate (mM)	12.00	2.00	0.90	0.24	3.00	0.60
tHb (g/dL)	18.0	1.6	14.0	1.6	8.0	1.0
% O_2Hb	78.0	3.0	92.0	3.0	60.0	3.0
% HHb	2.5	4.0	2.5	4.0	16.0	4.0
% COHb	3.5	5.0	3.5	5.0	18.0	5.0
% MetHb	16.0	3.6	2.0	4.6	6.0	3.6
n-Bilirubin (mg/dL)	20	4.0	12	2.8	5	2.4

Table 1: AQC target and acceptable range for each reported parameter and each level of QC

This is due to two unique system characteristics:

- Each AQC batch is manufactured to be identical in numerical values to previous batches. This allows operators to compare data over years rather than just months.
- There is no exposure to room air. Exposure to atmosphere when using ampuled QC tends to generate the most variability.

With these two sources of potential error virtually eliminated, the use of traditional 2SD QC limits could cause any small data change to look significant, despite not being clinically significant.

The suggested fixed or absolute QC limits are designed to be consistent with the medical needs of clinicians. These limits reduce to an absolute minimum the number of “false rejections” due to erroneous QC signals, as noted by comparing the small actual standard deviations to the absolute QC limits in Table 1.

If operators were to evaluate RAPIDLab 1200 or RAPIDPoint 400 Series analyzer QC results using traditional 2SD statistical limits, they might overreact to small shifts or trends associated with a change of the measurement cartridge, and possibly request unnecessary and potentially costly service interventions. Additionally, traditional QC management only addresses the process capabilities of the instrument based upon recent history.

Absolute limits evaluation allows users to apply clinical decision-making to the measurement process over extended periods of time, thereby avoiding an overreaction and expenditure of time and energy resulting from a change that is statistically, but not clinically, significant or relevant.

In summary, the fixed QC limits represent the largest possible error that may be present in a test result. These are sometimes referred to as “medical need” or “medical usefulness” limits. Because these limits are much larger than the standard deviation of highly precise RAPIDLab 1200 or RAPIDPoint 400 analyzer results, false positives and erroneous “out of control” signals are essentially eliminated.

Checks and balances to ensure quality results

QC checks, performed either manually or by means of the AQC system, represent an important and independent verification of the stability of both analyzers and overall analyte performance. Nevertheless, calibrations, multiple algorithm checks on patient samples, and multiple quality checks post-patient sample analysis remain the primary guardians of patient result quality.

Siemens blood gas systems incorporate a variety of analyzer functions and flagging mechanisms to ensure the quality of the patient results:

- Calibration routines are set to run after every sample for the first eight hours after installation, and then run at a minimum of once every half hour thereafter.
- The drift limits for calibrations are set well below clinically significant limits.
- Any calibration that fails is repeated a maximum of two times, or until the analyte passes. If the analyte does not pass, the parameter is turned off until the next scheduled calibration.
- The sensors for each analyte have hard-coded limits for slope and offset. Any changes are corrected and adjusted through a calibration cycle. Once any of these reach their limits, the analyte is permanently disabled.
- In addition to traditional calibration cycles, all sample, calibration, QC and AQC responses are quality-checked with up to eight internal software algorithms. If any of these fail, the sample will be flagged and no result will be reported.
- A solution is run between each sample to execute multiple sensor quality checks on the analyzers.
- Additional evaluations of results include checks for bubbles in the sample, and temperature.
- All function checks are performed automatically.
- All actions are recorded and documented in the event log.
- All raw data may be downloaded and forwarded to Siemens for further analysis.

The totality of independent quality checks available with Siemens blood gas analyzers, in combination with the Automatic Quality Control system, helps to ensure the integrity of all reported patient test results.

Peace of mind with AQC

Siemens AQC system offers:

- The flexibility to set a quality control schedule that meets your individual hospital standards and complies with local regulatory guidelines.
- A unique design that ensures control of the entire sample path—the AQC material is introduced at the same point as the patient sample.
- Three different levels of aqueous material that cover the critical reporting ranges as well as the normal ranges.
- QC materials that are truly independent from on-board calibrators.
- The ability to interrupt the QC routine to run a patient sample.
- Cost-effectiveness and ease of use versus ampuled QC.

AQC Specifications	
AQC Cartridge	
Use-life:	28 days
Shelf-life:	4 months
Storage:	Temperature: 2–8° C
Humidity	0–95%, non-condensing
QC Method	Aqueous QC Material
Time to Result	60 Seconds
User Interface	Color Touch Screen
QC Lock-out	Yes
Automatic Repeat	Yes, if enabled
Constant Expected Ranges	Yes
Customizable Ranges	Yes
Maintenance	None required
Sensitive to Operator Handling	No
Data Management	Yes, with external RAPIDComm® Data Management System

What should I do now?

If your organization is using a Siemens analyzer equipped with AQC, you have to decide your approach to QC limits based on the facts presented above. You should also discuss the information with your medical director.

Ultimately the final decision rests with your medical director. Based on the statistical data, the most practical solution would be the use of fixed limits with AQC, since this avoids unnecessary sample rejection while still allowing for error detection, when applicable. This will ensure that you maintain maximum instrument uptime and operational cost-effectiveness.