SIEMENS

White Paper

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

For over 50 years, Siemens Healthcare Diagnostics has been developing, manufacturing, and marketing critical care products, including blood gas analyzers that now incorporate an innovative Automatic Quality Control (AQC) system.

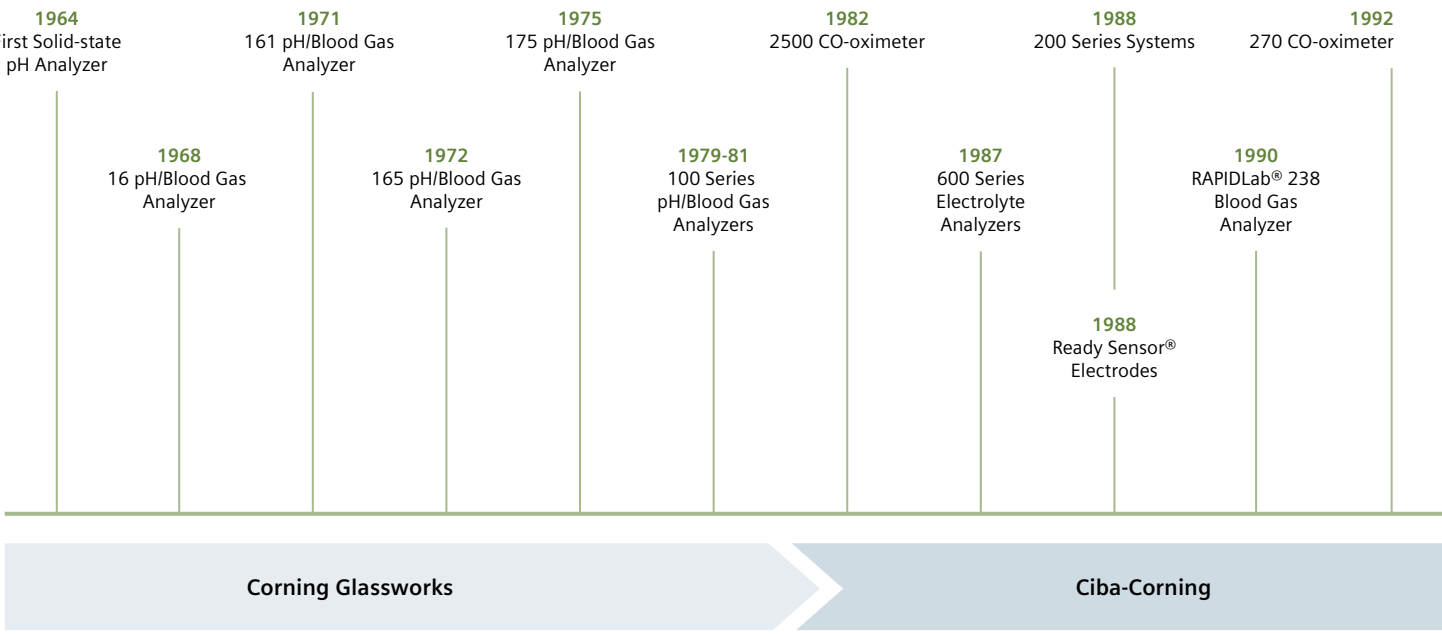


Figure 1. Siemens Blood Gas Testing Milestones

*Not available for sale in the U.S. Product availability varies by country.
†Product availability varies by country.

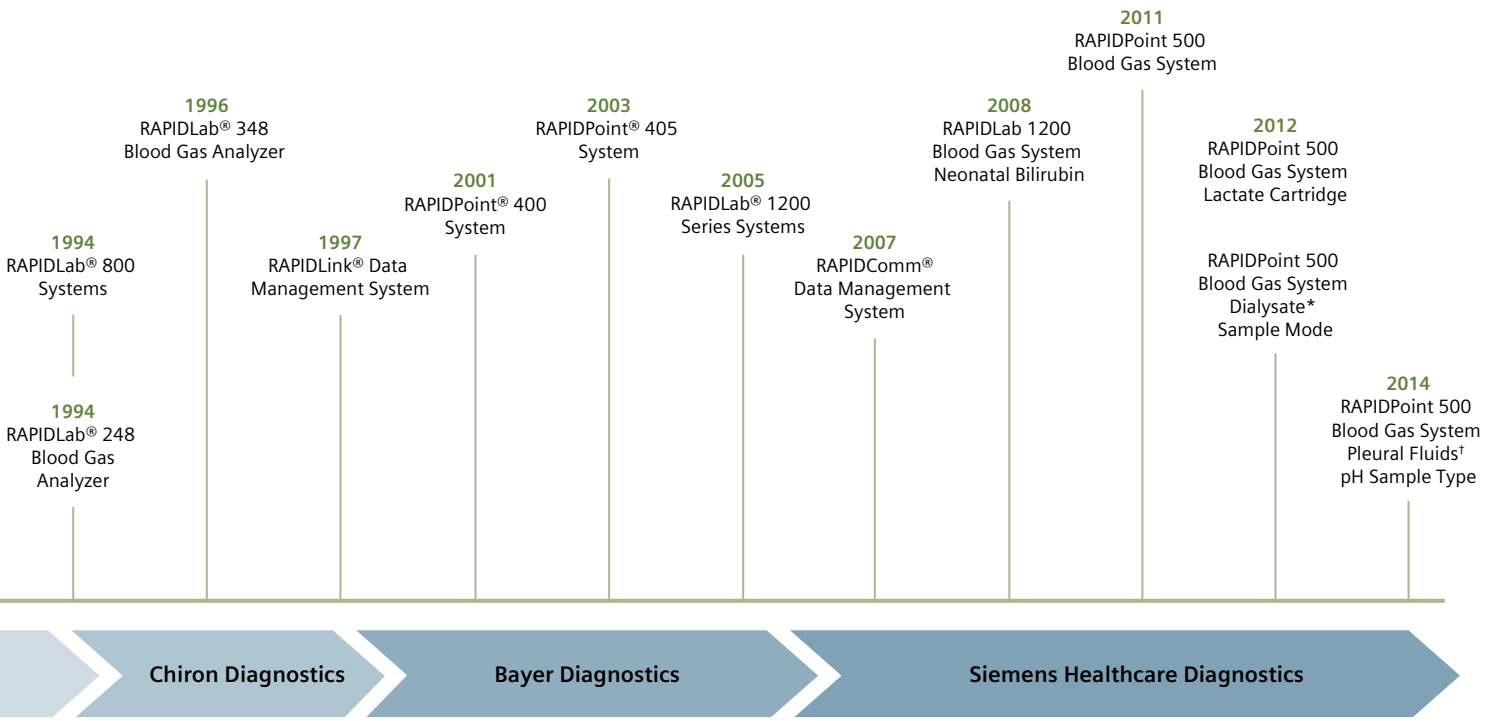
Introduction

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 analyzer's 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, preventive maintenance, proficiency testing, and routine analysis of materials of known concentration, referred to as controls.



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

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.

Siemens RAPIDLab 1200 and RAPIDPoint 400/405/500 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.

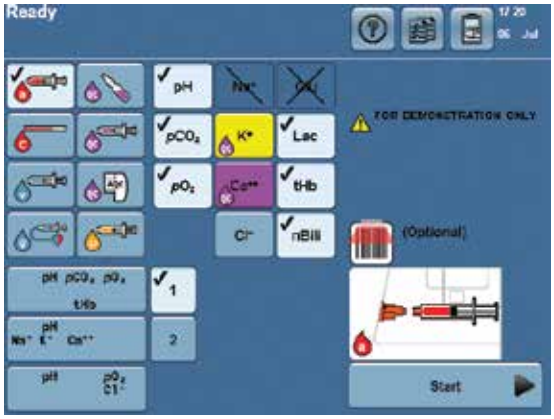


Figure 2. RAPIDPoint 500 system automatically reports acceptable QC results for multiple analytes and indicates when QC and calibration routines are unacceptable.

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 400/405/500 Series analyzers automatically run the desired level of AQC at a frequency that meets or exceeds regulatory requirements.

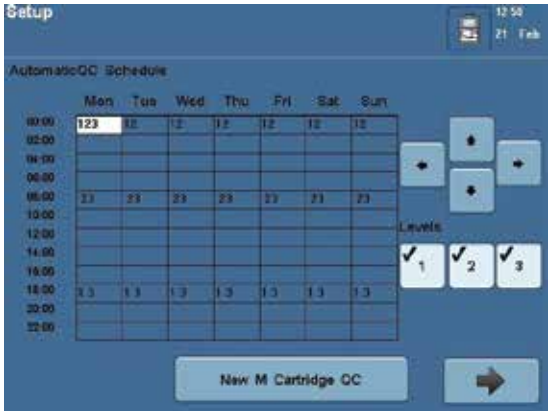


Figure 3. Siemens blood gas analyzers can be configured to meet user-defined QC schedules. Fully customizable QC schedules include selecting the day, time interval and level of QC to be run.

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.

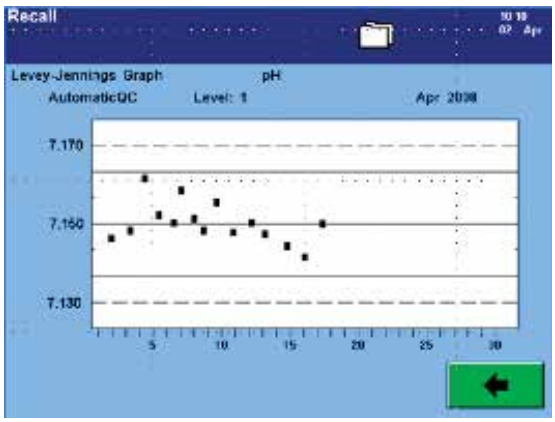


Figure 4. Levey-Jennings graph showing Level 1 AQC results for pH over time on a RAPIDLab 1200 system.

How Has Blood Gas QC Evolved In 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 tedious 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. The Siemens RAPIDQC™ Complete product is an example of this type of quality control material.

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.

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

RAPIDQC Complete quality control product, packaged 30 ampules per level, three unique levels.

Onboard AQC requires no operator intervention during its 28-day use-life.

What Is AQC?

AQC is an acronym for the Automatic Quality Control system used on Siemens RAPIDLab 1200 and RAPIDPoint 400/405/500 Series blood gas analyzers. This cartridge-based system provides QC material 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.

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 entirely external to the measurement system, and the controls are value-assigned to a master lot by the manufacturer. 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.

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 bag to account for repeats. The three levels of control material span the clinically significant ranges.
- **Data Manager**: built into the blood gas analyzer software. Includes a fully customizable, automatic schedule and decision rules that determine the availability and frequency for testing each parameter.

How Does the AQC System Work?

AQC fluidics are 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 5, 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 exactly the same sample path in the reagent/measurement cartridge.

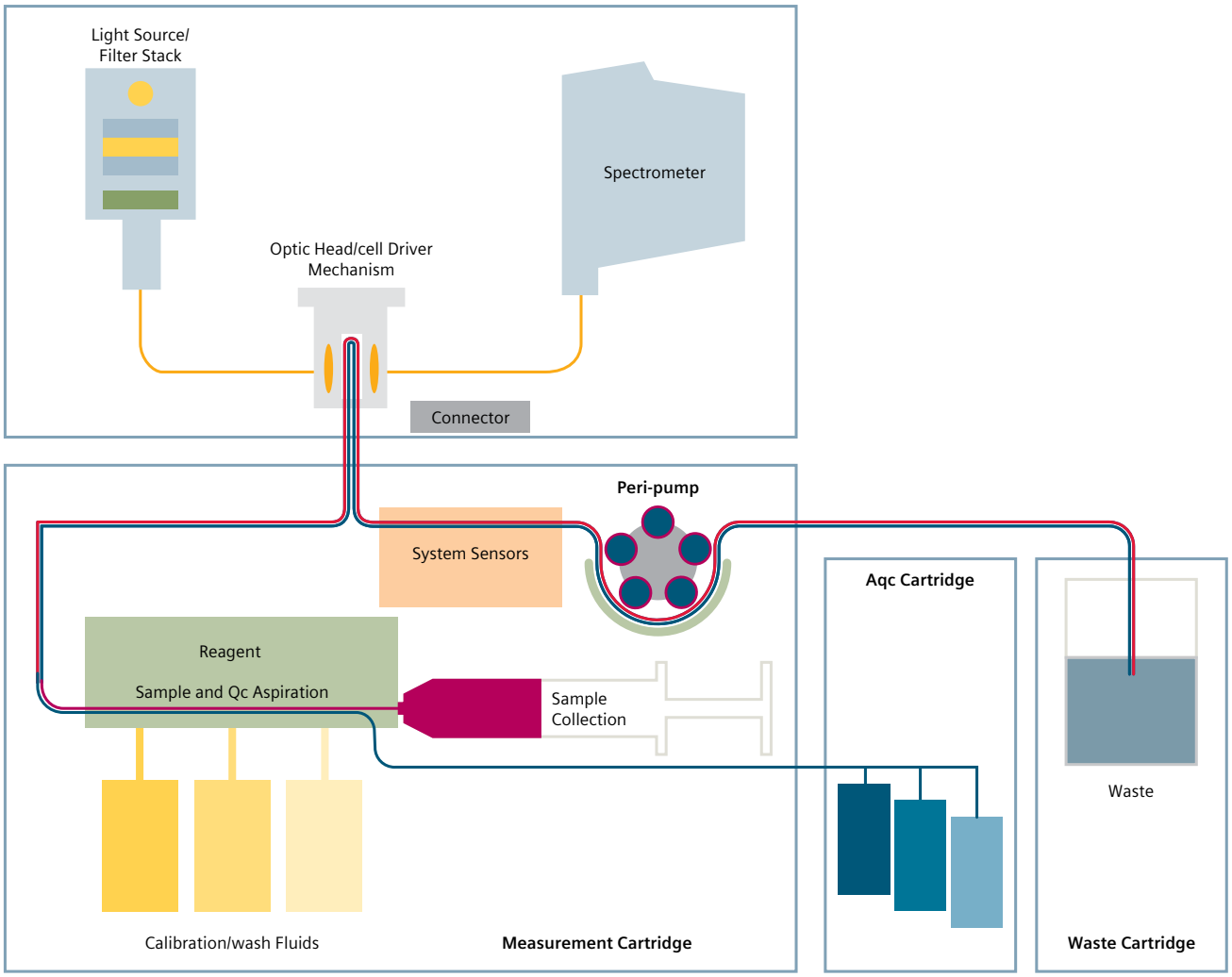


Figure 5. System fluidics schematic: Patient and QC flow paths are the same from sample entry to waste.

QC Statistical Application

Siemens recommends the evaluation method of 3SD (standard deviations) absolute limits for RAPIDLab 1200 and RAPIDPoint 400/405/500 Series analyzers when using onboard 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 replacement 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 248 analyzers), typically every 6–12 months. However, the amount of change seen with RAPIDLab 1200 or RAPIDPoint 400/405/500 Series analyzer cartridges is minimal compared to that seen with more traditional blood gas systems.

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.
- 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 appear 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.

		AQC Level 1		AQC Level 2		AQC Level 3	
Parameter	**Units**	**Target**	**Range (+/-)**	**Target**	**Range (+/-)**	**Target**	**Range (+/-)**
pH		7.150	0.020	7.350	0.020	7.550	0.026
H^+	nmol/L	70.8	3.2	44.7	2.1	28.2	1.7
pCO_2	mmHg	70.0	6.4	40.0	5.0	22.0	3.0
pCO_2	kPa	9.33	0.85	5.33	0.67	2.93	0.40
pO_2	mmHg	150.0	11.0	100.0	7.8	65.0	9.2
pO_2	kPa	20.00	1.47	13.33	1.04	8.67	1.23
Na^+	mmol/L	115.0	5.0	135.0	5.0	155.0	7.0
K^+	mmol/L	3.00	0.30	5.00	0.30	7.00	0.30
Ca^{++}	mmol/L	1.60	0.12	1.20	0.10	0.80	0.10
Ca^{++}	mg/dL	6.4	0.5	4.8	0.4	3.2	0.4
Cl^-	mmol/L	80	6	100	6	120	8
Glu	mg/dL	200	14	100	10	50	10
Glu	mmol/L	11.1	0.8	5.6	0.6	2.8	0.6
Lac	mmol/L	12.00	2.00	0.90	0.24	3.00	0.60
Lac	mg/dL	108.1	18.0	8.1	2.2	27.0	5.4
tHb	g/dL	18.0	1.6	14.0	1.4	8.0	1.0
tHb	g/L	180	16	140	14	80	10
tHb	mmol/L	11.2	1.0	8.7	0.9	5.0	0.6
O_2Hb	%	78.0	3.0	92.0	3.0	60.0	3.0
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
HHb	%	2.500	4.000	2.500	4.000	16.000	4.000
nBili	mg/dL	20.0	4.0	12.0	2.8	5.0	2.4
nBili	umol/L	342	68	205	48	86	41

		AQC Level A		AQC Level B	
Parameter	**Units**	**Target**	**Range (+/-)**	**Target**	**Range (+/-)**
Hct	%	25	4	50	4

Table 1. AQC target and acceptable range for each measured parameter and each level of QC.

If operators were to evaluate RAPIDLab 1200 or RAPIDPoint 400/405/500 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 overreaction and expenditure of time and energy in response to 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 400/405/500 analyzer results, false positives and erroneous "out-of-control" signals are essentially eliminated.

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

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 after analysis of patient samples remain the primary guardians of patient result quality.

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

- Calibration routines are set to run after every sample on the RAPIDPoint systems for a short period of time after a measurement cartridge installation, with a 1-point calibration 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 and patient values are not reported until the next successful 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 temperature and bubbles in the sample.
- 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.

RAPIDPoint 500 Blood Gas System with AQC cartridge

RAPIDLab 1200 Blood Gas Series System with AQC cartridge

RAPIDPoint 400/405 Blood Gas Series System with AQC cartridge

What Should I Do Now?

If your organization is using a Siemens analyzer equipped with AQC, you must decide your approach to QC limits based on the facts presented here. 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.

Peace of Mind with AQC

The 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 onboard 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:	9 months
Storage:	Temperature: 2–8° C
Humidity	0–95%, noncondensing
QC Method	Aqueous QC material
Time to Result	60 seconds
User Interface	Color touchscreen
QC Lockout	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

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.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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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