



April 2009

**Re: Siemens Introduces NEW RTQC Features**

Dear Valued RTQC Customer,

As part of our commitment to the quality and continuous improvement of our critical care product portfolio, Siemens Healthcare Diagnostics will be implementing enhancements to the RTQC peer data statistical program.

The enhancements will be enabled beginning July 15, 2009 and will include:

- Continuous Monthly Summary Report
- Monthly Exception Report
- Enhanced CVI/SDI Limits flagging

The additional RTQC reports will provide the ability to quickly identify statistical flags and a simplified method for comparing instrument statistical QC data month to month. Enhanced CVI/SDI Limits will provide more granular control over statistical flagging within RTQC.

For further information about the enhancements or about CVI/SDI statistics, please see the attached documents:

- RTQC Enhanced Features Guide
- The Use of SDI and CVI in Quality Control Review

We are confident that the RTQC enhancements will aid in your review of the statistical QC peer group data and that this demonstrates our commitment to delivering updated products to you our valued customer. We thank you for your continued support to Siemens and our Blood Gas products and services.

If you should have any questions, please contact your **Technical Solutions Center at 1-877-229-3711, prompts 12 then 6.**

Siemens Healthcare Diagnostics

Thank You,

Best Regards,  
Nancy Gunther  
Marketing Manager, RAPIDLab® 1200

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## RTQC Enhanced Features Guide

### Monthly Summary and Exception Reports:

- Where:** To access the Lab Reports page click on the “Reports” link (see figure below) for the analyzer desired on the Home page. Then “Build” the report of choice.
- How:** The new reports have been incorporated into the report “Build” process.

Home - TCC SAMPLE LAB

Peer Group: USA Shift: 1 Time Frame: Monthly Change

Month: \*MAR 2005 Report Options: Plot Against: Group Monthly

Report Type: Inst/Test Inst Class Submit [Instrument List](#)

Peer Group: USA Shift: 1 Month: MAR-2005						
Plot Against: Group Monthly Report Type: Inst/Test(Inst Class)						
Instrument		Lot Kit			Report	
Name	Serial#	Level 1	Level 2	Level 3		
BAYER 800 Series	12345	<a href="#">TRL1</a>	TRL2	TRL3	<a href="#">Reports</a>	
BAYER 800 Series	98989	<a href="#">TRL1</a>	<a href="#">TRL2</a>	<a href="#">TRL3</a>	<a href="#">Reports</a>	

Log Off

### Enhanced CVI/SDI Limits:

- Where:** New settings for CVI/SDI limits have been added to the Instrument - Test List page. The following path is the most direct route to the new settings: **Home > Instrument List > click the “Name” link on the row for the instrument desired > click on the “Seq.” number for the Test to be edited.**
- How:** The default CVI/SDI settings for new instruments are set by the customer on the main menu, **Configuration** page. The new Test List page provides additional control of the CVI/SDI limits by allowing adjustment on a per-instrument, per-test, per-QC level basis. The Copy Test List function can be used to copy CVI/SDI limits from previously configured instruments to new instruments in order to minimize efforts. (See electronic Users Manual on the Accessory Kit CD) The figure below displays the new Test List page.

(Note: The CVI/SDI limits shown are for demonstration. Each laboratory is responsible for setting the appropriate CVI/SDI limits for its organization.)

#### Test List - Sample

Instrument: BAYER 1200 Series Serial#: Sample Lot Kit: Z03-1 Z03-2 Z03-3

[Edit Test List](#)

[Copy Test List](#)

Click seq# to update SDI limits and CVI limits

Seq.	Test Code	Test Name	Unit	SDI Limit			CVI Limit		
				Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<a href="#">1</a>	PH	pH	PH	2	2	2	2	2	2
<a href="#">2</a>	PCO2	pCO2	MMHG	2	2	2	2	2	2
<a href="#">3</a>	PO2Q	pO2 (Quick Adapter)	MMHG	2	2	2	2	2	2
<a href="#">4</a>	NA	Sodium	MMOL/L	2	2	2	2	2	2
<a href="#">5</a>	K	Potassium	MMOL/L	2	2	2	2	2	2
<a href="#">6</a>	CA	Ionized Calcium	MMOL/L	2	2	2	2	2	2
<a href="#">7</a>	CL	Chloride	MMOL/L	2	2	2	2	2	2
<a href="#">8</a>	GL	Glucose	MG/DL	2	2	2	2	2	2
<a href="#">9</a>	LA	Lactate	MMOL/L	2	2	2	2	2	2
<a href="#">10</a>	THB	Total Hemoglobin	G/DL	2	2	2	2	2	2
<a href="#">11</a>	O2HB	Oxyhemoglobin	%	2	2	2	2	2	2
<a href="#">12</a>	COHB	Carboxyhemoglobin	%	2	2	2	2	2	2
<a href="#">13</a>	METH	Methemoglobin	%	2	2	2	2	2	2
<a href="#">14</a>	HHB	Deoxyhemoglobin	%	2	2	2	2	2	2

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## The use of SDI and CVI in Quality Control Review

SDI is an abbreviation for standard deviation index. This parameter reports your performance relative to the group of participants. The formula is as follows:

$$\text{Lab SDI} = (\text{Lab Mean} - \text{Group Mean}) / \text{Group SD}$$

An SDI of +1.0 means that your laboratory's reported mean is 1 group SD (standard deviation) above the reported group mean. For example, if the reported lab mean is 110, the group mean is 100, and one group SD is 5, then the reported Lab SDI would be +2.0.

If the lab SDI is positive then the reported lab mean is showing a positive bias relative to the group, similarly if the SDI is negative the reported lab mean is negative relative to the group. Lab accuracy is demonstrated when the lab mean is close to the group mean, providing the group mean is believed to be correct. SDI values greater than  $\pm 2.0$  SDI should generally be investigated.

CV is an abbreviation for coefficient of variation, which describes the standard deviation as a percentage of the mean. CV is a relative term for variation or bias where as SD is an absolute term in the units of measurement. The formula for CV is:

$$\text{CV \%} = (\text{SD} / \text{mean}) \times 100$$

CVI is derived from CVs and shows how reproducible the lab values are relative to the group reproducibility. The formula for CVI is:

$$\text{Lab CVI} = \text{Lab CV} / \text{Group CV}$$

For an example if the group CV is 5% and the reported lab CV is 10% then the lab CVI is 2.0.

When evaluating precision the traditional action limit for CVI is 2.0. The problem is that CVI can be misleading if the reported lab mean being reviewed is small. Why? Because CVI's are based on CV's and in the calculation for CV, as the reported mean approaches zero the reported CV will approach infinity, so for some tests with traditionally small means the higher CV may not be clinically significant.

The following example illustrates this point. A lab reports a mean of 2.37 for COHB with an SD of 0.677. The 2 SD range for the Lab data would be 1.02 to 3.72. A COHB result anywhere in this range would have no clinical significance, yet the calculated CV for this COHB mean would be 28.6%. Now compare the Lab mean to a Group mean of 2.87 with an SD of 0.374 and CV of 13.0%. Again there is no clinical significance between the Lab mean and the Group mean, but the CVI would be 2.2.

Using a CVI of 2.0 as an action limit for all tests does not always make practical sense. In fact for some assays with low mean values or low SD's it may be appropriate to increase the CVI action limit to 3.0. This could avoid running unnecessary quality control.

In summary, we recommend that both statistics and clinical significance be used when setting SDI and CVI action limits for QC data review.