

Evaluation of glucose testing performance in clinical laboratory by single-rule and Westgard multi-rules

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Background : *Blood glucose testing is one of the most common laboratory requests for diabetes. Generally, internal quality controlled (IQC) using single-rule is used to monitor its precision while the accuracy is assured by an external quality assurance scheme (EQAS); and both results are then evaluated separately. Thus, the problems of imprecision and inaccuracy are not simultaneously solved. Therefore, the Westgard multi-rule scheme was later developed and used to evaluate imprecision and inaccuracy together, making it a useful QC.*

Objective : *The goal of this study is to evaluate laboratory performance in blood glucose testing by using the single-rule and Westgard multi-rule scheme while aiming to optimize the QC rules for the parameters.*

Methods : *Analysis of the data from glucose IQC and EQAS performed on Hitachi 917 (Roche Diagnostics GmbH, Mannheim, Germany) was used from September 2006 to May 2007 for retrospective review, and from June to August 2007 for prospective evaluation.*

Results : *Our IQC means of Precinorm U (PNU) and Precipath U (PPU) were in designed ranges of the manufacturer; meanwhile our standard deviations (SDs) were lower than the designed SDs. Our glucose testing performance from prospective study are in acceptable limits, i.e., between 3.01-4.65 sigma, while that of the retrospective review are 0.91-8.66 sigma. Although the single-rule is easier to monitor, it is not appropriate for accuracy.*

Conclusion : *Our study has demonstrated that the multi-rule scheme provides useful data for improving the performance in terms of precision and accuracy for glucose testing QC making it more appropriate than the single-rule since it could be used to evaluate imprecision and inaccuracy simultaneously. The multi-rule scheme could be an optimized QC tool for errors detection and false rejection.*

Keywords : *Glucose, Quality control, Single-rule, Multi-rule, Westgard rules.*

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กฤษณรงค์ เกียรติศิริ, อมรรัตน์ กันกา, กฤษณา เลิศสุขวิบูลย์, ชัชวาลย์ สันต์รัฐกิจ, พรศักดิ์ ทับสีรัก, วิษย์ศักดิ์ สุขสะอาด, นวพรรณ จารุรักษ์. การประเมินสมรรถภาพการตรวจวิเคราะห์กลูโคสในห้องปฏิบัติการคลินิกโดยการใช้กฎกฎเดียวและกฎหลายกฎของเวสต์การ์ด. จุฬาลงกรณ์เวชสาร 2552 มี.ค. - เม.ย.; 53(2): 91 - 106

- ภูมิหลัง** : การตรวจวิเคราะห์กลูโคส นับเป็นการทดสอบที่มีการส่งตรวจมากที่สุดการทดสอบหนึ่งในผู้ป่วยโรคเบาหวาน โดยทั่วไปการควบคุมคุณภาพภายในจะใช้กฎกฎเดียวในการควบคุมความแม่นยำ ขณะที่ความถูกต้องจะควบคุมด้วยการร่วมโครงการควบคุมคุณภาพจากภายนอก ทำให้ผลการควบคุมคุณภาพภายในและภายนอกต่างก็จะถูกประเมินแยกจากกัน ซึ่งหมายความว่า การแก้ไขปัญหาเกี่ยวกับความแม่นยำและความถูกต้องไม่ได้รับการดำเนินการไปด้วยกัน ต่อมาจึงได้มีการพัฒนากฎหลายกฎของเวสต์การ์ด เพื่อให้ประเมินให้ผลการควบคุมคุณภาพภายในและภายนอกไปด้วยกัน ทำให้กฎหลายกฎเป็นเครื่องมือควบคุมคุณภาพที่มีประโยชน์
- วัตถุประสงค์** : การศึกษานี้มีวัตถุประสงค์เพื่อประเมินสมรรถภาพการตรวจวิเคราะห์กลูโคสในห้องปฏิบัติการ โดยการใช้กฎกฎเดียวและกฎหลายกฎของเวสต์การ์ด รวมทั้งการเลือกใช้กฎที่เหมาะสมที่สุดสำหรับการตรวจวิเคราะห์กลูโคส
- วิธีการ** : เก็บข้อมูลและวิเคราะห์ผลการควบคุมคุณภาพภายในและภายนอก สำหรับการตรวจวิเคราะห์กลูโคส ที่ทำการวิเคราะห์ด้วยเครื่องอิตาซี 917 (โรช ไดแอกโนสติกส์ ประเทศเยอรมัน) ด้วยการเก็บข้อมูลย้อนหลังช่วงเดือนกันยายน 2549 ถึงเดือนพฤษภาคม 2550 และเก็บแบบไปข้างหน้าในช่วงเดือนมิถุนายนถึงสิงหาคม 2550
- ผลการศึกษา** : พบว่าค่าเฉลี่ยของสารควบคุมคุณภาพ PNU และ PPU ของห้องปฏิบัติการ อยู่ในพิสัยที่ผู้ผลิตกำหนดโดยมีค่าเบี่ยงเบนมาตรฐานต่ำกว่าของผู้ผลิต ผลการศึกษา ยังได้แสดงให้เห็นว่าในการศึกษาแบบเก็บข้อมูลไปข้างหน้าของการตรวจวิเคราะห์กลูโคสอยู่ในขอบเขตที่ยอมรับได้โดยมี ค่าซิกม่าระหว่าง 3.01-4.65 ขณะที่การศึกษาแบบเก็บข้อมูลย้อนหลังผลซิกม่าระหว่าง 0.91 - 8.66 แม้ว่ากฎกฎเดียวจะใช้ได้ง่ายในการควบคุมความแม่นยำ แต่ไม่เหมาะสมในการควบคุมความถูกต้อง

สรุป : ผลการศึกษานี้แสดงว่ากฎหลายกฎให้ข้อมูลที่เป็นประโยชน์ในการพัฒนาสมรรถภาพของห้องปฏิบัติการในด้านความแม่นยำและความถูกต้องสำหรับการตรวจวิเคราะห์กลูโคส ทำให้การใช้กฎหลายกฎมีความเหมาะสมกว่าการใช้กฎกฎเดียว เนื่องจากสามารถทำการประเมินความไม่แม่นยำไปพร้อมกับความไม่ถูกต้อง กฎหลายกฎยังเป็นเครื่องมือในการควบคุมคุณภาพที่เหมาะสมสำหรับการใช้ในการค้นหา และปฏิเสธความผิดพลาด

คำสำคัญ : กลูโคส, ควบคุมคุณภาพ, กฎเดียว, หลายกฎ, กฎของเวสต์การ์ด.

Blood glucose testing is a well-known and useful laboratory test used for screening, diagnosis and monitoring of diabetes. Nowadays, diabetes is one of the most common health problems in Thailand.⁽¹⁻²⁾ Thus, blood glucose testing is the most common laboratory testing requested parameters, especially in diabetic clinics. The test results provide useful information for making medical decisions. Because of this, its precision and accuracy are expected to tell the truth about what is happening in the patients.⁽³⁾ This means that the quality control (QC) tool should ideally provide the probability for error detection (P_{ed}) of 100%, and the probability for false rejection (P_{fr}) of 0%. Unfortunately, such a perfect QC tool does not exist. Practically, the P_{ed} of 90% and the P_{fr} of 5% or less are generally accepted as the optimization internal quality control (IQC) performance.⁽⁴⁻⁵⁾

Usually, hospital laboratories use IQC for precision monitor and external quality assurance scheme (EQAS) for accuracy checking.⁽⁶⁾ Most laboratories in Thailand routinely monitor IQC of the tests using single rule, either 1_{2s} or 1_{3s} (especially 1_{2s}), which has been practiced worldwide for several decades since it is non-complicate. However, there is a false-alarm problem with a 1_{2s} rule, such as the Levey-Jennings chart (L-J Chart) with two standard deviation ($\pm 2SD$) control limits. When the number of control measurements is two ($N = 2$), it is expected that 9% of the good runs will be falsely rejected; with $N = 3$, it is even higher, about 14%; with $N = 4$, it is almost 18%. This means that almost 10-20% of the good runs will be thrown away, which wastes a lot of time and effort in the laboratory. While the L-J chart with $\pm 3SD$ control limits has a very low false rejection rate, only

1% or less with N s of 2-4, its error detection (true alarms) will also be lower. Thus, the problem with the 1_{3s} control rule is that medically important errors may not be detected. Additionally, the single-rule could provide only precision information that gives limitation to improve laboratory performance. Laboratories need to enroll the EQAS for accuracy or bias monitoring. When IQC and EQAS are evaluated separately, the optimizing QC process for solving of imprecision and inaccuracy is then not possible. Due to the mentioned limitations of the single rule, the multi-rule system for optimizing assay error detection for both precision and accuracy originally developed by James Westgard and others has been widely used in clinical pathology laboratories for decades.⁽⁷⁻⁸⁾ With the multi-rule QC program, EZ Rules[®]3 (Westgard QC Inc, Madison, WI, USA), the operating specifications charts (OPSpecs charts) and the power function charts could be generated.⁽⁹⁾ The power of various combinations of rules to detect changes in assay performance can be assessed by the use of power function charts, some of which are freely available on the Westgard QC website.⁽¹⁰⁾ The OPSpecs chart is a graphic tool that shows the relationship between the quality requirement for the test, the precision and accuracy observed for a method, and the rejection characteristics for different control rules and numbers of control measurements.⁽¹¹⁾ Each chart is created from several combining information, therefore it makes the multi-rule scheme more complicated and too difficult to understand. Although the multi-rule QC procedures are more complicated than the single rule procedure, it is a disadvantage. The major advantage is that it allows the improvement of laboratory performance. To achieve the benefits in laboratory performance, the multi-rule scheme is currently being deployed in several

laboratories worldwide. Although it is an interesting issue, very few articles have been published on this subject, especially in Thailand. The aim of this article is to evaluate the potential applications in clinical laboratories of the single-rule and the multi-rule programs.⁽¹²⁻¹³⁾

Therefore, the authors have designed a study at the Department of Laboratory, Bumrungrad International Hospital (BIH) to evaluate laboratory performance in blood glucose testing by both the single-rule and Westgard multi-rule. The authors also aim to optimize the quality control rule for glucose testing. In addition, this information would be useful for our laboratory as well as others in using the proper IQC to evaluate and improve laboratory performance.

Materials and Methods

The IQC data of blood glucose concentration performed on a Hitachi 917 (Roche Diagnostics GmbH, Mannheim, Germany), at the Department of Laboratory, BIH, from June to August 2007 were collected and evaluated prospectively for evaluate performance in blood glucose test by using multi-rule while IQC and EQAS from September 2006 to May 2007 were reviewed and evaluated retrospectively for evaluate performance by using single-rule. There were neither patients' names nor samples involved in this study.

Percinorm U, Lot 176469 Ver.1 and Precipath U, Lot 176287 Ver.1 were used as control materials for glucose testing. Mean, standard deviation (SD), and coefficient of variation (CV) for each control during the first ten days or forty consecutive data ($n = 40$) of each month were calculated. The method bias of glucose testing was calculated from EQAS of the Royal College of Pathologists of Australia (RCPA) that

performed at the same period of time of IQC. Based on the Clinical Laboratory Improvement Amendments (CLIA) the criteria for acceptable performance in proficiency testing (allowable total errors, TE_a), the TE_a for glucose is 10%.⁽¹⁴⁻¹⁵⁾ Results of IQC in each month performed by the single rule (1_{2s}) were evaluated and compared to the multi-rules which were analyzed by using the multi-rule QC program, EZ Rules[®]3 (Westgard QC Inc, Madison, WI, USA) using 90% analytical quality assurance (90% AQA).⁽¹⁶⁾ Laboratory performance was assessed on the sigma scale with a benchmark for minimum process performance of 3-sigma and a goal for world-class quality of 6-sigma.^(15,17)

Results

Retrospective mean, SD, and CV of each control during September 2006 to May 2007 were calculated and presented in Table 1. We found that all of our IQC means were in the designed ranges of the manufacturer and all of our SDs were lower than manufacturer's designed SDs. With the CLIA criteria for glucose is 10% and equation of sigma metric is $[(TE_a - bias_{obs})/S_{obs}]$ ^(3, 14 - 15), we calculated the performance during September 2006 to May 2007 using the sigma metric and demonstrated in Table 1. The retrospective data presented the wide scatter of performance in term of sigma metric (0.91 - sigma to 8.66 - sigma).

As for the prospective study, glucose IQC of Precinorm U and Precipath U of each month during June to August 2007 were assessed and presented by L-J Charts (Figure 1 and 2). With the single rule of 1_{2s} (Figure 1), results of our IQC of PNU demonstrated one, two and one out ($\pm 2SD$) in June, July, and August, respectively. Meanwhile (Figure 2), the results of our

IQC of PPU demonstrated nine and two out in June and July, respectively. The mean, SD, and CV of each control from June to August, 2007 were calculated and presented in Table 2. From Table 2, all of our IQC means of PNU and PPU were in the designed ranges of the manufacturer. In addition all of our SDs were lower than manufacturer's designed SDs. Based on the CLIA criteria, the calculated sigma values of our performance on glucose in June to August 2007 using sigma metric equation were also calculated and demonstrated in

Table 2. The results demonstrated that our performance for glucose testing from June to August 2007 are within the acceptable limits, i.e., between 3.01 - sigma to 4.65 - sigma.⁽¹⁵⁾ The OPSpec charts of glucose testing performance of each month generated by EZ Rules[®]3 are presented in Figure 3 and 4. Recommended control rules from multi-rules, P_{rr}, and N/R are demonstrated in Table 3. With the multi-rules, the recommended rules for glucose control are different from the usual 1_{2s} rule that is used routinely in our current practice.

Table 1. The results of mean, SD, and CV of glucose testing from September 2006 to May 2007, manufacturer's designed values, method bias, and sigma metric are evaluated retrospectively.

Parameter	Unit	Month	Control	Results			Designed values			Method	Sigma
				mean	SD	%CV	mean	range	SD	Bias (%)	Metric
Glucose	mg/dL	Sept. 2006	PNU	90.28	1.41	1.57	93.7	79.6-107.8	4.7	1.43	5.46
			PPU	249.78	2.47	0.99	259	220-298	13	1.43	8.66
		Oct. 2006	PNU	91.30	1.52	1.67	93.7	79.6-107.8	4.7	3.60	3.83
			PPU	248.88	2.14	0.86	259	220-298	13	3.60	7.44
		Nov. 2006	PNU	90.78	1.23	1.35	93.7	79.6-107.8	4.7	5.75	3.15
			PPU	247.78	2.71	1.09	259	220-298	13	5.75	3.90
		Dec. 2006	PNU	91.18	2.22	2.43	93.7	79.6-107.8	4.7	0.00	4.12
			PPU	247.73	2.87	1.16	259	220-298	13	0.00	8.62
		Jan. 2007	PNU	91.93	1.64	1.78	93.7	79.6-107.8	4.7	1.91	4.54
			PPU	249.05	2.73	1.09	259	220-298	13	1.91	7.42
		Feb. 2007	PNU	96.10	2.90	3.02	93.7	79.6-107.8	4.7	1.44	2.83
			PPU	265.95	8.91	3.35	259	220-298	13	1.44	2.56
		March 2007	PNU	92.90	2.00	2.15	93.7	79.6-107.8	4.7	3.53	3.01
			PPU	257.10	5.99	2.33	259	220-298	13	3.53	2.78
		April 2007	PNU	92.78	2.34	2.52	93.7	79.6-107.8	4.7	7.71	0.91
			PPU	256.15	6.16	2.41	259	220-298	13	7.71	0.95
		May 2007	PNU	93.73	2.74	2.92	93.7	79.6-107.8	4.7	1.84	2.79
			PPU	257.93	7.83	3.04	259	220-298	13	1.84	2.68

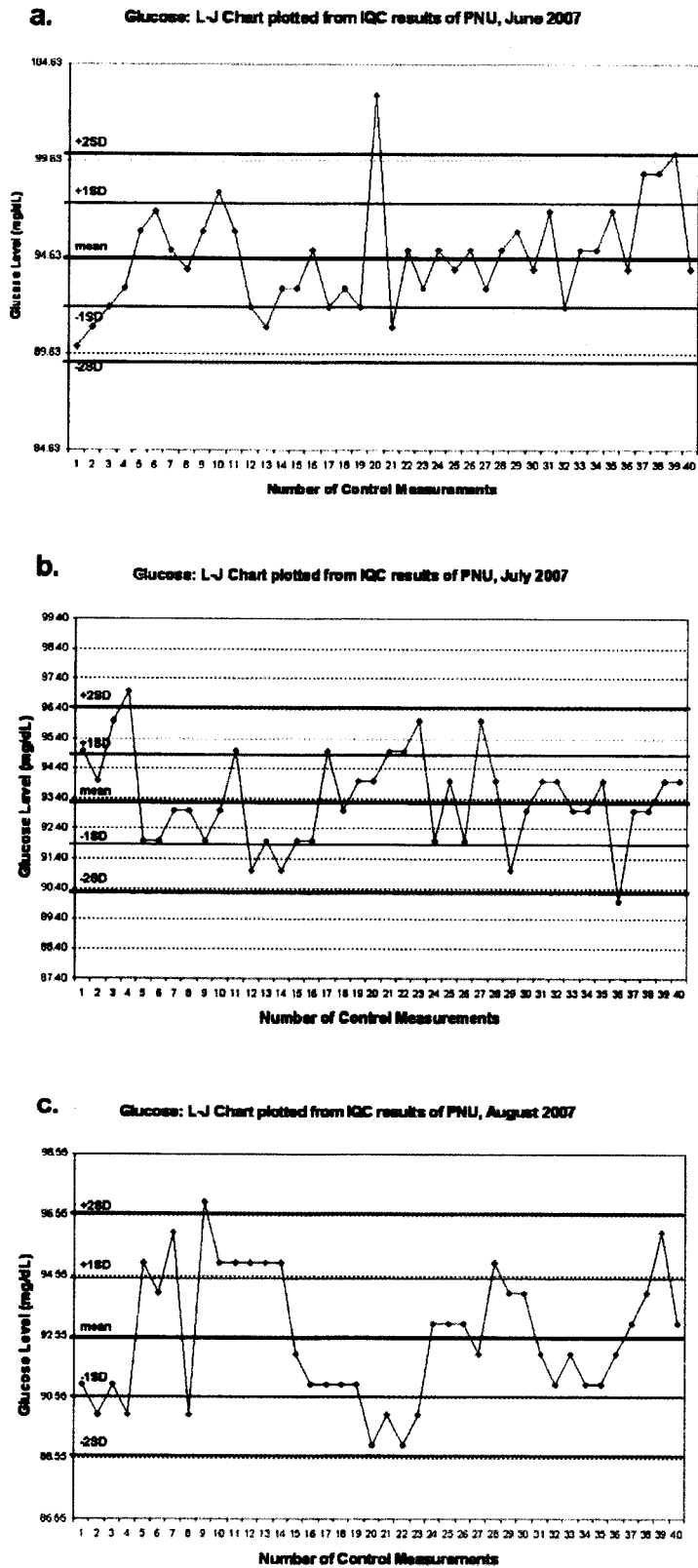


Figure 1. Levey-Jenning (L-J) Charts for glucose IQC of PNU of each month from June to August 2007; a.) L-J Chart of June, b.) L-J Chart of July, and c.) L-J Chart of August. Horizontal lines represent mean of control material measurements and mean \pm the given number of SDs. The IQC rule is violated if the lines representing mean \pm 2SDs are exceeded.

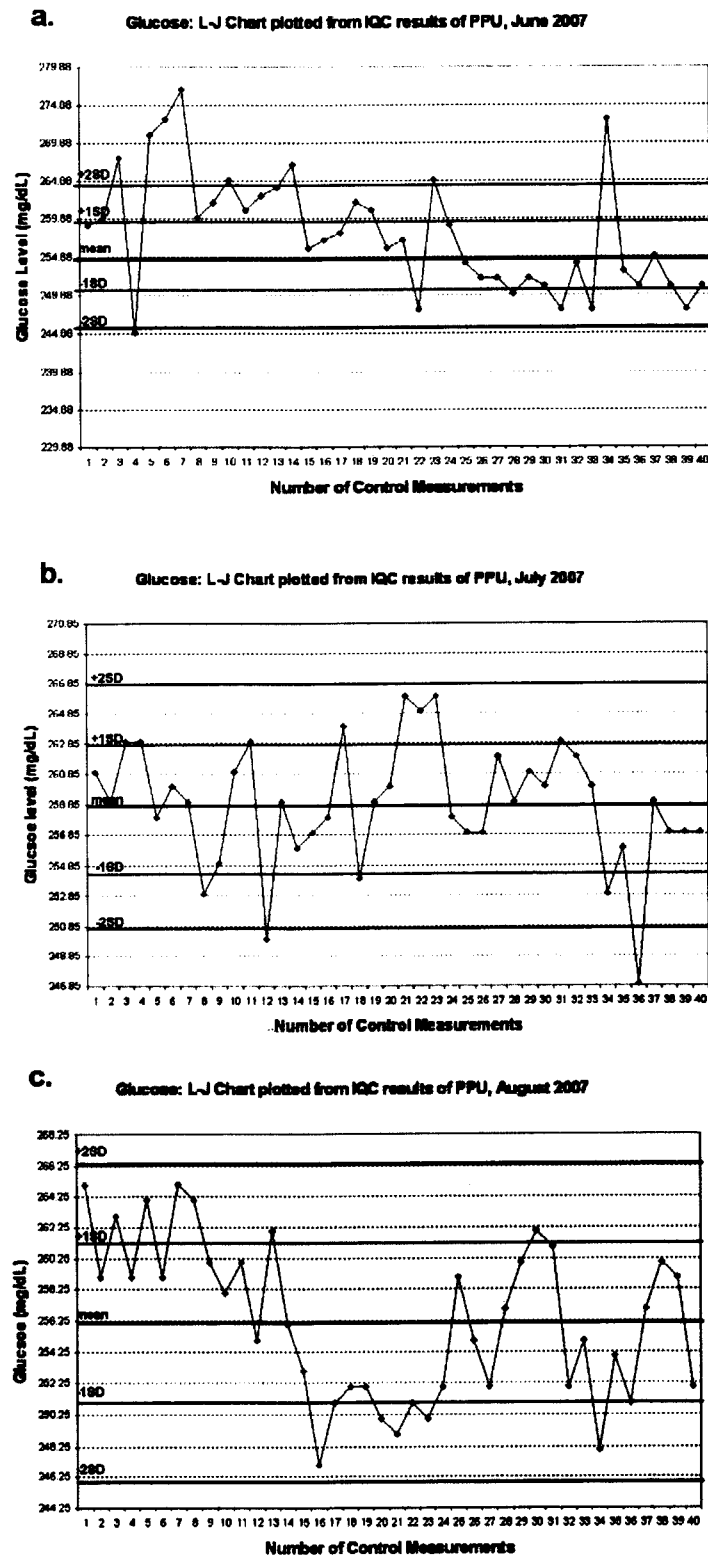
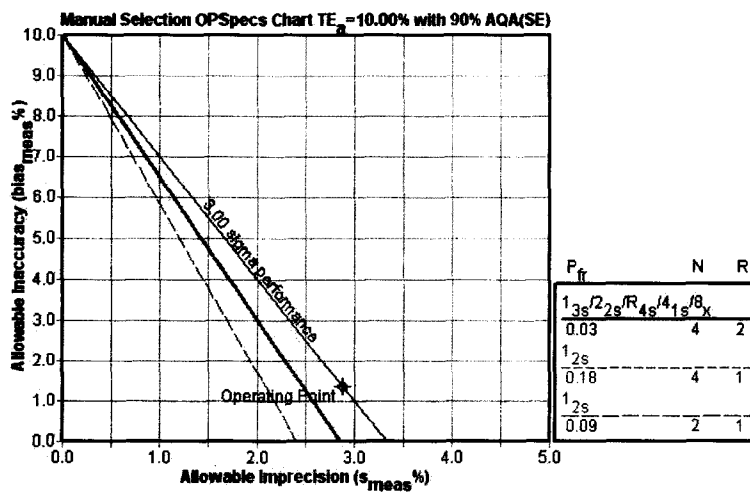


Figure 2. Levey-Jenning (L-J) Charts for glucose IQC of PPU of each month from June to August 2007; a.) L-J Chart of June, b.) L-J Chart of July, and c.) L-J Chart of August. Horizontal lines represent mean of control material measurements and mean \pm the given number of SDs. The IQC rule is violated if the lines representing mean \pm 2SDs are exceeded.

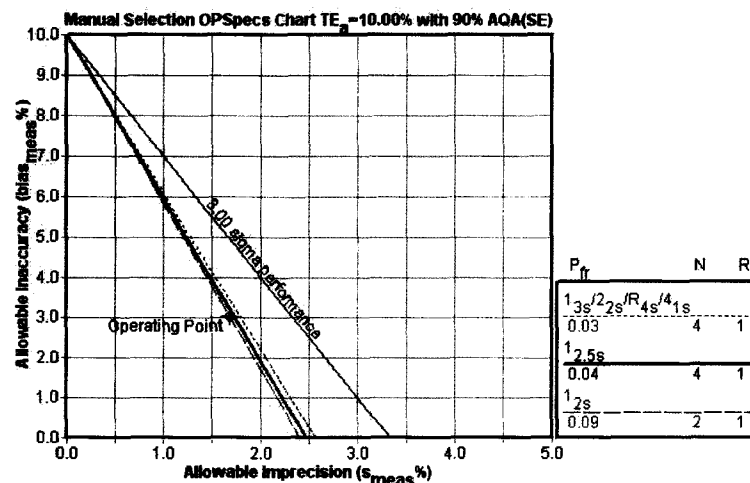
Table 2. The results of mean, SD, and CV of glucose testing from June to August 2007, manufacturer's designed values, method bias, and sigma metric are monitored and evaluated prospectively.

Parameter	Unit	Month	Control	Results			Designed values			Method Bias (%)	Sigma Metric
				mean	SD	%CV	mean	range	SD		
Glucose	mg/dL	June	PNU	94.63	2.71	2.87	93.7	79.6-107.8	4.7	1.36	3.01
			PPU	254.88	4.79	1.86	259	220-298	13	1.36	4.65
		July	PNU	93.40	1.57	1.68	93.7	79.6-107.8	4.7	3.04	4.14
			PPU	258.85	4.05	1.56	259	220-298	13	3.04	4.46
		August	PNU	92.55	2.12	2.29	93.7	79.6-107.8	4.7	2.95	3.07
			PPU	256.25	5.07	1.98	259	220-298	13	2.95	3.56

a. Glucose: PNU, June 2007



b. Glucose: PNU, July 2007



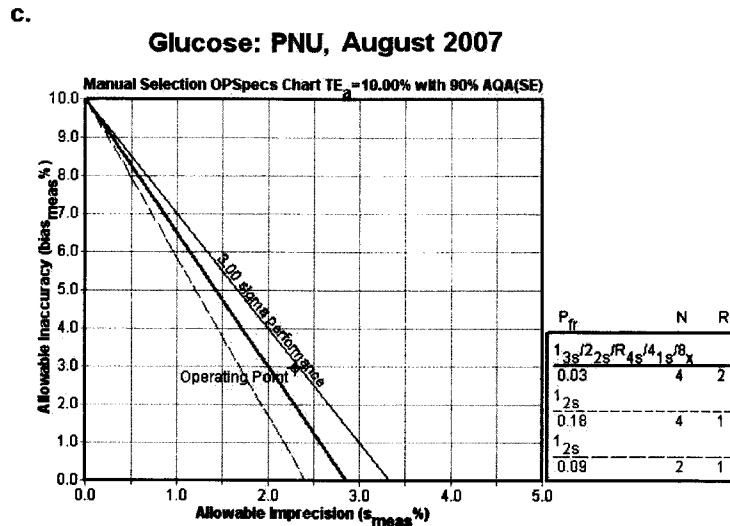


Figure 3. OPSpec chart of glucose IQC of PNU of each month from June to August 2007; a.) OPSpec Chart of June, b.) OPSpec chart of July, and c.) OPSpec chart of August. Maximum allowable error (Tea = 10%) is plotted, with inaccuracy on the y-axis and imprecision on the x-axis.

Table 3. The single rule and recommended control rules from multi-rules are demonstrated.

Parameter	Unit	Month	Control	Sigma Metric	Single-rule			Multi-rule		
					rule	P _{fr} *	N/R**	recommended Rule	P _{fr}	N/R
Glucose	mg/dL	June	PNU	3.01	1 _{2s}	9%	2/1	1 _{3s} / 2 _{2s} / R _{4s} / 4 _{1s} / 8 _x	3%	4/2
			PPU	4.65	1 _{2s}	9%	2/1	1 _{3s}	1%	4/1
	July	PNU	4.14	1 _{2s}	9%	2/1	1 _{2.5s}	4%	4/1	
		PPU	4.46	1 _{2s}	9%	2/1	1 _{2.5s}	4%	4/1	
	August	PNU	3.07	1 _{2s}	9%	2/1	1 _{3s} / 2 _{2s} / R _{4s} / 4 _{1s} / 8 _x	3%	4/2	
		PPU	3.56	1 _{2s}	9%	2/1	1 _{3s} / 2 _{2s} / R _{4s} / 4 _{1s} / 8 _x	3%	4/2	

*P_{fr}, probability of false rejection

**N/R, number of control measurements/ number of runs

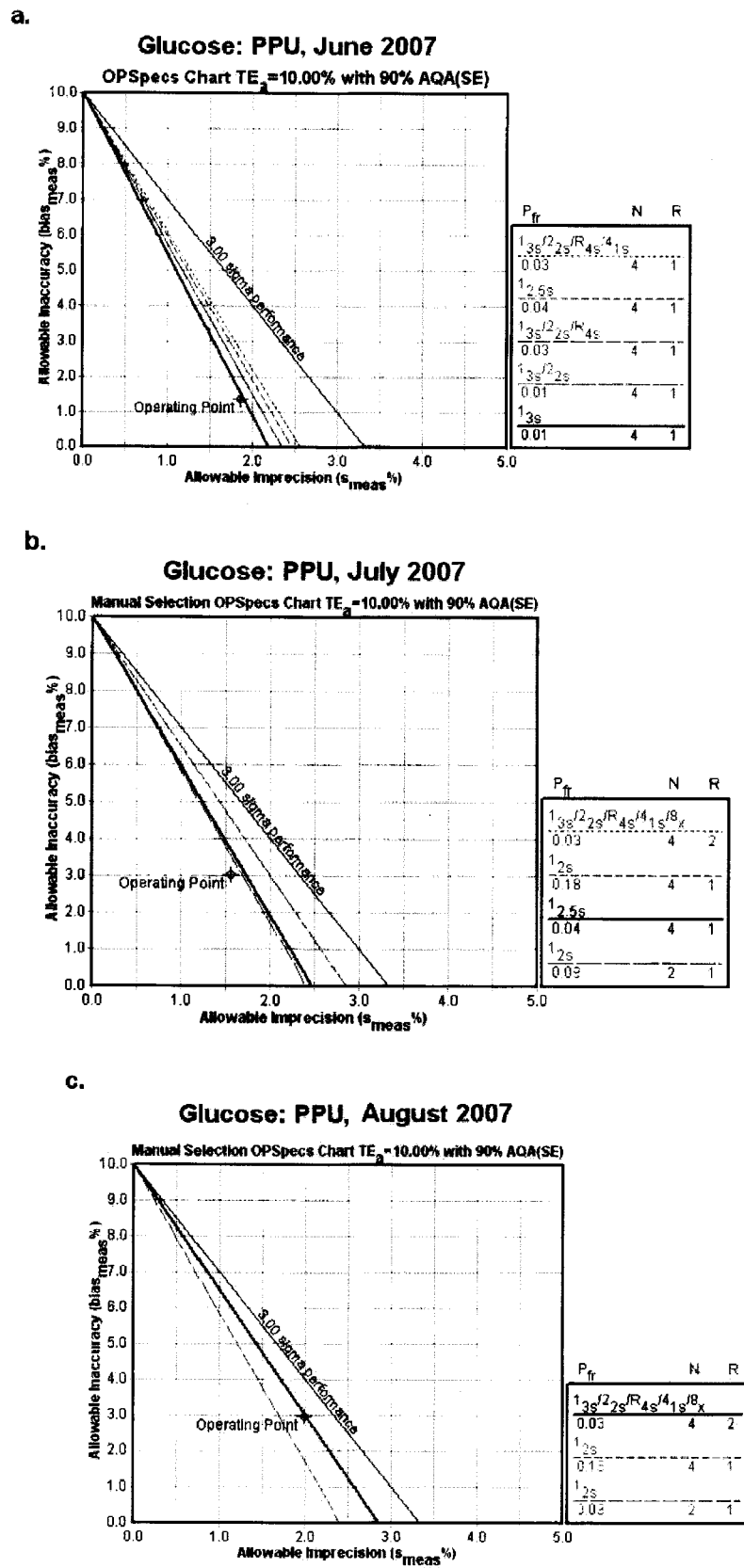


Figure 4. OPSpec chart of glucose IQC of PPU of each month from June to August 2007; a.) OPSpec Chart of June, b.) OPSpec Chart of July, and c.) OPSpec Chart of August. Maximum allowable error ($TE_a = 10\%$) is plotted, with inaccuracy on the y-axis and imprecision on the x-axis.

Discussion

It is not beyond the expectation to have all of our means of control materials in the designed ranges of the manufacturer and SDs lower than designed SDs. Due to the generally designed values of the control materials are generated from a group of several laboratories, the designed values have wider ranges and higher SDs. Any IQC result out of the designed values should be the first alarm of errors to raise the concern of the laboratories that their performance. IQC is needed to for checking their testing precision. Thus, any violation of the IQC control rule should be solved before their routine analysis. In order to monitor and improve laboratory performance, accuracy should also be controlled by EQAS.⁽¹⁸⁻¹⁹⁾ Usually the information of EQAS is separately evaluated after several weeks or months of testing. The data of retrospective review of our previous record of IQC and EQAS data from September 2006 to May 2007 demonstrated the inconsistency of testing performance which varied from 0.91-sigma to 8.66 - sigma (Table 1). According to the results, we found that separate evaluation of IQC and EQAS is not a sensitive tool to monitor QC and improve laboratory performance. The retrospective results suggested that QC procedures used for monitoring the performance should be reviewed and the multi-rule QC tool that can provide IQC and EQAS evaluation together should be more appropriate.

As for the prospective study from June to August 2007, the results were evaluated by the single rule of 1_{2s} (Figure 1 and 2), we found that some results of our IQC are out of $\pm 2SD$. Usually, when IQC is out of $\pm 2SD$, our technicians are advised to follow our brief check list which was developed for detection of systemic and random errors. Furthermore, we found

that most of our IQC problems are solved finally by repeated IQC. Despite the IQC results in term of sigma metric which are not in good stability and range between 3.01 - sigma to 4.65 - sigma (Table 2), they are more consistent when compared to previous retrospective results (Table 1). These results suggested that starting to evaluate the QC data prospectively with both single-rule urged the technicians to pay more attention to QC and using multi-rules could provide more consistent laboratory performance. In addition, the staff training in assay performance and QC interpretation should be useful. As for the aspect of P_{fr} , due to P_{fr} for 1_{2s} is 9% when $N = 2$, this P_{fr} is too high regarding acceptable P_{fr} of 5% or less. Therefore with $N = 2$, our technicians have to repeat IQC at least 9%. The mentioned problems are explained by the separation of evaluation of IQC and EQAS which create separate precision and accuracy improvement. In order to improve laboratory testing performance, precision and accuracy should be analyzed and corrected together. In addition, planning and implementation of IQC in clinical chemistry laboratories are important to ensure that the results with medically important errors in both imprecision and inaccuracy will be analyzed properly.⁽⁵⁾

The Westgard multi-rules were developed for optimizing assay error detection for both precision and accuracy. Therefore, it should be appropriate for evaluation of our IQC and EQAS together at the same time. In using the multi-rule program to evaluate and analyze our IQC and EQAS, several different rules are recommended (Table 3). We found that the 1_{3s} ($N/R = 4/1$) which provides $P_{ed} = 90\%$ and $P_{fr} = 1\%$ is recommended for 4.65-sigma, while 4.14-sigma and 4.46-sigma, $1_{2.5s}$ ($N/R = 4/1$) which provide $P_{ed} = 90\%$ and $P_{fr} = 4\%$ is appropriate. As for performance that is

lower than 4-sigma, multi-rule program such as $1_{3S}/2_{2S}/R_{4S}/4_{1S}/8_X$ ($N/R = 4/2$) which provide $P_{ed} = 90\%$ and $P_{fr} = 3\%$ should be applied. With recommended rules our P_{fr} would be improved to 1% to 4%, which are acceptable and more appropriate ($P_{fr} < 5\%$) to test the performance when compared with 9% generated from single rule.^(9, 14) In addition, using 90% AQA is appropriate to make at least a 90% chance of detecting the critical systematic error when operating within the allowed limits for imprecision and inaccuracy for the given control rules and total number of control measurements (N).⁽⁵⁾ Thus, our settings provide possibility of error detection (P_{ed}) of 90% or higher. In other word, with the multi-rule QC, more appropriate rules that give P_{ed} of 90% or higher and the P_{fr} of 5% or lower are generated. Therefore, multi-rule QC could generate the optimizing control rules for our testing performance. In order to improve our performance from acceptable level (3-sigma to 4-sigma) to more satisfied level of 5-sigma or even excellent level for world-class quality of 6-sigma, our results suggested that the multi-rule QC should be adaptable to QC monitoring.⁽²⁰⁾ We plan for further study using the multi-rule QC to improve our performance. We also plan to set a quality team to support and monitor the performance of the routine operation team. In addition, a quality team is needed to support the technicians to assess and fix the systemic and random errors.⁽²¹⁾

In conclusion, to improve the glucose testing performance from the acceptable level of 3-sigma to the world-class quality of 6-sigma, we found the need of more appropriate QC rules. Our study also provides the tendency of the potential benefits of applying multi-rule program to improve QC for our glucose testing. Additionally, we have demonstrated the possibility to

evaluate IQC and EQAS results together at the same time by multi-rules. We expect that the precision and accuracy would be solved in the same direction with less or no discrimination as well as better consistency sigma metric would be achieved.⁽²²⁾

Finally, to improve the quality of the clinical chemistry system, it does not require only the increased focus on error in analytical phase but also in the pre- and post-analytical phases of testing which depend on increased cooperation between the laboratory and non-laboratory personnel. The results also indicated the need to improve staff training in assay performance and QC interpretation. In addition, our results demonstrated that a multi-rule QC design should be a useful tool for monitoring the assay performance.

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