External Quality Assessment Survey for Hematological Laboratories in Mongolia

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To evaluate the inter-laboratory variation of CBC parameters among hematology laboratories in Mongolia, we first set up the External Quality Assessment (EQA) scheme, called "Mongolian External Quality Assessment Scheme (MEQAS) for Hematology" in the national capital (Ulaanbaatar) region in 2008, under organization of Ministry of Health. Control blood and fresh whole blood were used to investigate the effectiveness of survey materials for the national and local EQA scheme, where a wide range of technology and methods are implemented among laboratories. The number of participants has been increasing; 56 for 1st, 90 for 2nd and 106 for 3rd MEQAS in 2008 and 2009. To evaluate each laboratory's result, we divided into 2 peer groups (G1: automated hematology analyzer, G2: manual method) and calculate standard deviation index (SDI) based on peer group mean and group SD. The ratio of G1: Auto and G2: Manual were 61% and 39%, respectively in the 3rd MEQAS. 3 units of standard hematology analyzers were used for validating the accuracy of peer group mean and monitoring the quality of survey materials. The peer group mean for CBC 5 parameters of G1: Auto were very close to the target values assigned by the standard analyzers. As for the inter-laboratory variation, G1: Auto showed smaller CV% values than G2: Manual (e.g. 3.8% (G1) and 7.3% (G2) for HGB). From these surveys, we obtained a good reference and clues for future laboratory improvement.

Key Words Complete Blood Count, External Quality Assessment (EQA), Hematology

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INTRODUCTION

Mongolia is a landlocked country in the northern part of Central Asia located between Russia and China, with a relatively small population (2.5 million) living a large geographical territory of 1.56 million square kilometer. Administratively Mongolia is divided into 21 provinces. The capital city is Ulaanbaatar of Mongolia, where 1.2 million of the total population lives. Hematology laboratories, over the capital city and 21 provinces including governmental and private sectors in this country, have to take responsibility for providing hematology data. A wide range of technology and methods have been implemented among these laboratories. Harmonization of the hematology laboratories with standard service all over the country is the major goal to reach. We organized the MEQAS (Mongolian External Quality Assessment Scheme) in 2008 on basis of the cooperation agreement between the Ministry of Health (Mongolia) and Sysmex Corporation (Kobe, Japan) in the establishment of a hematology external quality control and reference laboratory system in Mongolia. We report our 1-year experience of MEQAS as the national project, covering increasing numbers of laboratory members. In 2008-2009 years we set up 1st, 2nd, 3rd MEQAS in Mongolia. This is the report of these surveys.

MATERIALS AND METHODS

Materials

Survey Materials

In each survey, the following two kinds of survey materials were used;

Sample A : Eightcheck-C® Normal Level (2.0 mL / vial) *
Sample B : Fresh Whole Blood Sample **

* Hematology Control Material provided by Sysmex Corporation

** Under cooperation of National Center for Transfusiology, a fresh whole blood sample was drawn from a healthy donor and prepared on the same day of sample delivery, according to the procedures reported by Kondo et al [1].

Standard Analyzers

3 units of fully-automated standard analyzers (KX-21, pocH-100*i*, XS-1000*i*), installed at the Shastin Central Hospital, were used to assign the target values for the survey materials. These standard analyzers have been calibrated with SCS-1000® (Sysmex Corporation, Kobe, Japan) before the survey, and monitored with hematology controls, e-CHECK(XS)® (Sysmex Corporation, Kobe, Japan) and EIGHTCHECK-3WP® (Sysmex Corporation, Kobe, Japan) on daily basis.

Methods

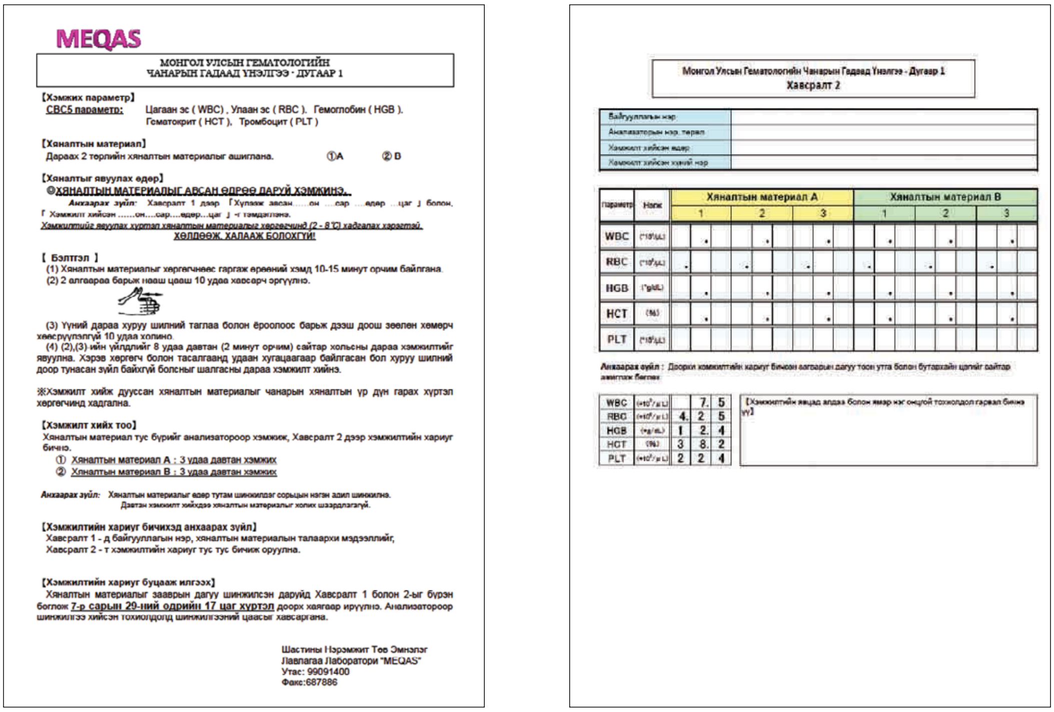
Instructions & Sample Distribution

On every survey, the workshop was held to give guidance and distribute the survey samples to each participant. (***Fig. 1***, ***Fig. 2 (a), (b)***).

Fig. 1 *Photo of survey workshop*

(a)

(b)



(a)

MEQAS

МОНГОЛ УЛСЫН ГЕМАТОЛОГИЙН
ЧАНАРЫН ГАДААД ҮНЭЛГЭЭ - ДУГААР 1

【Хэмжих параметр】
CBC5 параметр: Цагаан эс (WBC), Улаан эс (RBC). Гемоглобин (HGB). Гематокрит (HCT), Тромбоцит (PLT)

【Хяналтын материал】
Дараах 2 төрлийн хяналтын материалыг ашиглана. ①A ②B

【Хяналтыг явуулах өдөр】
◎ХЯНАЛТЫН МАТЕРИАЛЫГ АВСАН ӨДРӨӨ ДАРУЙ ХЭМЖИНЭ.
Анхаарах зүйл: Хавсралт 1 дээр 「Хүлээж авсан......он ....сар ....өдөр ...цаг 」 болон, 「 Хэмжилт хийсэн ....он....сар....өдөр...цаг 」 -г тэмдэглэнэ.
Хэмжилтийг явуулах хүртэл хяналтын материалыг хөргөгчинд (2 - 8℃) хадгалах хэрэгтэй.
ХӨЛДӨӨЖ, ХАЛААЖ БОЛОХГҮЙ!

【 Бэлтгэл 】
(1) Хяналтын материалыг хөргөгчнөөс гаргаж өрөөний хэмд 10-15 минут орчим байлгана.
(2) 2 алгаараа барьж нааш цааш 10 удаа хавсарч эргүүлнэ.
(3) Үүний дараа хуруу шилний таглаа болон ёроолоос барьж дээш доош зөөлөн хөмөрч хөөсрүүлэлгүй 10 удаа холино.
(4) (2),(3)-ийн үйлдлийг 8 удаа давтан (2 минут орчим) сайтар хольсны дараа хэмжилтийг явуулна. Хэрэв хөргөгч болон тасалгаанд удаан хугацаагаар байлгасан бол хуруу шилний доор тунасан зүйл байхгүй болсныг шалгасны дараа хэмжилт хийнэ.

※Хэмжилт хийж дууссан хяналтын материалыг чанарын хяналтын үр дүн гарах хүртэл хөргөгчинд хадгална.

【Хэмжилт хийх тоо】
Хяналтын материал тус бүрийг анализатороор хэмжиж, Хавсралт 2 дээр хэмжилтийн хариуг бичнэ.
① Хяналтын материал A : 3 удаа давтан хэмжих
② Хлналтын материал B : 3 удаа давтан хэмжих

Анхаарах зүйл: Хяналтын материалыг өдөр тутам шинжилдэг сорьцын нэгэн адил шинжилнэ.
Давтан хэмжилт хийхдээ хяналтын материалыг холих шаардлагагүй.

【Хэмжилтийн хариуг бичихэд анхаарах зүйл】
Хавсралт 1 - д байгууллагын нэр, хяналтын материалын талаарх мэдээллийг,
Хавсралт 2 - т хэмжилтийн хариуг тус тус бичиж оруулна.

【Хэмжилтийн хариуг буцааж илгээх】
Хяналтын материалыг зааврын дагуу шинжилсэн даруйд Хавсралт 1 болон 2-ыг бүрэн бөглөж 7-р сарын 29-ний өдрийн 17 цаг хүртэл доорх хаягаар ирүүлнэ. Анализатороор шинжилгээ хийсэн тохиолдолд шинжилгээний цаасыг хавсаргана.

Шастины Нэрэмжит Төв Эмнэлэг
Лавлагаа Лаборатори "MEQAS"
Утас: 99091400
Факс:687886

(b)

Монгол Улсын Гематологийн Чанарын Гадаад Үнэлгээ - Дугаар 1
Хавсралт 2

Байгууллагын нэр	
Анализаторын нэр, төрөл	
Хэмжилт хийсэн өдөр	
Хэмжилт хийсэн хүний нэр	

Параметр	Нэгж	Хяналтын материал A			Хяналтын материал B		
		1	2	3	1	2	3
WBC	(*10³/μL)						
RBC	(*10⁶/μL)						
HGB	(*g/dL)						
HCT	(%)						
PLT	(*10³/μL)						

Анхаарах зүйл : Доорх хэмжилтийн хариуг бичихдээ аравтын дагуу тоон утга болон бутархайн цэгийг сайтар анхаарч бөглөх

WBC	(×10³/μL)		7.	5
RBC	(×10⁶/μL)	4.	2	5
HGB	(×g/dL)	1	2.	4
HCT	(%)	3	8.	2
PLT	(×10³/μL)	2	2	4

【Хэмжилтийн явцад алдаа болон ямар нэг онцгой тохиолдол гарвал бичнэ үү】

Fig. 2 *Instructions (a) and Data Submission Sheet (b)*

Categorization of Peer Group

Participating data were divided into two peer groups, based on methodology; Group 1: automated hematology analyzer group (G1: Auto), Group 2: manual method group (G2: Manual). Each laboratory was given ID number and was asked to analyze the samples 3 times and report all data for the CBC 5 parameters.

Statistical Evaluation Method

After categorizing into the above two groups, results for each participant were evaluated and expressed according to peer group mean and standard deviation index (SDI) methods. The group mean was derived from the group mean after removing outliers detected by double-truncation with ± 3SD. The SDI was calculated according to the following formula:

SDI = (Participant Data - Peer Group Mean)/ Peer Group SD

The SDI indicates the relative position of each participant. See report form and historical SDI report form (***Fig. 3 (a), (b)***).

Scoring System

Based on the historical SDI data, continuous laboratory performance was evaluated as "converted-score" for the survey programs (***Table 1 (a), (b)***).

(a) (b)

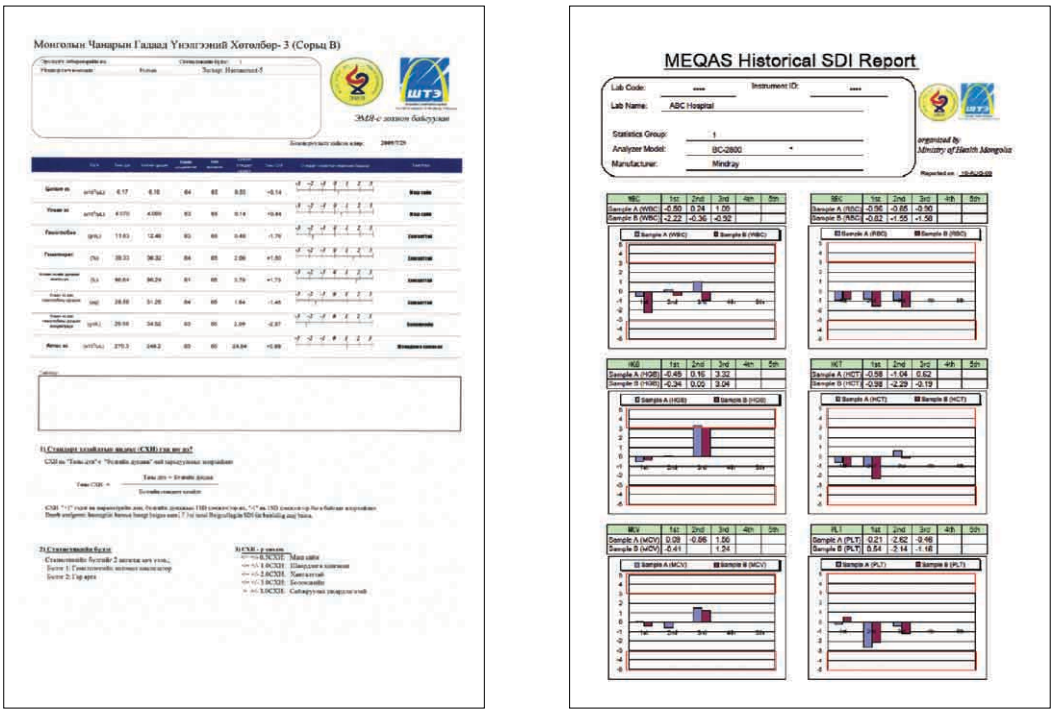


Fig. 3 *Report Form (a) and Histrical SDI Report Form (b)*

Table 1 *Basic Rule of "Scoring System"*

(a) Scoring Rule

SDI	Score
0 ~ ±1.0	5
±1.0 ~ ±2.0	4
±2.0 ~ ±3.0	3
±3.0 ~ ±4.0	2
±4.0 ~ ±5.0	1
±5.0 ~	0

(b) An example of scoring based on SDI values

SDI	1st	2nd	3rd
Sample A (WBC)	0.11	2.50	0.40
Sample B (WBC)	-0.14	3.41	1.50

Score	1st	2nd	3rd
Sample A (WBC)	5	3	5
Sample B (WBC)	5	2	4
Score	10	5	9

Determining the Target Values

The target values of the survey samples were assigned, based on the multiple measurement (n = 20) with the standard analyzers of Shastin Central Hospital.

Monitoring the Quality of the Survey Samples

During the period of the survey, the stability of the survey samples was monitored on the standard analyzers in Shastin Central Hospital.

RESULTS

Participating laboratories

Table 2 shows the change in the number of participating laboratories and its peer group from 1st to 3rd survey. The total number of participating laboratories has increased from 56 to 106. The percentage of G1: Auto and G2: Manual was 61% and 39%, respectively in the 3rd MEQAS.

Fig. 4 shows the change in the number of participants by manufacturer (G1: Auto) from 1st to 3rd survey. It was found that a wide variety of manufacturers' analyzers were used among the laboratories.

STATISTICAL SUMMARY OF 3rd MEQAS

The statistical results for sample A (control blood) and sample B (fresh whole blood) of the 3rd MEQAS are summarized in ***Table 3 (a) ~ (d)***.

Fig. 5 (1) ~ (10) shows the Box plots by peer group for the CBC 5 parameters of the 3rd MEQAS.

Table 2 *Summary of 1st - 3rd MEQAS*

		1st MEQAS	2nd MEQAS	3rd MEQAS
Period of survey		July, 2008	December, 2008	June, 2009
Number of participant	total	56	90	106
	G1: Auto	43 (74%)	55 (61%)	65 (61%)
	G2: Manual	15 (26%)	35 (39%)	41 (39%)

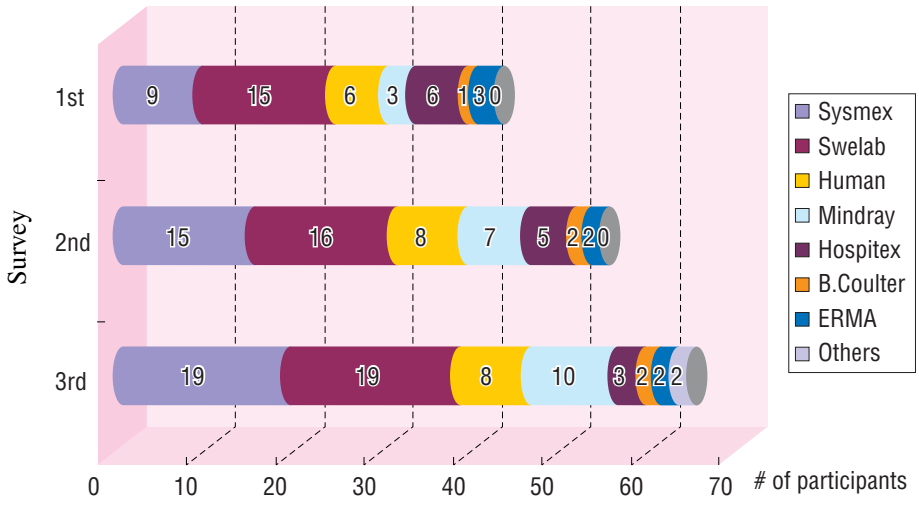


Fig. 4 *Change of number of participants by manufacturer (G1: Auto)*

Table 3 *Statistical Summary (3rd MEQAS)*

(a) Sample A (G1: Auto)

Parameter	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	7.09	4.239	13.08	36.34	85.70	31.21	36.33	214.2
SD	0.44	0.196	0.52	2.08	4.45	1.88	2.55	25.1
CV%	6.2%	4.6%	4.0%	5.7%	5.2%	6.0%	7.0%	11.7%
MAX	8.23	4.703	14.70	43.0	97.8	36.6	42.8	270.7
MIN	6.07	3.720	11.77	32.7	77.4	27.0	29.5	148.7
N	63	64	63	63	64	63	64	64

(b) Sample A (G2: Manual)

Parameter	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	5.64	3.937	13.07	35.50	90.86	33.18	38.16	218.8
SD	1.23	0.551	1.04	3.78	16.39	5.42	3.26	40.0
CV%	21.8%	14.0%	8.0%	10.6%	18.0%	16.3%	8.5%	18.3%
MAX	7.73	4.927	14.67	43.5	131.2	48.2	43.5	313.0
MIN	2.97	2.363	10.93	31.0	79.2	17.9	33.6	103.3
N	40	40	39	9	9	39	9	34

(c) Sample B (G1: Auto)

Parameter	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	6.10	4.009	12.48	36.32	90.24	31.25	34.52	248.2
SD	0.50	0.139	0.48	2.00	3.70	1.84	2.09	24.8
CV%	8.3%	3.5%	3.8%	5.5%	4.1%	5.9%	6.0%	10.0%
MAX	7.03	4.320	13.93	42.3	98.8	36.8	39.7	302.7
MIN	4.67	3.643	11.20	30.6	79.4	26.3	28.5	173.0
N	64	63	63	64	61	64	63	63

(d) Sample B (G2: Manual)

Parameter	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	5.34	3.802	12.57	38.19	99.50	32.88	34.20	215.5
SD	1.07	0.425	0.92	3.17	14.70	3.30	1.99	40.0
CV%	20.1%	11.2%	7.3%	8.3%	14.8%	10.0%	5.8%	18.6%
MAX	7.07	4.750	14.67	43.5	133.3	41.4	36.8	325.0
MIN	2.63	2.667	9.90	34.8	87.7	23.7	30.8	133.3
N	40	41	40	9	9	39	9	35

Note: The above statistical results were obtained after excluding outliers outside Mean +/- 3SD.

Unit: WBC ($\times 10^3/\mu L$), RBC ($\times 10^6/\mu L$), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT ($\times 10^3/\mu L$)

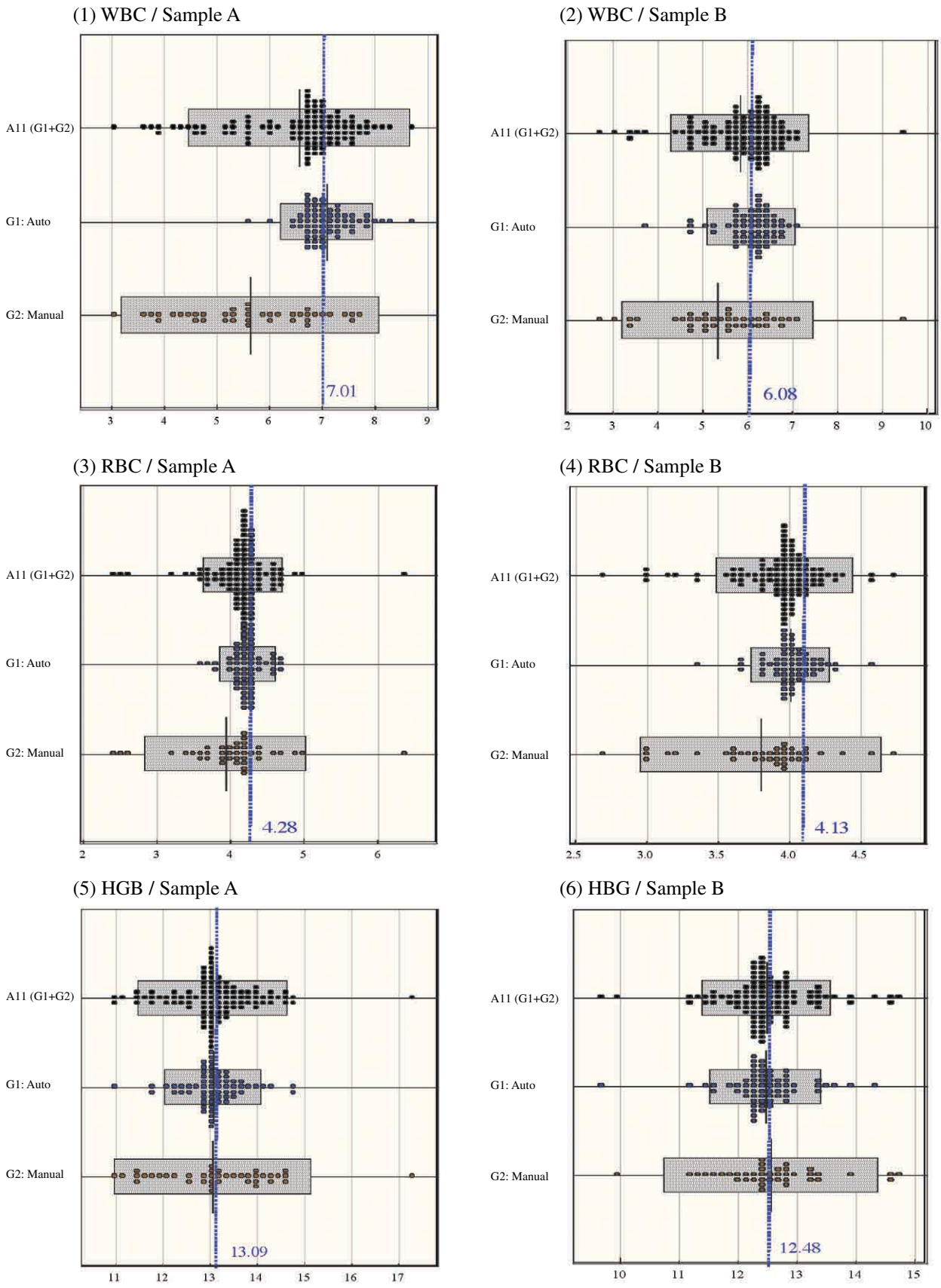


Fig. 5 *Box plots by peer group for CBC 5 parameters (3rd MEQAS)*

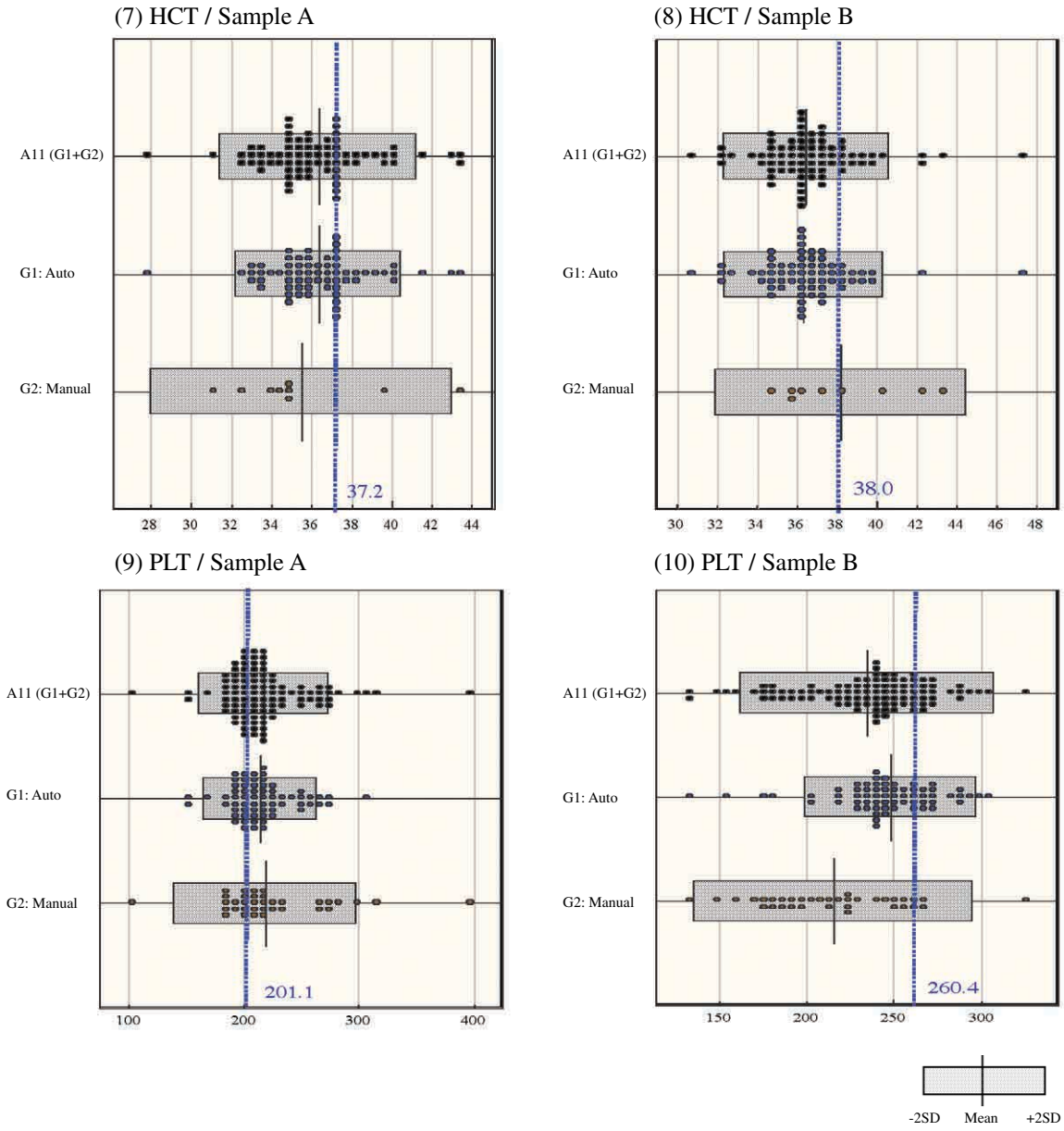


Fig. 5 *Box plots by peer group for CBC 5 parameters (3rd MEQAS)*

The target values assigned by 3 standard analyzers are shown in blue dotted line.
Unit: WBC (× 10³/μL), RBC (× 10⁶/μL), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), PLT (× 10³/μL)

From these results, we found that;

a) G1: Auto showed smaller CV(%) than that of G2: Manual for the CBC 5 parameters on both samples (***Table 4***).

b) Good agreement was observed between the peer group mean of G1: Auto and the target value assigned by three standard analyzers for the CBC 5 parameters on the both samples.

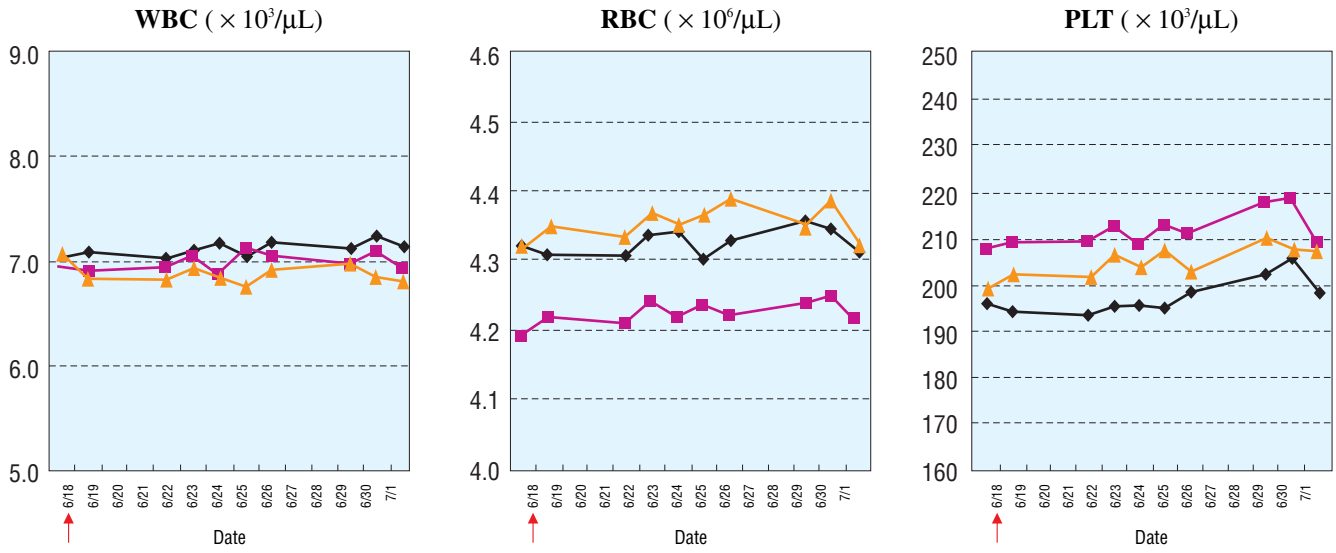
SAMPLE STABILITY

The stability of sample A (control blood) and Sample B (fresh whole blood) was monitored by the standard analyzers for 2 weeks from the delivery day. The results are summarized in ***Fig. 6***. We observed that sample A showed good stability for the CBC 5 parameters, but a decreasing trend was observed for WBC and PLT on sample B after 4 days of sample preparation. From these results, we found out that the fresh whole blood samples must be analyzed within 4 days after preparation.

Table 4 *Comparison of CV% by peer group (from 3rd MEQAS results)*

Parameter	Peer Group	WBC	RBC	HGB	HCT	PLT
Sample A (Control Blood)	G1: Auto	6.2%	4.6%	4.0%	5.7%	11.7%
	G2: Manual	21.8%	14.0%	8.0%	10.6%	18.3%
Sample B (Fresh Whole Blood)	G1: Auto	8.3%	3.5%	3.8%	5.5%	10.0%
	G2: Manual	20.1%	11.2%	7.3%	8.3%	18.6%

(1) Sample A stability



(2) Sample B stability

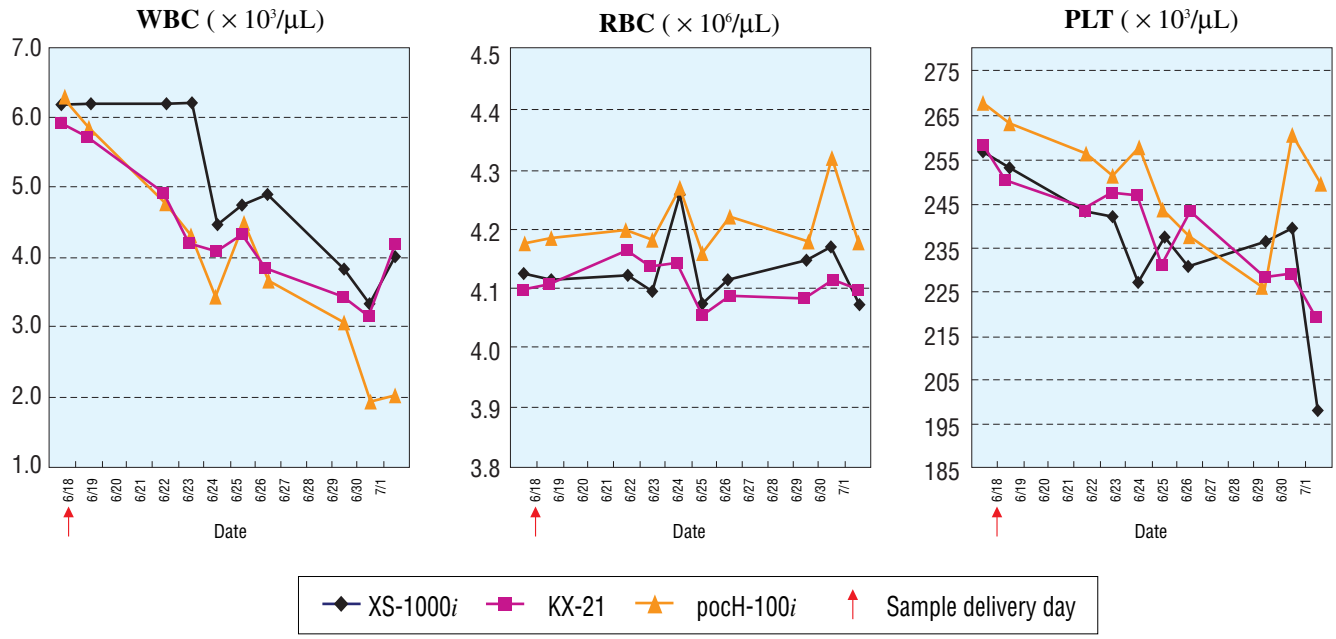


Fig. 6 *Comparison of Stability between Sample A (control blood) and Sample B (fresh whole blood)*

CHANGE OF INTER-LABOLATORY CV

Fig. 7 shows the time-series change of inter-laboratory variation (CV) from 1st to 3rd MEQAS by sample (A: control blood, B: fresh whole blood) and peer group (G1: Auto, G2: Manual) for WBC, RBC, HGB and PLT. From these result, we found that;

a) For RBC and PLT, CVs of G1: Auto has been decreasing for the both samples. (e.g. for PLT, CV of sample B has decreased from 14.5% to 10.0%)
b) For WBC, G2: Manual data showed different trend between sample A and sample B. CVs of G1: Auto were stable through 1st to 3rd survey.
c) For HGB, CVs of G2 : Manual showed decreasing trend for the both samples.
d) G1: Auto data showed much lower CV values than G2: Manual for all parameters.

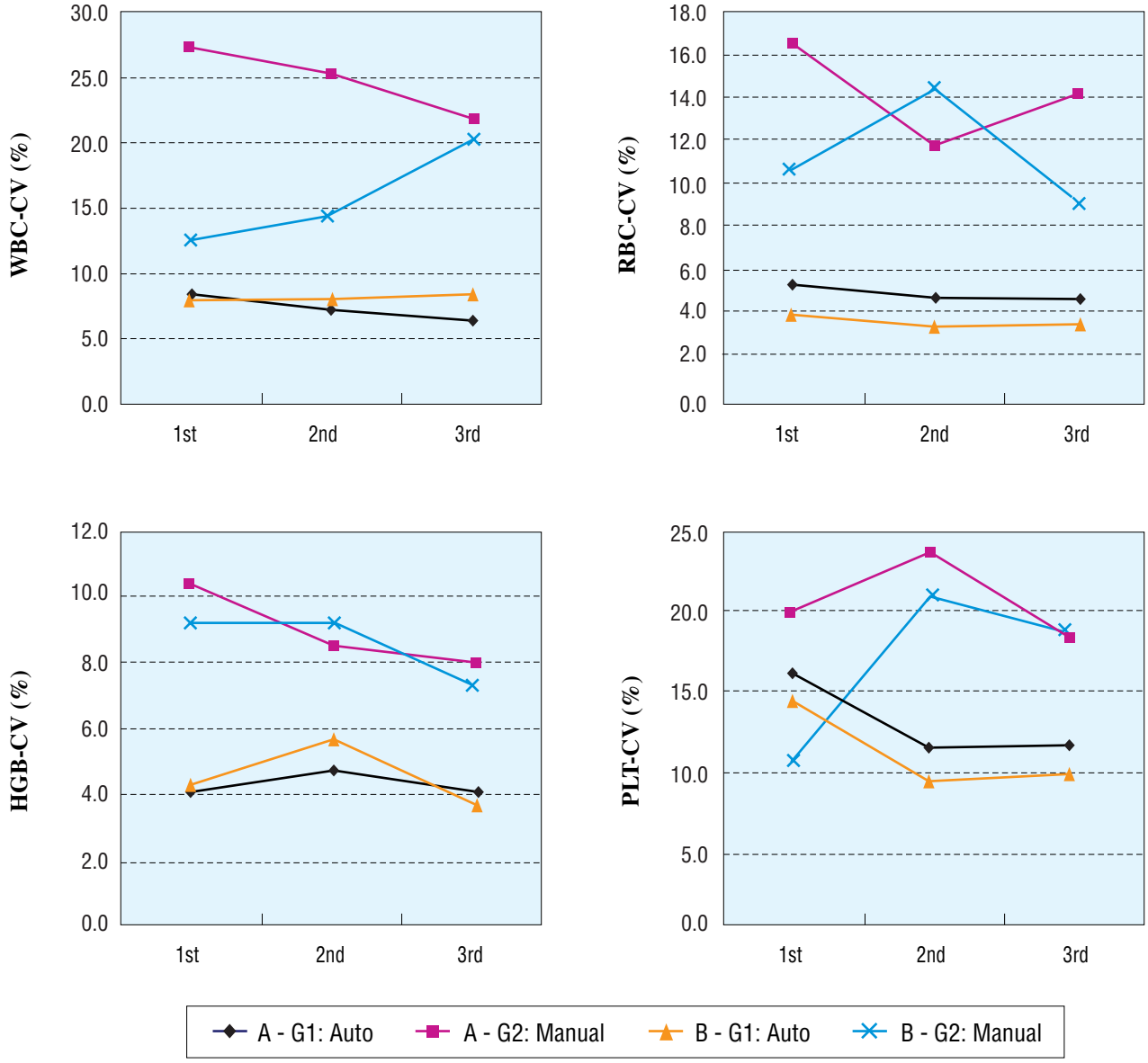


Fig. 7 Time-series change of CV among 1st, 2nd and 3rd MEQAS (by peer group)

DISCUSSION

Since 2008, under collaboration between the Ministry of Health and Sysmex Corporation, we've established a unique External Quality Assessment Scheme for hematological laboratories in Mongolia, on the following points;

- Setting up the referral laboratory in Hematology to assign the target values and monitor sample stability
- Holding workshop for guidance and sample delivery to participants
- Evaluating laboratory's data based on SDI method using control blood and fresh whole blood
- Holding scientific seminar on QC/QM concepts (IQC/EQA, Traceability, ISO15189) to educate participants for improving the laboratory performance

The total numbers of participating laboratories have increased from 56 (1st) to 106 (3rd) laboratories in 1 year. As was expected results from the group with automation is in better control than the manual method.

Examination of the 1st to 3rd MEQAS, shows the EQA results to be at a satisfactory level — only a minority of the participating members (15.6%) were out of range. Some of laboratory's results are out of range ± 3SD and poor repeatability is also not acceptable. This is why we need to improve the ACTION, follow by PDCA cycle in these laboratories:

a) Check the analyzer and reagent
b) Do and check internal QC
c) Check pre- and post- analytical process

However, to enroot the continuous laboratory improvement activities nationwide in this country, we need to improve the EQA scheme step-by-step and motivate laboratories to participate in such EQA scheme continuously.

ACKNOWLEDGEMENTS

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References

1) Kondo H et al. A method of preparing fresh blood samples for external quality assessment. Journal of Analytical Bio-Science. 2002; 25(3): 275-278.