Introduction of the XE-2100 Online QC System

Hiroyuki Morihara, Atsushi Shirakami, Katsuya Wada and Keiji Fujimoto

Scientific Division, Sysmex Corporation, 4-4-4 Takatsukadai, Nishi-ku, Kobe 651-2271, Japan.

The XE-2100 online QC system is the next generation's External QC model and utilizes its "networking" function to the maximum. In this system, daily internal QC data using specific control material is automatically transmitted to the online QC server via a computer network and the Sysmex QC server updates the inter-laboratory statistics results "every ten minutes." This online QC system enables XE-2100 customers to refer to their latest inter-laboratory statistics results whenever they wish.

Online QC has the following features; a) automatic data transmission, b) real time external quality assurance, c) automatic judgement, d) browsing capability, e) historical SDI (Standard Deviation Index) chart and numerical table and f) combination with online support system (SNCS; Sysmex Network Communication System).

Since circumstances in the medical field change rapidly and dramatically, we believe that online QC will be a reliable IT (Information Technology)-based analytical Quality Assurance System for Clinical Laboratories for the 21st century.

(Sysmex J Int 10 : 13 - 17, 2000)

Key Words > Quality Assurance, External Quality Assessment (EQA), Sysmex Network Communication System (SNCS)

INTRODUCTION

Almost 50 years have elapsed since the concept of quality control was introduced into the field of the clinical laboratory test^{1, 2)}. The environment surrounding the clinical laboratory has been changing radically in recent years; 1) the introduction of DRG/PPS (Diagnosis related group/prospective payment system), 2) the introduction of electronic medical records, 3) alteration in the information infrastructure by the increasing use of IT (penetration by the Internet), 4) increased precision and multifunctionality of analyzers (simultaneous measurement of multiple parameters, network-oriented), 5) promotion of global standardization of clinical laboratory tests, etc. In the midst of these changes, two elements, "data compatibility (standardization)" and "real time," are required for reliable daily functioning in the laboratory. To achieve these, it is necessary to revise our concept of exactly what analytical quality assurance is required.

Recently, an online QC System, which makes the best use of the network functions of the XE-2100 automated hematology analyzer, has been developed, and full-scale implementation of this system was inaugurated in Japan during December 1999. This paper outlines the system and discusses future prospects.

Note: The name of this system "Online QC" is used only in Japan. This system will be released as different name abroad.

BASIC CONCEPT

The online QC System is a next-generation analytical quality assurance service, which makes free use of networking technology. *Fig. 1* illustrates the concept of online QC. This system simultaneously combines daily internal quality control data following the use of control blood with external quality control, and automatically, in real time compares the data with statistical values obtained from many laboratories using control blood of the same lot. As shown in *Table 1*, the most attractive feature of the online QC is the advantage of combining conventional internal quality control and external quality assessment.

OUTLINE OF ONLINE QC

Applicable equipment:

XE-2100 automated hematology analyzer

Applicable control blood:

e-CHECK

(note: we should use the new name, as it is valid from July 2000 on.)

Applicable measuring mode:

Manual (open) mode and sampler (closed) mode *Applicable statistical period:*

QC data is collected from the next day of shipment of the control blood to expiration date.

Parameters analyzed statistically:

CBC+DIFF related items: 36 items,



Fig. 1 Conceptual drawing of online QC (Japan)

	Online QC	Internal quality control (IQC)*	External quality control (EQA)
Objectives	 (1) Assessment and control of accuracy and precision of equipment (2) Correction of difference between laboratories. 	Control of equipment accuracy - confirmation of day-to-day variation (shift, trend).	 Index and assessment of measurement precision. Promotion of standardization.
Advantages	 (1) IQC data is able to be used simultaneously as EQA data. (2) Statistical results are able to be offered in real time. (3) Quick support is able to be provided by automatic outlier detection. 	It is easily implemented by commercially available controllers.	Evaluation of precision is possible on the basis of comparison with other laboratories.
Disadvantages		 Unable to assess precision. When controllers are degraded, causes are difficult to be located. 	 (1) Implementation frequency and time are limited. (2) It takes time to report the results. (3) It is trouble some to measure and report data.

 Table 1
 Comparison of online QC and QC technique

 \ast In this case, discussion will be made on the internal accuracy control using controllers.

RET related items: 9 items

(note: new *e*-CHECK will no longer have sensitivity parameters given as assay values.)

The features of the XE-2100 online QC System will be described in procedural order.

Automatic Data Transmission

In participating XE-2100 laboratories the measured data from the Control Blood is stored in the QC file of the quality control program of the XE-2100 as before, but, at the same time, the data are automatically transferred to the online QC statistics server via the WAN (wide area network) system. Consequently, the operator does not need to transmit data manually.

Real Time EQA

The current external quality control (EQC) system in Japan for our conventional blood cell counting equipment is carried out two to four times a year. It usually takes about 2 weeks to have the statistical analysis returned after measurement.

With the introduction of the new system, the statistics results are provided for review within 10 minutes of measuring the control blood in the laboratory. If any malfunction occurs, it will be detected at an early stage.

Automatic Judgment

The automatically transmitted QC data from each laboratory is monitored for abnormality by comparing with peer group statistical values on three aspects, namely, "accuracy," "precision," and "trend," by means of our original problem detection algorithms. The data judged abnormal is automatically registered to the database of our Technical Support Center (TSC) From the TSC, the abnormality is notified to the respective department, thus enabling an immediate confirmation of the equipment condition, and taking necessary measures to solve any error function or problem.

Note: This is an operation example in Japan as of April 2000.

Browsing Latest Results

As shown in *Fig.* 2, it is possible to quickly confirm the online QC data statistics results by entering the laboratories' identification (ID) number. And password on the Web screen. Thorough consideration has been given to user data security, and includes provision of a special-purpose network, and/or network connection which can only be enabled by each institution whose telephone number has been registered in advance, etc.

Historical SDI Chart and Numerical Table

The display format of the statistics results can be selected from either "SDI Chart" or "Numerical Table," and the measurement item the user wishes to display (RBC/HGB, RET, PLT, WBC/BASO, DIFF, IMI, NRBC) selected with a "one click" operation. In either format, the data of the individual institution, the mean values of population, the mean group value of Sysmex reference analyzers and



Fig. 2 Perusal method of latest statistics results

the daily changes, such as drifts and shifts, can be perused.

Historical SDI Chart

The SDI Chart displays a daily time-series graph for each parameter. It is therefore possible to confirm the relationship between individual QC data of each laboratory, peer group statistics value, and reference group data from one day to the next (see *Fig. 3*).

Numerical Table

Daily statistics values (latest updated values for the day) are also displayed in a numerical table. The following items are displayed (see *Fig. 4*).

- Date (Date)
- Preparation name (Name)
- Measurement data (Your data)
- Reference group* mean value (Reference Group)
- Your instrument's SDI (Your SDI)
- Total number of peer group data (Group 'n')
- Note: The reference group mean value is the mean value of several Sysmex standard counters installed in different laboratories within Sysmex facilities.

Combination with Online Support System (SNCS)

From December 1999, a new network service (Sysmex Network Communication System: SNCS) that combines the above online QC and an online support service* was

Individual Tradentes - Minimuch Report Date	-		
27-CU(2) ARE(2) RETAL BROOM	ANY SALARY - HE CONS.		0
7916 = Champellange and an and and and an	ja induningi		2
Individual Statistics			
Las tapate 20.00 Obt - tan tapate 20.00 Obt - Lot 20.00 (20.00) (20.000 Second Obsect 3) Page 5 Obt - Parato Perset Parato Perset Para		SD(Dust Lapera Pracy Mail Trans Adda Performant Graup 2 30 range 2 30 range 2 30 range	
204 II IS 0 2 R			
214 H B B B B			
	RBC 24 26 28 30	4/1 3	<u> </u>
		4/1 3	

Fig. 3 Historical SDI chart

の町ちょうちょう														
lividual Stat	listics													
real Train.		S fant +												
Updates		io italiff +0							formerca.	Late Las	and .			
C LEARNER	100-4 MO	pigen et	1000 (200	104-04					100	dile.				
-0052000119/0404									Citolal I	fact of	_			
ort Format	- 3100	Caro al							der march 1	tion I				
SD Chart		Autor	1.00						Greek		_			
and Parameters		Normal State	a toke											
REC/HDB /7 RE		r f in	-	C DIFF.	6.60 3	interest				588 8				
HOLD HELD . HE	0.0		CARRADO.	c inc		Heldor.			Larra	whi	-			
and a second														
10.00														
ibe		_	_	_	_	_								_
	146R-27	449-25	white he	LWR-35	-taeli-da	LB-8-21	1644R-55	1444-24	(007-3)	MARI-SI	A99-21	100-11	AFR-DI	RFR-CR
iber	MBG	FIEC .	HEC.	HBC.	PEC.	PIEG	1750	mec.	MBC-	FIDC-	100	PEC	INDC -	REC
bar bar	1005 10 ⁴ 191	HBG 10 ⁴ /pt.	100°/#L	HBC IN ^N AL	1000 101/jp	1950 19 ⁴ /µL	11/1/16	10 ⁴ //L	NDO 10 ⁴ (pL	1000 10 ⁴ /101	1000 10 ⁴ /pt	HEG H ⁴ GL	TESC TO ⁴ /aL	1000 10 ⁴ /al
there there Vicentities	1005 10 ⁴ 192. 400	HEG 10 ⁴ /µL 4ES	100°//pl. 400	HBC HO ^R /at_	PEC.	7050 193 ⁴ 776 1940	1194/16 1194/16	10 ² /µL	10 ⁴ /3L 885	1000 90 ⁴ / pc	10 ⁴ /µL	PEC	PEC TE ^A /AL ME	10 ⁴ /al.
Dar Dar Hone Vointito Drog Mer	7005 10 ⁴ cpt. 400 8479	10 ⁶ /µL 10 ⁶ /µL 450 4470	10 ² /µL 483 483	HEIC HO ⁴ Value HAILA	1000 101/jp	1935 19 ⁴ /µL 840 440.0	7550 11 ⁴ 2/pL 4400 4440.0	10 ⁴ /µ.	800 10 ⁴ /3L 445 445	1000 10 ⁴ /100 441 441	NDC- 10 ⁴ /µL #	HEG H ⁴ GL	1055 10 ⁴ ////. 8451 8451	10 ⁴ /.sl. 10 ⁴ /.sl. 10 ²
bas bas tans Vesetats Drog Mar Drog Mar	705 15 ⁴ mr. 400 8479 8471	105 10 ⁴ /µL 452 4775 4775	100 10 ⁸ /µL 423 845.5 845.0	150 10 ⁴ /al.	100 10 ¹ / JL 1 1	1995 19 ⁴ 7µ6 1480 1480 1480 1	10% 10 ⁴ 7/10 400 400 400	10 ⁴ /µ. 444 4450 4450	10 ⁴ /pL 445 445	1000 90 ⁴ /100 441 448 A	1005 10 ⁴ /µL 44814	nes 1/ ⁴ /jt	1055 10 ⁴ 7 <i>A</i> L 4461 4451 44710	10 ⁴ /al. 10 ⁴ /al. 10 ⁴ /al.
bas bas tens Voundats Desig later Intervocational Series SD	105 10 ⁴ 172, 420 440 440 440 440 82	10 ⁴ /µL 10 ⁴ /µL 452 4776 4775 4775	1000 10 ⁴ /µL 4457 4457 4450 53	180 10 ⁴ /at.	1000 101/jp	1935 19 ⁴ /µL 840 440.0	70% 11 ⁴ 2/pL 440 4414 4414 4416	10 ⁴ /µL 444 445 445 445 445 445 1 445 1 445 1	FED: 10 ⁴ gL 445 445 445 445 445 445 445 445 445 44	1000 90 ⁴ /92 441 448 448 448 448 448 448 448 448 448	NDC- 10 ⁴ /µL #	HEG H ⁴ GL	1000 110 ⁴ /al. 440 440 440 440 440 80	1005 10 ⁴ / al. 482 141 141 141 172
Das Das tame Vesetato Derug Menn Detervice/Loop Derug SD Your SD	105 10 ⁴ qc. 420 420 420 420 420 421	105 10 ⁴ //d. 452 4776 44775 447 447 447 447 447 447 10 447 10 447 10 447 10 447 10 447 10 447 10 447 10 447 10 44 10 44 10 44 10 44 10 44 10 44 10 44 10 44 10 44 10 44 10 44 10 44 10 10 10 10 10 10 10 10 10 10 10 10 10	100 / pl. 423 4455 4450 52 52 512	150 10 ⁴ /at. 4	105 10 ¹ /µ. 1 1	7050 10 ⁴ /µL 340 441.4 1.5 1.5 1.5	700 11 ⁴³ /st. 440.6 440.6 440.6 440.6 440.6 440.6 440.6 440.6 140	10 ⁰ /µL 444 4410 4410 4410 4410 4410 4410 4410	10 ⁸ /µL 445 445 445 445 445 447 5 44 5 4 4 7 5	100 10 ⁴ /pc 401 401 401 40 40 40 40 40 40	1005 10 ⁴ /µL 44814	PBG H ⁴ /gL	105 10 ⁴ /al. 440 441 411 411 411 411 411 411 411 411	10 ⁴ /al. 10 ⁴ /al. 10 ²
Das Das Voiros Herr Droug Herr Droug SD Voir SD Group H	PES 10 ⁴ rpt. 420 440 440 440 420 421 421 421 421 421 421 421 421 421 421	HDG 10 ⁴ //d. 452 4775 44775 44775 44775 44775 44775 44775 15	100°/m. 413 413 415 415 415 415 415 415 415 415 415 415	100 M + 10 + 1	105. 10 ⁴ /µ. 1 1 1 1 1 1	FESQ 19 ⁴ /pL 948 440.4 440.6 15 15 15 15	11 ⁴ /µL 440 4400 4400 4400 4400 4400 4400 440	10 ⁰ /µ. 444 445 445 445 445 10 10 10	10 ⁸ /µL 485 485 485 485 485 485 485 485 485 485	100 10 ⁴ /pc 401 400 400 40 10 10 10	HDC 10 ⁴ /pL 848.at	FEG H ⁴ /gL	105 10 ⁴ /al. 440 441 4410 410 11 11 12	10 ⁴ /al. 10 ⁴ /al. 10 ⁴ /al. 10 ⁴ 10 ⁴ 10 ⁴ 10 ⁴ 10 ⁴ 10 ⁴
base base tame Voundata Droug Marr Before Colloop Droug Marr Your 500 Group H Open	PEDS 10 ⁴ rpt. 420 440 440 440 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 420 4204 420 420 420 4444444444444	FEDG 10 ⁴ //d. 452 44726 447666 44766 44766 447666 44766 44766 44766 44766 447	100°/ml. 423 4455 4455 4455 52 4129 52 4129 53 52 52 52 52 52 52 52 52 52 52 52 52 52	100 10 ⁴ /st. 10 10 10 10 10 10 10 10 10 10 10 10 10	PEDC 10 ⁴ / pL 10 10 10 10 10 10 10 10 10 10 10 10 10	FESC 198 ⁴ /pL 848 440.0 440.0 15 15 10 10 10 10 10 10 10	1114/pt. 4400 4400 4400 100 100 100 100 100 100	10 ⁴ /µ. 444 445 445 445 445 445 445 41 41 41 41 41 41 41 41 41 41 41 41 41	000 10 ⁴ /st. 485 485 485 485 84 84 84 84 84 9 9 9 9 9 9 9 9 9 9 9 9	FIDC 90 ⁴ / pc 441 441 448 440 440 440 440 440 440 440 440 440	HDC 10 ⁴ /pL 848.4 818 818 818 818 818 818 818 818 818 81	FESC 19 ⁴ /gL * * *	FESC TO ⁴ V.eL #461 #451 #4710 #171 #171 #171 #171 #171 #171 #171 #	880 10 ⁴ / al 482 840 72 48 (al 72 14 (al 84) 6 14 (al 14 (al)1)))))))))))))))))))))))))))))))))))
Das Das Voiros Herr Droug Herr Droug SD Voir SD Group H	PES 10 ⁴ rpt. 420 440 440 440 420 421 421 421 421 421 421 421 421 421 421	HDG 10 ⁴ //d. 452 4775 44775 44775 44775 44775 44775 44775 15	100°/m. 413 413 415 415 415 415 415 415 415 415 415 415	100 M + 10 + 1	105. 10 ⁴ /µ. 1 1 1 1 1 1	FESQ 19 ⁴ /pL 948 440.4 440.6 15 15 15 15	11 ⁴ /µL 440 4400 4400 4400 4400 4400 4400 440	10 ⁰ /µ. 444 445 445 445 445 10 10 10	10 ⁸ /µL 485 485 485 485 485 485 485 485 485 485	100 10 ⁴ /pc 401 400 400 40 10 10 10	HDC 10 ⁴ /pL 848.at	FEG H ⁴ /pL	105 10 ⁴ /al. 440 441 4410 410 11 11 12	10 ² /al. 10 ² /al. 10 ² /al. 10 ² 10 ² 10 ² 10 ² 10 ²
base base tame Voundata Droug Marr Before Colloop Droug Marr Your 500 Group H Ode	PDS H ⁴ -ycL 420 440 440 440 440 440 440 14 14 14 16 16 16 16 16 16 16 17 17 17 17 17 17 17 17	FEDC 10 ⁴ //d. 450 4776 4975 497 497 497 497 497 497 497 497 497 497	10 ⁶ /µL 483 485 485 53 4155 53 4155 53 53 4155 53 53 53 53 53 53 53 53 53 53 53 53 5	HENC HENC	PESC 10 ⁴ //pL 10 10 10 10 10 10 10 10 10 10 10 10 10	PESC 19 ⁴ /pL 948 440.4 440.4 440.4 10 10 10 10 10 10 10 10 10 10 10 10 10	PES 11 ⁴ / ₁₀ 440 440 440 440 440 440 440 40 10 10 10 10 10 10 10 10 10	10 ⁴ /µ, 444 445 445 445 445 445 44 445 45 45 45	RD0 H0 ^A /gL 445 445 445 445 445 445 445 445 445 44	FIDC 90 ⁴ / m; 441 441 448 440 440 440 440 440 440 440 440 440	HDC 10 ⁴ /yd 4 4 4 4 4 4 4 4 4 4 5 4 4 7 5 4 7 5 4 7 5 5 4 7 8 5 8 10 10 10 10 10 10 10 10 10 10 10 10 10	FBS 11 ⁴ /gL * * * * * * *	TOP AND	10 ² /.m. 482 840 73 488.00 73 488.00 73 488.00 73 488.00 75 488.00 75 488.00 75 488.00 75 488.00 75 488.00 75 488.00 75 488.00 75 488.00 75 489.00 75 76 76 76 76 76 76 76 76 76 76 76 76 76

Fig. 4 Numerical table



Fig. 5 Conceptual drawing of SNCS (Japan)

introduced in the Japanese market. *Fig. 5* illustrates the concept of SNCS.

* The online support system is a technical support system which has two functions: 1) remote access function and 2) automatic monitoring function of equipment operating log information, utilizing the latest network technology.

Case Report

This is a case in which the SNCS proved to function effectively and thus the problem was quickly solved.

- a) Detection that PLT-O of QC data of a certain laboratory was abnormal when compared to the peer group mean by the automatic judgment function of the online QC.
- b) Information was immediately transmitted automatically to the telephone service center (TSC).
- c) The specialist at the TCS confirmed the condition of the laboratory's equipment using the screen-sharing remote software, and determined that it was a problem with the laser unit.
- d) The TSC notified the responsible Field Service Representative (FSR) about the condition and proposed appropriate countermeasures.
- e) The FSR received the detailed information, brought necessary parts, visited the laboratory, replaced and adjusted the laser unit, and solved the problem without affecting patient samples next morning.

CONCLUSION

This report introduces an outline of the online QC function for the latest multi-parameter automated hematology analyzer, the Sysmex XE-2100. We are convinced that the use of this system will enable the user to report the daily patient sample data with the highest level of confidence. In the future, we plan to deploy the system worldwide.

Online QC is an innovative QC technique that makes free use of the latest network technology. This system has an open design to incorporate any new requirements and improvements, which result from an interactive communication between the customers and Sysmex.

References

- Belk WB, Sundermann FW : A survey of the accuracy of chemical analysis in clinical laboratories. Am J Clin Path, 17 : 853-861, 1947.
- 2) Levey S, Jennings ER: The use of control charts in the clinical laboratory. Am J Clin Path, 20: 1059-1066, 1950.