Introduction of the XE-2100 Online QC System

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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,

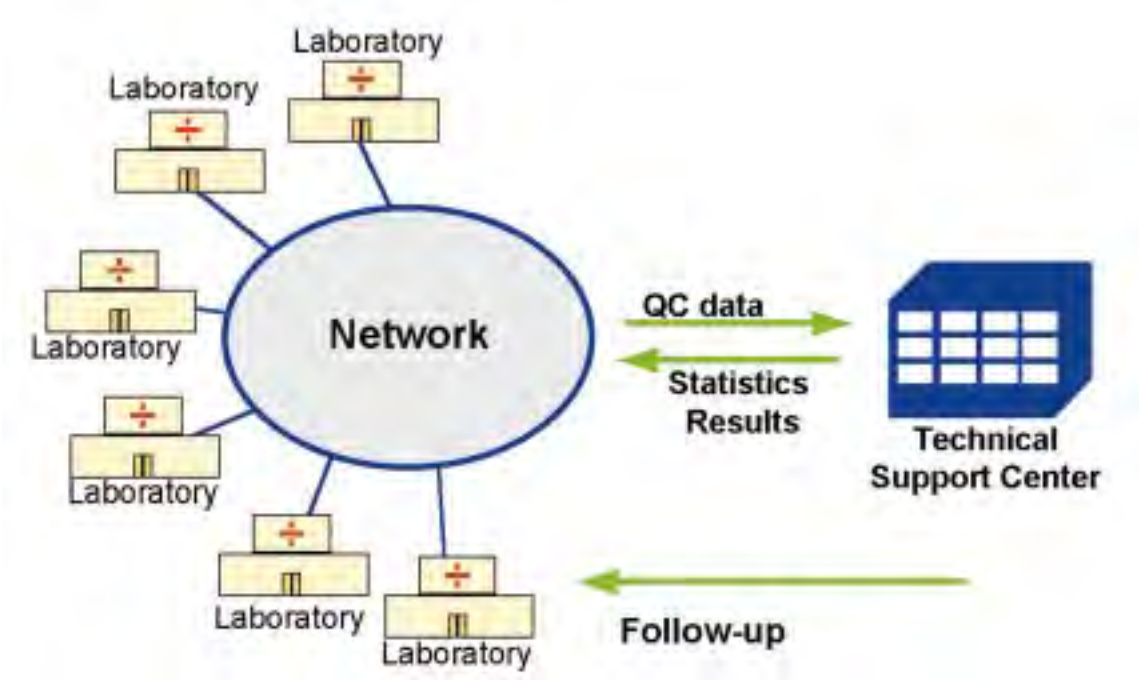

Fig. 1 *Conceptual drawing of online QC (Japan)*

Table 1 *Comparison of online QC and QC technique*

	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).	(1) Index and assessment of measurement precision. (2) 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		(1) Unable to assess precision. (2) 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.

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

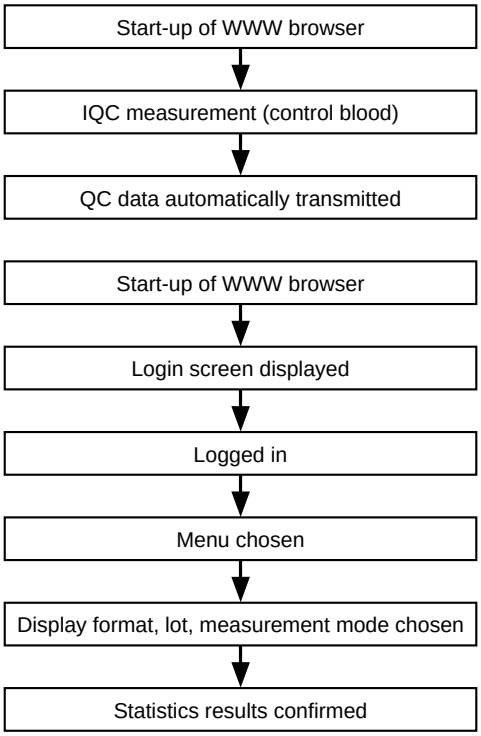

Fig. 2 *Perusal method of latest statistics results*

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

Fig. 3 *Historical SDI chart*

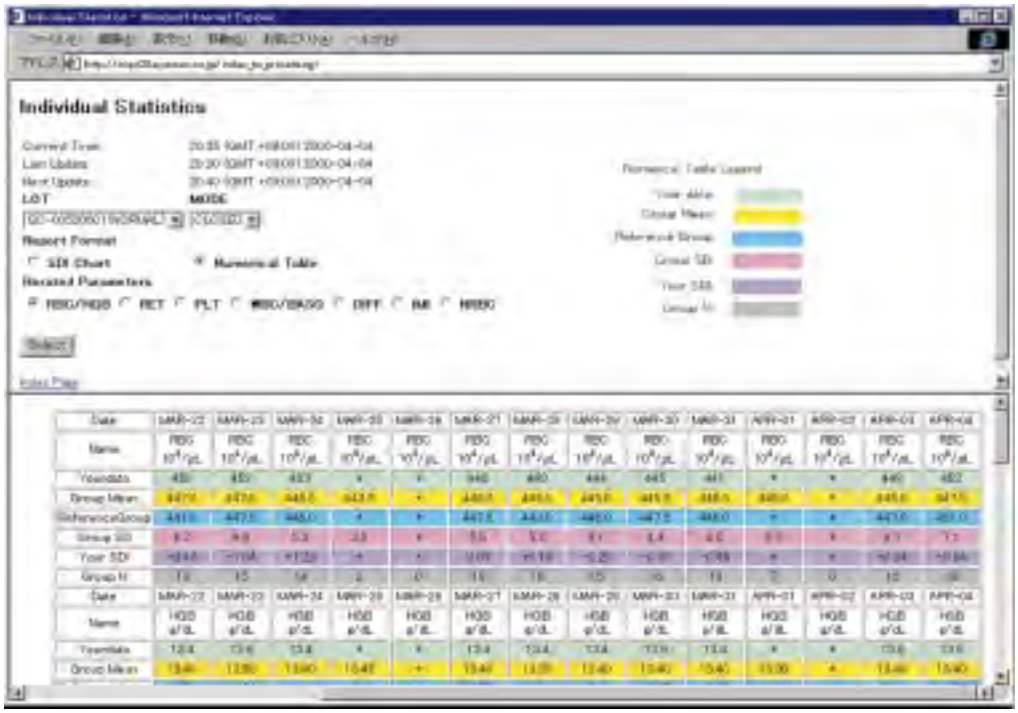

Fig. 4 *Numerical table*

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

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