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SNCS – the quality control solution for the haematology laboratory

The purpose of this newsletter is to provide an overview of the concept and functionality of the Sysmex Network Communication System (SNCS) illustrating its value to the haematology laboratory as an integral component of the quality management system.

Key words:
SNCS IQAS Online, quality control, EQA, proficiency testing, accreditation, ISO/IEC 15489, ISO/IEC 17043, corrective action.

What is SNCS?

SNCS stands for Sysmex Network Communication System. SNCS is a tool that exploits the IT networking capabilities of Sysmex haematology and urinalysis analysers (for a full list see table 1). It is comprised of a quality control (QC) module, called SNCS IQAS Online, as well as a technical module. The latter is geared towards the remote monitoring of the technical performance of the analyser (e.g. cycle counts) and service access. This newsletter will only address the concept of SNCS IQAS Online and its value in the context of overall haematology laboratory quality management. Detailed discussions of the full functionality of SNCS IQAS Online are beyond the scope of this newsletter.

Table 1 Sysmex Analysers with SNCS capability

Haematology	Urinalysis
X-Class (except XS-500)	UF Series
XN Series	UX-2000
XN-L Series (XN-350, XN-450, XN-550)	
XP-300	

SNCS IQAS Online – what is it and how does it work?

SNCS IQAS Online is a daily external quality control scheme which continuously monitors the performance of the analyser based on the routine use of Sysmex quality control materials (see table 2).

Table 2 Sysmex Quality Control Material used for SNCS IQAS Online

QC material	Analysers
e-CHECK (XS)	XS series
e-CHECK (XE)	All X class analysers (including XS)
XN CHECK & XN CHECK BF	XN and XN-L series
Eightcheck-3WP	XP-300
UF II CONTROL	UF series, UX-2000

It is standard practice for laboratories to perform daily internal quality control, the primary purpose of which is to detect any systematic errors within the analytical system that may cause an erroneous patient result to be issued, and consequently an inappropriate clinical action to be taken. To

ensure reliability of results, continuous monitoring of the analyser is an absolute requirement. The classical daily internal quality control (IQC) checks comparing results against the expected pre-determined values provided in the lot number specific assay data sheet fulfil this criterion.

The networking capabilities of Sysmex haematology analysers enable the transmission of the QC data obtained from the routine IQC processing to an external SNCS server via the internet. This process happens seamlessly and in parallel to the traditional IQC assessment whereby data is recorded and filed on the analyser computer directly. Data received from all other analysers globally that are connected to the SNCS IQAS Online programme is statistically evaluated in order to calculate the international peer group mean and standard deviations for each parameter. This is done for all parameters including service parameters, not just those that are reportable. This calculation is performed once every 24 hours and is used to evaluate the performance of each analyser in relation to the international peer group which is comprised of the same model of analyser (e.g. XN), same mode of analysis (i.e. open or closed mode), same level of control material (i.e. level 1 or 2 or 3) and the same lot number of control blood.

Fig. 1 The SNCS Concept: daily IQC data is transmitted to an international server. Every IQC sample therefore doubles up as an EQA sample.

SNCS data review and error notification

Immediately after processing, the laboratory's IQC data is transmitted to the global server for judgment by comparing it to the international peer group data. The SNCS server is programmed with a set of rules which include accuracy, precision, trend and shift checks. If any relevant deviation is detected in relation to these rules, an error message is automatically generated. This error notification email, which will specify the parameter, QC level and analysis mode affected as well as the nature of the poor performance, is dispatched to the designated recipient (see figure 2). This is usually the service provider but could also be the quality manager of the laboratory. These alerts are sent in real time and feedback received almost immediately depending on the speed of the internet connection. In the example shown in figure 2 below, the DIFF-Y parameter for all three levels of control is reading more than 3 standard deviations lower than the group mean. DIFF-Y is a service parameter which documents the degree of fluorescence (Y axis in DIFF Scattergram) of the neutrophil cluster. The most common cause of a low DIFF-Y is the use of expired reagents (where the intensity of the fluorescent dye is diminished) or the analyser is in need of sensitivity adjustment. DIFF-Y would certainly not be included in traditional EQA schemes nor would laboratory staff pay close attention to this and other service parameters as it is not a clinically relevant reportable parameter. It is however a sensitive measure of analytical performance hence being alerted early on that the values are drifting away from the expected group mean will facilitate proactive intervention before clinical parameters, in this case the differential count, would become affected.

Dear Customer,

This is an automatic IQAS ONLINE notification mail.
Some suspect error(s) has/have been detected for Intraday statistics when comparing the individual data displayed in the column "Your data" to the group mean (peer group: ALL / at judgement) :

Model	Serial number	Error occurance date and time	Measurement time	Measurement number	Control material	Lot	Level	Measurement mode	Parameter	Your data	Group mean	Error code
XT-4000i	11296	05.06.2015 08:12:53	09:57:41	1	e-CHECK(XE)	5093	1	CLOSED	DIFF-Y	52.1	64.928	3SDI over
XT-4000i	11296	05.06.2015 08:13:11	09:58:27	1	e-CHECK(XE)	5093	2	CLOSED	DIFF-Y	46	59.76	3SDI over
XT-4000i	11296	05.06.2015 08:13:12	09:59:12	1	e-CHECK(XE)	5093	3	CLOSED	DIFF-Y	44.1	56.775	3SDI over

Please visit http://www.sysmex-europe.com/sncs and check the details of the detected error(s) for your instrument.
For data review please select the peer group "ALL / at judgement" and data type "Intraday".
If you need further advice, please contact your Sysmex service representative.
Sincerely,

Administrator
Sysmex Europe GmbH

Fig. 2 An example of an error notification email.

How does the laboratory access its own data?

The analyser data specific to a laboratory can be viewed on the SNCS website (http://sysmex-europe.com/sncs/) using a password protected login (see figure 3). No data from other laboratories is ever visible to the end-user. However, if there are several laboratories that belong to the same organisation, an organisational group can be set up allowing the overarching quality manager oversight of all analysers under his/her responsibility with a single login.

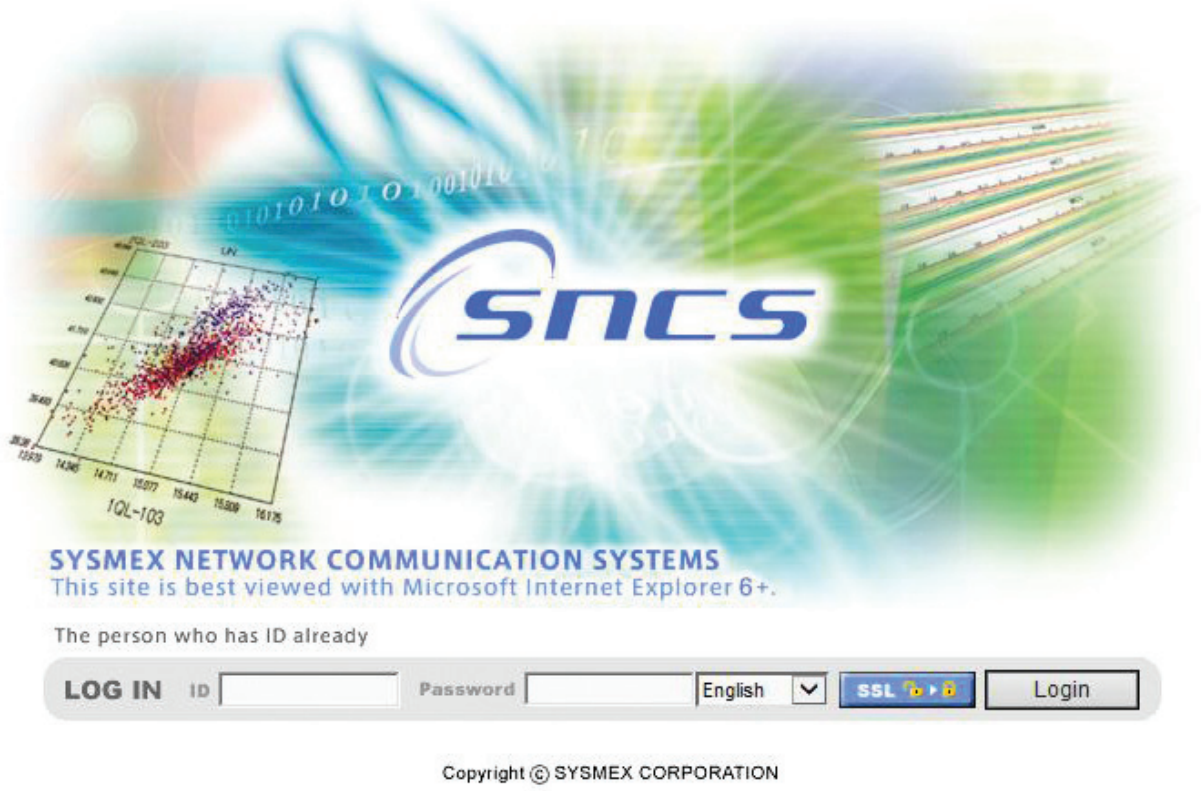

Fig. 3 SNCS Login page.

What does the data look like?

The data can be reviewed in several formats, with the most popular being the "time-series table" (figure 4) or "time-series chart" (figure 5). These tabulate and plot each individual data point for each parameter and level and mode of QC material in relation to the peer group data. The nature of any deviation detected is identified by means of an error code in the "judgment" row. The example shown in figure 4 below shows no errors. Results that fall within 3 standard deviations (expressed as a standard deviation index (SDI)) are generally acceptable. The same example is shown as a chart in figure 5 where any data point exceeding 3SDIs will be marked with a red cross for easy oversight.

External Quality Assurance – why is this important?

The principles of good laboratory practice stipulate that laboratories should participate in external quality assessment (EQA) schemes or some form of inter-laboratory comparison, in addition to their IQC procedures. There are several EQA or proficiency testing (PT) providers, both internationally and regionally. The most popular international haematology schemes are UK NEQAS (UK based), CAP (US based) and RCPA (Australia based). Unlike IQC where the target values are known (provided with assay data sheet specific to each lot number of material), these traditional EQA schemes involve the analysis of samples with values that are unknown to the laboratory technician. As such EQA effectively serves as an external verification of a laboratory's analytical performance. Medical laboratories that are accredited in accordance with ISO/IEC 15189 are required to provide evidence that they have satisfactory performance in an EQA scheme or equivalent inter-laboratory comparison testing.

Date: Intraday | Peer Group: ALL : at Judgment | Judged by: Total-SD

Parameter: MCV | Condition 1: 0 | Condition 2: 02 | Model: JAB514 | Calibration: 69 | Temperature: 08 | Reagent: 999 | Unit: FL

Date - Number	09-MAY-02	10-MAY-01	10-MAY-02	11-MAY-01	11-MAY-02	12-MAY-01	12-MAY-02
Time(HH:MM:SS)	16:07:51	08:29:46	16:15:31	08:02:20	15:54:48	09:16:04	14:32:03
Parameter Unit	MCV FL	MCV FL	MCV FL	MCV FL	MCV FL	MCV FL	MCV FL
Control Lot	#5094 (L1)_CL	#5094 (L1)_CL	#5094 (L1)_CL	#5094 (L1)_CL	#5094 (L1)_CL	#5094 (L1)_CL	#5094 (L1)_CL
Your data	76.700	77.000	77.000	77.600	77.100	77.300	77.400
Group Mean	77.754	77.761	77.761	77.769	77.769	77.772	77.772
Your SDi							
Your SDI	-1.185	-0.852	-0.852	-0.189	-0.749	-0.527	-0.416
Peer group Inter-SD	0.814	0.816	0.816	0.811	0.811	0.812	0.812
Your SD							
Peer group Total-SD	0.889	0.893	0.893	0.892	0.892	0.895	0.895
Group N	216	219	219	219	219	219	219
Judge	-	-	-	-	-	-	-

Fig. 4 Example of a "Time series table".

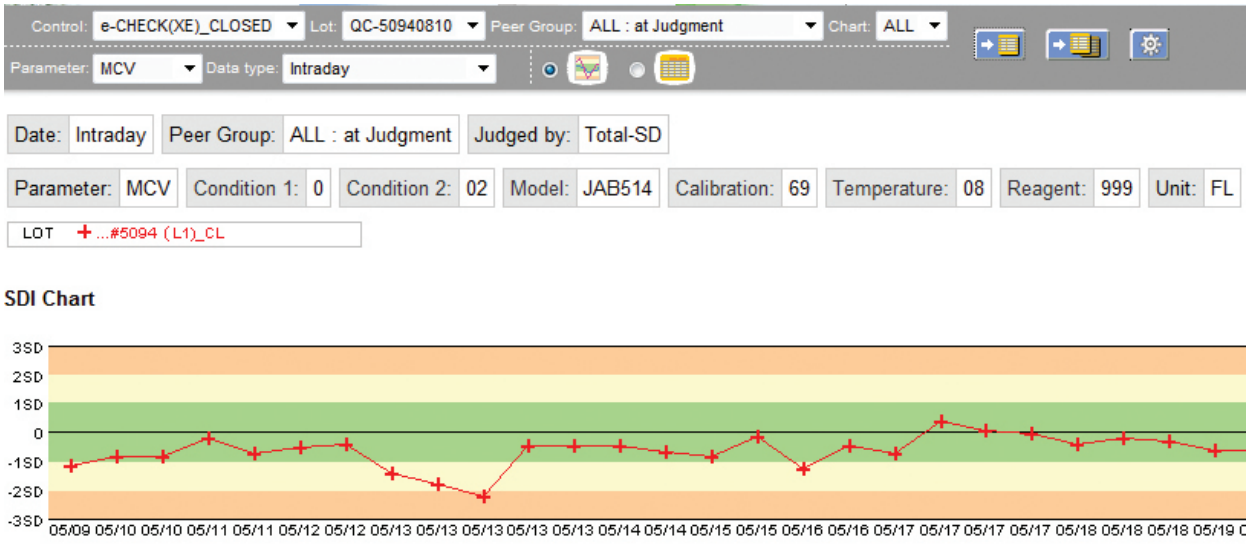

Fig. 5 Example of a "Time series chart".

Are all EQA schemes equal?

There is a strong drive for laboratories to be accredited in accordance with ISO/IEC 15189 (or ISO/IEC 17025) as it is widely acknowledged that laboratories that set systems in place that make people quality conscious and foster continuous improvement, have a far higher probability of issuing results that are trustworthy and give the clinician the assurance that they can safely be relied upon for patient management. Likewise, there is an accreditation standard for PT/EQA schemes, namely ISO/IEC 17043 to achieve a similar standard of performance.

a. What is ISO/IEC?

ISO (International Standards Organisation) and IEC (International Electrotechnical Commission) collectively are tasked to set international standards that stipulate the benchmark for acceptable performance. ISO/IEC 15189 and ISO/IEC 17043 are the standards that are used to assess the competence of medical testing laboratories and providers of external quality assessment based on inter-laboratory comparison respectively.

b. What is the value of an EQA scheme being accredited?

Just like any laboratory can issue a laboratory report, so can any EQA scheme provide a performance report to the laboratory. Whilst we instinctively would choose to use one laboratory over another, given the choice, does the same apply to laboratories when deciding which EQA scheme to participate in?

Schemes that are accredited in accordance with ISO/IEC 17043 are more likely to be well managed and able to, with good sensitivity, detect any deviant analytical performance and duly notify the laboratory that corrective action is required. Hence, laboratories are more likely to place their trust in accredited schemes and consequently these tend to have a larger participant group.

c. Are there any shortcomings inherent in conventional EQA schemes, with or without accreditation?

In theory the spot checks of analytical performance using samples of unknown values is good practice but there are several shortcomings that should be considered.

- **The frequency of measurements**
  EQA schemes send-out samples for analysis to laboratories at pre-determined intervals, the exact number of assessment cycles per annum may vary, but at most would be once per month. This means that for a laboratory processing 100 samples a day, performance is only externally validated once every 3000 samples.

- **The time between analysis and feedback being received**
  The time lapse between the day of analysis and receipt of the EQA performance report is usually 4 – 8 weeks, but can be longer. Hence, if any parameter was identified as being "out of consensus" for which corrective action is required, it will be difficult to conduct a thorough root cause analysis that will lead to meaningful corrective action considering the time that has passed since the error occurred.

- **The tendency for EQA samples to be afforded special handling**
  Whilst the EQA samples are supposed to be handled in the identical fashion as the routine laboratory samples, this is rarely the case. It is common practice for EQA samples to be put aside for processing and reporting by the most senior person, rather than the more junior staff who process the patient samples.

- **Most EQA samples only cater for open mode analysis**
  The EQA checks should be assessing the routine sample processing within the laboratory. EQA samples invariably need to be processed in the open mode as most have a non-pierceable cap. Yet in most laboratories the bulk of samples are processed in the sampler or closed mode. There is therefore no EQA check for the mode that is used for routine testing.

- EQA schemes use samples (most use commercial control blood) that may show variable performance based on the principle of measurement of the individual analysers. Although most schemes take this into account by grouping users based on the model of analyser, the concept of a matrix effect influencing results must always be considered when evaluating poor performance. The more esoteric or "rare" the analyser the greater the impact will be. For example, this will discriminate against those labs that are first to take up a new analyser, as a minimum of 10 participants is required for meaningful statistical analysis as a standalone group. Consequently such users will be judged against the total group with a higher probability of being judged as an outlier, because of this matrix effect rather than true poor performance.

How does SNCS IQAS Online fare as an EQA scheme?

SNCS has several advantages over the more traditional schemes.

- Daily QC (Eightcheck-3WP, e-CHECK (XS), e-CHECK (XE), XN CHECK or XN CHECK BF for haematology) doubles up as the EQA analysis – no extra effort is required. This also eliminates the possibility that EQA samples are given "special attention" and therefore documented performance may not necessarily reflect the quality of daily analysis.
- The feedback is provided in real-time allowing for proactive and meaningful troubleshooting and implementation of corrective action.
- All analysis modes are evaluated.
- There is no matrix effect – each EQA measurement is assessed against the identical analyser, mode of analysis and lot number. Hence, any outliers are due to genuine performance issues.
- There is no special handling required.
- Transcription errors and late submissions are eliminated – the most frequent cause of "failed" EQA. If the wrong level of QC was accidentally measured, this will not be judged as "failed" EQA in the same light as a transcription error as the operator will immediately repeat the analysis using the correct level (control blood vial or QC File selection amended) which will be reflected in the SNCS IQAS Online data records.
- There are no costs involved.
- All reportable and service parameters are evaluated – not just the basic parameters as is the case in traditional EQA schemes.

- Advanced clinical parameters (E.g. RET-He, IG, and IPF): Whilst the clinical value of these parameters is recognised, they are not included in traditional EQA schemes as there are too few users to make this cost effective. Clinicians may be more inclined to use these advanced clinical parameters, and hence increase the utilisation, if they knew that they were being monitored by an EQA scheme.
- Service parameters: The inclusion of service parameters (e.g. DIFF-Y as explained in the paragraph "SNCS data review and error notification) serves as an early warning mechanism that analytical performance may be drifting and hence proactive intervention can be undertaken before there is a documented "QC failure" of a clinical parameter which would result in analyser down time.

- Email alerts are issued for matters requiring attention.
- Proactive intervention is possible as trends are observed before QC failure occurs.

SNCS IQAS Online – what about ISO/IEC 17043?

Whilst many Sysmex haematology users have appreciated the value of SNCS IQAS Online as a quality management tool, a frequently posed question has been, "but is it recognised as an EQA scheme by accreditation authorities?" Our answer to that has always been that if the laboratory has clear documentation explaining how they use SNCS as an EQA scheme, then that complies with the requirements of the ISO/IEC 15189 (and ISO/IEC 17025) standards for medical laboratories. The responsibility for proving acceptability to the authorities lay with the individual laboratory.

SNCS IQAS Online has now officially been accredited by the Japan Accreditation Board in accordance with ISO/IEC 17043 – the international accreditation standard for proficiency testing schemes. As ISO is an international standard, the Japanese accreditation certificate covers SNCS IQAS Online globally. Laboratories with Sysmex haematology analysers can now use SNCS IQAS Online with confidence as their haematology EQA scheme. Proof of participation can be provided upon request from your service provider (see figure 6).

Fig. 6 Certificate of confirmation of participation in SNCS IQAS Online.

Conclusions

SNCS IQAS Online is an excellent haematology laboratory quality management tool. Furthermore, daily IQC processing on Sysmex haematology analysers doubles up as input into the SNCS IQAS Online scheme which has been awarded ISO/IEC 17043 accreditation status - the international accreditation standard for proficiency testing schemes. Consequently Sysmex haematology users have the distinct advantage over other laboratories in having free access to an internationally accredited EQA scheme which has many features that are superior in terms of achieving the objective of independent "spot checks" with the intention of identifying poor analytical performance which in turn leads to appropriate and timely corrective action as required, in comparison to the traditional EQA schemes.

Take home message

- SNCS IQAS Online is quality management tool that exploits the IT networking capabilities of Sysmex haematology analysers.
- Daily internal quality control data is transmitted to a global server thereby doubling up as an EQA scheme.
- SNCS IQAS Online has many features that are superior to traditional EQA schemes.
- SNCS IQAS Online is an ISO/IEC 17043 internationally accredited EQA scheme.
- SNCS IQAS Online is fully compliant with the EQA requirements of the ISO 15189 accreditation standard for medical laboratories.

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