KAISER MEDICAL CARE PROGRAM
ORANGE COUNTY AREA
POLICIES AND PROCEDURES

TITLE:	HEMATOLOGY P&P	INDEX NO:	02-015-01
SECTION:	QUALITY CONTROL	ORGIN DATE:	2/16
SUBJECT:	PROCESSING QUALITY CONTROL for IQAP on SYSMEX XE2100	REVIEW DATE:	
		REVISION DATE:	

PROCESSING QUALITY CONTROL for IQAP on SYSMEX XE2100

PRINCIPLE

Quality control files for the Sysmex eCheck Controls are uploaded to the Sysmex Insight Quality Assessment Program on the Sysmex website monthly by a CLS with advance operator access. The data is used for evaluation and comparison with other XE2100 analyzers. The Interlaboratory Quality Assurance Program (IQAP) is a service provided by Sysmex Corporation. The IQAP report provides interlaboratory comparison indicating precision and accuracy relative to peer data.

PROCEDURE

Saving the data to files:

Follow the steps below to save the data from the XE2100 quality control files to be sent to Sysmex Insight.

Step	Action
1.	Click Sysmex Insight icon on Main Menu.
2.	Click combo boxes to select QC chart: • **Material** to select e-Check • **Level** to select Level 1, Level 2, Level 3. • **Analysis Mode** to select Manual or Closed Mode. • **Lot** to select Lot No. (New or Current). • **Verify QC data Info in right column.**
3.	Click Save. Then click Cancel to insert disk.
4.	Click InsightData and create new folder. Name it as QC File Lot #.
5.	Save each level and mode in that folder.

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PROCEDURE, continued

Print Control File:

Follow the steps below for printing the control files.

Step	Action
1.	On IPU, click on QC icon. Choose control (e-check, Lot, Current, Level, Mode). QC chart is displayed.
2.	Set Range of QC data to print. Click on dark green line and drag line to include all QC data or press CTRL and A to select all.
3.	Print QC data in line format. Select range and click Report, Ledger (LP).
4.	Print QC charts, select range and click Report, GP.
5.	Repeat steps 1-4 until all files are printed.
6.	Submit generated hard copies to Hematology supervisor. Data is reviewed by supervisor and data uploaded to Sysmex Insight.

Upload File:

Follow the steps below for uploading file to Sysmex Insight

Step	Action
1.	Access Sysmex website on the IPU. (Insight icon on desktop). http://www.sysmex.com/Insight
2.	Click-on: **Login**
3.	Enter: User Name:_____ Password: _____
4.	Click-on: **Submit QC Data**
5.	Select analyzer.
6.	Click Browse and select each QC data file in newly created folder.
7.	Click Submit Data File for each level and each mode.
8.	Data is immediately available to review under View QC Data Report icon.

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REVIEWING the IQAP REPORT

IQAP data report can be generated immediately after upload, however, all peer groups may not have been received. The IQAP program determines how the laboratory instrument compares with participant instrument peers. The Hematology supervisor reviews the IQAP report for accuracy and precision, investigates possibility of system error and documents results of investigation on the IQAP report.

Mean Diff

This is an expression of the difference of your analyzer's mean from the peer group. It can be used to determine the absolute magnitude of an accuracy error.

SDI

This is a standard measure of you analyzer's inaccuracy. It provides the distance of your mean from the "truth" (the peer group mean) in units of standard deviations.

Positive and negative SDIs indicate error above and below the Group Mean, respectively. Zero values may occur when Your Mean is close to Group Mean. The formula is the same as used for "z-score" or "SDI".

Your CV

This ratio is a measure of your precision, which can be compared across control levels and lot numbers.

Group CV

This is a measure of the level of precision obtained by the laboratories contributing to the peer group statistics. It does not reflect the average obtained by the group, but is expressed as the degree of variability within the group in a manner consistent with that for assessing the individual laboratory. If Your CV is greater than the Group CV, your result is presented in **bold** type.

Note: When Your CV result is greater than the Group CV, this does not necessarily indicate that your precision is unacceptable. Both CV and SD should be reviewed to assess analyzer performance. CV's of extreme levels are usually due to anomalous data.

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REVIEWING the IQAP REPORT, continued

IQAP Checklist:

Situation	Action
Your data agrees with that of other participating labs: no flags	No action necessary.
Your SDI for one or more parameters/levels should be reviewed	Your accuracy needs to be reviewed. • Verify that the data on the report matches the data you submitted and that your data was submitted correctly. • Check for a pattern by comparing the data with other levels of the same parameter on the report. • Check for similar patterns in both previous and current lots of control.
Your CV for one of more parameters/levels should be reviewed.	Your precision needs to be reviewed. • Verify that the data on the report matches your records and that you submitted the data correctly. • Review maintenance procedures. • Review handling techniques of the cell control product.
Both SDI and CV for one or more parameters/levels should be reviewed.	First resolve the precision problem, then troubleshoot the accuracy problem. Follow the steps listed above.

REFERENCE

Sysmex XE2100 Operator's Manual, MKT-2579-3 January, 2010
Insight ™ Participant Report Guide, MKT-40-1104 May, 2012

ATTACHMENT

A - Peer Group Comparison

Attachment A

A. Peer Group Comparison

The second page of the Period Report displays the **Peer Group Comparison** for each parameter. This section provides comparison of the laboratory's performance with regard to accuracy and precision. An example is shown below.

sysmex *Insight*

Peer Group Size
L1 N= 367
L2 N= 371
L3 N= 368

Prepared for
Sysmex Test

e-CHECK™

Lot 9204, Cumulative Report, 7/22/2009 - 10/12/2009
Analyzer: XE-2100 Serial#: A1111 Closed Mode, Shift 0

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Peer Group Comparison

		Assay Mean	Your Mean	Your SD	Group Mean	Group SD	Mean Diff	Delta %	SDI Range	Notes	SDI	Your CV	Group CV
RBC x10^6/uL	L1	2.280	2.281	.02	2.281	.03	.000	.0			.0	.8	1.2
	L2	4.370	4.355	.04	4.371	.04	-.016	-.4			-.4	.8	1.0
	L3	5.270	5.239	.05	5.253	.05	-.014	-.3			-.3	**1.0**	1.0
HGB g/dL	L1	5.70	5.68	.08	5.63	.08	.04	.8			.5	1.3	1.5
	L2	12.90	12.88	.13	12.84	.13	.04	.3			.3	1.0	1.0
	L3	16.90	16.96	.22	16.86	.17	.10	.6			.6	**1.3**	1.0
HCT %	L1	17.00	17.52	.12	17.03	.27	.49	2.9			1.8	.7	1.6
	L2	37.10	38.03	.29	37.06	.49	.97	2.6			2.0	.8	1.3
	L3	48.00	49.24	.51	47.97	.62	1.27	2.6			2.0	1.0	1.3
MCV fL	L1	74.60	76.83	.64	74.67	.92	2.16	2.9		P	2.4	.8	1.2
	L2	84.80	87.33	.56	84.80	.91	2.53	3.0		P	2.8	.6	1.1
	L3	91.10	94.00	.55	91.33	.94	2.68	2.9		P	2.8	.6	1.0
MCH pg	L1	24.80	24.90	.24	24.71	.35	.19	.8			.6	1.0	1.4
	L2	29.50	29.57	.17	29.37	.32	.20	.7			.6	.6	1.1
	L3	32.10	32.35	.25	32.10	.35	.25	.8			.7	.8	1.1

Measures of accuracy include the **Mean Diff (absolute rounded difference between your mean and the group's mean)**, **Delta % (expression of this difference in percent)**, and the **Standard Deviation Index (SDI)**. The SDI represents the number of SDs by which the laboratory's mean value for a parameter differs from the peer group's mean. On this report, it is expressed in numeric and graphic form. Values outside of the ±2 SDI range will be flagged in the **Notes** column. For example, on the report displayed above, the SDI for the MCV, level 1, is 2.4. This represents a statistically significant accuracy bias and is therefore flagged with a **P (Positive Bias)**. A quick review of this column will readily reveal any potential problems. A description of messages and corresponding flags are provided on the **Peer Group Comparison Notes Page** in the report. An example of these messages is shown below.

Accuracy Bias Codes

P	Your Mean on this level has a positive statistical bias in accuracy.
N	Your Mean on this level has a negative statistical bias in accuracy.
SP	Your Mean on this level has a strong positive statistical bias in accuracy.
SN	Your Mean on this level has a strong negative statistical bias in accuracy.
*	Indicates that the Mean also exceeds CLIA PT Criteria.

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Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Imp.
New		Julius Salomon 2/17/2016			

Imp. =Implemented