

Clinical Diagnostic Solutions, Inc.
**Quality Assurance
Program**

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INTRODUCTION

Welcome to Clinical Diagnostic Solutions Quality Assurance Program (CQAP) – the Hematology Interlaboratory Quality Assurance Program. This program presents your data in a user-friendly format where your data can be compared to your peer group for the instrumentation that you are using.

The main features of CQAP are:

- Data collection on a calendar month basis
- The same submission date every month
- Rapid turnaround time
- Staff that is responsive to customer needs

This manual contains detailed information that will help you as you participate in the CQAP and will allow you to maximize its utility. It contains:

- Descriptions of the Data Submission Options and directions on how to use each method
- Detailed explanations of all reports that make up the Output Report
- Example report printouts with detailed explanation of key attributes
- Examples of SDI graphs showing historical trends in data
- Definitions of key Quality Control Concepts
- Mail, Fax, E-Mail and Telephone information

DATA SUBMISSION

Your monthly data can be submitted by using one of these forms:

- CQAP Summary Form
- Instrument Summary Form
- CQAP Data Submission Form (can only be submitted via email)

Please access the Clinical Diagnostic Solutions, Inc. website to acquire the current CQAP Summary Form and the CQAP Data Submission form.

www.cdsolinc.com

The form you select **must be submitted via one of the following three options:**

Postal Mail

Clinical Diagnostic Solutions, Inc.
Attn: CQAP Processing Center 4155
Lawrenceville Hwy., #8147
Lilburn, GA 30047

Fax

770-931-8740

Email

cqap@cdsolinc.com

CQAP Summary Form

This form is the standard form for participants that wish to submit and mail, email, or fax a summary of their data to the CQAP Processing Center.

For electronic input, use Microsoft Excel to input your data within the downloaded summary form.

For manual input, use a black pen to write your summary statistics on the form. Make sure all entries are legible.

For either manual or electronic input, please make sure the following items are entered within the CQAP summary form. Note that all three levels of controls should be reported on the CQAP Summary Form starting with all 16 parameters for the low control, followed by the 16 parameters for the normal control and high control.

- **Submission Date**
- **Laboratory Name (if not included on preprinted label)**
- **Laboratory ID (if not included on the preprinted label)**
- **QC Month**
- **Instrument type (model name and/or number)**
- **Instrument ID**
- **QC lot number**

*Please ensure that all forms are filled within the form or your lab may not receive valid test results. Each form MUST CONTAIN the **N** (number of control samples on the QC file), the **mean** and the **SD** (standard deviation) values to be processed correctly.*

****See following color-coded screenshot (Figure 1) of items to include in the CQAP Summary Form****

CQAP Summary Form

	A	B	C	D	E	F	G	H	I	J	K	Q
1	Submission Date (mm/dd/yy)											
2	Lab Name											
3	Lab ID											
4	QC Month(mm/yy)											
5	Inst Type											
6	Inst ID											
7	QC Kit Lot#											
8	ParamID	N	Mean	SD	2SD	Level	LabID	Instrument	InstrumentType	QCMonth	QCLot	
9	wBC				0	1	0	0	0	0	0	0
10	Lymp#				0	1	0	0	0	0	0	0
11	Mid#				0	1	0	0	0	0	0	0
12	Gran#				0	1	0	0	0	0	0	0
13	Lymp%				0	1	0	0	0	0	0	0
14	Mid%				0	1	0	0	0	0	0	0
15	Gran%				0	1	0	0	0	0	0	0
16	RBC				0	1	0	0	0	0	0	0
17	Hgb				0	1	0	0	0	0	0	0
18	Hct				0	1	0	0	0	0	0	0
19	MCV				0	1	0	0	0	0	0	0
20	MCH				0	1	0	0	0	0	0	0
21	MCHC				0	1	0	0	0	0	0	0
22	RDW				0	1	0	0	0	0	0	0
23	Plt				0	1	0	0	0	0	0	0
24	MPV				0	1	0	0	0	0	0	0
25	wBC				0	2	0	0	0	0	0	0
26	Lymp#				0	2	0	0	0	0	0	0
27	Mid#				0	2	0	0	0	0	0	0
28	Gran#				0	2	0	0	0	0	0	0
29	Lymp%				0	2	0	0	0	0	0	0
30	Mid%				0	2	0	0	0	0	0	0
31	Gran%				0	2	0	0	0	0	0	0
32	RBC				0	2	0	0	0	0	0	0
33	Hgb				0	2	0	0	0	0	0	0
34	Hct				0	2	0	0	0	0	0	0
35	MCV				0	2	0	0	0	0	0	0
36	MCH				0	2	0	0	0	0	0	0
37	MCHC				0	2	0	0	0	0	0	0
38	RDW				0	2	0	0	0	0	0	0
39	Plt				0	2	0	0	0	0	0	0
40	MPV				0	2	0	0	0	0	0	0
41	wBC				0	3	0	0	0	0	0	0
42	Lymp#				0	3	0	0	0	0	0	0
43	Mid#				0	3	0	0	0	0	0	0
44	Gran#				0	3	0	0	0	0	0	0
45	Lymp%				0	3	0	0	0	0	0	0
46	Mid%				0	3	0	0	0	0	0	0
47	Gran%				0	3	0	0	0	0	0	0
48	RBC				0	3	0	0	0	0	0	0
49	Hgb				0	3	0	0	0	0	0	0
50	Hct				0	3	0	0	0	0	0	0
51	MCV				0	3	0	0	0	0	0	0
52	MCH				0	3	0	0	0	0	0	0
53	MCHC				0	3	0	0	0	0	0	0
54	RDW				0	3	0	0	0	0	0	0
55	Plt				0	3	0	0	0	0	0	0
56	MPV				0	3	0	0	0	0	0	0

Figure 1. A color-coded screenshot of the downloaded CQAP Summary Form to be completed either manually or electronically.

Instructions for CQAP Summary Form Use

- For electronic forms, please ensure that the information detailed above is included within the CQAP Summary Form (see Figure 1)
- For manual forms, please affix the preprinted label to the form and fill in the missing information not provided by the preprinted label
 - Your preprinted labels should contain:
 - Laboratory Name
 - Your Laboratory ID
 - If more labels are needed, please notify Clinical Diagnostic Solutions, Inc. to obtain an additional supply. If necessary, clearly hand write the information on the reports until the preprinted labels arrive.
- After summary form is complete and all fields have been filled:
 - Send via email to cqap@cdsolinc.com
 - Send via fax transmission to 770-931-8740
 - Send via Postal Mail using the provided printed address labels.

- ALL SUMMARY FORMS MUST BE RECEIVED BY THE 6TH OF THE MONTH FOLLOWING DATA COLLECTION
- Number of samples, N, must be greater than or equal to ten for the program to successfully calculate results

Instrument Summary Printout

This method of data submission is for those CQAP participants who wish to submit their summary statistics by sending Instrument Summary Printouts to the CQAP Department.

Specific Instructions are listed for the CDS / Medonic CA-620 and the CDS / Medonic M-Series instruments. (see pages 7-9)

Preprinted labels supplied by the CQAP Processing Center must be affixed to the printouts in order for them to be accepted and processed.

The following information is preprinted on your labels:

- Laboratory Name
- Your Laboratory ID

Instructions for Instrument Summary Printout Use

- To begin data collection, set up one control file per label at the beginning of the month. Do this each month, even if it is the second or third month of a QC Lot#. You may use the same files for the second or third month of a QC Lot# as long as the prior month's results are deleted. Be sure that the QC file includes the correct QC Lot# for the data that you are collecting.
- Collect data in each file throughout the month, deleting or rejecting data that is not to be included on the final analysis.
- At the end of the month, carefully review each file before printing. ANY DATA THAT NEEDS TO BE DELETED FROM THE FILE SHOULD BE DELETED BEFORE THE SUMMARY STATISTICS ARE CALCULATED AND PRINTED. If for some reason you cannot delete data prior to printing the summary statistics, highlight the line(s) of data that need to be deleted on the printout so that the data remains legible. DO NOT cross out the data with pen or pencil. Also, do not highlight any data that has already been excluded from the calculations. Make every effort to send in printouts in which the summary statistics are valid for that month, as this speeds processing.
- If your printout does not include the number of controls samples in the QC file (N), please mark this next to the cumulative statistics for each parameter. The N, the Mean and the SD (standard deviation) values are required information for each parameter.

- Separate the printouts at any perforations and staple together the printouts from each level, keeping the levels separate. Include all pages of the printout. Affix the appropriate preprinted label to the first page of each level set.
- Extra blank labels are supplied in case more are needed. Fill in the correct information as required and use one label per level.
- **IMPORTANT:** If you are submitting more than one set of summary statistics for each level, staple together each set of summary statistics separately and use a label for each set. Do not combine sets together under one label.
- Submit the labeled printouts using the method of your choice. All Instrument Summary Printouts must be received by the CQAP Processing Center by the 6th of the month following data collection.
- If you submit data after the cut-off date (the 6th of the following month) for data submission, your account will be handled as an exception. As an exception your data will be analyzed, processed and reported differently. It is up to you to review your data against those reports. Your results **have not** been included in the Peer Group calculations.
 - *Note: If your data was received late, you will receive an Output Report during next month's cycle. Your data will only be included in the historical SDI graphs. Example: If you missed the cut-off for November, your data will still be included in the SDI graphs of the December report*
- Number of samples, N, must be greater than or equal to 10 for the program to successfully calculate results

Instructions for Generating QC Summary Reports using the CDS / Medonic CA 620 Hematology Analyzer.

To generate a summary report to CQAP for analysis, follow the sequential steps below.

1. First access the CA 620 main menu.
2. From the main menu select QC Menu (option 7.)
3. Next select menu 7.1 'Control Memory.'
4. In menu 7.1, highlight and select menu 7.1.4 'Select Conditions.'
5. In this menu, there are two ways to select the correct control level and lot.
 - a. By using the left and right arrow buttons to highlight the control level desired.
 - b. If the control vials are accessible, you may simply scan in the barcode and the correct lot will be selected automatically.
6. After the desired control is highlighted, press the down arrow key.

7. Highlight the 'From DATE' option by using the up and down arrow keys. Enter the date of the beginning of the month in which the report is desired (i.e. 06/01/2009 for a summary report for June 2009.)
8. Press the 'Enter' key.
9. Highlight the 'To DATE' option by using the up and down arrow keys. Enter the ending date of the month in which the report is desired (i.e. 06/30/2009 for a summary report for June 2009.)
10. Press the 'Enter' key.
11. Verify that the correct samples (controls) are selected by looking to the bottom line of the display. It should read ### of ### controls selected.
12. Next, press the 'Menu-Operate' button to return to menu 7.1 'Control Memory.'
13. Use the up and down arrow keys to highlight and select option 7.1.6 'Statistical Calculations' and press the 'Enter' key.
14. Press the 'Print' button on the front panel of the instrument to print the summary report for the selected level of control. The printouts will show the mean, number of samples, SD, and CV values for the control level selected.
15. Repeat aforementioned steps for the other two levels of controls.
16. Send the acquired Summary Reports with affixed labels to COAP for review.

Instructions for Generating Summary Reports Using the CDS / M-Series Hematology Analyzer.

Generating a summary report with the M-series analyzers can be done by following these simple step-by-step instructions.

1. Select the 'LIST' tab.
2. Next, select the 'Search' button in the upper right corner.
3. There are two ways to select which control level to collect the summary report from.
 - a. If the control vials are accessible, you may simply scan in the barcode and the correct lot will be selected automatically.
 - b. By clicking on the 'Profile' box, a new menu will be brought up to show all control and calibrators that have been scanned into the instrument. By using the 'Prev' and 'Next' buttons, you can highlight and select the

correct lot of controls that you wish to analyze. Verify that you have highlighted the correct control lot and press the 'Ok' button.

4. Enter the date of the beginning of the month and end of the month in which QC is being analyzed. For example, to report data from June 2009, one should enter 06012009 (from date) and 06302009 (end date.)
5. Press the 'Stats' button.
6. Press the 'Print' button.
7. Repeat aforementioned steps for other two levels of controls.
8. Send the acquired Summary Reports with affixed labels for CQAP for review.

CQAP Data Submission Form

This method can be **ONLY** completed electronically and emailed with the saved CQAP Data Submission Form attached as a Microsoft Excel file. **If the CQAP Data Submission Form is not completed electronically and emailed with a Microsoft Excel file, the data will not be processed by the CQAP Processing Center.**

Note that each control level must have its own separate sheet with the control level identified.

- To complete this form electronically, you must first download the CQAP Data Submission Form from the Clinical Diagnostic Solutions, Inc. website. Data must then be entered via Microsoft Excel on a daily basis or whenever the controls are run. Upon completion of the form, the data must be saved and emailed to the CQAP Processing Center.
 - Tip: For each level of control, select the proper tab at the bottom left hand side of the Excel spreadsheet. Each level (low, normal, and high) should be completed before saving and emailing.

Each form **MUST CONTAIN THE FOLLOWING INFORMATION:**

- **Laboratory Name**
- **Laboratory ID**
- **Instrument type (model name and/or number)**
- **Instrument ID**
- **QC lot number**
- **QC Month**
- **Control level (low, normal, high)**

See following color-coded screenshot (Figure 2) of the CQAP Data Submission Form

CQAP Data Submission Form

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	LAB													Clinical Diagnostic Solutions, Inc.				
2	Lab ID													Quality Assurance Program				
3	Instrument Type																	
4	Instrument ID																	
5	QC Kit Lot #																	
6	QC Month (mm/yy)																	
7	Level																	
8																		
9																		
10																		
11																		
12																		
13																		
14	N	WBC	LYMP#	MID#	GRAN#	LYMP%	MID%	GRAN%	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	
15	1																	
16	2																	
17	3																	
18	4																	
19	5																	
20	6																	
21	7																	
22	8																	
23	9																	
24	10																	
25	11																	
26	12																	
27	13																	
28	14																	
29	15																	
30	16																	
31	17																	
32	18																	
33	19																	
34	20																	
35	21																	
36	22																	
37	23																	
38	24																	
39	25																	
40	26																	
41	27																	
42	28																	
43	29																	
44	30																	
45	31																	
46	32																	
47	33																	
48	From here to end of spreadsheet for CQAP use only																	
49																		
50																		
51	N	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	
52	1SD	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	
53	Mean	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	%DIV!0!	
54																		
55	ParamID	N	Mean	1SD														
56	WBC	0.000	%DIV!0!	%DIV!0!														
57	LYMP#	0.000	%DIV!0!	%DIV!0!														
58	MID#	0.000	%DIV!0!	%DIV!0!														
59	GRAN#	0.000	%DIV!0!	%DIV!0!														
60	LYMP%	0.000	%DIV!0!	%DIV!0!														
61	MID%	0.000	%DIV!0!	%DIV!0!														
62	GRAN%	0.000	%DIV!0!	%DIV!0!														
63	RBC	0.000	%DIV!0!	%DIV!0!														
64	HGB	0.000	%DIV!0!	%DIV!0!														
65	HCT	0.000	%DIV!0!	%DIV!0!														
66	MCV	0.000	%DIV!0!	%DIV!0!														
67	MCH	0.000	%DIV!0!	%DIV!0!														
68	MCHC	0.000	%DIV!0!	%DIV!0!														
69	RDW	0.000	%DIV!0!	%DIV!0!														
70	PLT	0.000	%DIV!0!	%DIV!0!														
71	MPV	0.000	%DIV!0!	%DIV!0!														

** Fill in data here **

Figure 2. A color-coded screenshot of the downloaded CQAP Data Submission Form to be completed electronically.

OUTPUT REPORTS

The Output Report contains all of the elements necessary for in-depth evaluation and continuous monitoring of your laboratory's performance. It is a concise yet easy-to-read report that will allow you to make informed decisions concerning your total quality controls performance.

Included in the Output Report are:

- Report messages
- Peer Group results
- Other Peer Group Results
- Historical SDI graphical information

In presenting your quality control information to you, the Output Report uses two key indicators of your laboratory's performance: the Mean Difference and the SDI (Standard Deviation Index). Refer to the Quality Controls Concepts on page 17 for the definitions of the important concepts.

The main purpose of the Output Report is to present your laboratory's results in comparison to those of your peer group.

The COAP will compare mean values of each individual lab computed from several individual determinations.

Output Report packages will be sent to all COAP active participants by the 16th of the month following the month of data submission. Example: If you submit data for the month of November, your report will be sent by December 16.

If you submit data after the cut-off date (the 6th of the following month) for data submission, your account will be handled as an exception. As an exception your data will be analyzed, processed and reported differently. It is up to you to review your data against those reports. Your results **have not** been included in the Peer Group calculations.

Note: If your data was received late, you will receive an Output Report during next month's cycle. Your data will only be included in the historical SDI graphs. Example: If you missed the cut-off for November but still submitted data from November, your data will still be included in the SDI graphs of the December report.

Report Messages

This report provides the program participant with information on any problems that may exist with the data and the statistics presented on the reports in the monthly Output Report package. Report messages are given to help explain or describe a situation and are meant to assist you in problem solving.

The Report Message ID corresponds with the number that appears in the NOTE REF column on the Peer Group Results Report (Figure 3). Below are the Report Message IDs that will be generated and seen on the Peer Group Results Report:

MESSAGE ID	MESSAGE DEFINITION
102	Your mean or SD value is outside the absolute range limits or is greater than fixed criteria limits.
103	Associated mean or SD value also rejected.
104	Your SDI values are wider than 2 SDIs for all levels of this parameter.
105	Less than 10 data points were submitted for this parameter and level.
106	Less than 6 labs submitted data for this parameter and level.

Note: If data is flagged with message ID 102 or 103, the data will not be included in the peer group data.

Below is an image of the Report Messages portion of the Output Report

REPORT MESSAGES			
Lab:			
	Peer Group:	Number Of Labs	
LabID:	Product:	CDS 3PD	Level 1: 3
Instrument:	QC Month:	10/08	Level 2: 3
Instrument ID:	Lot:	0809-496	Level 3: 3
Message ID	MESSAGE MEANING		
101	No data was received from your lab by the cut-off date.		
102	Your mean or SD value is outside the absolute range limits or is greater than fixed criteria limits.		
103	Associated mean or SD value also rejected.		
104	Your SDI values are wider than 2 SDIs for all levels of this parameter.		
105	Less than 10 data points were submitted for this parameter and level.		
106	Less than 6 labs submitted data for this parameter and level.		

Figure 3. An image of the Report Messages part of the Output Report received monthly. Note that your lab will only receive this Report Message printout if your data is consistent with a report message described previously.

Peer Group Results

This report presents your laboratory's performance in relation to your peer group. It summarizes your laboratory's quality control results in a well-organized and easy to read format for the QC month and lot # submitted. There are two key indicators of your laboratory's performance: The Mean Difference and the SDI (Standard Deviation Index).

The Peer Group Results includes the following information (see following color-coded image of an example Peer Group Results printout – Figure 4):

- **Parameters and levels**
- **Your Ns (Number of Control Sample Runs)**
- **Assay means**
- **Your Means**
- **Group Means**
- **Mean Difference**
- **Your 1 SDs**
- **Group 1 SDs**
- **SDIs**
- **Your 2 SDs**
- **Group 2 SDs**
- **Your % CVs**
- **Group % CVs**
- **Note references (as appropriate which are explained in the Report Messages Report)**
- **# of peer labs submitting per level**

The Peer Group Results include all of the parameters reported by your instrument and the assay value (mean) of the control product.

For each parameter listed, we suggest that you review your report utilizing the two key indicators as follows:

- Examine your Mean Difference
 - Is your lab mean significantly different from your peer labs? (The Assay mean is presented for reference only)
- Examine your SDI
 - If your SDI is between +2 and -2, your lab's accuracy is acceptable with the respect to your peers.

If your SDI is outside the +2 and -2 ranges, ask yourself these questions:

- Is the database large enough to make the SDI calculation valid? (Number of peer labs submitting this particular parameter/level combination should be at least 6)
- What is the clinical significance of the difference between Your Mean and the Group mean? Does the difference, even if not clinically significant, warrant a review to determine an underlying cause of the difference?

Compare Your Mean to the Group Mean, Your 1 and 2 SD to the Group 1 and 2 SD and Your % CVs to the group % CVs. Investigate the cause of any notable differences. Review any Note References by referring to the Report Messages page.

All explanations or corrective actions that result from this review should be properly documented according to your lab's protocol.

PEER GROUP RESULTS

Lab:

Instrument Type: Medonic CA620	Lab ID: 1	Kit Lot #: 0808-495	Number Of Labs ★
Instrument ID: 6500	Product: Bottle Con	Low Lot #: 0808-031	Low: 60 ★
Peer Group: CA620/530	QCMonth: 10/08	Norm Lot #: 0808-032	Normal: 59 ★
		High Lot #: 0808-033	High: 60 ★

★ Parameter	★ Your Mean	★ Group Mean	★ Your 1SD	★ Group 1SD	★ Your 2SD	★ Group 2SD	★ Your CV%	★ Group CV%	★ Note Ref
VBC Low 23	3.700	3.700	3.709	-0.009	0.690	0.072	-0.125	1.300	0.144 16.649 1.941
VBC Normal 21	8.900	8.700	8.750	-0.050	0.190	0.176	-0.284	0.300	0.352 2.164 2.011
VBC High 24	23.200	22.600	22.603	-0.003	0.400	0.474	-0.006	0.960	0.940 2.124 2.097
Lycop# Low 23	1.000	1.100	1.092	0.008	0.170	0.064	0.125	0.340	0.120 15.455 5.061
Lycop# Normal 21	4.000	4.000	4.064	-0.064	0.130	0.102	-0.627	0.260	0.204 3.250 2.510
Lycop# High 24	12.000	13.100	13.169	-0.069	0.300	0.305	-0.226	0.600	0.610 2.290 2.316
MB# Low 23	0.400	0.300	0.317	-0.017	0.090	0.037	-0.459	0.100	0.074 30.000 11.672
MB# Normal 21	0.500	0.600	0.554	0.046	0.060	0.050	0.920	0.120	0.100 10.000 9.025
MB# High 24	1.400	1.400	1.285	0.115	0.090	0.073	1.575	0.100	0.146 6.429 5.601
Grn# Low 23	2.200	2.300	2.303	-0.003	0.500	0.050	-0.060	1.000	0.100 21.739 2.171
Grn# Normal 21	4.000	4.100	4.132	-0.032	0.090	0.099	-0.323	0.100	0.190 2.195 2.396
Grn# High 24	7.900	8.200	8.158	0.042	0.190	0.170	0.236	0.300	0.356 2.317 2.102
Lycop% Low 23	30.000	29.000	29.826	-0.026	1.140	0.497	-0.052	2.200	0.994 3.826 1.666
Lycop% Normal 21	46.900	46.700	46.719	-0.019	0.730	0.406	-0.039	1.460	0.972 1.563 1.040
Lycop% High 24	58.300	57.900	58.236	-0.336	0.450	0.494	-0.600	0.900	0.900 0.777 0.848
MB% Low 23	8.000	7.700	7.596	0.104	1.030	0.517	0.201	2.060	1.034 13.377 6.006
MB% Normal 21	5.900	5.900	5.843	0.057	0.470	0.243	0.235	0.940	0.466 7.966 4.159
MB% High 24	6.000	5.900	5.531	0.369	0.250	0.201	1.313	0.500	0.562 4.237 5.000
Grn% Low 23	62.100	62.500	62.533	-0.033	1.730	0.444	-0.074	3.460	0.000 2.760 0.710
Grn% Normal 21	47.300	47.400	47.463	-0.063	0.750	0.400	-0.150	1.500	0.000 1.502 0.843
Grn% High 24	35.700	36.200	36.195	0.005	0.400	0.273	0.010	0.000	0.546 1.105 0.754
EBC Low 23	2.460	2.520	2.454	0.066	0.294	0.031	2.129	0.500	0.062 11.667 1.263
EBC Normal 21	4.290	4.340	4.259	0.081	0.043	0.069	1.174	0.006	0.130 0.991 1.620
EBC High 24	5.190	5.240	5.162	0.078	0.051	0.004	0.929	0.102	0.160 0.973 1.627
Hgb Low 23	6.200	6.400	6.231	0.169	0.600	0.101	1.673	1.360	0.202 10.625 1.621
Hgb Normal 21	12.700	12.000	12.676	0.124	0.130	0.141	0.879	0.300	0.202 1.172 1.112
Hgb High 24	16.900	17.200	17.005	0.195	0.240	0.207	0.942	0.400	0.414 1.395 1.217
Hct Low 23	16.000	16.400	16.045	0.355	1.700	0.310	1.116	3.560	0.636 10.854 1.902
Hct Normal 21	34.000	35.000	34.189	0.811	0.990	0.674	1.203	1.900	1.340 2.029 1.971
Hct High 24	47.700	49.000	47.389	1.611	1.000	1.020	1.579	2.120	2.040 2.163 2.152

Figure 4. Color-coded image of the Peer Group Results part of the Output Report received monthly.

Other Peer Group Results

This report lists other peer group results or statistics for the same control product and lot # used for that month. It allows a comparison of your results to that of other instruments and may aid in problem solving. It is also helpful in that it provides a reference in the event a laboratory has a secondary or back-up instrument for which data is not submitted to the CQAP.

The Other Peer Groups Results include the following information (see following color-coded image of an example Other Peer Groups Results printout – Figure 5):

- **Other Peer Groups**
- **Parameters and Levels**
- **# of Other Peer Group Labs Submitting per Level**
- **Group Means**
- **Group SDs**
- **Group % CVs**

Please note that this report shows only those other peer groups whose instruments appear on the control assay sheet received with your product. The report shows the results of other peer groups for the parameters reported by your peer group.

OTHER PEER GROUPS RESULTS												CDS Quality Assurance Program	
Lab :								Kit Lot #: 0806-490					
LabID: 4		Q CMonth: 10/08								Low Lot #: 0806-011			
Instrument Type:		Instrument ID:								Norm Lot #: 0806-012			
Group:		Product: CDS 3PD								High Lot #: 0806-013			
★ PEER GROUP NAME	Low ★				Normal ★				High ★				
	# OF LABS	GROUP MEAN	GROUP SD	GROUP %CV	# OF LABS	GROUP MEAN	GROUP SD	GROUP %CV	# OF LABS	GROUP MEAN	GROUP SD	GROUP %CV	
	★	★	★	★	★	★	★	★	★	★	★	★	
WBC	5	3.800	0.200	5.263	5	9.160	0.207	2.260	5	21.800	0.689	3.161	
Lymp#	5	1.080	0.084	7.778	5	4.140	0.182	4.396	5	12.240	0.541	4.420	
Mid#	5	0.300	0.000	0.000	5	0.560	0.055	9.821	5	1.340	0.055	4.104	
Gran#	5	2.340	0.230	9.829	5	4.380	0.217	4.954	5	8.220	0.148	1.800	
Lymp%	5	28.080	0.669	2.382	5	45.180	0.763	1.689	5	56.100	0.771	1.374	
Mid%	5	7.980	0.239	2.995	5	6.100	0.212	3.475	5	6.140	0.288	4.691	
Gran%	5	63.960	0.727	1.137	5	48.720	0.589	1.209	5	37.740	0.573	1.518	
RBC	5	2.516	0.038	1.510	5	4.270	0.040	0.937	5	5.188	0.065	1.253	
Hgb	5	5.860	0.152	2.594	5	12.800	0.141	1.102	5	17.480	0.148	0.847	
Hct	5	16.900	0.374	2.213	5	36.260	0.297	0.819	5	49.700	0.469	0.944	
MCV	5	67.060	0.764	1.139	5	84.980	0.782	0.920	5	95.840	1.006	1.050	
MCH	5	23.160	0.321	1.386	5	30.020	0.383	1.276	5	33.680	0.438	1.300	
MCHC	5	34.580	0.482	1.394	5	35.320	0.563	1.594	5	35.140	0.518	1.474	
RDW	4	17.375	0.275	1.583	4	14.700	0.548	3.728	4	14.000	0.566	4.043	
Plt	5	67.000	5.431	8.106	5	231.400	11.014	4.760	5	483.200	21.661	4.483	
MPV	4	11.600	0.735	6.336	4	11.875	0.427	3.596	4	12.550	0.465	3.705	

Figure 5. Color-coded image of the Other Peer Group Results part of the Output Report received monthly.

SDI Graphs

The final part of the output report generated by COAP is a printout showing SDI graphs. These SDI graphs show historical trends of the SDI values over the previous six months. The SDI graph printouts will show dedicated graphs for each of the parameters reported over the past six months. These graphs will be included after you have two (2) months of data on file within the previous six (6) month period.

SDI - History for Last 6 Months

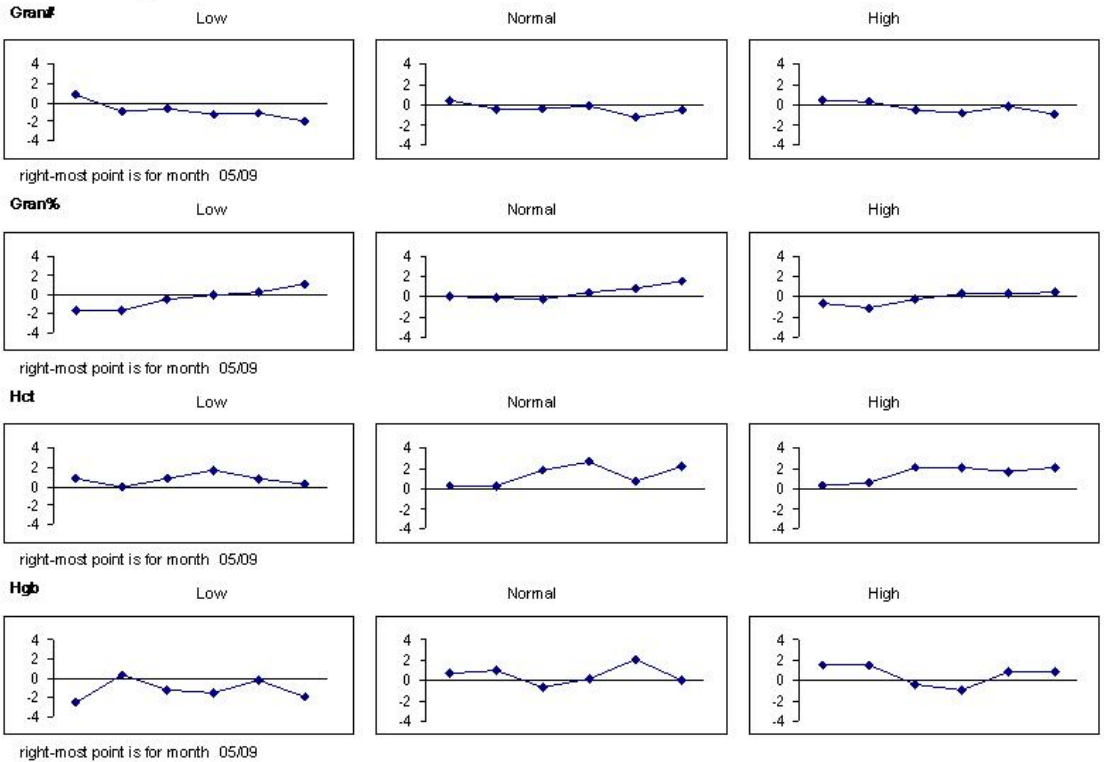


Figure 6. An image of the SDI Graphs portion of the Output Report received monthly. Please note that all parameters reported (over the previous six months) will be a part of the SDI Graph printouts.

QUALITY CONTROL CONCEPTS

ACCURACY Closeness to the true value or the measure of truth of a result.

ASSAY MEAN A peer group specific value printed on the assay sheet.

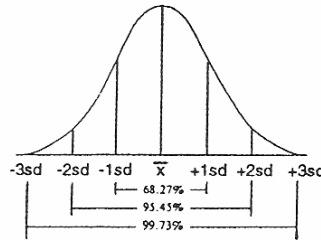
CALIBRATOR A material that is used to adjust instrumentation that is based on or traceable to a reference preparation or material, and whose values are determined by acceptable reference methods.

COEFFICIENT OF VARIATION (CV) The Standard Deviation expressed as a percentage of the mean.

$$\% CV = \frac{SD}{Mean} * 100$$

CONTROLS Materials that are solutions of chemically stabilized red cells, white cells and/or analogs, and platelets. The most important characteristics of control materials are their stability and physical similarity to real patient samples. They are used to monitor the performance of an instrument or procedure.

GAUSSIAN DISTRIBUTION A bell-shaped distribution of results from a normal sample population.



LATE DATA Data received by the CDS Quality Assurance Department after the cut-off date (6th of month). Late data will be processed and reported on the next month's cycle. The statistics from your Primary Parameters will appear on your next SDI graphical report.

LINEARITY CHECK A check or test to confirm that an instrument or method is linear over its published working range.

MEAN (\bar{X}) The mathematical average for a group of data points.

$$\bar{X} = \frac{\sum X}{N}$$

MEAN DIFFERENCE The difference between the peer group mean and your mean.

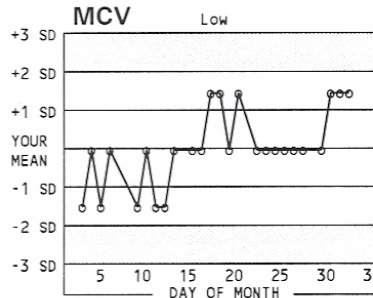
PATIENT CONTROLS Replicate testing of pooled or designated patient blood samples at specified times during a specific period of time.

PEER GROUP A grouping of similar instrument types for comparison purposes.

PRECISION The expression of the variability of analysis, or an indication of the amount of random error that exists in an analytical process.

PRIMARY PARAMETERS Those parameters that are mainly measured parameters and that are used as a basis for calculations of other parameters. They are: WBC, RBC, HGB, HCT, MCV, PLT, MPV, NEU% (GRAN%), LYM%, MON%, EOS%, BAS%, etc.

SHIFT An abrupt change in the pattern of data points on a plot, graph or chart of data points.



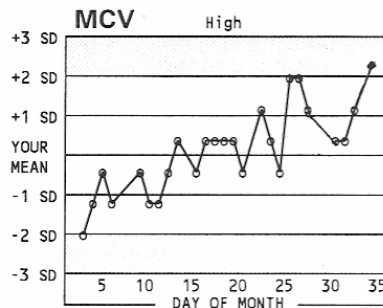
STANDARD DEVIATION (SD) A measure of the dispersion of a group of values around a mean, expressed in the units being measured. Since 95% of all results in a normal population fall within 2 SDs of the mean, \pm SD is considered an acceptable laboratory standard.

$$SD = \sqrt{\frac{\sum (x - \bar{x})^2}{(N - 1)}}$$

STANDARD DEVIATION INDEX (SDI) The number of Group Standard Deviations by which Your Mean differs from the Group Mean. SDI is a measure of relative accuracy.

$$SDI = \frac{(\text{Your Mean} - \text{Group Mean})}{(\text{Group SD})}$$

TREND A gradual change in the pattern of data points on a plot, graph or chart of data points.



XB The principle and application of moving averages to quality control statistical data. This is very similar to the daily average except that statistical smoothing techniques

are used in calculating the moving average to reduce the effect of individual values on the average.

Z-SCORE The same as Standard Deviation Index (SDI).

MAILING INFORMATION

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