

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

TABLE OF CONTENTS

Topic	Page
Introduction.....	3
Data Submission.....	4
Output Reports.....	6
Report Messages.....	7
Peer Group Results.....	8
Monthly History.....	10
Quality Control Concepts.....	12
Mailing Information.....	14

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 the 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 the reports that make up the Output Report
- Definitions of key Quality Control Concepts
- Mail and phone information

ENROLLMENT

Thank you for enrolling in Clinical Diagnostic Solutions Quality Assurance Program. Please keep the enclosed enrollment form for your records.

SUBMITTING YOUR DATA

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

- Written Data Summary Form
- Data Input Form
- Mail Input Form

Please refer to the back of this manual for the appropriate form.

The form you have selected **must be mailed to:**

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

DATA SUBMISSION

WRITTEN SUMMARY DATA FORM

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

USE A BLACK PEN TO WRITE YOUR SUMMARY STATISTICS ON THE FORM

INSTRUCTIONS FOR FORM USE

- The following information is a preprinted label affixed to your form:
 - Laboratory Name
 - Your Lab ID

- Your laboratory must complete the following information on each form that you are submitting. **This information is mandatory for data analysis.**
 - Instrument type (model name and/or number)
 - QC Month
 - Control level (low, normal, high)
 - Control lot number

- Use a black pen to write your summary statistics on the form. Record your summary statistics for each parameter you are submitting in the spaces provided. Write as clearly as possible, filling in the N (number of control samples on the QC file), the Mean and the SD (standard deviation) values.

- Mail the completed forms using the printed return envelope. All Written Summary Data forms must be received by the CQAP Processing Center by the 6th of the month following data collection.

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.

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

The following information is preprinted on your labels:

- Laboratory Name
- Your Lab ID

INSTRUCTIONS FOR 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#. Or, 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.
- Mail the labeled printouts using the printed return envelopes. All Instrument Summary Printouts must be received by the CQAP Processing Center by the 6th of the month following data collection.
- Output Report packages will be sent to all CQAP 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. Your Output Report will be processed with the comment "No data received for your lab". 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 under the Monthly History section for the month you submitted data late. Example: If you missed the cut-off for November, your data will be included in the Monthly History section of the report for December. This report will be published by January 16.

ALTERNATE METHODS

As new technologies develop, alternate methods for submitting data to the CQAP are being investigated and implemented. You will be notified of new developments in this area as they become available. Or, you may call the CQAP Processing Center to discuss your options with a technical representative.

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 Groups Results
- Monthly History

In presenting your quality controls 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 12 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 CQAP will compare mean values of each individual lab computed from several individual determinations.

Output Report packages will be sent to all CQAP 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. Your Output Report will be processed with the comment "No data received for your lab". 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 under the Monthly History section for the month you submitted data late. Example: If you missed the cut-off for November, your data will be included in the Monthly History section of the report for December. This report will be published by January 16.

REPORT MESSAGES

This report provides the program participant with information on any problems that might exist with the data and statistics presented on the reports in the monthly Output Report package. It helps determine potential areas of concern by listing the following, as appropriate:

Note references from the Peer Group Results, along with an explanation of each reference. (The Note Ref# corresponds with the number that appears in the NOTE REF column on the following Peer Group Results Report).

Rejected Data/Statistics, designated by an R or R*. If designated by an R, the rejected data/statistics are outside of the fixed criteria limits of the program. They are excluded from your lab's data and the peer group's data, and are rejected before any peer group calculations are done. If designated by an R*, the rejected statistics are within the fixed criteria limits of the program and are reported to you but because they are greater than three standard deviations (3 SDs) from the peer group, they are excluded from the peer group's data. On your report, the actual values of any rejected data/statistics are listed for clarification.

- Report Messages which are given to help explain or describe a situation and are meant to assist you in problem solving.
- Messages from the CQAP Department to you in order to communicate changes problems, or updates.
- Valuable insights can be gained by first examining this page before proceeding to the rest of the report.
- List of comments that could appear on the Report Messages report and their meanings:

COMMENT

NO DATA RECEIVED FROM YOUR LAB

YOUR MEAN OR SD IS OUTSIDE THE ABSOLUTE RANGE LIMITS OR IS GREATER THAN FIXED CRITERIA LIMITS

MEANING

No data was received from your lab by the cut-off date.

Your mean or SD value has fallen outside acceptable limits and has been rejected.

COMMENT

ASSOCIATED MEAN OR SD VALUE ALSO REJECTED

MEANING

If your mean value was rejected, then the SD value associated with it is also rejected. The same is true if your SD value is rejected. The mean value associated with it is also rejected.

YOUR SDI VALUES ARE WIDER THAN 2 SDIs FOR ALL LEVELS OF THIS PARAMETER

For all levels of a parameter, the SDI values were greater than 2 SDI.

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). These indicators are presented within the bold boxes on the report for easy identification.

The Peer Group Results includes the following information:

- Parameters and levels
- Your Ns (Number of Control Sample Runs)
- Assay means
- Your Means
- Group Means
- Mean Difference
- Your 1 SD's
- Group 1 SDs
- SDIs
- Your 2 SDs
- Group 2SDs
- 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 both reported by your instrument and assayed on 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.

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

OTHER PEER GROUPS 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 because 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:

- Other Peer Groups
- Your 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 assay control sheet received with your product. The report shows the results of other peer groups for the Parameters reported by your instrument. For example, if your instrument does not report platelets, then platelets will not show up on this comparison even though instruments in the order peer groups report platelets.

MONTHLY HISTORY

This report contains your laboratory's statistical summaries by QC lot # and month for the past 6 months. It presents the data chronologically across the page to aid in the detection of shifts and trends. The most recent month is listed on the left.

The Monthly History includes the following information:

- QC Months and Lot #'s
- Your parameters and levels
- # of labs submitting per level
- Your Means
- Group Means
- Mean Differences
- Your SDs
- Group SDs
- SDIs
- Your % CVs
- Group % CVs

Things to watch for any given parameter:

- A consistent Mean Difference over several months of data is indicative of instrument bias.
- A consistent SDI sign (positive or negative) over several months of data also is indicative of an instrument bias that should be watched and corrected if it is considered to be a significant difference.
- An increasing numerical value in the mean Difference or SDI over several months of data is indicative of a trend that may need some correction.
- An abrupt shift in any value indicates a sudden problem or corrective action that should be handled accordingly with proper documentation according to your laboratory's QC protocol.

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. Your Output Report will be processed with the comment "No data received for your lab". 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 under the Monthly History section for the month you submitted data late. Example: If you missed the cut-off for November, your data will be included in the Monthly History section of the report for December. This report will be published by January 16.

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.

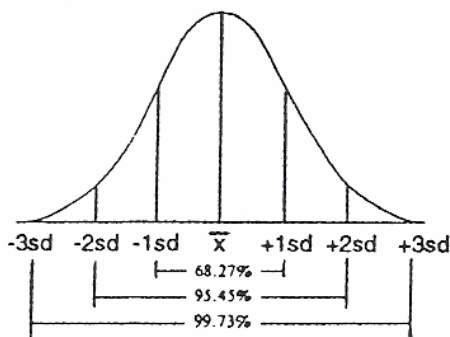
CALIBRATOR A material that is used to adjust instrumentation that is based on or traceable to a reference preparation or material, and whose values are determined by acceptable reference methods.

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

$$\% \text{ CV} = \frac{\text{SD}}{\text{Mean}} \times 100$$

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 Monthly History Report under the correct monthly heading.

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

MEAN 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.

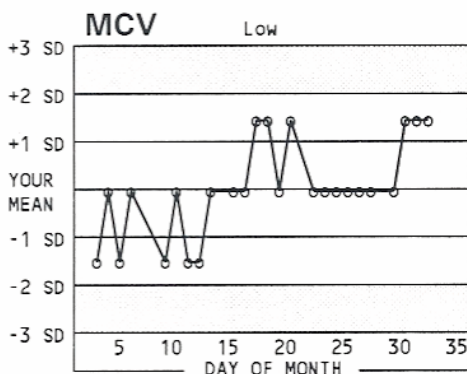
PEER GROUP A grouping of similar instrument types for comparison purposes.

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.

REJECTED DATA Data that is excluded from your lab's data and the peer group's data (R) or is only excluded from the peer group's data (R*).

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



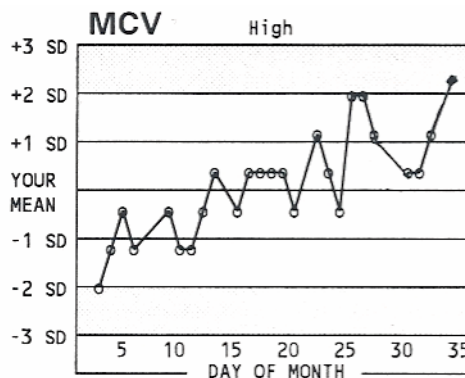
STANDARD DEVIATION (SD) A measure of the dispersion of a group of values around a mean, expressed in the units being measured. Since 95% of all results in a normal population fall within 2 SDs of the mean, \pm SD is considered an acceptable laboratory standard.

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

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 ADDRESS

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

PHONE NUMBER:

Call toll-free for CQAP inquiries: 800-453-3328

International: 954-791-1773

IMPORTANT

Output Report packages will be sent to all CQAP 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. Your Output Report will be processed with the comment "No data received for your lab". 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 under the Monthly History section for the month you submitted data late. Example: If you missed the cut-off for November, your data will be included in the Monthly History section of the report for December. This report will be published by January 16.