



## STEM CELL LABORATORY (STCL)



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Using the CBC Monitor Data Entry System

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## FLOW-GEN-042

### USING THE CBC MONITOR DATA ENTRY SYSTEM

#### 1 PURPOSE

- 1.1 The purpose of this procedure is to provide instruction to use the R&D Systems on-line inter-laboratory quality control program, CBC Monitor.

#### 2 INTRODUCTION

- 2.1 Daily assessment of the flow cytometric testing systems used by the Stem Cell Laboratory is accomplished with the use of Status Flow and Status Flow<sup>Pro</sup> Process Control cells manufactured by R&D Systems. The data obtained from this testing may be used to monitor antibody staining, RBC Lysis, instrument set-up, instrument performance, and data analysis. Data obtained from this testing may then be entered into R&D Systems' CBC-Monitor, a web based system that provides on-line access for data submission, report retrieval, and daily monitoring of STCL flow cytometer instruments. Stem Cell Laboratory results are compared with peer group data using the same process control cells and specific antibody staining but using potentially variable testing methods, reagent manufacturers, and instrumentation. By reviewing these results, the flow cytometry supervisor and staff are able to detect process errors that can lead to trends or shifts which may require corrective action.

#### 3 SCOPE AND RESPONSIBILITIES

- 3.1 This procedure should be used when submitting flow cytometry process control data into the CBC-Monitor program. The Stem Cell Laboratory Medical Director, Laboratory Manager, and Flow Cytometry personnel are responsible for ensuring the requirements of this procedure are successfully met.

#### 4 DEFINITIONS/ACRONYMS

- 4.1 **Accuracy-** Closeness to the true value or the measure of truth of a result.
- 4.2 **Process Control-** Materials that are solutions of chemically stabilized red cells, white cells and/or analogs, and platelets that are used to monitor the performance of an instrument or procedure. The most important characteristic of a Control is its physical similarity to real patient samples.
- 4.3 **CV Coefficient of Variation-** The Standard Deviation expressed as a percentage of the Mean. The smaller the CV, the more precise is the analytic method.
- 4.4 **Reporting Number of reporting Peers-** A minimum of 6 instruments reporting provides better comparative results.
- 4.5 **Mean-** The mathematical average for a group of data points.
- 4.6 **Number of Results- (N)** Number of results entered per parameter per level. Good statistical analysis is based on a minimum of 10 results or 10 N.

- 4.7 **Peer-** An instrument from a group of similar instrument types, using the same control product of the same lot and level.
- 4.8 **PI Precision Index-** The ratio of a Lab's CV to the Group CV. PI is a measure of Relative Precision. A PI value between 0 and + 2 defines acceptable performance.
- 4.9 **Precision-** Reproducibility of replicate analyses.
- 4.10 **Preliminary Report-** Reports published before the end of a data collection month. These reports will be marked "Preliminary" after the month /year in the header. The date and time the report was generated is always at the bottom of the report. Final reports are available after the 15th of the month.
- 4.11 **Rejected Data-** This represents data falling outside the established acceptable ranges. Rejected data has been eliminated from the Peer group results.
- 4.12 **Run-** A single test that consists of a set of results of different parameters.
- 4.13 **Standard Deviation (SD)-** A measure of the dispersion of a group of values around a mean, expressed in the units being measured. 2 SDs is considered an acceptable laboratory standard because 95% of all results of a normal population fall within 2 SDs of the Mean.
- 4.14 **Standard Deviation Index (SDI)-** The number of group standard deviations by which a lab's mean differs from the group mean. SDI is a measure of relative accuracy. An SDI value between - 2 and + 2 defines acceptable performance.
- 4.15 **Shift-** An abrupt change in the pattern of data points on a plot, graph, or chart of data points.
- 4.16 **Target Value-** A peer group specific value published on the Assay sheet of the Control.
- 4.17 **Trend-** A gradual change in the pattern of data points on a plot, graph, or chart of data points.
- 4.18 **STCL-** Stem Cell Laboratory

## 5 MATERIALS

- 5.1 NA

## 6 EQUIPMENT

- 6.1 NA

## 7 SAFETY

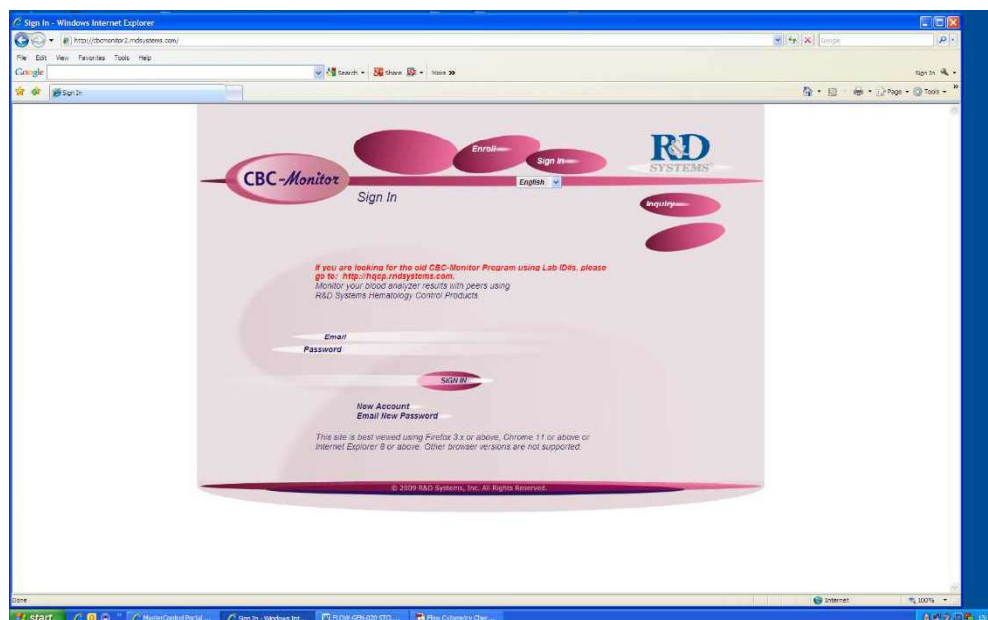
- 7.1 NA

## 8 PROCEDURE

- 8.1 Obtain the process control testing results for the day recorded on FLOW-FORM-008.

- 8.2 After logging onto the computer using your Duke ID and password, click on the shortcut icon for the CBC-Monitor data entry system.

Fig.1 Login page



- 8.3 Enter the appropriate login information assigned to the STCL. See Fig. 1.
- 8.4 Once into the system choose **Detail Data** from the list at the top of the page.

Fig. 2 Detail Data→Analyzer→Data period and lot# CD34% and absolute value

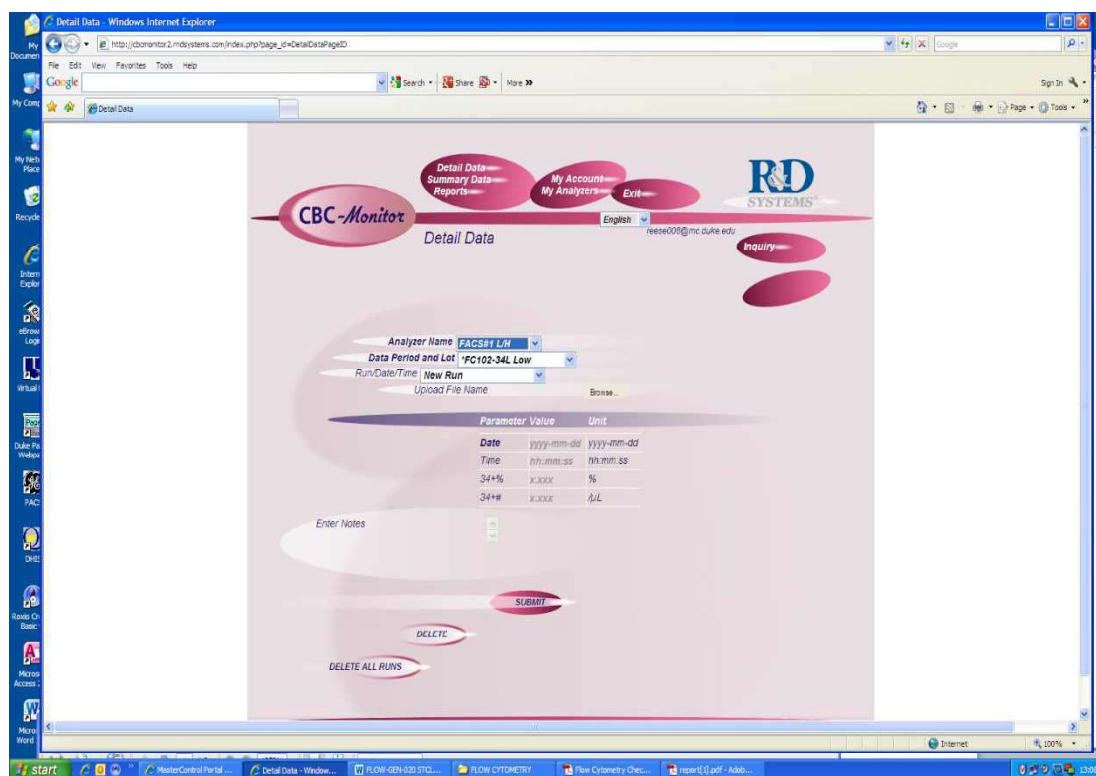


Fig. 3 Detail Data→Analyzer→Data period and lot# Normal

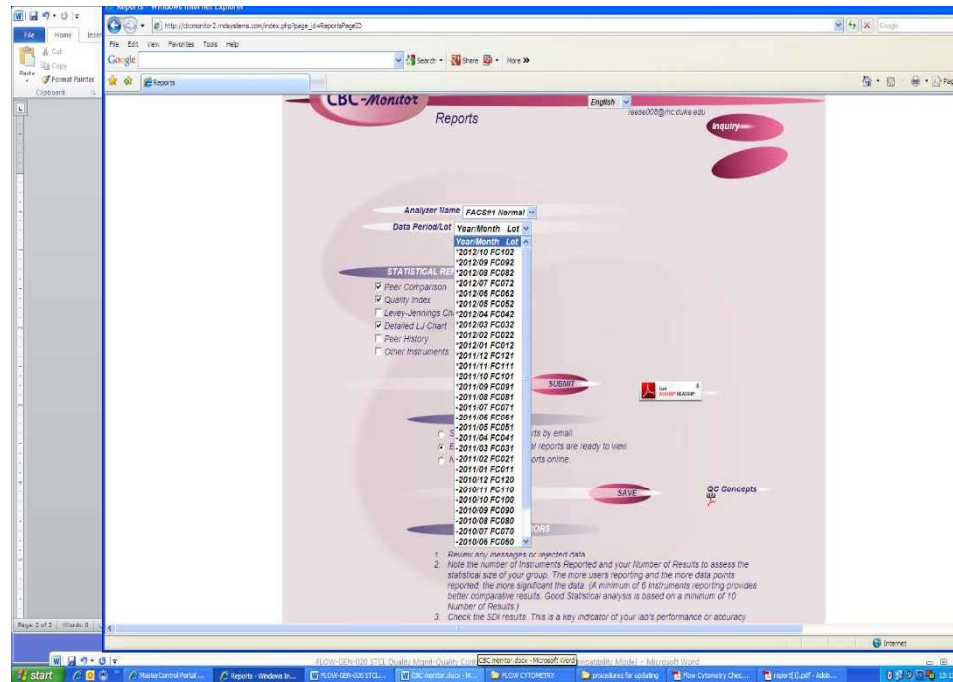
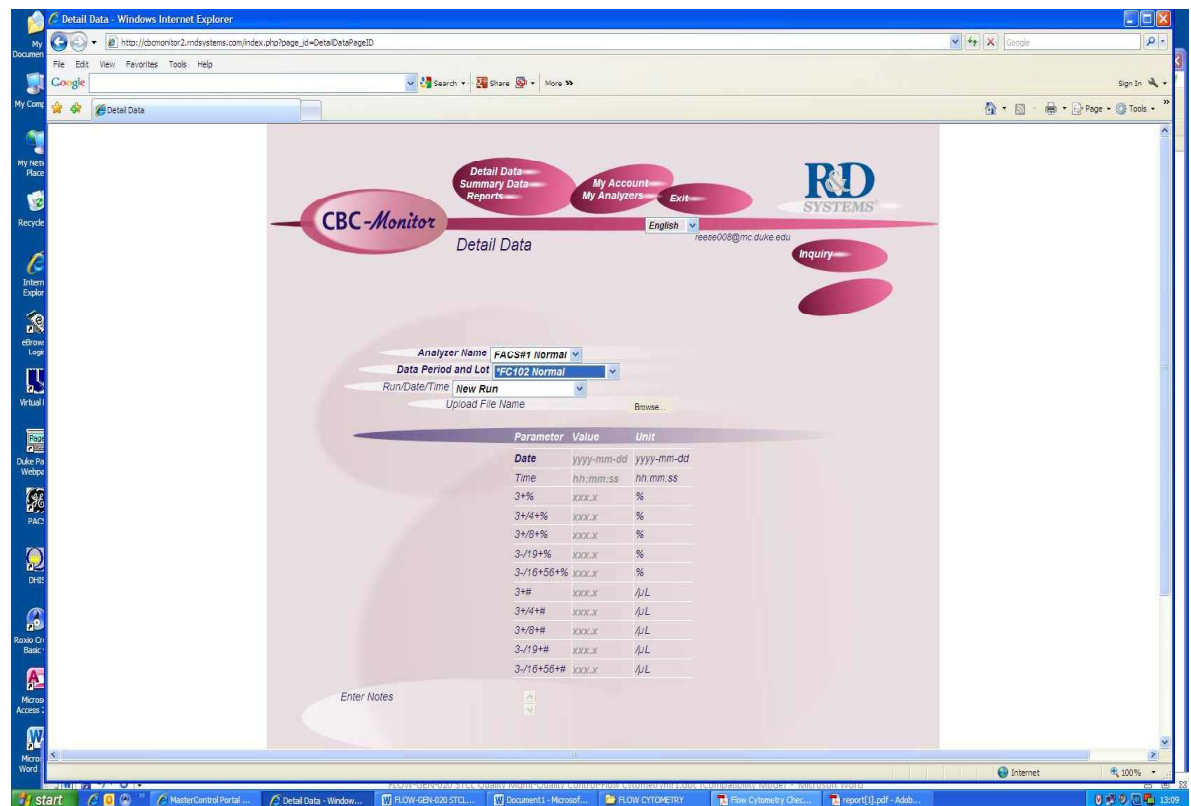
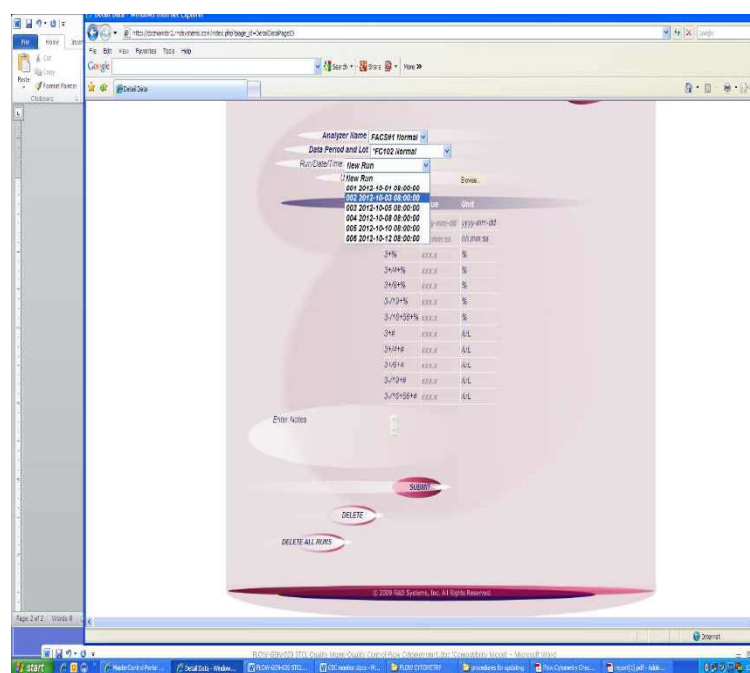


Fig. 4 Lymphocyte marker % and absolute result entry screen.



- 8.5 Refer to figures 3 and 4. From the **Analyzer Name** list choose the STCL flow cytometer model that was used to collect the process control CD34 L/H or normal (lymphocyte) data for the day.
- 8.6 From the **Data period and lot#** list choose the correct lot of process controls that was used for the testing.
- 8.6.1 If entering the CD34 test result, select the current lot# for the Status Flow Pro H/L cells.
- 8.6.2 If entering lymphocyte results, select the current lot# for the Status Flow Normal cells.
- 8.7 Choose **New Run** in the field for Run/Date/time.

**NOTE:** If correcting an entry error, use this field to browse to a prior date entry to modify the result as shown below.



- 8.8 Proceed to enter the results of testing according to the corresponding labeled fields.
- 8.9 Once the entry is complete, click on the **Submit** button.
- 8.10 **Rejected data** will display the incorrect value stricken and in red. This occurs due to data entry errors which must be corrected before the final report is issued.

**NOTE:** Results that are out of the control cell target value range when the results are recorded on FLOW-FORM-008, must be investigated prior to entering results into the CBC-Monitor system. Patient test specimens should not be stained until the root cause for the out of range value is determined. Rules for determining the root cause are defined in FLOW-GEN-020.

- 8.11 Preliminary reports may be reviewed at any time during the course of data collection for a given lot of control cells and for any STCL instrument.

- 8.12 At the close of each months data collection for a given lot, an email with result attachment will be sent to the designated lab recipient with the compiled results.
- 8.13 The reviewer (usually the flow cytometry supervisor) should follow the following quality assurance practices:
- 8.13.1 Note that the number of instruments (6) reported and the number of data points entered from Stem Cell Lab testing meets the minimum (10) for good statistical analysis.
  - 8.13.2 Correct any data entry errors that remain and note error review in the review box on the Detail Data or Summary Data pages.
  - 8.13.3 Check that the SDI is between -2 and +2.
  - 8.13.4 Check that the PI is between 0 and +2.
  - 8.13.5 Review the mean, SD, 2SD and CV results to assure that there are no rejected data and that all values are acceptable by CBC-Monitor criteria.
  - 8.13.6 If the criteria in 8.13.2-5 are not met, an investigation into the root cause must be performed to determine if patient testing was impacted according to STCL Policy.

## 9 RELATED DOCUMENTS/FORMS

- 9.1 FLOW-FORM-008 Flow Cytometry Process Control Record Sheet
- 9.2 FLOW-GEN-020 Stem Cell Laboratory Quality Management-Quality Control Policies for Flow Cytometry

## 10 REFERENCES

- 10.1 Product insert R&D Systems StatusFlow and StatusFlow<sup>Pro</sup> Flow Cytometry Control cells.

## 11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	M. Reese	1. Corrected formatting 2. Corrected document name in section 9- 3. Added reference to document in section 9

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