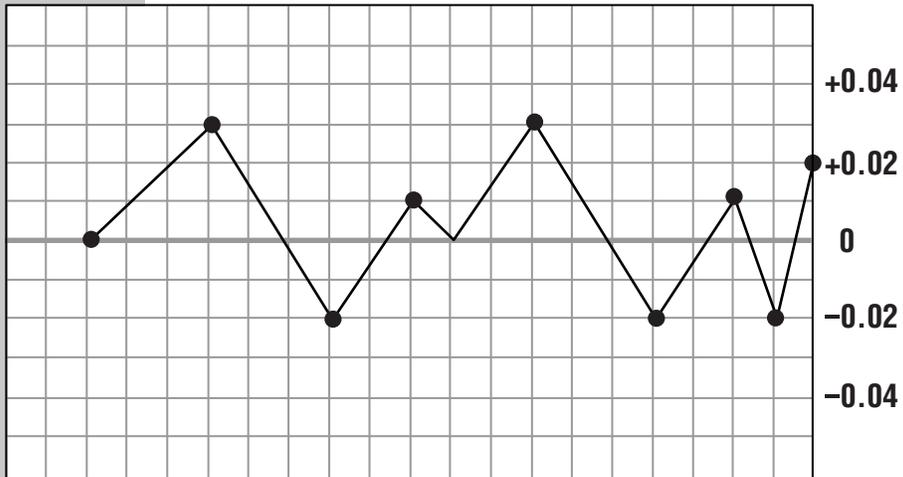


# Basic Concepts of Quality Control



READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL  
BEFORE ATTEMPTING TO OPERATE INSTRUMENT.

### **HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS**

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

- WARNING** - Might cause injury.
- CAUTION** - Might cause damage to the instrument.
- IMPORTANT** - Might cause misleading results.

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**CAUTION** System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
  - You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
  - You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.
- 

Beckman Coulter, Inc. urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but it is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

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**WARNING** Risk of operator injury if all covers are not secured in place prior to instrument operation or you attempt to replace a part without carefully reading the replacement instructions. Do not attempt to replace any component until you carefully read the instructions for replacing the component.

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**IMPORTANT** If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

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*This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.*

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## PURPOSE

The purpose of this document is to:

- introduce you to quality control (QC),
- identify and define the basic concepts of QC,
- list the components of a good QC program, and
- instruct you how to set up a QC program in your laboratory or office.

## SCOPE

Intended for someone with little or no QC experience, this document contains the basic concepts of quality control. Laboratory or office staff familiar with QC can also benefit from the explanations and examples provided. For in-depth explanations of scientific or mathematical formulas, you may want to refer to other documentation.

The information in this document is organized as follows:

- **Using This Document:** States the purpose and scope of this document and defines the purpose and components of quality control (QC).
- **Introduction to Quality Control:** Defines quality control and explains the fundamental components of a QC program.
- **Chapter 1, Basics of Quality Control (QC) Programs:** Defines terminology and explains the benefits of implementing a QC program.
- **Chapter 2, Determining if the Control is “In” or “Out”:** Explains how to determine if a control is “in” or “out”.
- **Chapter 3, Outliers, Trends, and Shifts:** Defines outliers, trends, and shifts, and shows how to detect each one on a graph.
- **Chapter 4, Calibration:** Defines calibration and calibrators, instructs you how to determine if calibration is required, and provides a procedure for calibrating.
- **Chapter 5, Lab-to-Lab Comparison Programs:** Defines Beckman Coulter’s Interlaboratory Quality Assurance Program (IQAP) and its benefits; also provides enrollment instructions.
- **Glossary:** Defines basic terminology used in QC programs.
- **Appendix A, Self-Evaluation:** Provides a self-evaluation to test your understanding of QC and your ability to graph results.
- **Appendix B, Blank Log Sheets:** Provides blank log sheets for WBC, RBC, Hgb, MCV, Plt, LY%, LY#, Hct, MCH, and MCHC for use in your QC program.

## GRAPHICS

All graphics used in this manual are for illustration purposes only and must not be used for any other purpose, unless otherwise stated.

**USING THIS DOCUMENT**  
*GRAPHICS*

## QUALITY CONTROL

### Definition

In laboratory testing, quality control (QC) is the assurance that results are reported correctly (for *accuracy*) and that subsequent results do not change significantly (for *precision*) unless the patient's condition changes.

### Purpose

The purpose of QC within a laboratory is to ensure that an instrument consistently reports reliable sample results. Each laboratory should have its own QC program.

## FUNDAMENTAL COMPONENTS OF A QC PROGRAM

For your QC program to be successful, there are several things that you need to know. See Table 1 for details.

**Table 1 Things You Need to Know for a QC Program to be Successful**

You Must Know	What This Means	Why This is Important
The instrument.	You need to know the normal sights and sounds of your instrument; its principles of operation; and the proper startup, operation, and shutdown procedures.	By knowing your instrument, you can readily detect when it is not working properly.  <b>Note:</b> To learn more about your system, refer to your product manuals. If you need additional information beyond what is in the product manuals, contact your Beckman Coulter representative.
Proper specimen collection and storage procedures.	Only specimens that were properly collected and properly stored should be analyzed on your instrument.	For your instrument to report accurate results, the specimen must be collected and stored according to the instructions in the product manuals and/or reagent package inserts.  For example, if you collect a specimen by venipuncture, the proper amount of blood must be drawn into the anticoagulated collection tube and mixed thoroughly.  An insufficient amount of blood in the collection tube may result in cell damage. Improper mixing may result in small clots. In either case, the final results will be distorted.  If you collect a sample from a finger stick or microcollection method, you must keep dirt, gauze material, or tissue juices out of the blood sample.  <b>Note:</b> Refer to your product manuals for proper specimen collection, handling, and storage information.

**Table 1 Things You Need to Know for a QC Program to be Successful (Continued)**

<b>You Must Know</b>	<b>What This Means</b>	<b>Why This is Important</b>
How to check sample results for flags, normal values, and consistency with the patient's condition.	You need to be able to recognize and understand the printed flags on a sample report.	By reviewing the sample data, you will be able to determine if there is a problem with the sample. By knowing what to expect from a patient's sample, you can determine if the instrument is operating normally.
How to effectively monitor results to determine if they fall within your instrument's expected ranges.	By comparing the reported results against the results of known control materials, you can determine if the instrument is operating effectively.	If you determine that the instrument is not operating effectively, you may need to check reproducibility and/or calibrate the instrument. For detailed reproducibility and calibration procedures, refer to your product manuals.
How to keep detailed, accurate troubleshooting records in your log book.	Any time you encounter a problem with the instrument, a reagent, or a sample, record the details in your log book. Also record any procedures that you did in an attempt to correct the problem.	If you suspect that your instrument is not running properly, refer to the Troubleshooting section of your product manuals. In your log book, be sure to record any procedures that you performed and the results of those procedures.  If you need assistance, contact your Beckman Coulter representative.
How to compare your control results with those of other laboratories operating the same model of Beckman Coulter instrument that you use.	As an active member of Beckman Coulter's IQAP (Interlaboratory Quality Assurance Program), your laboratory's control results are compared with those of your peers.	The IQAP report gives you a complete statistical analysis of your instrument's performance and shows you how your instrument's performance compares with those of your peers. Your instrument's QC performance is plotted on an Instrument Performance Matrix, which is a graphical representation of accuracy and precision.  <b>Note:</b> For IQAP enrollment information in the United States and Canada, call us toll free at 1-800-526-7694. In other countries, contact your Beckman Coulter representative.

## 1.1 TERMINOLOGY DEFINED

### Precision (Reproducibility)

*Precision* is also referred to as *reproducibility*, and is defined as a measure of how close the instrument comes to repeatedly duplicating the same result on the same sample.

Comparing QC terms to a target, Figure 1.1 illustrates that the results are precise (close together) but not accurate (they are not in the bull's-eye).

**Note:** You can have precision without accuracy. However, you cannot have accuracy without precision. See Figure 1.2.

**Figure 1.1 Precision, No Accuracy**



### Checking Precision (Reproducibility)

Before your Beckman Coulter instrument was shipped to you, it met very strict reproducibility specifications. However, you may need to check reproducibility:

- If your instrument requires calibration.
- When troubleshooting your instrument.

For procedures on checking your instrument's reproducibility, refer to your product manuals. If you require additional assistance, contact a Beckman Coulter representative.

### Accuracy

*Accuracy* is defined as the closeness of a result to the true (accepted) value. For example, if your target value is 100, and the sample you analyzed hits the target value of 100, your instrument's performance is *accurate*. **Note:** Before determining accuracy, you must first determine precision. See Precision (Reproducibility) for details.

Again comparing QC terms to a target, Figure 1.2 illustrates that the results are accurate (in the bull's-eye) and precise (close together).

**Note:** You cannot have accuracy without precision. However, you can have precision without accuracy. See Figure 1.1.

Figure 1.3 illustrates that the results are neither accurate nor precise. None of the results are close together, and none of them are in the bull's-eye.

**Figure 1.2 Accuracy and Precision**



**Figure 1.3 No Accuracy, No Precision**



### Checking Accuracy

For procedures on checking your instrument's accuracy, refer to your product manuals. If you require additional assistance, contact your Beckman Coulter representative.

### Carryover

*Carryover* is defined as a number of cells remaining behind following the cycling of a blood sample. This test is performed to determine if one sample interferes with the accurate analysis of the next sample. Ideally, carryover will be very low.

### Checking Carryover

For procedures on checking your instrument's carryover, refer to your product manuals. If you require additional assistance, contact your Beckman Coulter representative.

### Control Materials

An *assayed control material* is a substance used to monitor the performance of a process or an instrument. By comparing control results against the assay (known) value, you can determine your instrument's accuracy and precision.

By repeatedly testing a sample on many different instruments, we can determine a close estimate of the true value. This process is known as *assaying*. When assaying is complete, we can obtain an average of all the results using the prepared sample (control). The value we determine is called an *assigned value*.

Beckman Coulter's cell controls are designed specifically for your instrument. Take a moment to familiarize yourself with two of our control materials (Figures 1.4 and 1.5).

**Figure 1.4 4C® PLUS Cell Control**



**Figure 1.5 IMMUNO-TROL™ Cells**



### Package Inserts

With any hematology or flow cytometry control product that you order from Beckman Coulter, you will receive a package insert that contains specific information pertaining to the batch or lot of controls from which your control product was manufactured. The assay values will be listed on an Assay Sheet or on a Table of Expected Results within the package insert.

Since the Assay Sheet or Table of Expected Results is specific to the batch or lot of controls you received, be sure to use the appropriate document with each of your controls. For example, if we send you a control manufactured in our *Batch A*, you would receive an Assay Sheet or Table of Expected Values specific to *Batch A*. If we send you a control manufactured in our *Batch B*, you would receive an Assay Sheet or Table of Expected Results specific to *Batch B*. You must use the *Batch A* Assay Sheet or Table of Expected Values only with *Batch A* controls.



Interpreting the numbers from Figure 1.6, we see that the assigned value for the normal level control for WBCs is 8.7 and the expected range is  $\pm 0.7$ . The values you obtain when running the control with your instrument should be between 8.0 and 9.4.

- If the result you obtain is *within* the range on the Table of Expected Results, your control is “in”, meaning it is within the acceptable range on the package insert. At least 95% of the control results should fall within the range limits from the assay sheet.
- If the result you obtain is *higher* than the upper limit or *lower* than the lower limit of that range, your result is outside the limits. Your control is “out”, meaning it is not within the acceptable range on the package insert.

To determine if your instrument’s results are within the control parameter, refer to Heading 2.1, DETERMINING IF THE CONTROL IS “IN” OR “OUT”.

**Example: Flow Cytometry Cell Control Table of Expected Results**

Figure 1.7 is an example of an IMMUNO-TROL™ Cells Table of Expected Results. IMMUNO-TROL Cells is an assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents and flow cytometry. It provides a positive cell control that is processed in the same manner as a whole blood sample. This allows verification of reagent performance and the methods used for staining targeted cells, lysing erythrocytes, and analyzing samples with flow cytometry.

**Figure 1.7 IMMUNO-TROL™ Cells Table of Expected Results**

Lot Number \_\_\_\_\_ Expiration Date \_\_\_\_\_

**TABLE OF EXPECTED RESULTS ( see Notes to Table below)**

Percent Positive Results				Population	Gate	Absolute Count Results			
U.S. units		SI units				U.S. units		SI units	
Mean %+	$\pm$ Expected Range	Mean %+	$\pm$ Expected Range			Mean cells/mL	$\pm$ Expected Range	Mean $\times 10^9$ cells/L	$\pm$ Expected Range
8		0.08		CD2+	LY	313		0.313	
9		0.09		CD3+	LY	260		0.260	
5		0.05		CD4+	LY	180		0.180	
9		0.09		CD3+/CD4+	LY	165		0.165	
12		0.12		CD5+	LY				
7		0.07		CD8+	LY	137		0.137	
6		0.06		CD3+/CD8+	LY	118		0.118	
20		0.20		CD14+	MO				
5		0.05		CD19+	LY	67		0.067	
				CD45+	LY				
4		0.04		CD3-/CD56+	LY	56		0.056	

**TABLE OF EXPECTED RESULTS ( see Notes to Table below)**

The CD populations listed below are not cleared by the United States Food and Drug Administration For in Vitro Diagnostic Use.

Percent Positive Results				Population	Gate	Absolute Count Results			
U.S. units		SI units				U.S. units		SI units	
Mean %+	$\pm$ Expected Range	Mean %+	$\pm$ Expected Range			Mean cells/mL	$\pm$ Expected Range	Mean $\times 10^9$ cells/L	$\pm$ Expected Range
18		0.18		CD7+	LY				
				CD10+	GR				
15		0.15		CD13+	MO				
13		0.13		CD13+	GR				
12		0.12		CD19+/kappa+	LY				
9		0.09		CD19+/lambda+	LY				
11		0.11		CD22+	LY				
17		0.17		CD33+	MO				
6		0.06		HLA-DR	LY				

5526033C

The IMMUNO-TROL Cells Table of Expected Results identifies the leukocyte population assayed to establish percent positive and absolute count ranges in the GATE column for LY (lymphocytes), MO (monocytes), or GR (granulocytes). The mean values are determined for each antigen using an XL or XL-MCL flow cytometer with the ImmunoPrep Reagent System and CYTO-STAT, CYTO-STAT/Coulter Clone, or IOtest antibodies. Absolute count results are determined using Flow-Count™ Fluorospheres. Under these conditions, 95% of the recovered values should fall within the stated expected range on the package insert.

There are specific notes associated with the Table of Expected Results for IMMUNO-TROL Cells. It is important that you read and understand each of the notes.

### Calibration

Calibration is defined as the procedure used to standardize the instrument for accuracy by determining the instrument's deviation from calibration references and applying any necessary calibration correction factors. These factors are designed to fine-tune instrument accuracy.

### Calibrator

A calibrator is a substance that is traceable to reference methods for the preparation of material used to calibrate a measurement on our *hematology* instruments. S-CAL® Calibrator (Figure 1.8) is one of the calibrators that we manufacture for use with our instruments.

Figure 1.8 S-CAL® Calibrator



### Outliers

*Outliers* are results that fall outside the low/high limits for any parameter. For additional information on outliers, see Heading 3.1, OUTLIERS, TRENDS, AND SHIFTS.

### Trends

A *trend* occurs when five or more control values show a gradual increase or decrease. For additional information on trends, see Heading 3.1, OUTLIERS, TRENDS, AND SHIFTS.

### Shifts

A *shift* occurs when there is a sudden change in results from one day to the next. For additional information on shifts, see Heading 3.1, OUTLIERS, TRENDS, AND SHIFTS.

## **1.2 BENEFITS OF IMPLEMENTING A QUALITY CONTROL PROGRAM**

There are several benefits of implementing a QC program:

- to report accurate sample results,
- to verify that the instrument is in good working order, and
- to document a standard set of procedures for all laboratory staff to follow.

### **Reporting Accurate Sample Results**

Check procedures are the foundation for a QC program. It is the laboratory's responsibility to ensure that its QC program is established and strictly followed to ensure that accurate sample results are reported. Consider this example:

Jason Jones, age 33, had a hemoglobin test on 10/13/99, and his hemoglobin results were reported as 8.0 g/dL by ABC lab.

Based on these results, Dr. Shanley admitted Jason to the hospital for a possible anemia condition. During admission, Jason's blood was again tested for hemoglobin. The hospital lab reported Jason's hemoglobin results as 14.5 g/dL, well within the normal range for a male Jason's age.

Dr. Shanley could not be certain which hemoglobin test result was correct. 8.0 g/dL is considered very low for a male Jason's age; however, 14.5 g/dL is considered within the normal range for a male Jason's age.

It appears that one of the labs did not have a QC program in place. Unfortunately, without researching each lab's methods, one cannot determine which results were correct. Therefore, Dr. Shanley most likely ordered additional tests for Jason before deciding which course of action to take.

If the laboratory at fault had performed its daily QC checks, the problem could have been detected and corrected.

If a patient's sample results are reported incorrectly, the patient can be misdiagnosed and treated for a condition that he/she may not have. A good QC program helps ensure that accurate sample results are reported.

### **Verifying If Instrument Is In Good Working Order**

By knowing how your instrument operates when it is in good working order, you can quickly detect if there is a problem. Early detection and correction of potential problems reduces the risk of incorrect sample results and minimizes instrument down-time. By reviewing your QC data, you can determine if the instrument is working as efficiently as it did, for example, one month ago.

### **Documenting a Standard Set of Procedures**

Consistently following analysis procedures is crucial when analyzing samples. Everyone in the laboratory should follow the same sample analysis procedure. Without following a standard set of laboratory procedures, the operator runs the risk of incorrectly analyzing the sample, which translates into incorrect sample results being reported. Each laboratory should have its own checklist for laboratory staff to follow when analyzing patient samples.

### **Checklist for Processing Samples**

The checklist should at least include the following items:

- Check reagents to ensure that they are not expired.
- Verify that the appropriate specimen collection method was followed.
- Ensure that the appropriate sample preparation methods were followed.
- Document that the Startup and Shutdown procedures were followed.
- Determine if the instrument's background test passed.
- Verify that the equipment produces accurate results.

**BASICS OF QUALITY CONTROL (QC) PROGRAMS**  
*BENEFITS OF IMPLEMENTING A QUALITY CONTROL PROGRAM*

# DETERMINING IF THE CONTROL IS "IN" OR "OUT"

## 2.1 DETERMINING IF THE CONTROL IS "IN" OR "OUT"

In explaining how to determine if results are within the control parameters on the assay sheet (package insert), we are going to use the Table of Expected Results for 4C PLUS cell control (Figure 2.1). Keep in mind that your assay sheet and/or its values will probably differ from what is shown here.

As you can see on this particular assay sheet, there are three control levels: abnormal low, normal, and abnormal high. Each level has a specific lot number and expiration date. If today's date comes after the expiration date on the assay sheet, DO NOT use the control – it is expired.

The values for each control level are listed for a specific instrument, such as the A<sup>C</sup>•T Series analyzer in this example. An assigned value is an estimate of the true value based on repetitive analysis of the control product on multiple instruments.

Figure 2.1 Table of Expected Results for 4C PLUS Cell Control

**4C<sup>®</sup> PLUS**  
COULTER<sup>®</sup> Cell Control

TABLE OF EXPECTED RESULTS  
SOLLWERTTABELLE  
TABLEAU DES VALEURS CIBLES  
TABLA DE VALORES ESPERADOS  
TAVOLA DEI VALORI ATTESI

ABNORMAL LOW    NORMAL    ABNORMAL HIGH



Unit  
Format/Einheiten  
Unit s/Unidades  
EE.UU./Formato  
Unit /

Open Vial Limit/Mind haltbar nach Öffnung/  
Flacons ouverts ne pas utiliser apr ès /  
Cauducidad del vial despu s de abierto/  
Limite di utilizzo per fiala aperta/

Abnormal Low/Abnormal Niedrig/ Anormal Bas/Anormal Bajo/ Patologico Basso/				Normal/Normal/Normal/ Normale/				Abnormal High/Abnormal Hoch/ Anormal Haut/Anormal Alto/ Patologico Alto/				Lot No./Lot-Nr./No. de Lot/Nr mer o de Lote/Numero di Lotta/		Exp. Date/Verfallsdatum/Date de p remption/ Fecha de caducidad/Data di scadenza/		U.S.		Parameters		Parameter		Param tres		Par metros		Parametro	
A <sup>C</sup> •T <sup>®</sup> 8/10*	A <sup>C</sup> •T diff <sup>†</sup> **	A <sup>C</sup> •T diff <sup>†2</sup> **	A <sup>C</sup> •T Series*	A <sup>C</sup> •T 8/10*	A <sup>C</sup> •T diff <sup>†</sup> **	A <sup>C</sup> •T diff <sup>†2</sup> **	A <sup>C</sup> •T Series*	A <sup>C</sup> •T 8/10*	A <sup>C</sup> •T diff <sup>†</sup> **	A <sup>C</sup> •T diff <sup>†2</sup> **	A <sup>C</sup> •T Series*	U.S.	Parameters	Parameter	Param tres	Par metros	Parametro	Parameter	Parametro	Parameter	Parametro	Parameter	Parametro				
060602	078002	080302	060602	078002	080302	060602	078002	080302	060602	078002	080302	060602	078002	080302	060602	078002	080302	060602	078002	080302	060602	078002	080302				
05OCT99	04OCT99	30SEP99	05OCT99	04OCT99	30SEP99	05OCT99	04OCT99	30SEP99	05OCT99	04OCT99	30SEP99	05OCT99	04OCT99	30SEP99	05OCT99	04OCT99	30SEP99	05OCT99	04OCT99	30SEP99	05OCT99	04OCT99	30SEP99				
4.0	4.0	4.0	± 0.5	8.7	8.7	8.7	± 0.7	17.5	17.6	17.4	± 1.2	x 10 <sup>12</sup> /µL	WBC	LEU	Lkc	LEUC	WBC	WBC	WBC	WBC	WBC	WBC	WBC				
2.48	2.47	2.47	± 0.25	4.20	4.16	4.16	± 0.25	5.45	5.37	5.37	± 0.30	x 10 <sup>12</sup> /µL	RBC	ERY	Erc	ERIT	RBC	RBC	RBC	RBC	RBC	RBC					
7.0	6.9	6.9	± 0.7	12.7	12.8	12.7	± 0.9	17.7	17.9	17.7	± 0.9	g/dL	Hgb	HGB	Hb	Hgb	Hgb	Hgb	Hgb	Hgb	Hgb	Hgb					
19.8	19.8	19.8	± 2.7	37.0	36.6	36.6	± 3.0	51.9	50.5	50.5	± 4.0	%	Hct	HKT	Ht	Hct	Hct	Hct	Hct	Hct	Hct	Hct					
80.0	80.0	80.0	± 4.0	88.1	88.1	88.1	± 4.5	95.3	94.1	94.1	± 5.0	fL	MCV	MCV	VCM	VCM	MCV	MCV	MCV	MCV	MCV	MCV					
28.2	27.9	27.9	± 3.0	30.2	30.8	30.5	± 3.3	32.5	33.3	33.0	± 3.6	pg	MCH	MCH	TCMH	HCM	MCH	MCH	MCH	MCH	MCH	MCH					
35.4	34.8	34.8	± 3.4	34.3	35.0	34.7	± 3.7	34.1	35.4	35.0	± 3.6	g/dL	MCHC	MCHC	CCMH	CHCM	MCHC	MCHC	MCHC	MCHC	MCHC	MCHC					
14.7	14.7	14.7	± 2.5	13.0	13.0	13.0	± 1.5	13.5	13.5	13.5	± 2.0	%	RDW	EVB	IDC	ADE	RDW	RDW	RDW	RDW	RDW	RDW					
75†	75†	75	± 2.0	22.9	22.5	22.5	± 4.0	424	414	422	± 60	x 10 <sup>12</sup> /µL	Plt	THR	PLT	PLA	Plt	Plt	Plt	Plt	Plt	Plt					
9.7	9.7	9.7	± 1.5	10.2	10.2	10.2	± 2.0	10.3	10.3	10.3	± 2.0	fL	MPV	MTV	VPM	VPM	MPV	MPV	MPV	MPV	MPV	MPV					
0.073	0.073	0.073	± 0.030	0.230	0.230	0.230	± 0.050	0.426	0.435	0.435	± 0.060	%	Pct	TKT	Tct	Tct	Pct	Pct	Pct	Pct	Pct	Pct					
13.7	13.7	13.7	± 2.0	13.7	13.7	13.7	± 2.0	13.7	13.7	13.7	± 2.0	ratio	PDW	TVB	IDP	ADP	PDW	PDW	PDW	PDW	PDW	PDW					
25.1	28.5	29.5	± 7.0	34.6	42.4	42.4	± 5.0	38.1	47.4	47.4	± 5.0	%	LY %	LY %	LY %	LINF %	LY %	LY %	LY %	LY %	LY %	LY %					
11.3	11.3	10.3	± 4.0	10.2	9.8	9.8	± 4.0	14.6†	14.6†	14.6	± 5.0	%	MO %	MO %	MO %	MONO %	MO %	MO %	MO %	MO %	MO %	MO %					
60.2	60.2	60.2	± 6.0	47.4	47.8	47.8	± 6.0	38.0	38.0	38.0	± 5.0	%	GR %	GR %	GR %	GRA N %	GR %	GR %	GR %	GR %	GR %	GR %					
1.0	1.1	1.2	0.5 ±	3.0	3.7	3.7	± 0.8	6.7	8.3	8.3	± 1.5	x 10 <sup>12</sup> /µL	LY #	LY #	LY #	LINF #	LY #	LY #	LY #	LY #	LY #	LY #					
0.5	0.4	0.4	± 0.3	0.9	0.9	0.9	± 0.5	2.6†	2.5	2.5	± 1.2	x 10 <sup>12</sup> /µL	MO #	MO #	MO #	MO #	MO #	MO #	MO #	MO #	MO #	MO #					
2.4	2.4	2.4	± 0.6	4.1	4.1	4.1	± 0.9	6.7	6.6	6.6	± 1.4	x 10 <sup>12</sup> /µL	GR #	GR #	GR #	GRA N #	GR #	GR #	GR #	GR #	GR #	GR #					

7504518-A R 11-98

\*Applcabi s only for parameter s measure d by the Instrument/Anwendba r nur f f Parameter , die mit dem GeUl gemess n werden/Concoro s uniquement l les param ètre s mesur s par l Instrument/S applica unicamente per a questo s param ètro s misur o por il Instrumento/Applicabili e solo per i param ètri misurati dallo strumento.  
 \*\*Assume s that the Instruccion e Seccio n of the packag e is insert ed performe d a maximum of 31 times within 35 days/ s wird angenom men , da ß die Kontrol l ma ximal 31 mal innerhal b von 35 Tage n benutz t wird./Sachst que l'utilisatio n est effe ct ee poy 31 ouvre ture s sur un e p eriod e de 35 jours./Assu m e que la Seccio n de l'instruccion e s de l'ins trument o de l'product o de l'product o se ejec u ta un ma ximo de 31 veces e n el 35 das/dias/ e , nel caso n el cu l la seccio n e l'instruccion e l'ins trument o e l'ins trument o se e mplea a un ma ximo de 31 volte entro 35 giorn i.  
 \*\*\* tags for platelet , MON O % and MON O # param eter s confir m that distribu to criteria are not met. Refe r to the Product I Manual s for flag criteria.

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## **Is Control In or Out?**

Using the assay sheet in Figure 2.1, practice determining if the results printed by your instrument are within the control value parameters for the control level that you analyzed on your instrument.

For this example, presume that you ran the Normal control on your instrument.

1. Find the WBC assigned value for the Normal control.  
(Answer: 8.7.)
2. Find the WBC expected range.  
(Answer: The expected range is 8.0 to 9.4. 8.0 is seven-tenths less than the assigned value of 8.7, and 9.4 is seven-tenths greater than the assigned value of 8.7.)
3. If your instrument printed WBC results of:
  - 9.2, is the control “in” or “out”?  
(Answer: The control is “in” because 9.2 falls within the range of 8.0 to 9.4.)
  - 9.7, is the control “in” or “out”?  
(Answer: The control is “out” because 9.7 falls outside the range of 8.0 to 9.4.)
4. Record the results on a log sheet. See Recording Control Results on a Log Sheet (Data Entry Form) in this chapter.

### **What to Do If the Control is “In”**

If the control is “in”, run the remaining levels of control before you start your patient samples. After running all control levels and determining that your instrument is performing as expected, you can run patient samples.

### **What to Do If the Control is “Out”**

In step 3 above, the WBC value of 9.7 was “out” of control because it was higher than the upper limit of 9.4. Anytime your control is “out”, DO NOT run any patient samples until you determine what caused the control to be out and remedy the situation. Before troubleshooting the problem, record the information on a corrective action log sheet, located in an appendix of your product manuals.

To record your control information on a corrective action log sheet:

1. Write the date on the corrective action log sheet.
2. Write the condition, such as “WBC low on 4C PLUS normal”; include the lot number and expiration date.
3. Write the initials of the person who noted the condition.
4. Write the date the control was run.
5. Write the action that you performed, such as “Repeated-back in range”.
6. Write the initials of the person who performed corrective action.
7. Troubleshoot the problem(s) as instructed in Table 2.1.



**Table 2.1 Troubleshooting When a Control is “Out”**

Possible Cause	What this Means	Recommended Corrective Action
Chance	The probability for this value to be outside the limit is about one time out of every 20 times you run the control. If chance is the cause, the result is usually not very much over the limit. If you run the control one more time, and the result is in, you can presume the original result was out on chance.	<ol style="list-style-type: none"> <li>1. Rerun the control. Always follow the directions on the package insert for proper handling.</li> <li>2. If the control is still out, then the problem may be due to a change in the control material.</li> <li>3. See the next possible cause.</li> </ol>
Control material	If there has been any change in the control material, your control may be out. Be sure to handle the control carefully as instructed in the package insert. If the control is treated roughly, stored improperly, or used beyond the expiration date, the results may be outside the expected range. If the control material is the cause for the control being out, generally only one level of control or one vial will show the problem.	<ol style="list-style-type: none"> <li>1. Rerun another vial or level of control. Always follow the directions on the package insert for proper handling.</li> <li>2. If the control is still out, then the problem may be a change in the instrument.</li> <li>3. See the next possible cause.</li> </ol>
Instrument	If there has been any change to the instrument regarding the test system, the controls will be out. If this is the problem, then the result will still be out when you rerun the control. This will also affect more than one level of control.	<ol style="list-style-type: none"> <li>1. Refer to the troubleshooting section of your instrument’s manuals.</li> <li>2. If you still have problems, contact your supervisor.</li> <li>3. If your supervisor cannot resolve the problem, contact a Beckman Coulter representative.</li> </ol>

**Recording Control Results on a Log Sheet (Data Entry Form)**

Careful record keeping is an important part of a good quality control program. If your instrument does not automatically store control results, write them on a log sheet. Typically, you will run a control for a month; be sure your results are recorded each time.

The log sheet you use depends upon the cell control that you process. For example, if you run 4C PLUS cell control, you should record the results on a log sheet similar to Figure 2.3.

As a participant of Beckman Coulter’s IQAP (Interlaboratory Quality Assurance Program), you may receive log sheets called Data Entry Forms to use for recording results. You can order these forms by calling 1-800-526-7694. **Note:** Your instrument may have an internal QC program that collects control data for submitting to IQAP.

You can send a copy of the completed form to Beckman Coulter for interlaboratory comparison of your results. Even if you do not send the form to us, be sure to write down your cell control results every day and keep the log sheet in a special notebook, or keep printouts of your results.

**To record control results on an IQAP 4C/4C PLUS Cell Control Data Entry Form (Figure 2.3)**

- 1 Mark the box next to the appropriate control level.
- 2 Locate the lot number on the control's assay sheet and record the number on the Data Entry form.
- 3 If you submit data by shift, write the shift number in this box.
- 4 Enter the date started and the date completed.
- 5 Mark the appropriate box for your reporting format.
- 6 Mark the appropriate box for your reagent system.
- 7 Fill in the page number information.
- 8 Locate the expected values on the assay sheet for only the parameters you use in your laboratory. Write the expected results for each parameter, one number or decimal point per box. Record only the assigned values for the parameters analyzed in your laboratory. For example, if you do not analyze MPV, do not write an assigned value for MPV on the IQAP Data Entry Form.
- 9 Write the dates and corresponding control results in their boxes, one number or decimal point per box.

The remaining parameters are on the back of the form.

Send the form to our IQAP department and keep a copy of the form or result printouts in your instrument log book.

**Figure 2.3 Data Entry Form for 4C PLUS Cell Control Results**

**4C®/4C® PLUS CELL CONTROL**

**Marking Instructions**  
 Please print clearly in BLOCK CAPITALS. Use blue/black ink.  
 24.4

**DAILY DATA ENTRY FORM**

**BECKMAN COULTER**

Institution  
 City, State, Country  
 Instrument  
 SN  
 IQAP ID #  
 ICR Identifier

**1** Abnormal Low   
 Normal   
 Abnormal High

**2** CONTROL LOT NUMBER: 078200

**3** SHIFT: [ ]

**4** DATE STARTED: 05-09-1999  
 Month Day Year

**4** DATE COMPLETED: 05-29-1999  
 Month Day Year

**5** REPORTING FORMAT  
 US  SI3  
 SI1  SI4  
 SI2  Japan

**6** REAGENT SYSTEM  
 ISOTON® II  
 ISOTON® III / Pak / Tamer  
 ISOTON® 4  
 Other

Expected Results	9.1	4.19	12.8	36.8	87.8	30.5	34.8		
Month Day	WBC	RBC	Hgb	Hct	MCV	MCH	MCHC	RDW	
0504	9.0	4.29	12.7	37.9	88.3	29.6	33.5		
0505	8.9	4.18	12.6	37.1	88.7	30.2	34.1		
0506	8.6	4.01	12.3	35.5	88.7	30.6	34.5		
0507	9.0	4.08	12.6	36.1	88.5	30.9	34.9		
0508	9.1	4.08	12.6	36.3	88.9	30.8	34.7		
0511	9.0	4.15	12.7	37.0	89.1	30.6	34.4		
0512	9.3	4.03	12.2	35.5	88.0	30.4	34.5		
0513	8.9	3.93	12.1	35.0	89.0	30.8	34.5		
0514	9.0	3.87	11.9	34.4	88.9	30.6	34.5		
0515	8.8	4.00	12.3	35.5	88.7	30.9	34.8		
0518	9.1	3.92	12.1	34.8	88.8	30.8	34.7		
0519	9.2	4.03	12.3	35.6	88.3	30.5	34.5		
0520	9.0	4.06	12.3	36.1	88.8	30.2	34.0		
0521	8.7	3.97	12.2	35.3	88.8	30.7	34.5		
0522	8.9	3.96	12.1	35.2	88.8	30.5	34.4		
0525	9.1	3.97	12.1	35.3	88.9	30.5	34.3		
0526	9.3	4.01	12.2	35.5	88.6	30.4	34.3		

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**DETERMINING IF THE CONTROL IS “IN” OR “OUT”**  
*DETERMINING IF THE CONTROL IS “IN” OR “OUT”*

## 3.1 OUTLIERS, TRENDS, AND SHIFTS

By graphing your control results, you can detect outliers, trends, and shifts. For your convenience, we have provided blank log sheets in APPENDIX B.

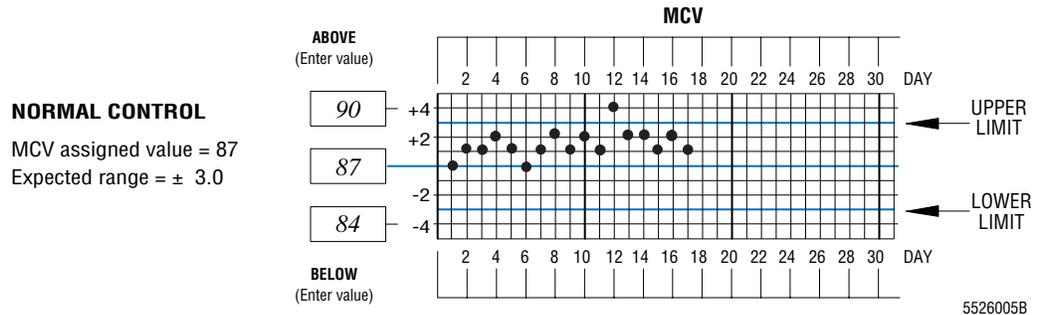
### Outliers

A result that falls outside the limits is call an *outlier*. Figure 3.1 shows a graph of MCV control results recorded for a 17-day period for a normal control level:

- The MCV assigned value is 87 and is used as the mid-line.
- The expected range is  $\pm 3.0$  and is used to define the low and high limits.

By using these lines, you can quickly spot the outlier on day 12. The reason for the outlier may have been “chance”. For additional information regarding chance, see Table 2.1 in Chapter 2.

**Figure 3.1 Outliers on MCV Results**



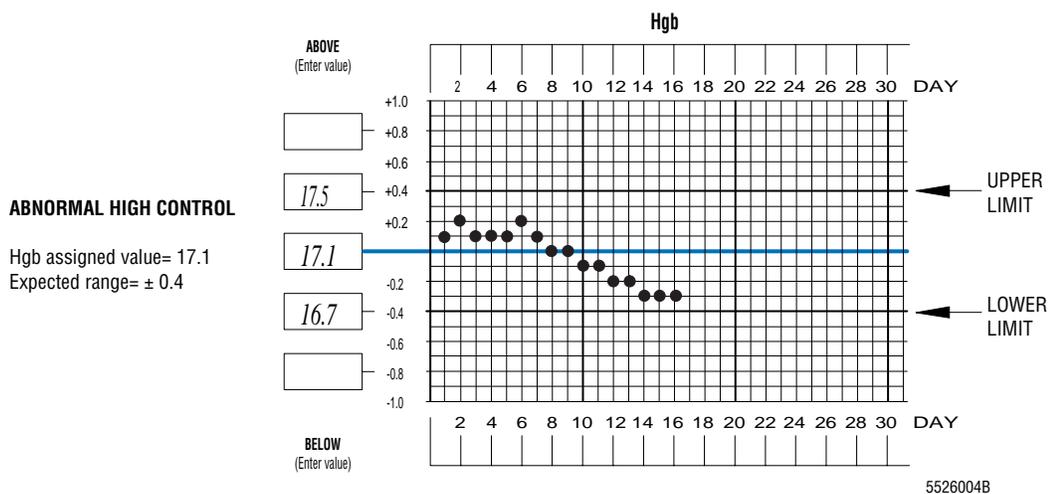
## Trends

A *trend* occurs when five or more values show a gradual increase or decrease. Figure 3.2 shows a trend in hemoglobin (Hgb) control results for an abnormal control level:

- The Hgb assigned value is 17.1 and is used as the mid-line.
- The expected range is  $\pm 0.4$  and is used to define the low and high limits.

Although none of the results are outside the limits, the graph indicates that a problem exists. Notice the gradual decline in the hemoglobin control results beginning after the sixth day.

**Figure 3.2 Trend of Hgb Control Results**



If you notice a trend:

1. Record the information on your corrective action log (Figure 2.2).
2. Troubleshoot the problem(s) and remedy the situation before running patient samples.

**Note:** Because hematology controls are cell-based, some trending in sizing parameters is expected. As stated in the Storage and Stability section of the control product insert, “The MCV and/or RDW parameters may show trending through the product’s shelf-life. This is inherent to the product and should not be considered an indicator of product instability. Recovered values for these parameters should remain within the Expected Range.”

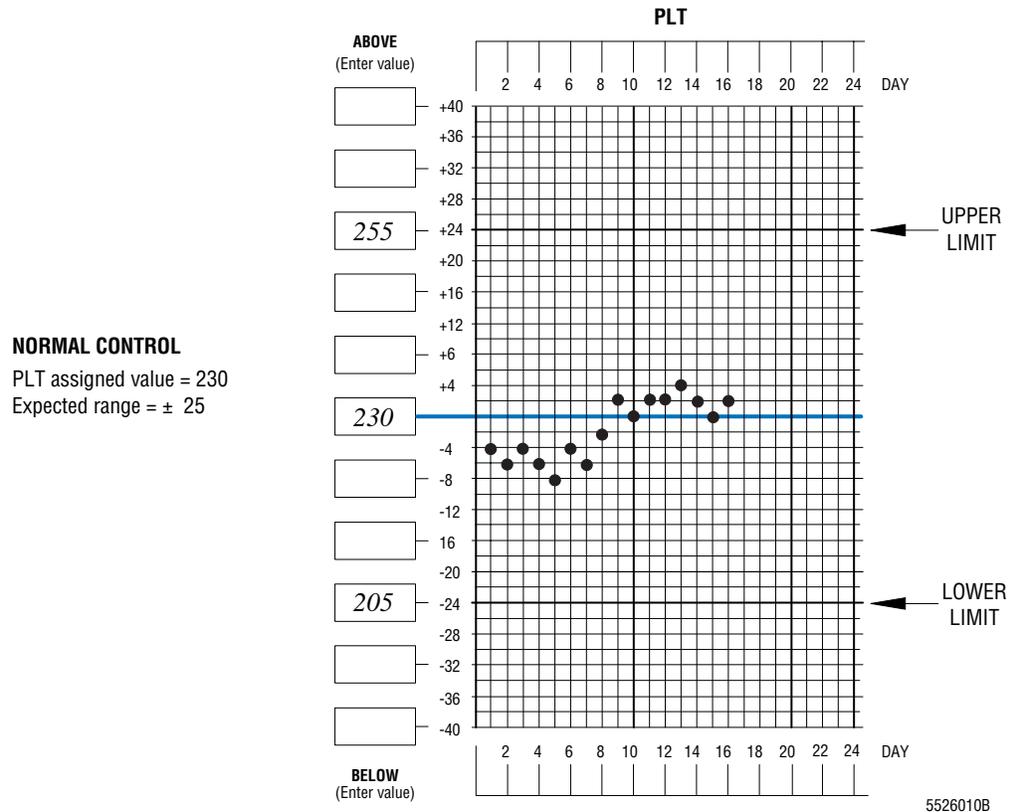
**Shifts**

A *shift* occurs when there is a sudden change in control results from one day to the next. Figure 3.3 shows a shift in platelet (PLT) control results for a normal control level:

- The PLT assigned value is 230 and is used as the mid-line.
- The expected range is  $\pm 25$  and is used to define the low and high limits.

Notice the sudden change in PLT control results between the seventh and ninth days.

**Figure 3.3 Shift in PLT Control Results**



If you notice a shift:

1. Record the information on your corrective action log (Figure 2.2).  
 Note: A shift does not always mean a problem exists. If you performed troubleshooting procedures or calibrated your system before you ran the control, a shift may occur.
2. Troubleshoot the problem(s) and remedy the situation before running patient samples.

**OUTLIERS, TRENDS, AND SHIFTS**  
*OUTLIERS, TRENDS, AND SHIFTS*

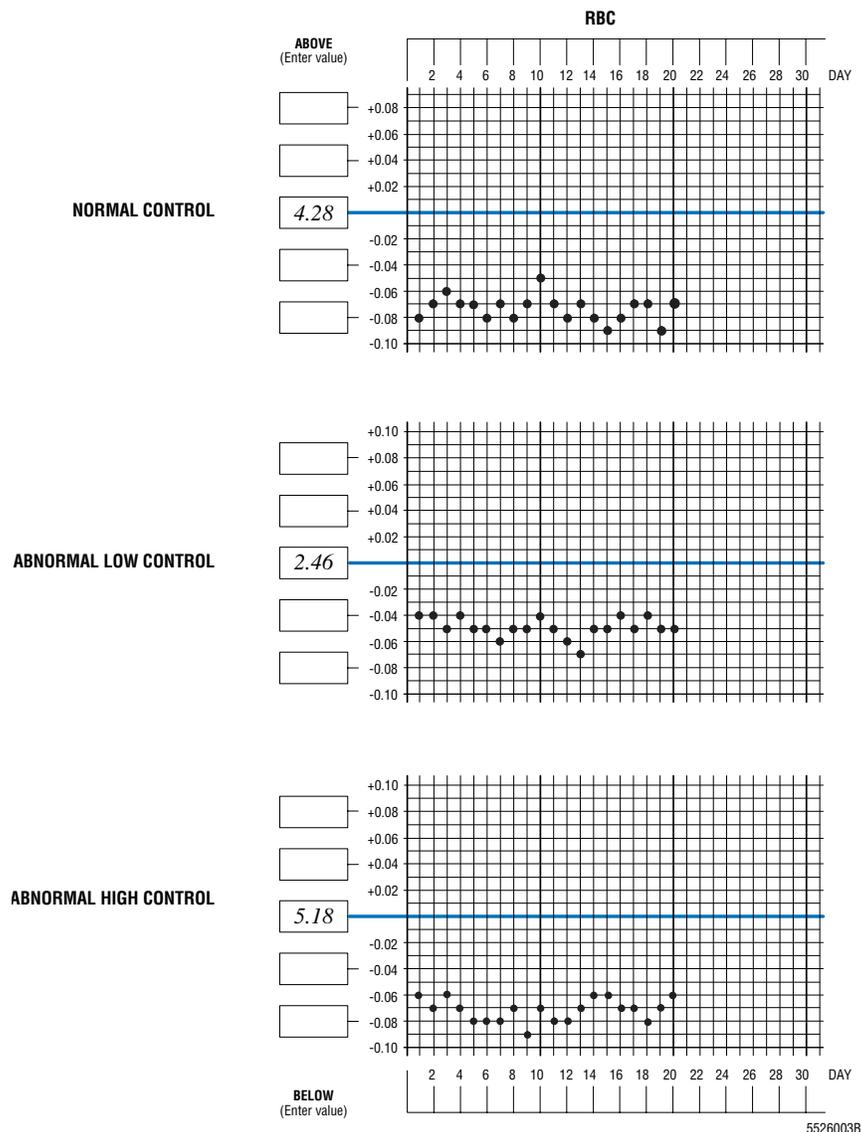
## 4.1 OVERVIEW

Calibration is the process used to adjust the accuracy of your instrument. Calibration requires the use of a *calibrator*, such as COULTER S-CAL<sup>®</sup> calibrator.

## 4.2 DETERMINING IF CALIBRATION IS REQUIRED

Control graphs can help you determine if calibration is required. Figure 4.1 shows the graphs of all three levels of control for the RBC parameter.

**Figure 4.1 Three Control Levels for RBC**



All three graphs show the same thing – the instrument is giving precise (reproducible) results but the results are not as accurate as they could be. The results for each control are on the low side of the assigned values. If there are no instrument problems, and you see a pattern in your graphs as shown here, then you may need to calibrate (adjust the accuracy) your instrument.

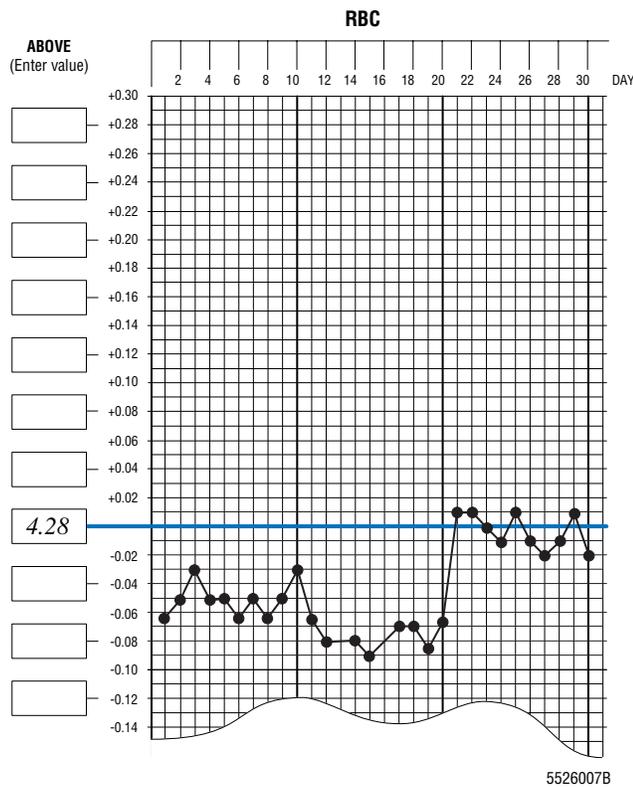
### 4.3 CALIBRATION PROCEDURE

For detailed procedures, refer to your instrument's Special Procedures and Troubleshooting manual.

After you calibrate your instrument, you most likely will see a shift in your control results. Calibration is a normal cause for a shift. See Figure 4.2.

This shows how the normal control graph for the RBC parameter, earlier illustrated in Figure 4.1, might look if you calibrated the instrument on day 20. Notice the shift in results as they moved from the lower side closer to the assigned value of 4.28.

**Figure 4.2 Calibration on Day 20 for RBC Normal Control**



## 5.1 INTERLABORATORY QUALITY ASSURANCE PROGRAM (IQAP)

### Purpose

Beckman Coulter's IQAP program allows you to compare your laboratory's performance with other laboratories using the same model of instrument and same lot of controls.

Comprehensive and easy to use, the IQAP program is a service offered worldwide to all users of Beckman Coulter cell controls and calibrators.

### Benefits of Participating in IQAP

For each set of data that you submit, you will receive a personalized report that summarizes your results and compares them to those of the peer group. There are four main sections to the report:

- Identification section, which provides demographics of your institution.
- Notes section, which provides informational bulletins and narrative notes on acceptability of results.
- Data Evaluation section, which is a statistical summary of your data and peer group results.
- Instrument Performance Matrix section, which is a visual summary of your instrument's accuracy and precision.

### Enrollment

We encourage you to enroll all of your Beckman Coulter instruments in this program. When you enroll, a unique, eight-digit identification (ID) number is assigned for each of your instruments. The ID number identifies your facility, the laboratory location of your instrument, and the name of the instrument.

For enrollment information in the United States and Canada, call us toll-free at 1-800-526-7694. In other countries, contact your Beckman Coulter representative.

**LAB-TO-LAB COMPARISON PROGRAMS**

*INTERLABORATORY QUALITY ASSURANCE PROGRAM (IQAP)*

<b>Accuracy</b>	The closeness of a result to the true (accepted) value.
<b>Assay</b>	A procedure of testing to determine the assigned value for a given lot of control material involving multiple analysis.
<b>Assigned value</b>	The value of the control parameter as defined by the assay process.
<b>Calibration</b>	The process of adjusting the accuracy of an instrument.
<b>Calibrator</b>	A substance that is traceable to reference methods so it can be used to adjust instrument accuracy.
<b>Control</b>	A substance used in routine practice for monitoring the performance of an analytical process or instrument.
<b>IQAP</b>	Interlaboratory Quality Assurance Program offered by Beckman Coulter as a lab-to-lab comparison program.
<b>Lab-to-lab comparison</b>	A method of comparing your instrument's performance with other laboratories using the same model of instrument. <i>See also</i> IQAP.
<b>Outlier</b>	In daily accuracy graphing, a result that falls outside the high and low limits.
<b>Parameter</b>	In hematology, one of the aspects of blood analysis, such as white blood cell (WBC).
<b>Precision</b>	Reproducibility; the ability of an instrument to duplicate a result on the same sample. <i>See also</i> reproducibility.
<b>Quality control (QC)</b>	In laboratory testing, quality control is the assurance that results are reported correctly (accuracy) and that subsequent results do not change significantly unless the patient's condition changes (precision).
<b>Reagent</b>	A substance added to a complex solution to determine the presence or absence of a certain other substance.
<b>Reproducibility</b>	Precision; the ability of an instrument to duplicate a result on the same sample. <i>See also</i> precision.
<b>Shift</b>	In daily accuracy graphing, a shift occurs when there is a sudden change in control results from one day to the next.
<b>Trend</b>	In daily accuracy graphing, a trend occurs when five or more values show a gradual increase or decrease.
<b>True value</b>	The hypothetical addition of an exact number of cells.



## A.1 OVERVIEW

This self-evaluation is designed to help you review the material covered in this document and to test your knowledge of quality control. Answers are provided in Heading A.3, ANSWER KEY. Note: Make a copy of this self-evaluation; do not write on the original.

## A.2 SELF-EVALUATION

### Multiple Choice

Circle the correct answer(s) for each question. There may be more than one correct answer.

1. Quality control is:
  - a. A program required for large laboratories only.
  - b. A program that ensures the patient results you report are as accurate as possible.
  - c. A set of check procedures that must be done correctly and consistently by anyone who performs laboratory tests.
  - d. An annual program for determining how the instrument is performing.
  
2. Quality control is necessary because:
  - a. The results you obtain for a particular patient should agree with results by other laboratories or with previous results you reported on the patient, unless there was a change in the patient's condition.
  - b. There are legal implications associated with reporting inaccurate results.
  - c. Federal or local laws may require inspections and documentation of accurate testing systems.
  - d. Good patient care requires accurate results for proper diagnosis and treatment.
  
3. If control sample results are outside the expected range limits due to *chance*, what action should you take?
  - a. Run the control material several times until it is in control.
  - b. Identify the problem and correct it, or contact your Beckman Coulter representative.
  - c. Run the control material one more time.
  - d. Run a different vial of control material.
  
4. If control sample results are outside the expected range limits because the *control vial was improperly stored*, what action should you take?
  - a. Run the control material several times until it is in control.
  - b. Identify the problem and correct it, or contact your Beckman Coulter representative.
  - c. Run the control material one more time.
  - d. Run a different vial of control material.

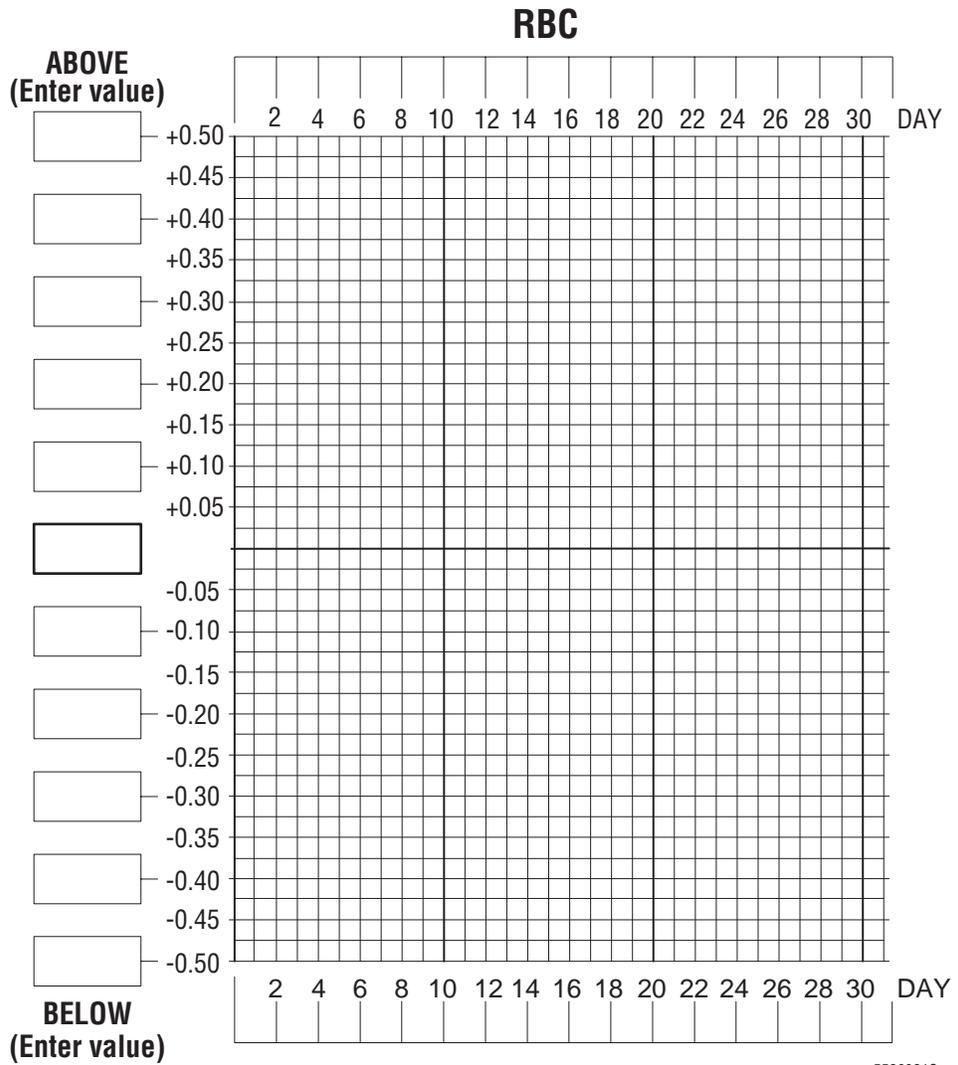
5. If control sample results are outside the expected range limits because of an *instrument problem*, what action should you take?
  - a. Run the control material several times until it is in control.
  - b. Identify the problem and correct it, or contact your Beckman Coulter representative.
  - c. Run the control material one more time.
  - d. Run a different vial of control material.

**Fill-in-the-Blank**

6. Precision and \_\_\_\_\_ have the same meaning.
7. You cannot have accuracy without \_\_\_\_\_.
8. \_\_\_\_\_ is defined as the number of cells remaining behind following the cycling of a blood sample.
9. Beckman Coulter's lab-to-lab comparison program is called \_\_\_\_\_.
10. You can adjust the accuracy of your instrument by going through a process called \_\_\_\_\_.



12. Plot the RBC values on the RBC graph, and write the values on the form.





**Figure A.2 Data Entry Sheet**

**4C®/4C® PLUS**  
CELL CONTROL

Abnormal Low   
Normal   
Abnormal High

**Marking Instructions**  
Please print clearly in BLOCK CAPITALS.  
Use blue/black ink.  
24.4  Correct Mark

**DAILY DATA ENTRY FORM**

Beckman Coulter logo

Institution \_\_\_\_\_  
City, State, Country \_\_\_\_\_  
Instrument \_\_\_\_\_  
SN: \_\_\_\_\_  
IQAP ID #: \_\_\_\_\_  
ICR identifier \_\_\_\_\_

CONTROL LOT NUMBER  SHIFT   
078200

DATE STARTED 05.04.1999  
Month Day Year

DATE COMPLETED 05.29.1999  
Month Day Year

REPORTING FORMAT  
 US  S13  
 S11  S14  
 S12  Japan

REAGENT SYSTEM  
 ISOTON® II  
 ISOTON® III / Pak / TANK®  
 ISOTON® 4  
 Other

Expected Results	9.1	4.19	12.8	36.8	87.8	30.5	34.8		
Month Day	WBC	RBC	Hgb	Hct	MCV	MCH	MCHC	RDW	
0504	9.0	4.29	12.7	37.9	88.3	29.6	33.5		
0505	8.9	4.18	12.6	37.1	88.7	30.2	34.1		
0506	8.6	4.01	12.3	35.5	88.7	30.6	34.5		
0507	9.0	4.08	12.6	36.1	88.5	30.9	34.9		
0508	9.1	4.08	12.6	36.3	88.9	30.8	34.7		
0511	9.0	4.15	12.7	37.0	89.1	30.6	34.4		
0512	9.3	4.03	12.2	35.5	88.0	30.4	34.5		
0513	8.9	3.93	12.1	35.0	89.0	30.8	34.5		
0514	9.0	3.87	11.9	34.4	88.9	30.6	34.5		
0515	8.8	4.00	12.3	35.5	88.7	30.9	34.8		
0518	9.1	3.92	12.1	34.8	88.8	30.8	34.7		
0519	9.2	4.03	12.3	35.6	88.3	30.5	34.5		
0520	9.0	4.06	12.3	36.1	88.8	30.2	34.0		
0521	8.7	3.97	12.2	35.3	88.8	30.7	34.5		
0522	8.9	3.96	12.1	35.2	88.8	30.5	34.4		
0525	9.1	3.97	12.1	35.3	88.9	30.5	34.3		
0526	9.3	4.01	12.2	35.5	88.6	30.4	34.3		

PAGE 01 OF 02 ElinView™ by MCS M121836-1 454321 Printed in U.S.A. 836611

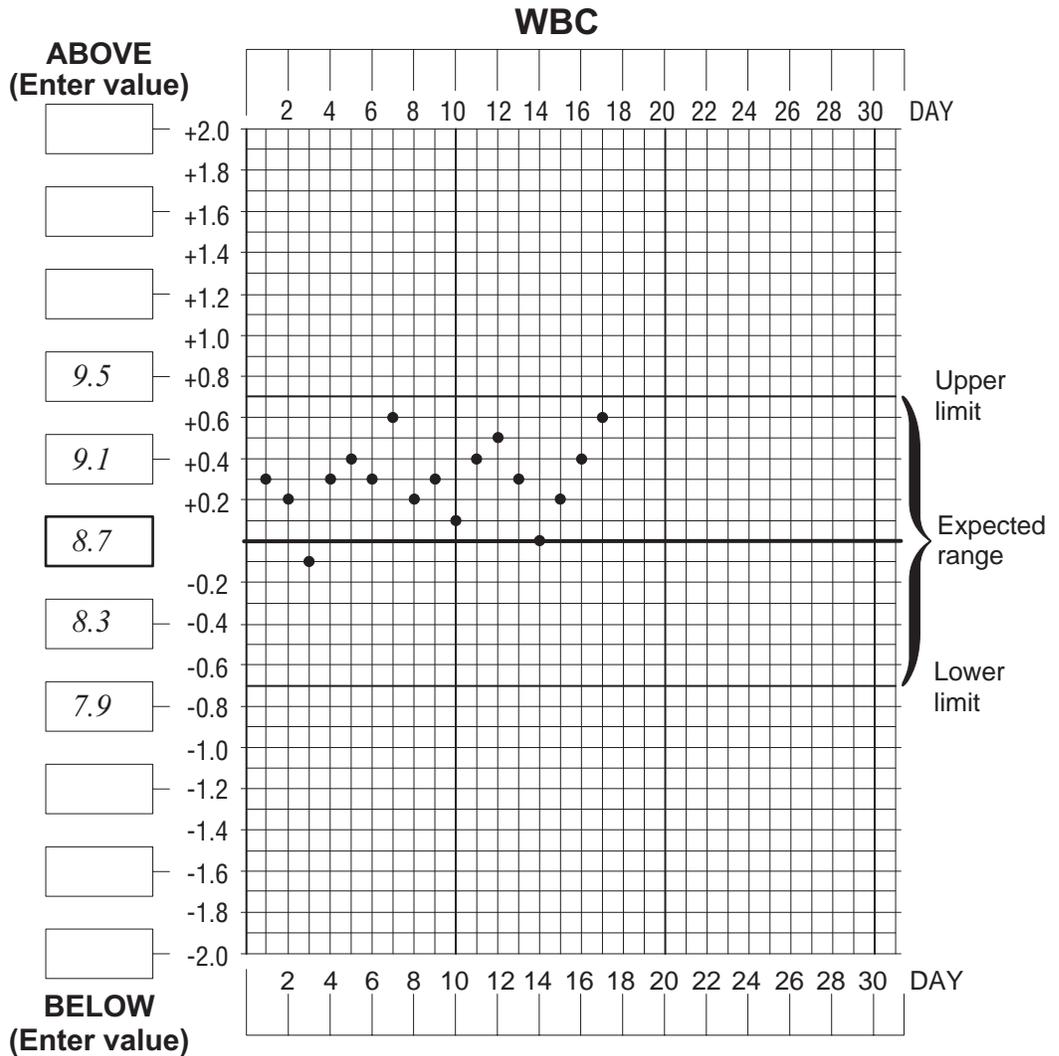
5526041C

Refer to the graphs you completed above to answer questions 13 through 16. Circle the correct answer(s) for each question. There may be more than one correct answer.

13. Which parameter has better precision?
  - a. RBC
  - b. WBC
  - c. Neither; both had bad precision.
  
14. The RBC graph illustrates which of the following?
  - a. A trend
  - b. Calibration required
  - c. Poor precision
  
15. The WBC graph illustrates which of the following?
  - a. A trend
  - b. Calibration required
  - c. A shift

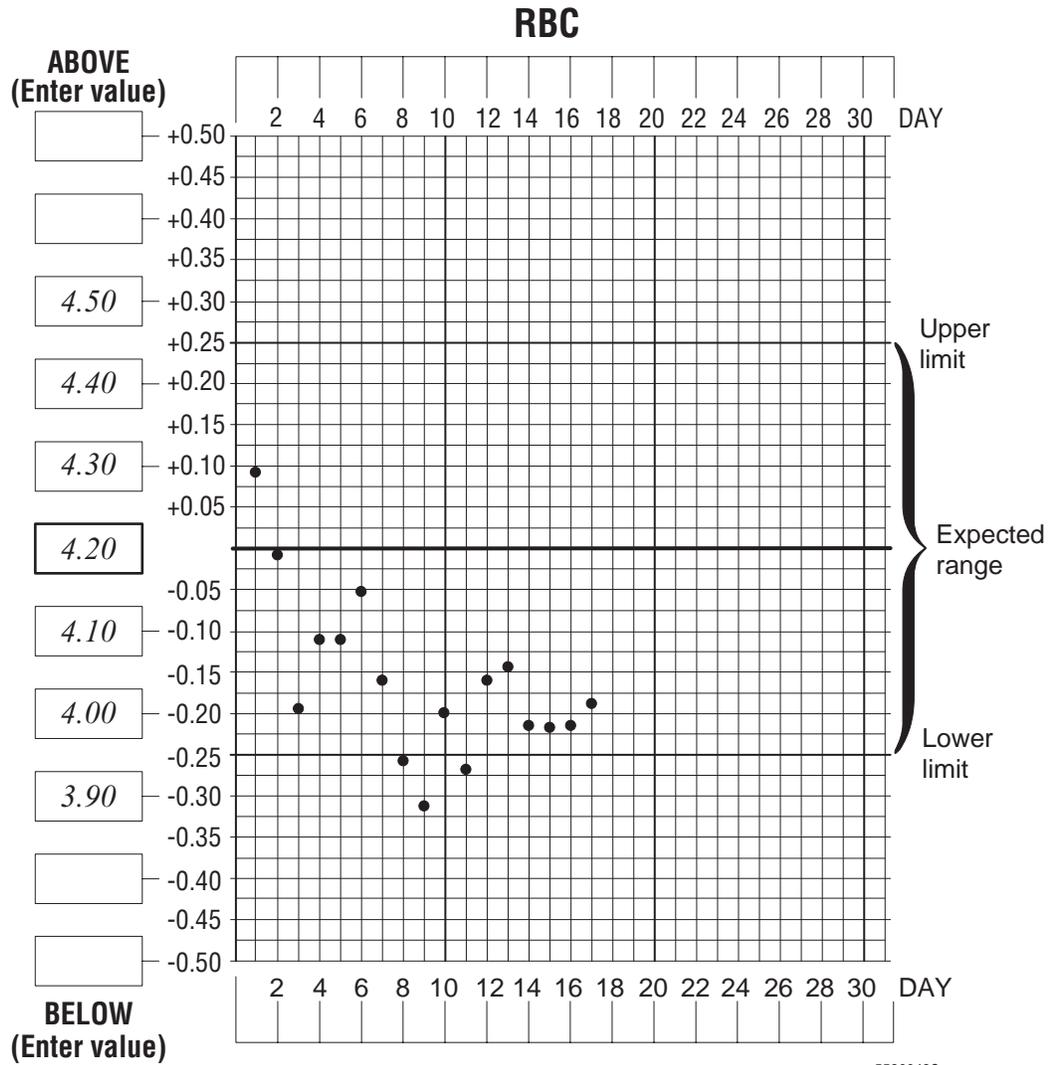
**A.3 ANSWER KEY**

1. *b, c*
2. *a, b, c, d*
3. *c*
4. *d*
5. *b*
6. *reproducibility*
7. *precision*
8. *carryover*
9. *IQAP (Interlaboratory Quality Assurance Program)*
10. *calibration*
- 11.



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12.



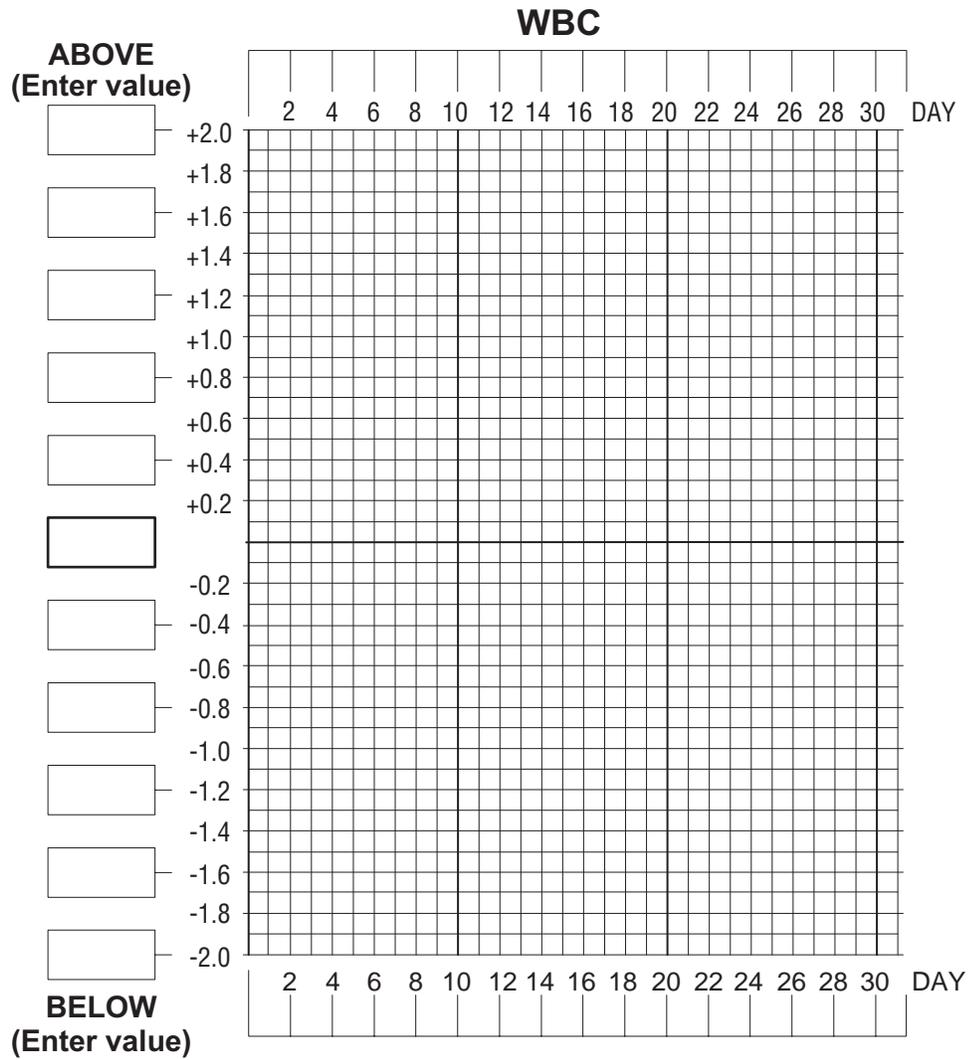
- 13. *b*
- 14. *a, c*
- 15. *a*

The following blank log sheets are available for your use:

- Figure B.1, White Blood Cell (WBC) Log Sheet
- Figure B.2, Red Blood Cell (RBC) Log Sheet
- Figure B.3, Hemoglobin (Hgb) Log Sheet
- Figure B.4, Mean Corpuscular Volume (MCV) Log Sheet
- Figure B.5, Platelet (PLT) Log Sheet
- Figure B.6, Lymphocyte Percent (LY%) Log Sheet
- Figure B.7, Lymphocyte Number (LY#) Log Sheet
- Figure B.8, Hematocrit (HCT) Log Sheet
- Figure B.9, Mean Corpuscular Hemoglobin (MCH) Log Sheet
- Figure B.10, Mean Corpuscular Hemoglobin Concentration (MCHC) Log Sheet

Photocopy these sheets as needed.

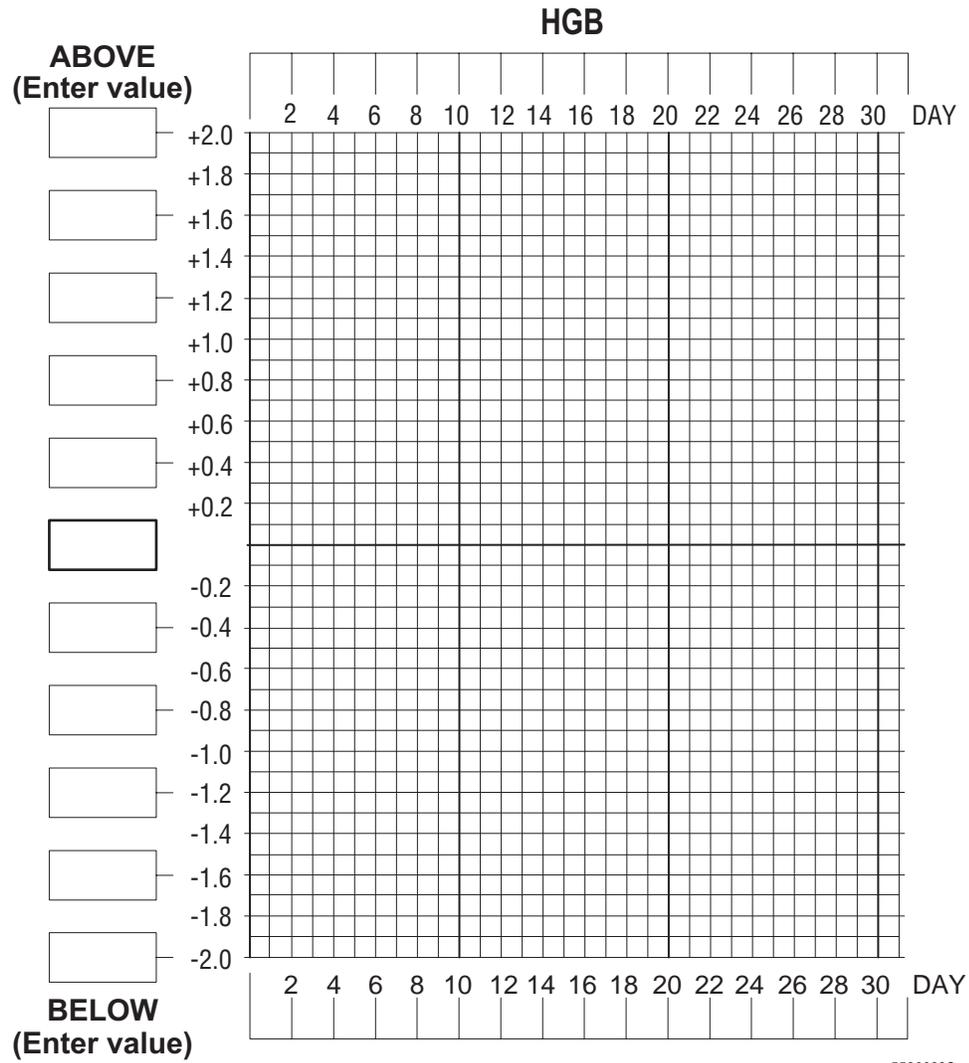
Figure B.1 White Blood Cell (WBC) Log Sheet



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Figure B.3 Hemoglobin (Hgb) Log Sheet



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Figure B.4 Mean Corpuscular Volume (MCV) Log Sheet

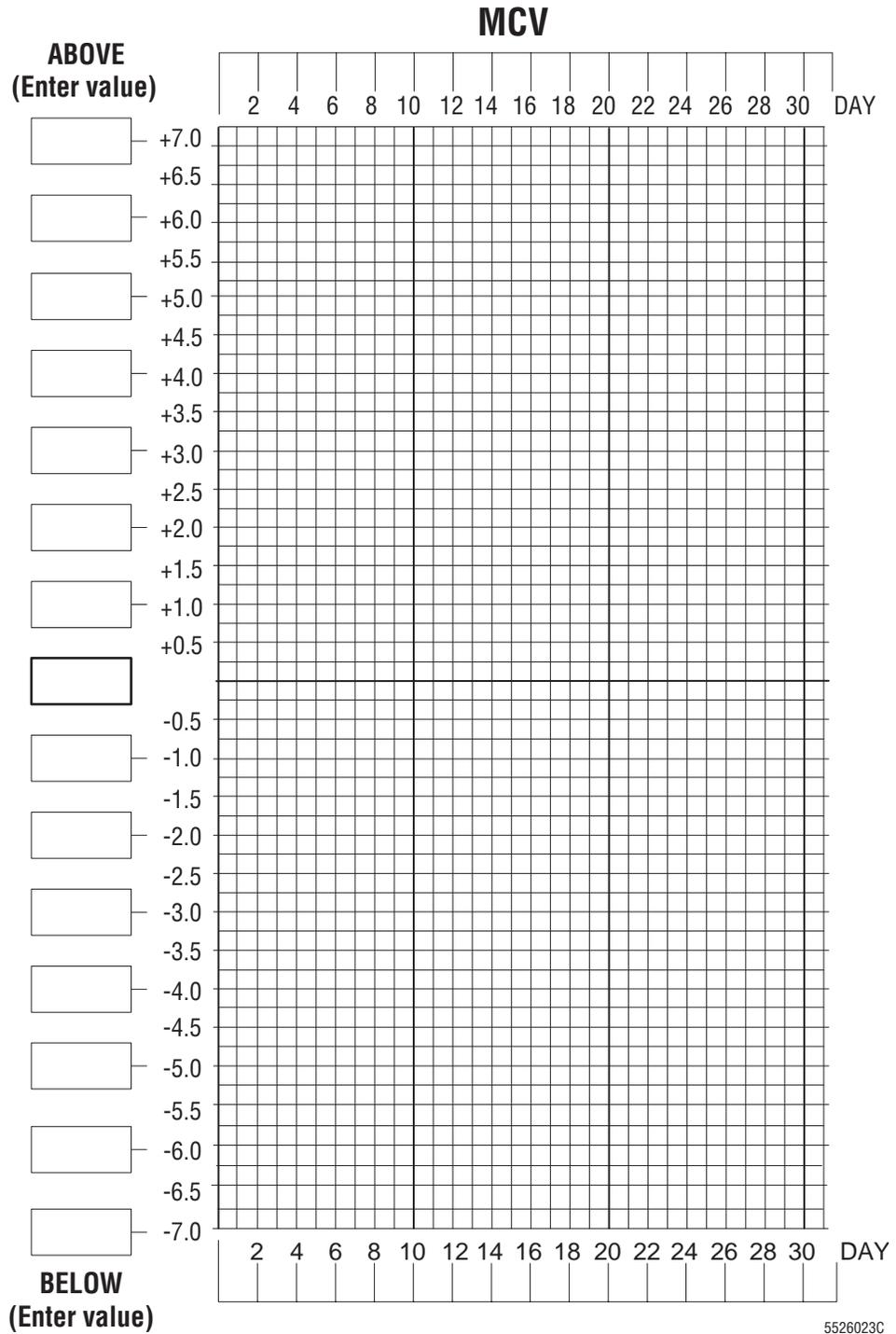
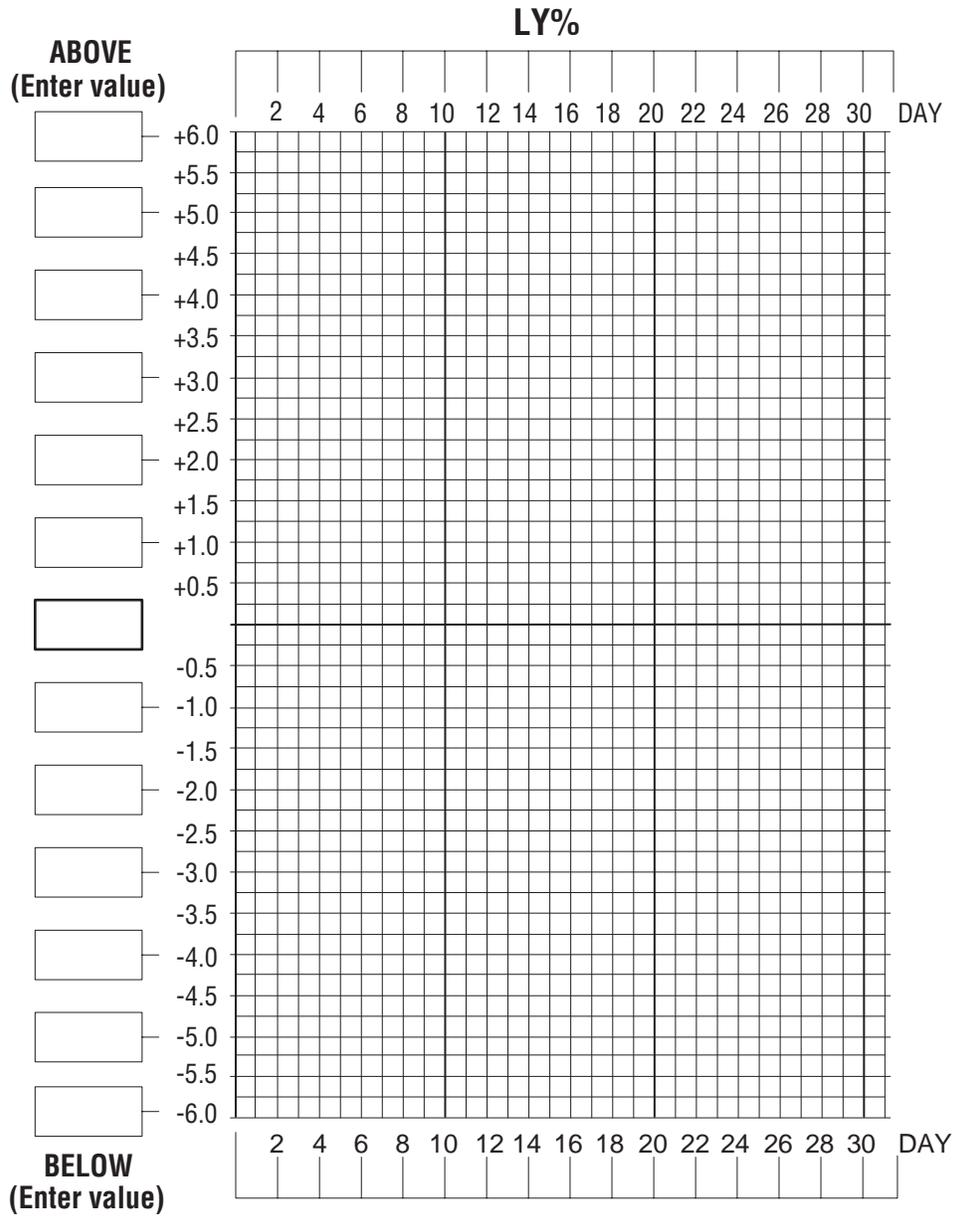




Figure B.6 Lymphocyte Percent (LY%) Log Sheet



5526025C

Figure B.7 Lymphocyte Number (LY#) Log Sheet

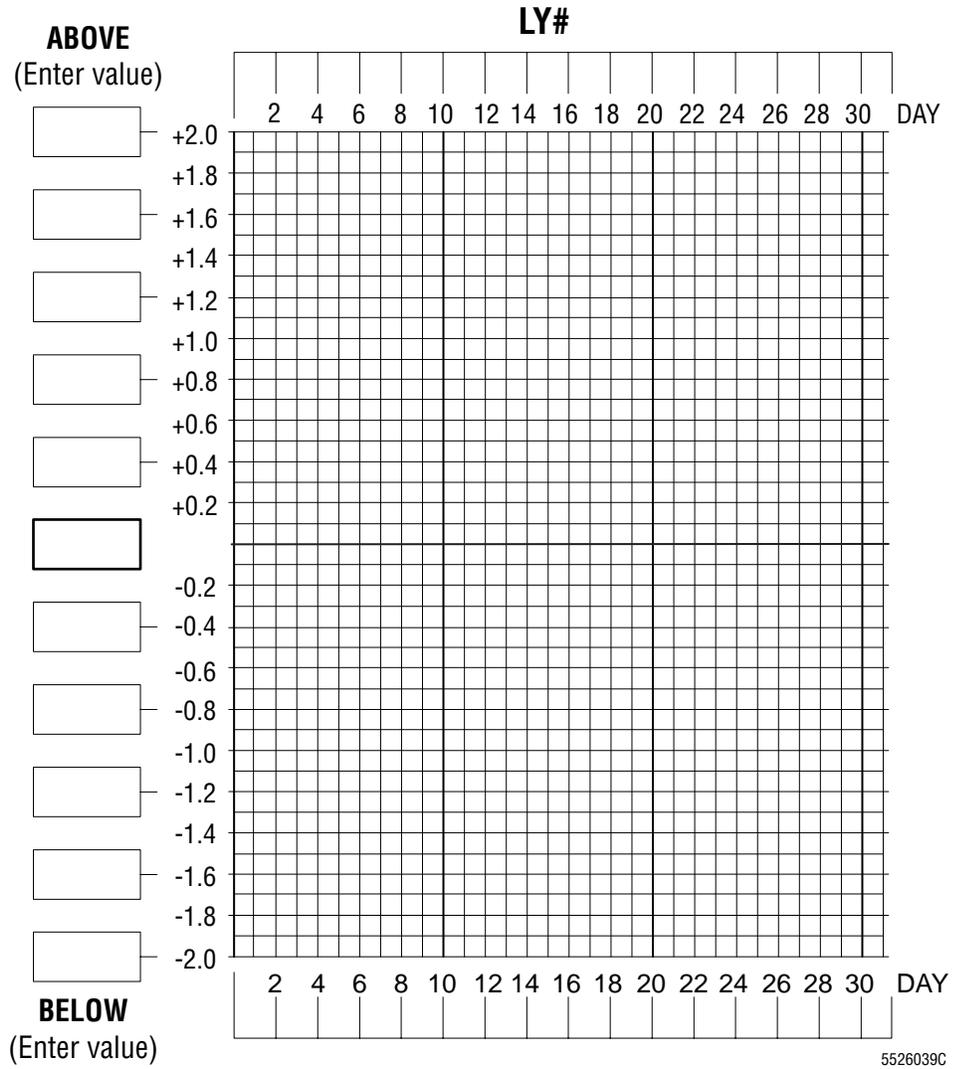
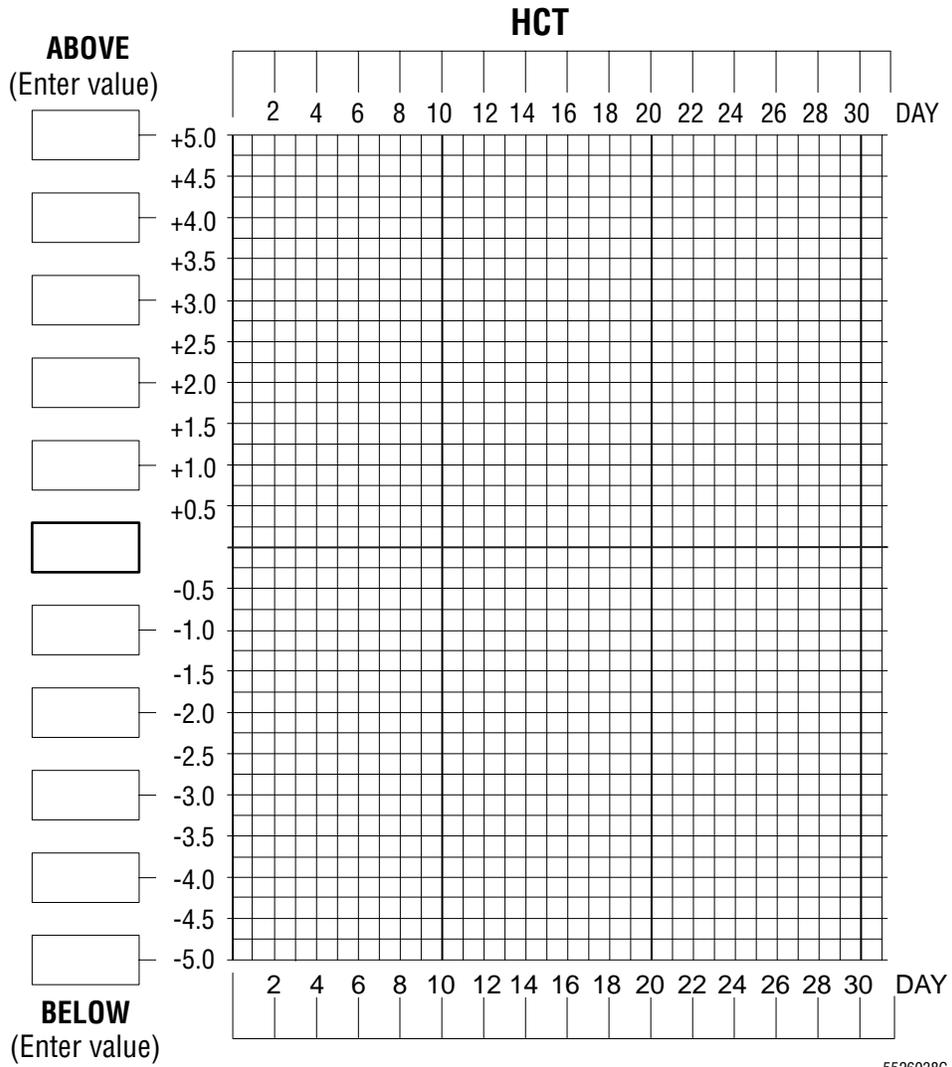


Figure B.8 Hematocrit (HCT) Log Sheet



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Figure B.9 Mean Corpuscular Hemoglobin (MCH) Log Sheet

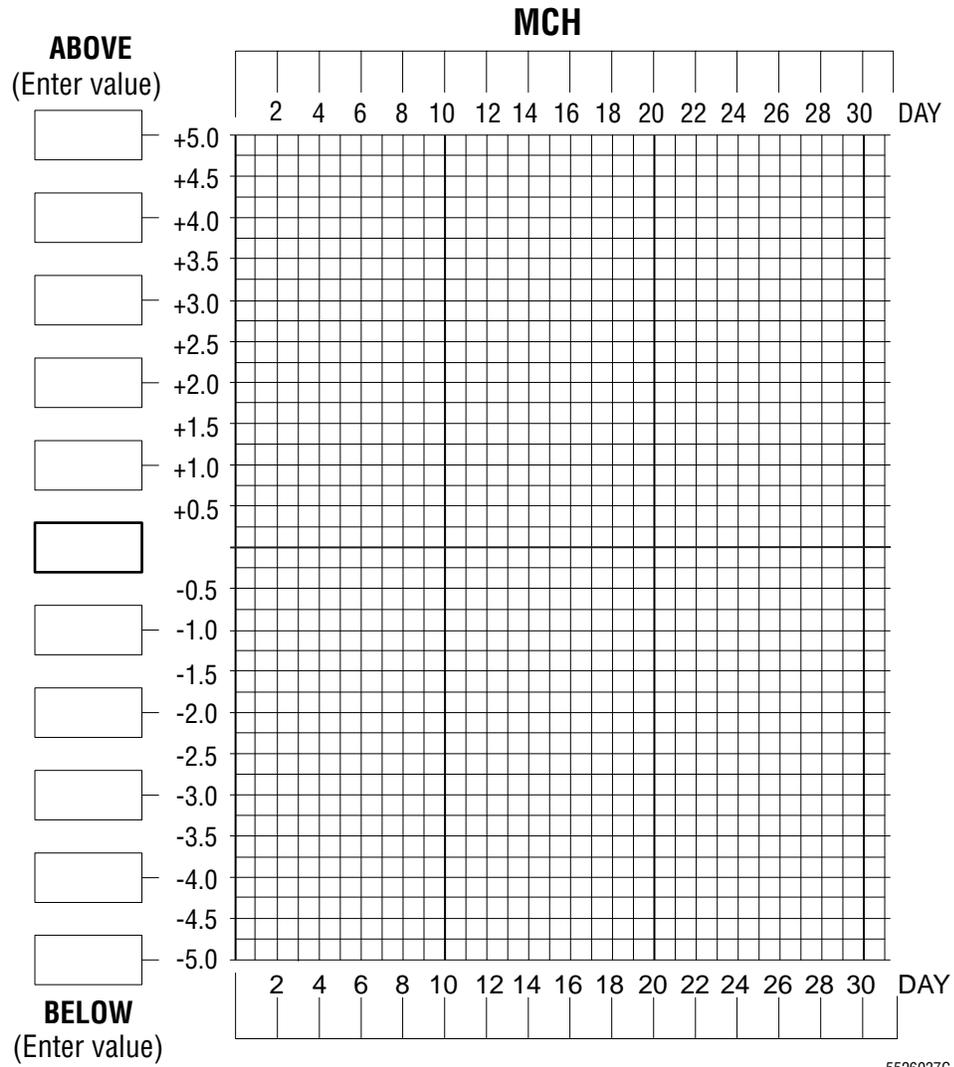
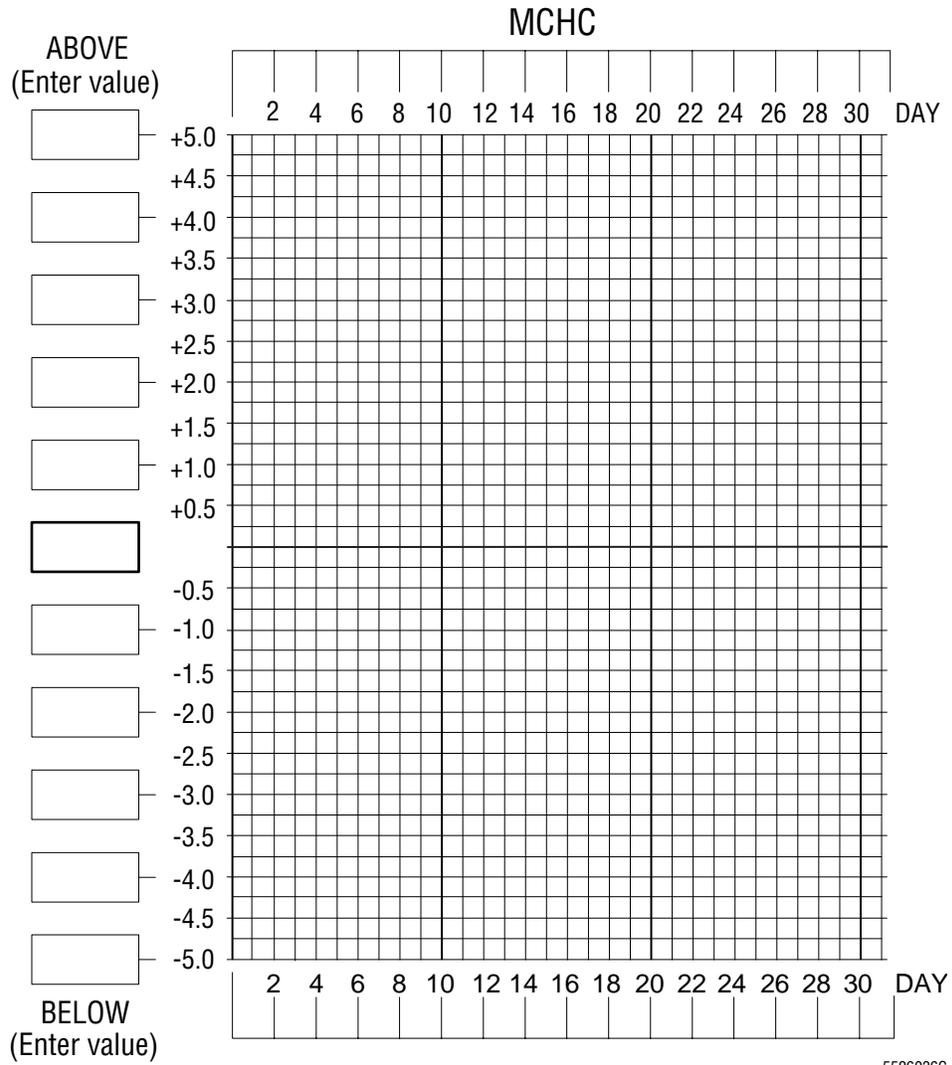
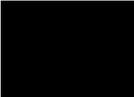


Figure B.10 Mean Corpuscular Hemoglobin Concentration (MCHC) Log Sheet



**BLANK LOG SHEETS**



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