Becton Dickinson

OPERATOR'S MANUAL

for the

Centrifugal Hematology System

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The QBC System is protected by U.S. Patent Numbers: 4,027,660; 4,082,085; 4,007,396; 4,159,896; 4,156,570; 4,091,659; 4,141,654; 4,137,755; 4,181,609; 4,209,226; 4,259,012; 4,190,328; as well as many foreign patents. Other patents pending.

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Section 1
INTRODUCTION

1.1 INTENDED USE

QBC® II Plus (Figure 1.1) is a hematology screening system for obtaining eight quantitative clinical values from a centrifuged tube of blood:

- Hematocrit (HCT)
- Platelet Count (PLT)
- White Blood Cell Count (WBC)
- Granulocyte Count (% and number)
- Lymphocyte-Monocyte Count (% and number) and
- Hemoglobin (HB).

Figure 1.1. QBC II Plus Centrifugal Hematology System.

The platelet and white blood cell counts and those of the granulocyte and lymphocyte/monocyte subpopulations are estimated counts derived from electro-optical measurements of the packed cell volumes in a specially-designed QBC blood tube. Some disease states are characterized by the presence of abnormal white cell types, which may yield normal quantitative relationships of granulocytes to lymphocytes/monocytes. The QBC II Plus system cannot discriminate between normal and abnormal cell types.

1.2 SUMMARY AND EXPLANATION

It has been known for many years that the thin grayish-white buffy coat in the hematocrit tube consists of packed leukocytes and platelets; and that platelets, being less dense, settle in a separate layer above the leukocytes (Figure 1.2).[1] In the 1930's Wintrobe[2] and Olef[3] described methods for estimating elevated white cell and platelet populations based on the milky appearance and thickness of the buffy coat. Quantitative measurements, however, proved difficult because of the very small size and non-homogeneity of the cell layers.

In later studies of cell density gradients, further subdivision or layering was found to occur between two subpopulations of leukocytes (see Figure 1.2) by virtue of their different specific gravities.[4,5,6] The upper layer was reported to contain predominantly lymphocytes and monocytes; the lower, predominantly the granulocytes, i.e., neutrophils (juvenile, segmented, band), eosinophils, and basophils.

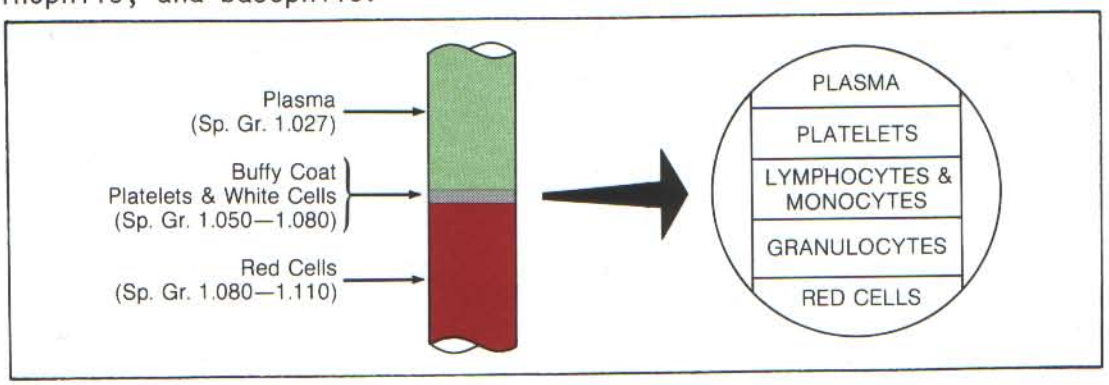


Figure 1.2. Section of Typical Spun Microhematocrit Tube, Showing Relative Densities and Layering of the Formed Elements.

Utilizing mechanical expansion and optical magnification, augmented by supravital cell staining, the QBC method derives a platelet count, white cell count, and counts of the two white-cell subgroups from linear measurements of the packed cell layers in the buffy coat.[13] As in conventional micro-centrifugation procedures, the hematocrit or PCV is also measured.

Expansion of the buffy layer is achieved by means of a precision-molded cylindrical float, inserted into a precision-bore QBC blood tube before centrifugation. Specific gravity of the float is approximately midway between that of the plasma and red cells, causing part of the float to settle in the buffy coat. Expanded layers of packed white cells and platelets are thereby formed in the annulus between the float and inner wall of the blood tube.

The QBC blood tube is internally coated with the supravital fluorochrome Acridine Orange (AO). Diamidines such as AO have long been employed in cytologic labeling and clinical diagnostics because of their uptake by cellular nucleo-proteins and by glycosamines in the granulocytic series. Under excitation by blue-violet light the cells differentially fluoresce. Histochemical studies of AO-treated blood by Jackson,[7] for example, confirmed that the granulocytic cells fluoresce orange-yellow; lymphocytes and monocytes, a brilliant green; and platelets, a pale yellow. Erythrocytes, however, are unaffected by AO and exhibit their normal dark red appearance.

The depth that the float sinks in the packed red blood cells when the QBC Tube is centrifuged is a function of red cell density. The lower the red cell density, the more the float will descend into the red cell layer.

Since the primary determinant of red cell density is cellular hemoglobin concentration, the correlation of float depth with hemoglobin concentration is highly significant. This relationship readily allows the hemoglobin concentration to be calculated from measurements of the float depth and the Hematocrit.

The CBC or complete blood count is perhaps the most frequently requested and clinically useful test performed on blood. QBC II Plus provides the physician with CBC-type information within approximately 7 minutes of blood collection. It also enables the physician to quickly identify specimens which have normal or abnormal quantitative relationships of granulocytes to lymphocytes/monocytes and thus to detect specimens which require further investigation and testing.

1.3 PRINCIPLES OF THE PROCEDURE

Two different types of precision bore, 75 mm glass tubes are utilized for QBC tests: one type for venous blood and a different type for capillary blood. The Venous-Blood Tube (Figure 1.3) incorporates a black calibration line and is normally filled by means of the semi-automatic QBC Pipetter supplied with the System. Filled volume is 111.1 µL.

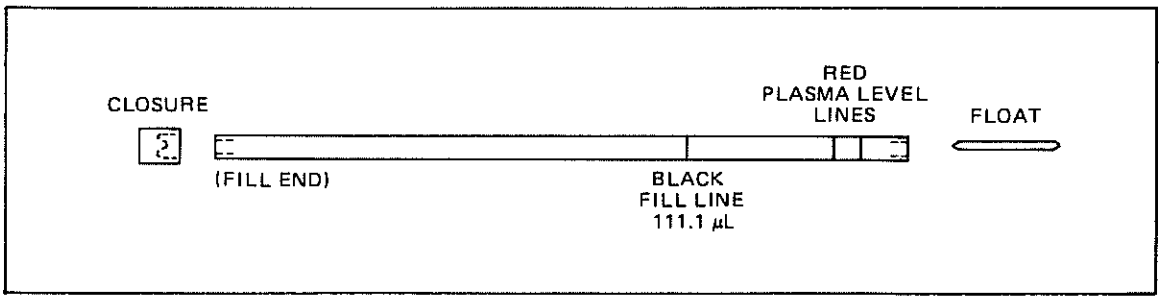


Figure 1.3. QBC Tube for Venous Blood.

To simplify blood collection from a finger puncture, the QBC Capillary-Blood Tube (Figure 1.4) is provided with 55 µL and 65 µL black fill lines. The tube is filled by capillary action to any level between the two lines. As subsequently described, the exact fill volume is measured during the tube reading procedure.

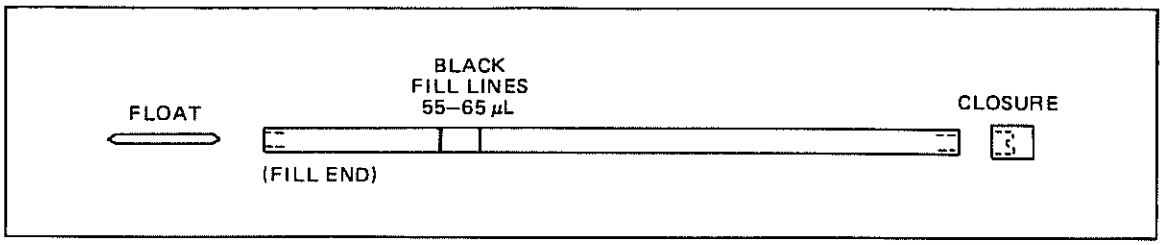


Figure 1.4. QBC Tube for Capillary Blood.

Both types of QBC tubes are internally coated with Acridine Orange and Potassium Oxalate. The former, a supravital fluorochrome, stains the white cells and platelets as previously described. The Potassium Oxalate osmotically removes water from the erythrocytes, causing their density to increase and their volume to shrink. This tends to prevent commingling of certain equal-density erythrocytes and leukocytes at the interfacing boundary between these cell layers.

QBC Capillary-Blood Tubes additionally contain a coating of sodium heparin and di-potassium EDTA to inhibit the clotting of finger-puncture blood.

Each QBC tube is supplied with a plastic closure and float (see Figures 1.3 and 1.4). The float, whose density approximates that of the white cells and platelets, is inserted into the sealed, filled tube immediately prior to high speed centrifugation. Under centrifugal force, the float settles into the buffy coat where it axially expands the formed cell layers by a factor of 10. Part of the float also descends into the red cells (to a variable depth), similarly expanding the upper portion of the packed erythrocyte column and forming a visibly lighter band of red cells surrounding the bottom portion of the float.

Two red plasma-level lines are printed on QBC Venous-Blood Tubes (see Figure 1.3) for checking fill volume in the blood tube prior to testing. Because of the specimen volume displaced by the float, the plasma level must rise between the two red lines after centrifugation. If the plasma is above or below the red lines, the blood tube must be discarded and a new tube prepared.

Layer lengths (packed cell volumes) are measured in the QBC II Plus Reader. A "MODE" button is provided to program the Reader for Venous-Blood Tubes or Capillary-Blood Tubes. By means of an external knob on the side of the Reader, the operator can control the axial position of the tube under a viewing microscope. The tube is "read" by sequentially aligning each interface (starting at the bottom of the red cell column or zero position) with a stationary reticle arrow or cursor within the optical system. The length or thickness of each cell layer is fed into a microcomputer by pressing an "ENTER" button each time an interface is aligned with the cursor. Values for HCT, PLT, WBC, GRANS, and LYMPH/MONO, are displayed on the front panel of the Reader after the last interface has been entered.

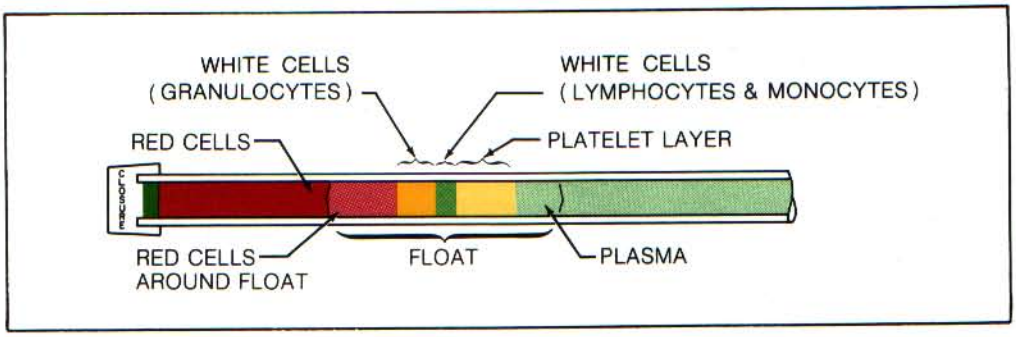


Figure 1.5. Color-Separated Cell Layers in the Spun QBC Blood Tube.

A total of six (6) interfaces in venous-blood tubes and seven (7) interfaces in capillary-blood tubes must be located and entered. In capillary-blood tubes, the length of the plasma column or 7th interface reading is measured in order to determine total fill volume. The latter measurement is utilized by the Reader in computing the capillary-blood hematology parameters.

Hemoglobin concentration is displayed in the "HB(g/dL)" panel readout by pressing the "MODE" button twice while the primary hematology values are on display.

1.4 WARNINGS AND PRECAUTIONS

The QBC II Plus system is intended for In Vitro Diagnostic Use.

Carefully observe all warnings and precautions in this Manual and on labeling accompanying QBC Blood Tubes concerning the safe handling of blood specimens and blood tubes. The use of protective laboratory gloves when handling blood is strongly recommended.

> WARNING
> BLOOD SPECIMENS MAY CONTAIN THE HEPATITIS B VIRUS OR HUMAN IMMUNODEFICIENCY VIRUS (HIV). ALWAYS HANDLE BLOOD SPECIMENS AND BLOOD-DERIVED CONTROLS AS POTENTIAL BIOHAZARDS CAPABLE OF TRANSMITTING INFECTION.

Exercise care when using QBC Tubes. Tubes are made of glass and may break.

SECTION 2
INSTALLATION PROCEDURES AND SPECIAL REQUIREMENTS

This Section summarizes instructions for installation, assembly and pre-test preparation of the QBC II Plus System.

NOTE: In the United States, installation of the System will normally be performed by a Becton Dickinson representative. To arrange for installation service or to obtain technical assistance, call the Technical Service Department of Becton Dickinson Primary Care Diagnostics: 1-800-631-8064. Outside the United States, contact your QBC distributor or nearest Becton Dickinson office.

2.1 SYSTEMS AND PACKAGING DETAILS

QBC II Plus Systems are available in 120 volt/60 Hz power ratings as follows:

System No. (for use in)	Reader Model No.	QBC Centrifuge Model No.
4451 (United States)	4452	4207
4450 (International)	4452	4207

The 4451 and 4450 Systems differ only in packaging and minor accessories. The QBC II Plus Reader is equipped with circuitry and a communications port for operation with an Epson printer (see Section 2.2.3).

The following accessories are packaged with the QBC II Plus Reader in addition to this Manual:

- QBC Venous-Blood Pipetter, including spare O-Rings and grease;
- Spare Parts and Accessories Kit containing the following items: Venous and Capillary Calibration Check Tubes; spare lamps, spare fuses; forceps for handling loose floats;
- Countertop Test Guide and Wall Chart; and
- Dust Cover.

A complete re-order list of components, accessories, test disposables and spare parts for the QBC II Plus System is provided in Appendix C of this Manual. For Warranty information, see Appendix D.

2.2 INSTALLATION REQUIREMENTS

2.2.1 Laboratory Environment

Locate the Reader, Centrifuge and test accessories of the QBC II Plus System on a level countertop surface in a clean, dust-free laboratory area. Keep all components of the System out of direct sunlight.

The operating area should be as free as possible from excessive electrical interference from solid state speed-controlled centrifuges, ultrasonic cleaners, diathermy equipment, and data processors, including computers and data terminals.

IMPORTANT: For optimum test results, ambient room temperature must be maintained between 68° and 90°F (20° and 32°C). See Section 7 for instructions on special temperature requirements of QBC hematology tests.

2.2.2 Power Requirements

Plug the power cords of the QBC II Plus Reader and QBC Centrifuge into grounded electrical receptacles rated for the line voltage and frequency specified on their respective data plates.

> CAUTION
> Connect power cords only to 3-wire grounded receptacles delivering the voltage and frequency specified on the data plate on the back of each instrument. When only a 2-wire receptacle is available, have it replaced with a properly grounded 3-wire receptacle by a qualified serviceman and in accordance with the National Electrical Code. Do not remove the grounding prong from the power cord. If an extension cord is required, use only a 3-wire grounded cord having the proper voltage and current rating.

For proper functioning of the QBC II Plus Reader and QBC Centrifuge, voltage output of the power source must be between 105 and 130 volts. If the line voltage is known to fluctuate outside these limits, notify the Installer. The use of a special voltage regulator may be required.

2.2.3 Printer Utilization

A Becton Dickinson Catalog No. 4482 Printer Package <u>or equivalent components</u> are required for automatic recording of QBC II Plus test results on pressure-sensitive labels. The Printer Package contains an Epson LX-series Printer, Printing Labels, Epson Manual, and a Reader-to-Printer Cable Assembly.

Note: An Epson LX-series Printer can be purchased locally; however, the special Reader-to-Printer Ribbon Cable Assembly (Catalog No. 4407) is required and must be ordered separately from Becton Dickinson via your local distributor.

a. <u>Connecting Reader-to-Printer Cable</u>

To install the special Ribbon Cable Assembly supplied in the Catalog No. 4482 Printer Package (or ordered separately under Catalog No. 4407), refer to Figure 2.1 and perform the following:

1) Insert the 25-pin plug of the Ribbon Cable Assembly into the "PRINTER" connector in the back panel of the Reader.
2) Secure the plug to the connector by manually tightening the knurled Captive Screws to the Jacksockets of the connector. Note: the Captive Screws are slotted and can be tightened with a screwdriver.
3) Connect the unattached connector of the Ribbon Cable to the plug on the Epson Printer as described in Epson's operating manual.

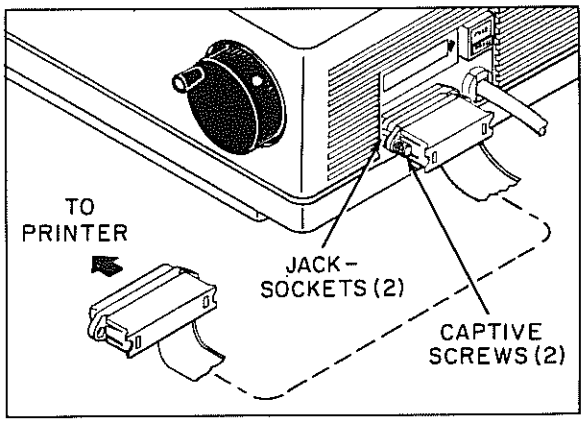


Figure 2.1. Ribbon Cable Connection From Reader to Printer.

b. Printer and Electrical Ratings

Interface circuitry and control codes in the QBC II Plus Reader are compatible only with Epson LX-series Printers. Do NOT attempt to connect any other printer.

If an Epson LX-series Printer is purchased locally, be sure the electrical rating of the Printer is compatible with the electrical rating of the Reader.

c. Operating Instructions

See Appendix B for operating details with a Reader-Printer system. Instructions for operating the Epson printer are provided in the manufacturer's handbook.

2.3 ASSEMBLY OF CENTRIFUGE ROTOR

The rotor of the QBC Centrifuge must be assembled onto the motor shaft of the instrument before use. Complete instructions are contained in the Operator's Manual supplied with the Centrifuge.

2.4 CALIBRATION CHECK TUBES

2.4.1 Description and Use

Two Calibration Check Tubes - one for Venous Mode and one for Capillary Mode - are included in the Spare Parts and Accessories Kit supplied with the QBC II Plus Reader. Each Check Tube consists of a 75 mm glass capillary tube containing alternating black and white segments of plastic in a stable liquid medium. Both ends are internally sealed to prevent fluid leakage; one end is capped with a standard QBC tube closure. When inserted in the Reader the white plastic segments fluoresce a pale green. Note: The Check Tubes are not designed to duplicate the color or appearance of cell layers in blood-filled QBC tubes.

The Check Tubes are provided to verify acceptable performance of the Reader prior to hematology tests of patient samples. Procedures for daily use of the Check Tubes are described in Section 4.6.1.

2.4.2 Determining and Recording Calibration Tolerances

Upon installation of the QBC II Plus Reader, tolerances for each Check Tube must be determined and recorded on the Package Insert within each Check Tube vial. The recorded tolerance values are then used in the daily performance checks of the Reader (see Section 4.6.1).

Detailed procedures for determining calibration tolerance values are described in the Package Insert within the Check Tube vials. The procedures should normally be performed by the primary operator of the Reader after suitable training and under the guidance of the Becton Dickinson Installer. New calibration tolerance values should always be established when there is a change in operators.

IMPORTANT: The Hemoglobin (HB) value obtained from reading the Calibration Check Tubes may flash on and off due to a software program in the Reader, which is designed to detect red-cell abnormalities in whole blood. Flashing HB values, however, should always be used when calculating the mean check values for hemoglobin as described in the direction inserts packaged with the Calibration Check Tubes.

Section 3
PRINCIPLES OF OPERATION AND SPECIFICATIONS

3.1 SYSTEM COMPONENTS

As previously described, the QBC II Plus System consists of an electro-optical Reader and a high speed QBC Centrifuge for producing packed, differentiated cell layers. Standard accessories include a Work Station and Venous-Blood Pipetter. Each of the above components is described in subsequent paragraphs of this Section.

3.2 QBC II PLUS READER

The QBC II Plus Reader (Figure 3.1) is a microprocessor-controlled electro-optical instrument for measuring packed cell volumes and converting these measurements into the hematocrit, blood cell counts, and hemoglobin.

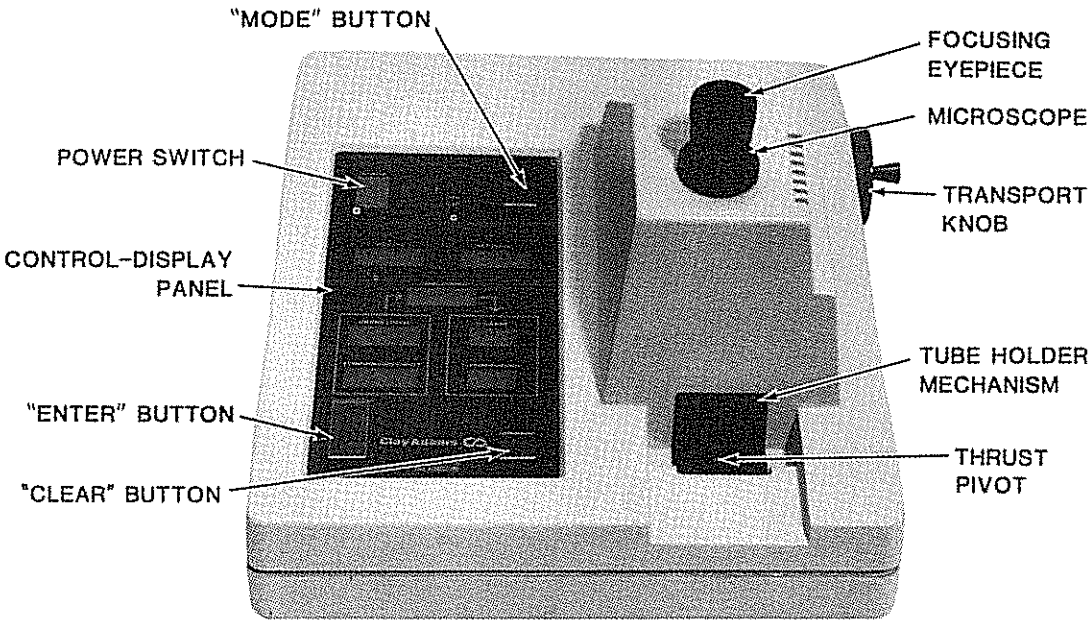


Figure 3.1. External Features of QBC II Plus Reader.

Major functional sections of the Reader are the mechanical-optical system and interconnecting microprocessor electronics system for mode selection, data input, information processing, and readout display.

3.2.1 Mechanical-Optical System

Mechanical and optical components of the QBC II Plus Reader are shown in Figures 3.2 and 3.3.

A centrifuged QBC blood tube is inserted into the Tube Carriage Mechanism and viewed through the Microscope as the tube is rotated about its longitudinal axis at approximately 1400 rpm. Rotational movement is imparted to the tube by a motor-driven roller within the Carriage Assembly. The Carriage Assembly can be moved axially, in and out, along a threaded shaft (lead screw) and guide rod. By means of miter gears linked to the external Transport Knob, the threaded shaft can be turned to move the complete Carriage Assembly and rotating blood tube under the Microscope lens. As the blood tube is moved, a position transducer (optical encoder) transmits electrical pulses proportional to the axial distance that the blood tube is moved.

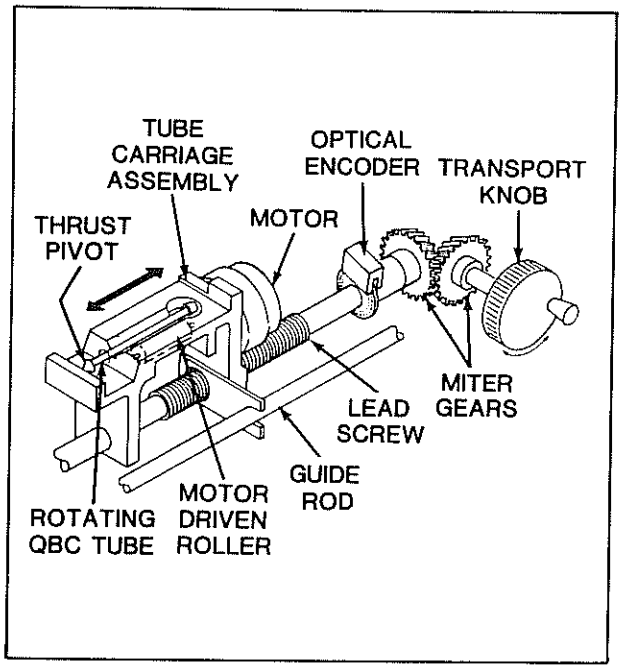


Figure 3.2.
Tube Reader Mechanical System

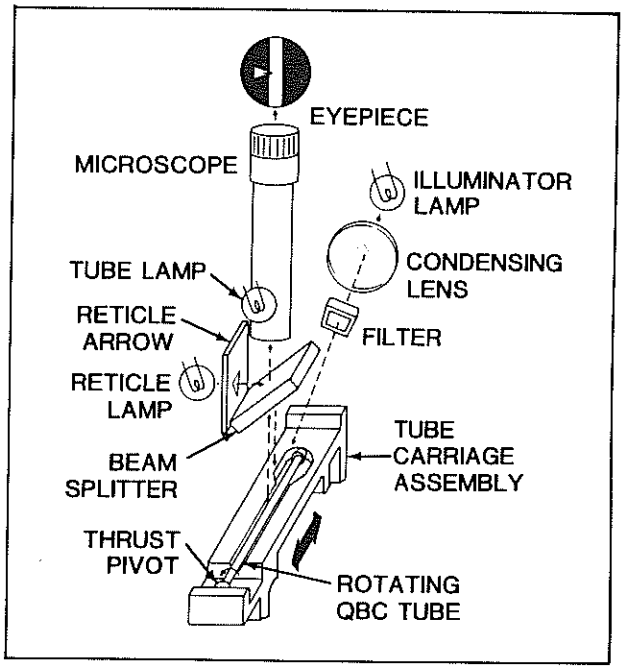


Figure 3.3.
Tube Reader Optical System.

An illuminator lamp, through a lens and filter system, continuously radiates blue-violet light at an excitation wavelength sufficient to cause the stained white cells and platelets to fluoresce. A barrier filter within the microscope effectively blocks the transmission of blue-violet from the viewer's eye. Momentary white light from a Tube Lamp illuminates the interface between the dark and light layers of red cells (2nd interface).

By causing the blood tube to rotate around its longitudinal centerline, cell layer boundaries are viewed around their entire perimeters, thereby optically averaging irregularities at their interfaces.

A stationary, back-lighted reticle arrow or cursor (see Figures 3.3 and 3.4) is provided in the optics for aligning and "reading" interfaces in the rotating blood tube. Starting at the first or I_1 interface (at the closure-to-bottom of the dark red cell layer), lengths of the five packed cell columns (and plasma column in Capillary Tubes) are measured. See Figures 3.5 and 3.6.

Figure 3.4. Reticle Arrow and QBC Tube Viewed Through Microscope of Reader.

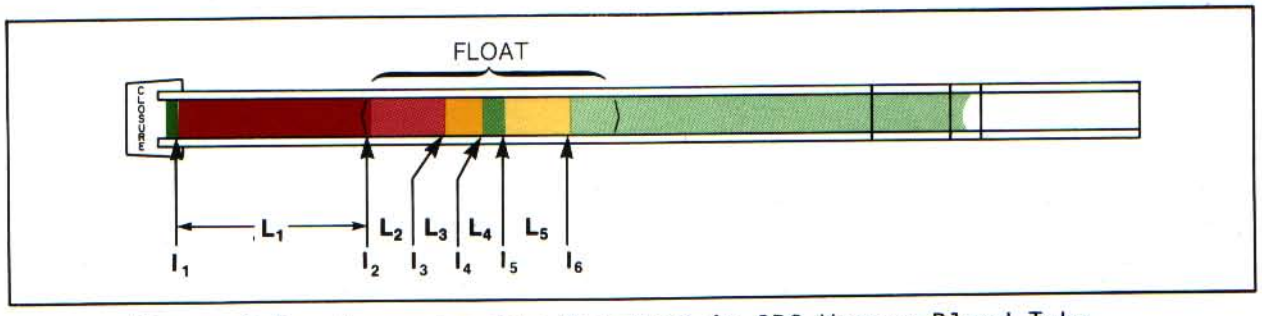


Figure 3.5. Layer Lengths Measured in QBC Venous-Blood Tube.

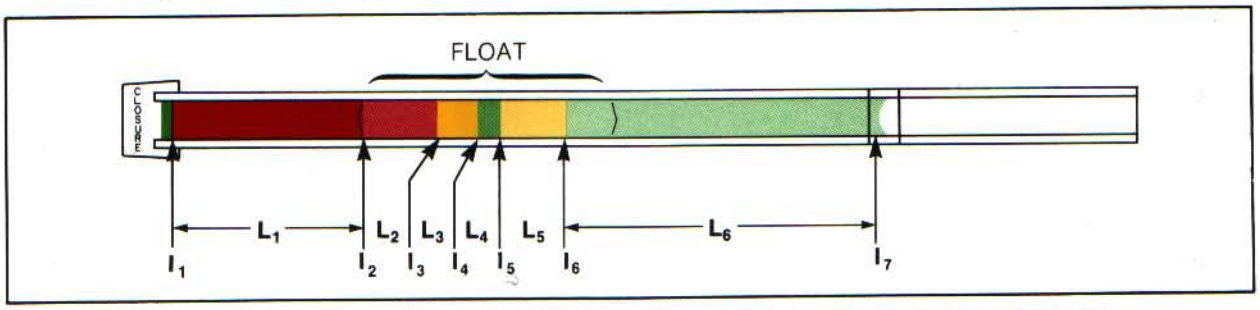


Figure 3.6. Layer Lengths Measured in QBC Capillary-Blood Tube.

As each interface is aligned with the reticle arrow, an "ENTER" button (see Figure 3.1) on the Control Panel is pressed. Electrical pulses generated by rotational movement of the optical encoder are fed to a pulse counter and processed by the microcomputer, which computes values for the hematology parameters from lengths of the measured cell layers (and plasma column in QBC Capillary-Blood Tubes). The lengths are also used to compute hemoglobin concentration based on a computer-stored algorithm.

3.2.2 Microprocessor-Electronics System

The microprocessor-electronics system includes the incremental position encoder, mounted on the threaded shaft or lead screw (see Figure 3.2). The encoder produces 2-phase electrical pulses proportional to the axial distance the blood tube is moved. An up/down counter converts the output pulses to a count proportional to the length of the cell layer being measured. Fixed and programmable constants are utilized by the computer in calculating the cell counts. The "ENTER" button controls operation of the counter and computer. Except for the first interface, each time "ENTER" is pressed, it signals the end of one layer measurement and the beginning of the next. After the final interface is read, the computer displays the test results. Hemoglobin is then displayed by pressing the MODE button twice within 2 seconds. Pressing "ENTER", at the 1st interface of the next blood tube, automatically clears the display and resets the Reader.

The microprocessor monitors the position ("VEN" or "CAP") of the MODE button and selects the correct program for computing test values from measurements of venous-blood or capillary-blood tube. QBC hematology parameters are functions of the following linear measurements (see Figure 3.5):

- Hematocrit: L_1 and L_2
- WBC: L_3 and L_4
- GRANS: L_3
- LYMPH/MONO: L_4
- Platelet Count: L_5
- Hemoglobin: Derived from L_1, L_2, L_3, L_4 and L_5

Stored constants utilized in the computation of hematocrit correct for: shrinkage of the red cells due to potassium oxalate; volumetric expansion of the packed cells by the float, and float and closure geometry. Mean cell volumes and float expansion factors are applied in the WBC and Platelet Count computations. Hemoglobin is derived from an algorithm based on the hematocrit (L_1 and L_2) and the lengths of the packed white-cell and platelet layers (L_3, L_4 and L_5).

The derivation of test values from QBC Capillary-Blood Tubes utilizes the same length measurements described above but different calculation functions based on length of the plasma column L_6 (see Figure 3.6).

The microprocessor also controls the readout displays, internal auxiliary light, and error detection systems. The latter systems actuate service and procedure alert "flags", which are displayed when an irregular condition is detected in the computer memory or in the tube-reading procedure. For a discussion of service and alert flags, see Sections 4.1 and 4.3.3.

3.2.3 Control-Display Panel

The control-display panel of the Reader (Figure 3.7) incorporates the following switch buttons:

- POWER: Energizes the Reader and initiates an automatic self-test sequence of lamps and microprocessor (see Section 4.1). Illuminated green when ON.
- MODE: <u>IN position</u> - activates the "VEN" mode indicator light and programs the Reader for venous blood tests. <u>OUT position</u> - activates the "CAP" mode indicator light and programs the Reader for capillary blood tests. Also activates a display of the Hemoglobin value.
- ENTER: Supplies data to the computer, locating the beginning and end of each packed cell layer.
- CLEAR: Erases test values from the displays, initiates a self-test sequence, and resets the Reader for a new test.

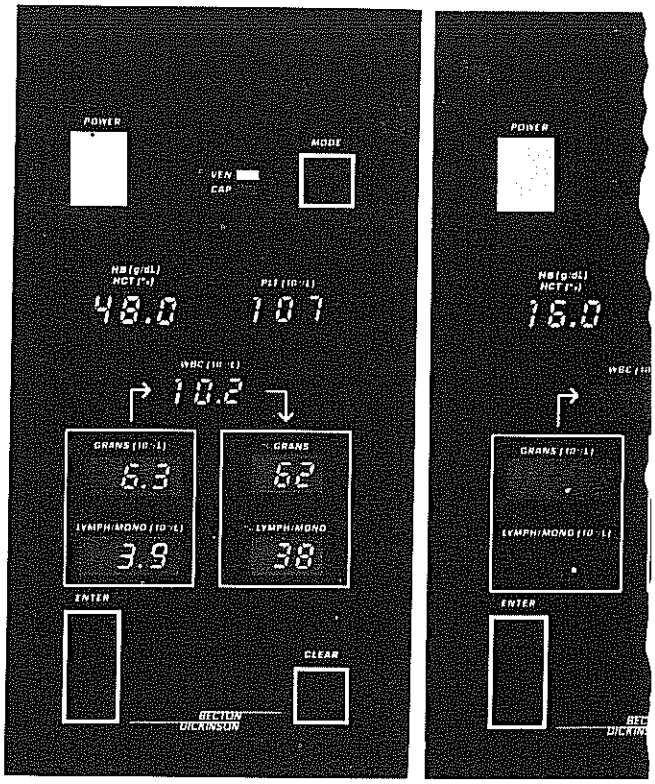


Figure 3.7. Control-Display Panel of QBC II Plus Reader.

The seven panel readouts will display test values momentarily after pressing "ENTER" at the final interface; the hemoglobin result is displayed by pressing the "MODE" button twice. Units and digit-decimal format of QBC II Plus test parameters are as follows:

• HCT (%)	XX.X	• GRANS (10^9/L)	XX.X
• HB (g/dL)	XX.X	• LYMPH/MONO (10^9/L)	XX.X
• PLT (10^9/L)	XXX	• GRANS (%)	XX
• WBC (10^9/L)	XX.X	• LYMPH/MONO (%)	XX

Upon detection by the microprocessor of an irregularity in the tube reading procedure, an alpha-numeric message will flash in the appropriate readout to alert the operator of an error condition. (See discussion in Section 4.3.3.)

3.3 QBC CENTRIFUGE

The QBC Centrifuge (Figure 3.8) is a high-speed instrument, specifically designed to meet the cell packing requirements of the QBC test methodology. Up to 12 blood tubes can be spun simultaneously at a nominal speed of 12,000 RPM and relative centrifugal force of approximately 14,387 x g. Spin time is fixed at 5 minutes.

A detailed description of the QBC Centrifuge, including set-up and operating instructions, is contained in the separate Operator's Manual shipped with the Centrifuge.

Figure 3.8. QBC Centrifuge.

3.4 WORK STATION

The QBC Work Station (Figure 3.9) is a convenient test accessory to facilitate the preparation and storage of QBC blood tubes.

The Work Station incorporates a platform to hold a 10-test tray of QBC blood tubes; a slotted receptacle for storage of the QBC Venous-Blood Pipetter (see below); various sized blood tube wells; and a notched front rack for storage of centrifuged QBC Blood Tubes.

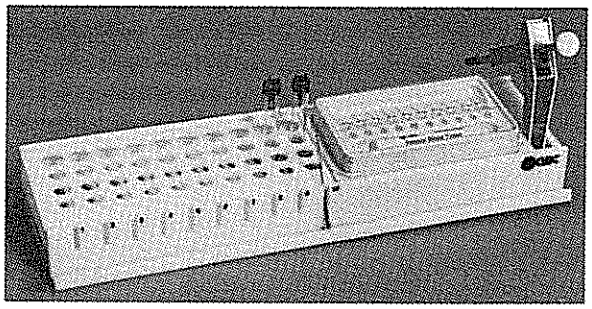


Figure 3.9. QBC Work Station and Venous-Blood Pipetter.

3.5 VENOUS BLOOD PIPETTER

The semi-automatic Pipetter shown in the Work Station in Figure 3.9 is a dedicated device, designed exclusively for filling QBC Venous-Blood Tubes. The plunger of the Pipetter has two positions: fully retracted and fully depressed. In the depressed position and with a QBC Venous-Blood Tube inserted into the metal coupling of the Pipetter, the plunger is gradually released to aspirate blood into the tube. Fill volume is fixed at 111.1 µL and is non-adjustable.

3.6 SYSTEM SPECIFICATIONS

3.6.1 QBC II Plus Reader

- Tube-Viewing Microscope:
  Magnification: 7.5x
  Adjustable Eyepiece with Blocking Filter

- Test Environmental Requirements:
  Temperature: 68° to 90°F (20° to 32°C)
  Relative Humidity: 10% to 95% (non-condensing)

- Electrical

Reader Model No.	Volt.	Freq.	Watts	Main Power Fuse
4452	120	60Hz	80	3AG 1-1/2 Amp Slo-Blo

Three-wire grounded cord and plug.

- Weights and Dimensions:
  Reader Weight: 4.3 kg (9.5 lb)
  Reader Dimensions: 36.2 cm deep x 34.3 cm wide x 25.4 cm high (14.25" x 13.5" x 10")
  Shipping Weight (including accessories): 6.8 kg (15 lb)
  Shipping Container Dimensions: 49.5 cm x 54.6 cm x 44.5 cm (19.5" x 21.5" x 17.5")

3.6.2 QBC Centrifuge*

- Speed: Nominal at Rated Voltage: 12,000 RPM
- Relative Centrifugal Force (RCF) at Nominal Speed: 14,387 x g
- Rotor Capacity: 12 QBC Blood Tubes
- Timer: Internal Electronic - 5 minutes (fixed)
- Electrical

Model No.	Volt.	Freq.	Amp.
4207	120	60Hz	4

*See QBC Centrifuge Operator's Manual for Complete Specifications.

Section 4
OPERATING INSTRUCTIONS

This Section contains general instructions for operating the various components and accessories of the QBC II Plus System. Maintenance and Service procedures are contained in Section 5.

Note: For detailed directions on blood collection, specimen preparation, and test procedures, consult Sections 6 and 7.

4.1 SELF-TEST SEQUENCE

Each time the "POWER" button of the Reader is activated a brief self-test sequence is initiated to check the operation of all lamps and to verify certain computer functions. The self-test sequence also occurs whenever the "CLEAR" button is pressed.

In the lamps check phase of self-test, numeral "8"s should appear in all digit positions of the readouts, and all panel indicator and internal lamps should momentarily light. Note: If a lamp segment in any readout digit is missing or an internal lamp fails to light, see Sections 5.3.3 and 5.3.4 for replacement procedures.

The computer check phase of self-test is satisfactory, provided a flashing service flag "P1" or "P2" does not appear in the PLT (Platelet) display. If a "P1" or "P2" flag appears, the Reader will not function until the problem is corrected. When either flag appears, the operator should check for a transient condition by pressing the "CLEAR" button several times. If the service flag persists, REQUEST TECHNICAL ASSISTANCE.

4.2 DAILY START-UP ROUTINE

Before daily testing of patient specimens, perform the following procedures in the order listed:

1) Press the POWER switch ON and monitor the Self-Test Sequence for satisfactory operation of all lamps and readout displays.

2) Run performance checks of the Reader in each mode ("VEN" and "CAP") according to 4.6 of this Section. The checks include mandatory testing of Calibration Tubes and optional testing of QBC Controls.

When satisfactory performance checks are completed, the Reader is ready for blood tube measurements.

4.3 OPERATING THE READER

4.3.1 Inserting and Removing Blood Tubes

Before inserting or removing a blood tube, always turn the Transport knob counterclockwise until it stops and the tube holder mechanism is in the fully down position as shown in Figure 4.1.

To insert a blood tube: hold the tube near the open end and insert the closure end upward into the Reader (Figure 4.2); then gently lower and release the tube so that the open end of the tube rests in the center of the thrust pivot.

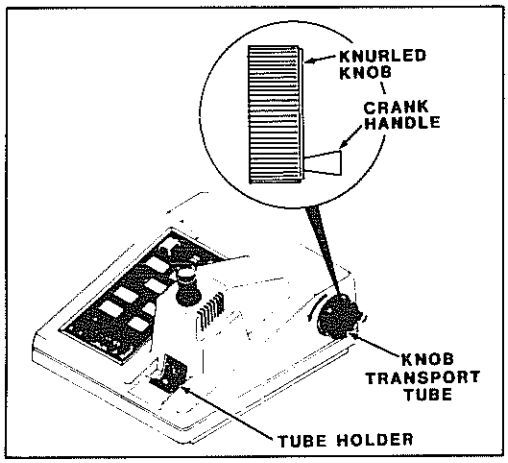


Figure 4.1.
Tube Holder Shown in Down Position.

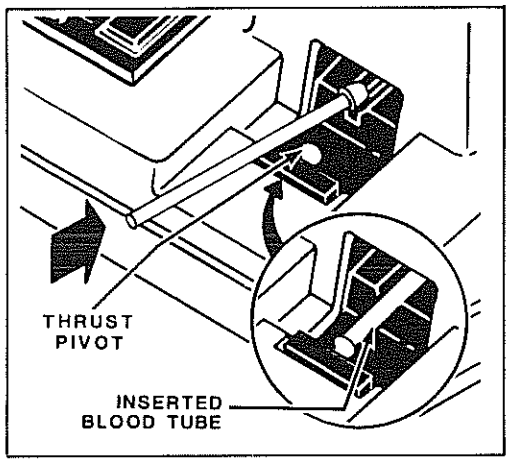


Figure 4.2.
Inserting Blood Tube into Reader.

Referring to the inset in Figure 4.1, the Tube Transport Knob consists of a small crank handle on a larger knurled knob. Use the crank handle for fast movement of the tube holder, e.g., when lowering the holder to remove a blood tube or when moving a tube inward to start a reading. For fine adjustment, use the knurled knob to align a cell interface with the reticle arrow.

4.3.2 Blood-Tube Reading Procedures

To read a blood tube, select the desired mode (VEN or CAP), insert the tube and perform the Reading Sequence described in Figure 4.3.

IMPORTANT: When reading QBC blood tubes, the two layers of Red Cells must always be followed by an ORANGE-YELLOW layer of granulocyte cells as shown in Figure 4.3. If a GREEN layer instead of an Orange-Yellow layer appears directly above the Red Cells, DISCONTINUE THE READING PROCEDURE AND DISCARD THE TUBE. If a freshly prepared QBC tube of the same patient specimen continues to exhibit a GREEN layer directly above the Red Cells, test the specimen by another method.

CAUTION
TEST VALUES OBTAINED BY AN INCORRECT READING PROCEDURE ARE INVALID AND MUST NOT BE USED FOR DIAGNOSTIC PURPOSES.

Test values for seven QBC parameters, except Hemoglobin, will automatically appear in the readouts momentarily after pressing "ENTER" at the 6th interface in Venous-Blood Tubes and 7th interface in Capillary-Blood Tubes. Refer to 4.3.3 to obtain a display of Hemoglobin results. Test values from the completed reading will remain displayed until "ENTER" is pressed again (i.e., 1st reading of next tube) or the "CLEAR" button is pressed.

4.3.3 Obtaining Hemoglobin Value

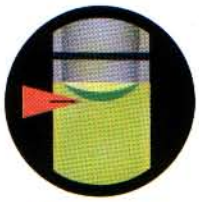
a. Normal Reader Operation

Hemoglobin concentration is displayed using the MODE button. Before activating a hemoglobin display, test values for the 'primary' hematology parameters

"CAP" Mode Only

7th (Final) Reading

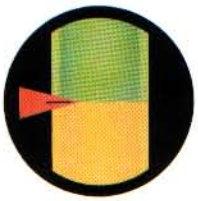
Move tube inward until cursor is at meniscus of TRANSLUCENT GREEN plasma column (7th Reading).



Press ENTER. Record the seven hematology values; then press the MODE button twice to obtain HB.

6th Reading

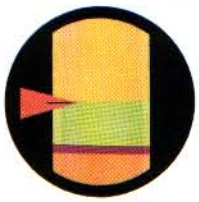
Move tube inward until cursor tip is at interface between PALE YELLOW layer and TRANSLUCENT GREEN plasma (6th Reading).



Press ENTER. In VENOUS mode: Record the seven hematology values; then press the MODE button twice to obtain HB.

5th Reading

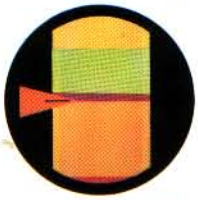
Move tube inward until cursor tip is at interface between BRIGHT GREEN and PALE YELLOW layers (5th Reading).



Press Enter.

4th Reading

Move tube inward until cursor tip is at interface between top of ORANGE-YELLOW layer and bottom of DARK BAND (4th Reading).



Press Enter.

3rd Reading

Move tube inward until cursor tip is at interface between LIGHT RED and ORANGE-YELLOW layers (3rd Reading).

Press Enter.

2nd Reading

Move tube inward until cursor tip is at bright edge of float between DARK RED and LIGHT RED layers (2nd Reading).

Press ENTER. The white tube lamp will turn off.

1st Reading

Move tube inward until cursor tip is at interface between GREEN closure and bottom of RED cells (1st Reading).

Press ENTER. The white tube lamp will light.

Figure 4.3. Tube Reading Sequence, QBC Venous and Capillary Blood Tubes.

must be on display in the seven readouts. To obtain Hemoglobin:

- Press and release the MODE button TWO TIMES within 2 SECONDS.
- The Hemoglobin concentration [in grams per deciliter (g/dL)] will appear in the Hematocrit display, and the remaining readouts will be blank.

To re-display the HCT, WBC, PLT, GRAN and LYMPH/MONO results from the same QBC tube, press and release the MODE button 2 TIMES within 2 SECONDS.

Note: If the MODE button is pressed twice, but the time delay between the first and second presses exceeds 2 seconds, the test results appearing in the readouts (7 parameters or HB only) will not change.

b. Causes for No HB or Flashing HB Values

Flashing dashes ("---") with no test value will appear in the HB display whenever an alert flag is present for any other test parameter (see 4.3.5 below). Additionally, no HB value will appear when the following occur:

- HCT is below 15 % or above 65 %; or
- The computed HB is below 5 g/dL or above 20 g/dL.

The HB test value will flash on and off when the red cell density factor, which is used in deriving hemoglobin, is above or below programmed limits. Whenever the HB test value flashes, the sample should be examined more closely (i.e., by a peripheral blood smear) to determine the nature of the abnormality.

4.3.4 Reader Operation with Optional Printer

When the QBC Plus II installation includes an Epson Printer and the Reader/Printer is operational, data transmission of test results - including Hemoglobin - is initiated within microseconds after pressing "ENTER" at the last (6th or 7th) interface of the QBC Tube. See Appendix B for additional information.

With an Epson LX-series printer, test results will appear on the panel while ticket printing is in progress. Hemoglobin concentration can be displayed without affecting the printing operation.

4.3.5 Procedure Alert Flags

When the Reader detects an out-of-range or irregular condition during tube reading, an alert flag, consisting of a flashing letter, number, or combination of both, will appear in a panel readout. The specific readout in which a flag appears, and whether or not the flag is accompanied by valid test values in other readouts, is determined by the nature of the flagged condition. Table IV-1 lists the alert flag program, the probable cause of each flag, and recommended corrective action.

The "Probable Causes" listed in Table IV-1 opposite the H1, H2, L2, A8 and 999 flags assume that the operator has read every interface in its correct sequence and that none was inadvertently skipped. For a more detailed discussion on the causes of each flag, consult Appendix A.

TABLE IV-1. QBC II Plus Alert Flags

FLASHING ERROR FLAG (TEST MODE)	PROBABLE CAUSE(S) OF ERROR FLAG	CORRECTIVE OPERATOR ACTION
-L (VEN or CAP)	1. Tube was inadvertently moved in wrong direction from last interface reading. 2. "ENTER" was inadvertently pressed twice while blood tube was at the same interface, resulting in a layer measurement of zero. 3. "ENTER" was pressed twice at the same interface to record the length of a *missing* white cell layer or the platelet layer.	1. Press "RESET" and repeat test from beginning. Follow proper tube-reading sequence. 2. Press "RESET" and repeat correct tube reading sequence. 3. DISCARD TUBE. Test the specimen by other methods.
H2 (VEN or CAP) AFTER ENTERING 2nd INTERFACE	1. Venous blood tube is plasma-rich because specimen was not mixed before filling the tube. 2. Float is defective. 3. Blood tube contains insufficient specimen due to filling error or blood loss.	1. DISCARD TUBE. Prepare new tube using *well-mixed* specimen and repeat test. 2. DISCARD TUBE. Prepare new tube and repeat test. 3. DISCARD TUBE. Prepare new tube and repeat test.
H1 (VEN or CAP) AFTER ENTERING 3rd INTERFACE	1. Float is defective, causing top of light red cell layer (L_2) to extend beyond top of float, preventing an accurate HCT, WBC, PLT and HB. 2. High HCT or blood abnormality.	1. DISCARD TUBE. Prepare new tube and repeat test. 2. DISCARD TUBE. Test specimen by other methods.
L2 (VEN Only) AFTER ENTERING 4th INTERFACE	1. High count or blood abnormality, causing top of orange-yellow GRAN layer (L_3) to extend beyond top of float, preventing an accurate WBC, PLT and HB. NOTE: Valid HCT value will be displayed.	1. Test the blood specimen by other methods for WBC, PLT and HB.
L2 (VEN Only) AFTER ENTERING 5th INTERFACE	1. High count or blood abnormality, causing top of green LYMPH/MONO layer (L_4) to extend beyond top of float, preventing an accurate WBC, PLT and HB. NOTE: Valid HCT will be displayed.	1. Test the blood specimen by other methods for WBC, PLT and HB.
L2 (VEN Only) AFTER ENTERING 6th INTERFACE	1. High count or blood abnormality causing top of orange-yellow layer (L_5) of platelets to extend beyond top of float, preventing an accurate PLT and HB. NOTE: Valid HCT, WBC, GRAN and LYMPH/MONO will be displayed.	1. Test the blood specimen by other methods for PLT and HB.
A8 (CAP Only)	1. Capillary Blood Tube contains too much specimen or insufficient specimen. 2 High count or blood abnormality, causing white cell or platelet layer to extend beyond top of float.	1. DISCARD TUBE. Prepare new tube, filled to required level. 2. DISCARD TUBE. Test the blood specimen by other methods.
OVER RANGE OR NO TEST VALUE FLAGS --- (VEN or CAP)	• In HCT: High computed value exceeds dynamic capabilities of instrument, preventing display of HCT. • In HB: No value due to other error flag or out-of-limit HCT or HB (see 4.3.3b).	• In HCT: DISCARD TUBE. Test the blood specimen by other methods. • In HB: Test for HB by other methods.
99.9 (VEN or CAP)	In WBC: Computed WBC exceeds three digit limitation of Reader display.	In WBC: Test specimen for WBC by other methods.
999 (VEN or CAP)	Computed PLT exceeds three digit limitation of Reader display.	Test specimen for PLT by other methods.

To clear an alert flag and re-set the microprocessor, press the "CLEAR" button. Repeat the reading sequence, depending on the nature of the flagged condition.

4.4 QBC CENTRIFUGE OPERATION

Place blood tubes on the rotor of the QBC Centrifuge by inserting the open end of the tube under the flange of the rotor nut and lowering the tube into the tube slots. Position the closure snugly against the outer rim of the rotor.

Always place blood tubes on the centrifuge rotor in a balanced array. When spinning an odd number of tubes, balance the rotor with an empty QBC blood tube, fitted with a Closure and Float, in the rotor position opposite the odd tube.

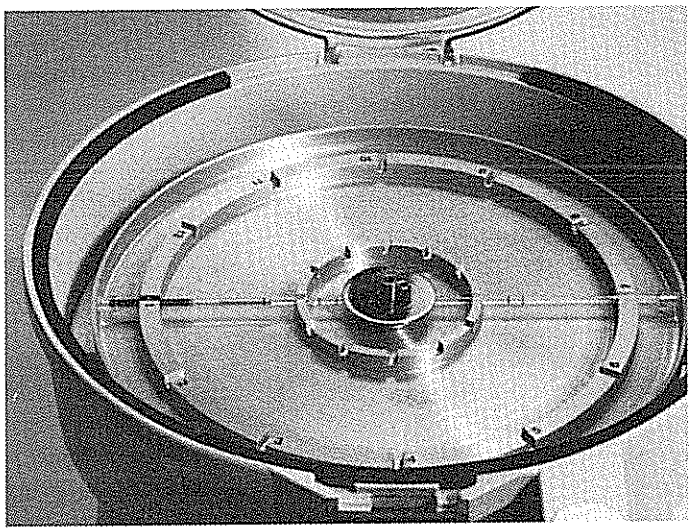


Figure 4.4. Single QBC Tube On Centrifuge Rotor, Showing Balance Tube in Opposite Position.

To install the rotor cover, place the cover onto the threads of the motor shaft and turn the knurled cover nut clockwise. Hold the cover with one hand and continue turning the nut clockwise until tight.

> CAUTION
> TO PREVENT TUBE BREAKAGE AND LOSS OF SAMPLES, NEVER CENTRIFUGE BLOOD TUBES UNLESS THE ROTOR COVER IS INSTALLED.

Close the lid by pressing firmly down until the lid latch engages the latch block. The Centrifuge will not operate unless the lid is securely latched.

Note: The timing cycle of the QBC Centrifuge is fixed at 5 minutes. The Centrifuge incorporates no timer selector or timing adjustment.

To start the Centrifuge, lightly press the PUSH-TO-START/PUSH-TO-STOP button. The button will light and remain on until the 5-minute spin cycle is completed and power to the motor is cut off. DO NOT OPEN THE CENTRIFUGE UNTIL THE ROTOR HAS STOPPED.

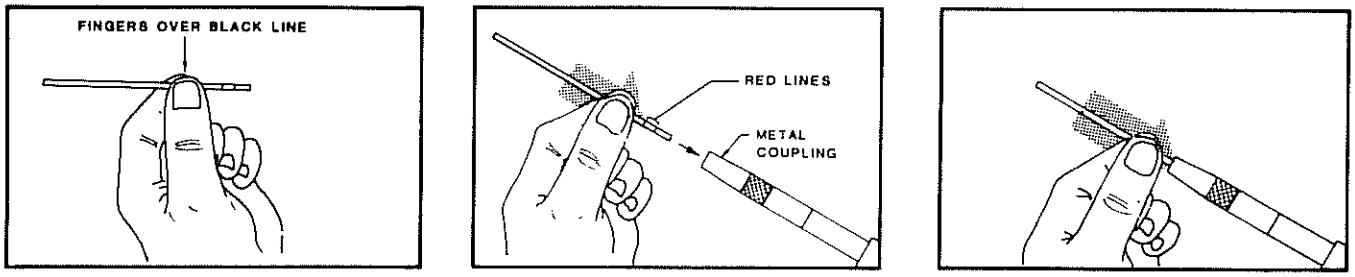
Note: Detailed operating instructions for the QBC Centrifuge are contained in the Manual supplied with the Instrument.

4.5 USING THE PIPETTER

The QBC Pipetter is a fixed-volume device designed exclusively for aspirating blood into QBC Venous-Blood Tubes. DO NOT USE THE PIPETTER WITH QBC CAPILLARY-BLOOD TUBES, WITH OTHER FLUIDS, OR FOR ANY OTHER PIPETTING PROCEDURES.

> CAUTION
> EXERCISE CARE WHEN INSERTING QBC TUBES INTO THE PIPETTER. THE TUBES ARE MADE OF GLASS AND MAY BREAK.

In order to prevent breakage and to assure complete seating of QBC Venous-Blood Tubes in the Pipetter, carefully observe the illustrated procedures in Figure 4.5 when inserting a tube.



STEP 1 — Hold the QBC tube between the thumb and forefinger directly over the black fill line. Maintain the same tube-holding position in Steps 2 and 3.

STEP 2 — Carefully insert the tube (end nearest the red lines) into the metal coupling of the pipetter until the tube appears to stop.

STEP 3 — Finally, press the tube firmly inward until it is fully seated and captured by the O-ring inside the coupling. Extra pressure is sometimes required to overcome a tight O-ring seal. IMPORTANT: **DO NOT ATTEMPT TO INSERT THE TUBE BY HOLDING AND PRESSING THE DISTAL END.**

Figure 4.5. Technique for Inserting QBC Venous-Blood Tube into Pipetter.

To fill a Venous tube, depress the plunger of the pipetter fully in until it stops (fill position); then insert the distal end of the tube into a well-mixed anticoagulated blood specimen. Release finger pressure slowly and smoothly until the plunger returns to its fully retracted position. Wipe excess blood from the outside surface of the tube with a lint-free tissue. Be careful not to touch the distal opening, which can result in the loss of specimen.

After each filling procedure, hold the Pipetter so that the tube is horizontal and check that the blood level is within ± 1 millimeter of the black line.

The QBC Pipetter is a precision device that has been factory-calibrated to aspirate 111.1 microliters of blood with an accuracy of ± 2%, equivalent to approximately ± 1 millimeter above or below the black fill line. After extended use, O-ring seals in the Pipetter may become worn and require replacement. Replacement is indicated by failure of the Pipetter to aspirate blood to within the ± 1 mm fill tolerance, or by leakage of blood from the distal end of the tube. A leakage check can be made by observing the blood level while holding the Pipetter so that the blood tube is vertical. If the blood level drops 1 mm within about 30 seconds, the O-rings should be replaced. Spare O-rings are supplied with the Pipetter. See Section 5.3.10 for O-ring replacement instructions.

Note: If the Pipetter malfunctions, tubes can be filled by capillary action.

4.6 CALIBRATION AND QUALITY CONTROL

As previously described, two Calibration Check Tubes are supplied with the QBC II Plus System to monitor acceptable performance of the Reader in the venous mode and capillary mode. (Use of the Check Tubes is specified as part of the Daily Start-up Procedures in Section 4.2.)

The Check Tubes serve to verify the ability of the Reader to measure band lengths and to derive values within factory-set tolerances. Acceptable performance of the following primary electro-optical and computer components is thereby confirmed: tube position encoder; encoder-to-microprocessor data link; write-in/readout functions of the Random Access Memory (RAM); readout function of the Read Only Memory (ROM); software computation module; and the algorithms (venous and capillary) for computing HCT, WBC, GRANS, LYMPH/MONO, Platelet and HB parameters at the specific assay levels (length measurements) defined by each Calibration Check Tube. Proper functioning of switches, tube illuminator lamp, power supplies, optics, displays, and mechanical components are also verified.

QBC Hematology Controls, normal and abnormal, are also available for daily quality control checks of the complete system, including the integrity of coating reagents and components of the blood tube devices.

Note: Optical, mechanical and electronic components of the Reader are calibrated at the factory and cannot be adjusted by the operator. In the event that target control values cannot be recovered, calibration adjustments must be made by an authorized service representative.

4.6.1 Using Calibration Check Tubes

At the time the QBC II Plus System is installed (and whenever a replacement Calibration Check Tube is required), tolerance limits for the Check Tube must be determined and recorded on the Package Insert supplied with the Tube (see Section 2.4.2). The resulting limits are then used by the Operator in the daily pre-test performance checks described below.

To perform the daily calibration checks:

(1) Place the Reader in the "VEN" mode and insert the Venous Calibration Check Tube.
(2) Referring to Figure 4.6, align the 1st interface (black-to-pale green) with the cursor and press "ENTER".
(3) Continue reading the 2nd through the 6th interfaces in the same manner.
(4) Record the Venous Cal Check values of the seven hematology parameters; then press the MODE button twice rapidly to obtain HB. Record the HB value and remove the Tube. Note: Record HB even if the check value is flashing.
(5) Select the "CAP" mode, insert the Capillary Calibration Check Tube and repeat the reading procedure, including the 7th interface, as shown in Figure 4.6.

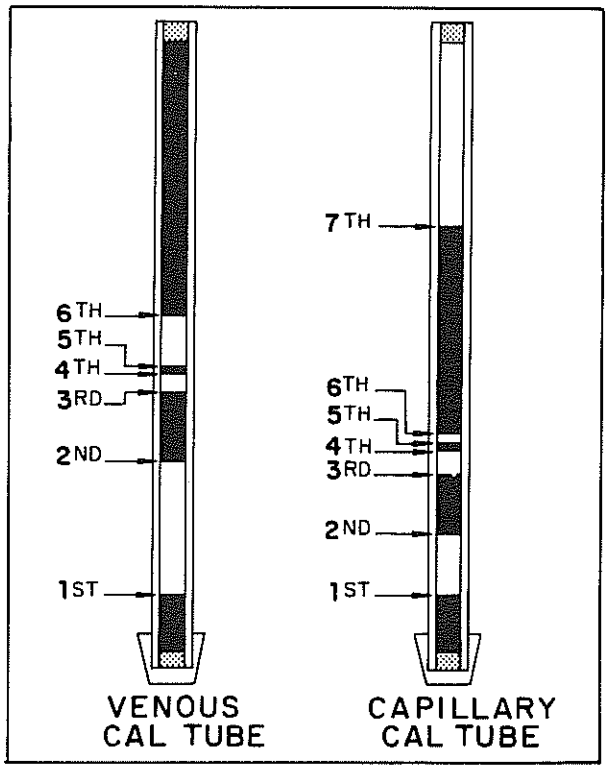


Figure 4.6. Interface Locations in QBC Calibration Tubes.

(6) Record the Capillary Cal Check values of the seven parameters. Press the MODE button twice, then record the displayed HB value. Note: Record HB even though the check value is flashing.

(7) Compare both sets of values (Ven and Cap) with the reference values and tolerances recorded on the Package Inserts of the Cal Check Tubes. If any value falls outside its tolerance limits, perform procedures (a) and (b) below in the order listed before requesting technical assistance.

(a) Carefully inspect the Check Tube yielding the out-of-tolerance value(s) for the presence of air bubbles between the black and white segments. Proceed to (b) if no bubbles are observed. If bubbles are present between segments, a replacement Calibration Check Tube should be ordered. Bubbles usually can be temporarily dislodged by shaking the tube down in the same manner as a clinical thermometer or by centrifuging for 5 to 10 seconds. If the bubbles are dislodged but the repeated Cal Check is still out-of-tolerance, proceed to (b).

(b) An out-of-tolerance value can be caused by parallax error due to incorrect focusing of the microscope. To minimize parallax error, align an interface in the Check Tube with the reticle arrow and observe the apparent alignment changes up or down while re-focusing the microscope. Determine the focus adjustment that gives the sharpest image of the arrow and interface, then repeat the tube-reading sequence.

Request Technical Assistance if the above procedures fail to correct the condition.

4.6.2 QBC Hematology Controls

QBC Hematology Controls (Catalog No. 4242) are available in refrigerated shipments, each containing a one-month supply of normal and abnormal material. Filling and tube preparation procedures with controls are the same as those for human blood. Detailed preparation and testing instructions are provided in the package insert of each control Kit, together with normal and abnormal assay values.

4.7 OPERATING PRECAUTIONS

- Power Connections: Connect the Reader and Centrifuge only to a 3-wire grounded A.C. outlet rated at the voltage and frequency specified on the data plate of the instrument.

- Calibration Checks: For reliable test results, be sure to observe the daily pre-test check procedures specified in 4.2 of this Section.

- Technique: Carefully observe the recommended blood collection, tube preparation, and test techniques described in Sections 6 and 7.

- Test Values: READINGS SHOULD NOT BE RECORDED FOR PATIENT EVALUATION UNLESS THE BLOOD TUBE EXHIBITS CLEAR COLOR DEMARCATIONS BETWEEN EVERY ADJACENT CELL LAYER. Consult "LIMITATIONS" in Section 8 for further details.

4.8 HAZARDS

The QBC II Plus System has been designed for maximum operator safety. In order to avoid hazards to personnel when using components of the system, observe the following basic safety rules:

Electrical

- Never remove the grounding prong from a power cord plug.
- Always unplug the power cord before attempting to perform authorized repair or service on any unit.
- If a power cord is damaged, have it replaced by a qualified service technician.

Blood Specimens

- Blood specimens should be handled with care, using accepted laboratory techniques. The use of protective laboratory gloves is recommended.
- Blood specimens may contain the Hepatitis B Virus or Human Immunodeficiency Virus (HIV) and should be handled with extreme care.
- Exercise care when handling QBC Blood Tubes. The blood tubes are made of glass and may break.

Section 5
MAINTENANCE AND SERVICE

5.1 INTRODUCTION

Maintenance and service to the QBC II Plus System that can be performed by the customer are limited to the procedures described in this Section. DO NOT ATTEMPT ANY OTHER SERVICE OR REPAIRS.

Appendix C contains a complete list of replacement parts and accessories for QBC II Plus. All listed items, including test disposables, can be ordered from your QBC Distributer. When ordering, be sure to include the full catalog or part number.

5.2 TECHNICAL ASSISTANCE AND REPAIR SERVICE

In the United States, the Technical Service Department of Becton Dickinson Primary Care Diagnostics provides unlimited telephone consultation through a toll-free number: 1-800-631-8064. Technical Service is staffed by a team of Medical Technologists who can, in many cases, resolve problems by providing expert technical guidance. For problems that cannot be resolved via telephone, Technical Service will provide one of several servicing alternatives. Outside the United States, technical assistance can be obtained through your QBC distributor or nearest Becton Dickinson and Company office.

DO NOT RETURN ANY COMPONENT OF THE SYSTEM WITHOUT SPECIFIC INSTRUCTIONS FROM THE TECHNICAL SERVICE DEPARTMENT.

5.3 MAINTENANCE AND CUSTOMER-SERVICEABLE PARTS

5.3.1 Reader Lubrication

In order to assure smooth movement of the tube holder mechanism over its full length of travel, the internal Lead Screw, Extension Shaft and Guide Rod should be lubricated approximately once each year. To gain access for lubrication, the top cover must be removed as follows:

a) DISCONNECT THE POWER CORD.
b) Referring to Figure 5.1, remove the rubber grommet from the Microscope.

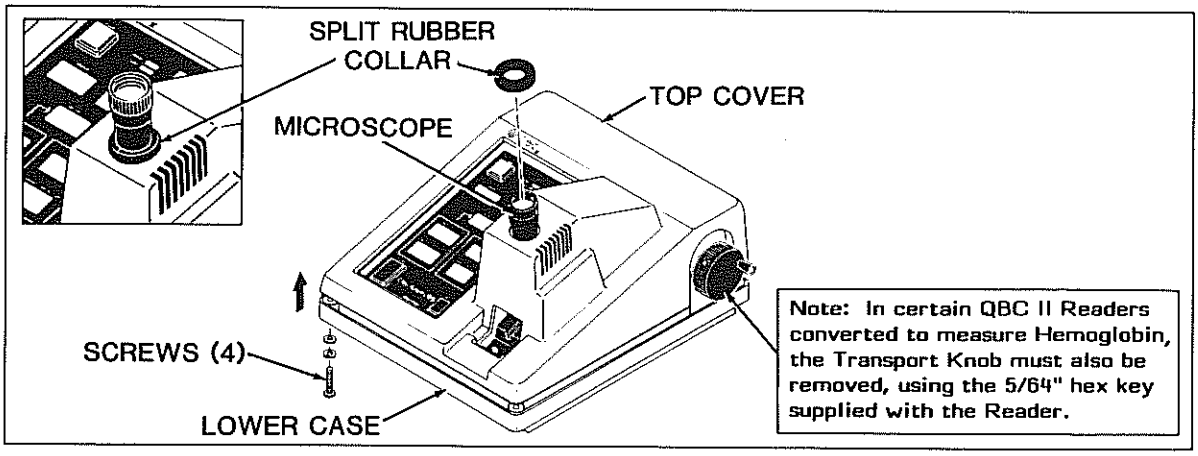


Figure 5.1. Top Cover Removal Details.

c) From the bottom of the Reader, remove the Phillips-head screws and washers from the four corners of the lower case. Then lift off the top cover.

Note: Removal of the top cover automatically activates a Safety Interlock Switch (see Figure 5.2) that cuts off electrical power to the Reader.

The Lead Screw, Extension Shaft and Guide Rod are shown in Figure 5.2. The recommended lubricant is Dow Corning Molykote Gn Paste, available from Becton Dickinson in a tube applicator, Catalog No. 4200-600-006. DO NOT USE OIL OR OTHER LIQUID LUBRICANTS.

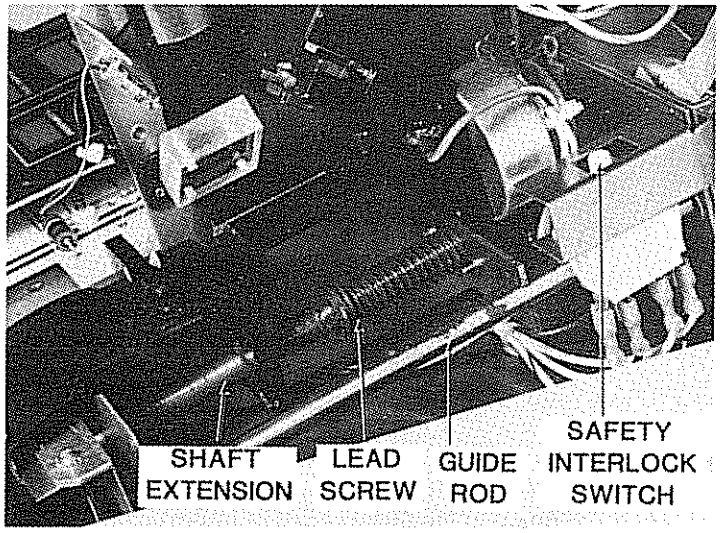


Figure 5.2. Lead Screw and Guide Rod (Top Cover Removed).

To lubricate the Lead Screw, apply small dabs of Molykote Gn paste at intervals along the complete length of the Lead Screw threads and Cylindrical Extension Shaft. Then rotate the screw ¼ turn, three times, each time applying dabs of Molykote Gn along its full length. To lubricate the Guide Rod, apply a very thin uniform film of Molykote Gn to the top and bottom surfaces of the Rod. After lubrication, move the mechanism back and forth against the front and back stops of the Lead Screw several times to work the lubricant into the Lead Screw threads and along the Guide Rod surface and Extension Shaft.

Referring to Figure 5.1, re-install the top cover and rubber microscope grommet.

5.3.2 Reader Internal Lamps

The Reticle Arrow, Illuminator and Tube Lamps are all operated under derated conditions in order to assure extended service life. Burnout of any of these lamps can be detected as follows:

- Reticle Arrow Lamp - when the reticle arrow is barely visible through the microscope.

- Tube Lamp (white light) - when an auxiliary light fails to appear after the first interface reading of a blood tube, making the 2nd interface difficult to locate. Lamp operation can be momentarily verified by pressing the "CLEAR" button.
- Illuminator Lamp - when the tube appears dark through the microscope.

A replacement for each lamp is supplied in the Spare Parts and Accessories Kit.

To gain access to the internal lamps, DISCONNECT THE POWER CORD. Remove the microscope grommet and top cover according to the procedures in Paragraph 5.3.1.

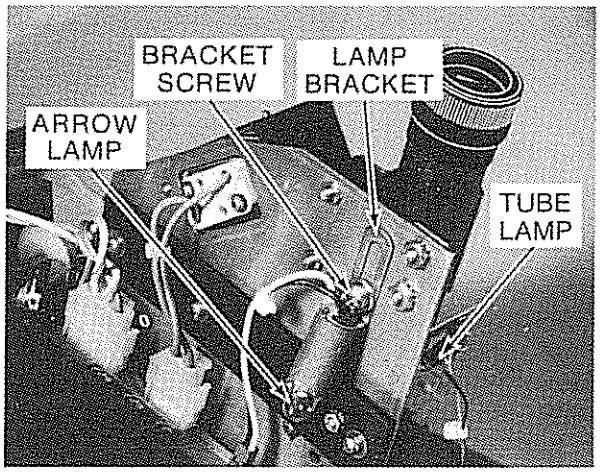


Figure 5.3. Reticle-Arrow Lamp Details.

a. Replacing Reticle Arrow (Cursor) Lamp

Referring to Figure 5.3, loosen the bracket screw, and pivot the Reticle Lamp Assembly forward. The lamp incorporates a bayonet-type base. Gently press and turn the bulb until the lamp springs free from its socket. Replace with a Catalog No. 2510-624-513 Reticle Arrow Lamp by pressing and turning the bulb into the Lamp socket. Wipe the bulb clean of fingerprints and smudges. Pivot the bracket assembly back. Before retightening the bracket screw, adjust the bracket so the filament of the lamp is in line with the reticle arrow.

Temporarily replace the cover. Reconnect the power cord, and press Power on. Check for uniform illumination of the reticle arrow, indicating correct adjustment of the lamp filament and bracket. Readjust as necessary. Then disconnect the power cord. Reinstall the top cover and microscope grommet.

b. Replacing Illuminator Lamp

Referring to Figure 5.4, loosen the wing nut and remove the cover from the illuminator assembly to expose the Illuminator Lamp (Figure 5.5). Pull the Illuminator Lamp from its socket. Replace with a Catalog No. 4227-602-000 Illuminator Lamp by inserting the base pins into the lamp socket. Be sure the lamp is seated straight in the socket. IMPORTANT: Wipe fingerprints and smudges from the bulb. Replace the cover and wing nut. Reinstall the top cover and microscope grommet.

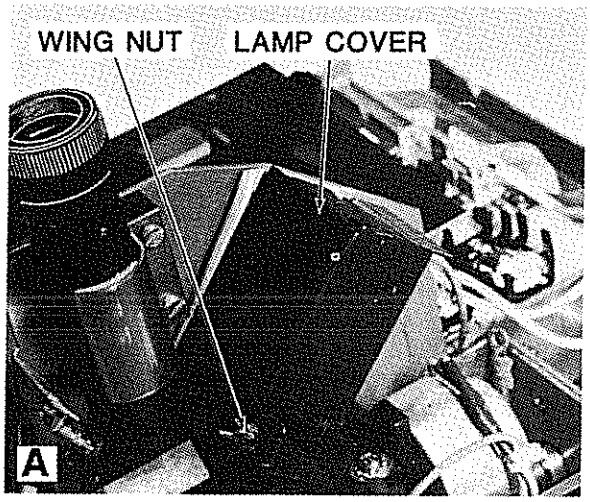


Figure 5.4. Illuminator Housing.

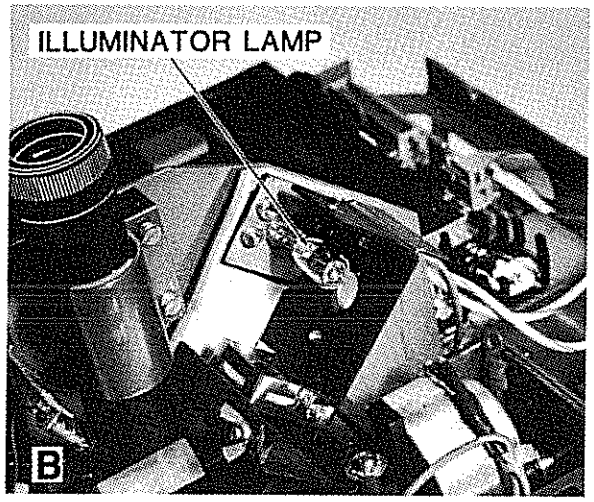


Figure 5.5. Illuminator Lamp and Socket.

c. Replacing Tube Lamp

To replace the tube lamp, the microscope must be loosened and moved up to provide access to the lamp (Figure 5.6).

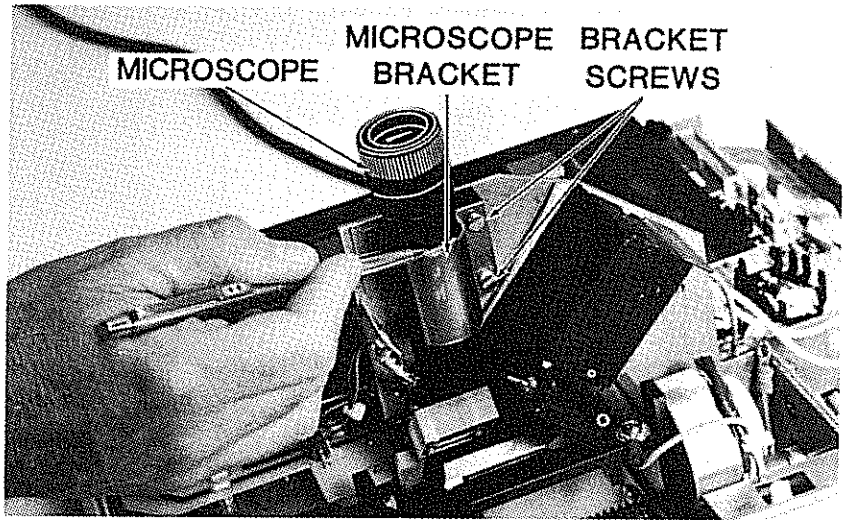


Figure 5.6. Tube Lamp and Microscope Bracket Details.

Before moving the microscope, scribe a pencil mark on the barrel at the top of the clamp as shown in Figure 5.6 so that the scope can be returned to its original position.

Loosen the two bracket screws; then slide the microscope up so that the Tube Lamp (Figure 5.7) can be removed. Pull the Lamp from its clip socket, and replace with a Catalog No. 2510-624-512 Tube Lamp.

Slide the microscope down until the pencil line is flush with the top of the barrel clamp; then tighten the clamp screws. Reinstall the top cover knob and microscope grommet.

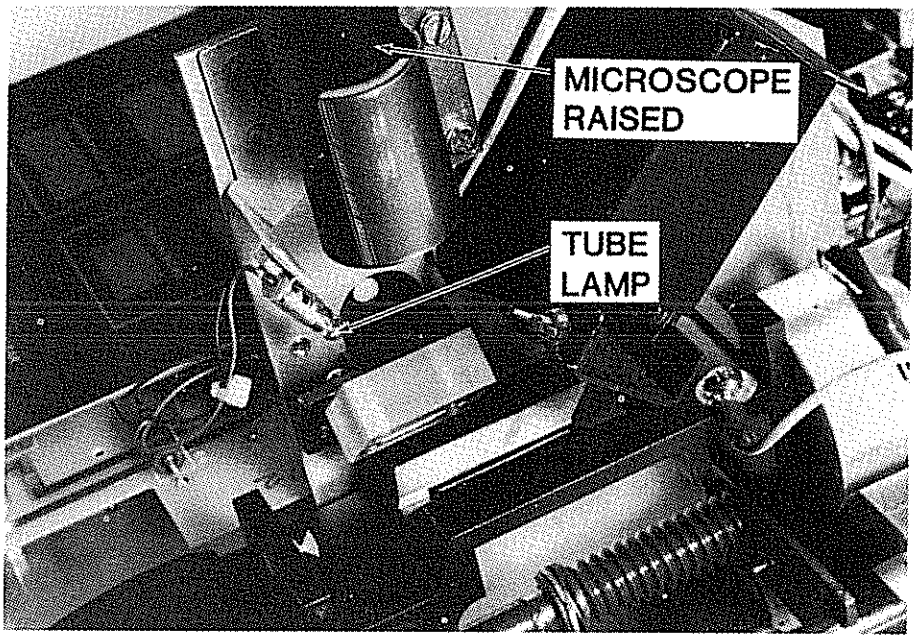
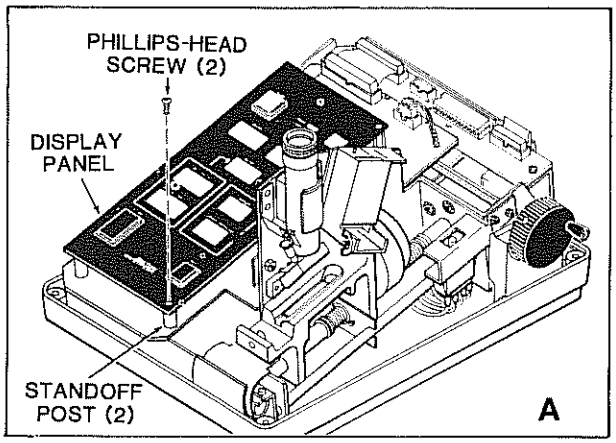


Figure 5.7. Tube Lamp, Showing Microscope in Raised Position.

5.3.3 Seven-Segment Readouts

Each digit of a panel readout consists of a seven-segment display (Figure 5.8) that plugs into sockets on a Main Printed Circuit Board. If a digit segment fails to light, the display digit can be replaced as described below.

a) DISCONNECT THE POWER CORD.
b) Remove the top cover from the Reader according to the procedures in Paragraph 5.3.1
c) Referring to Figure 5.8A, from the right corners of the display panel, remove the two Phillips-head screws that mount the panel to the standoff posts.
d) Lift and lay aside the display panel with attached POWER switch and wiring (Figure 5.8B). Do NOT disconnect the Power switch wires.



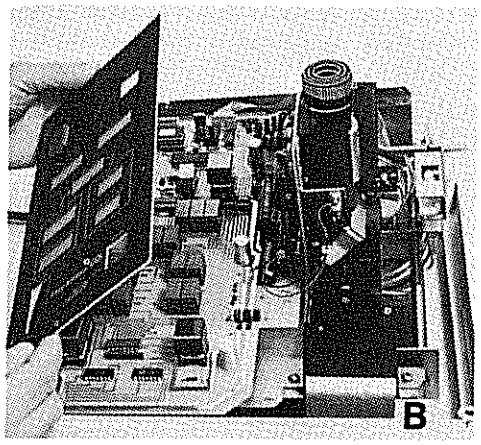


Figure 5.8. Removing Display Panel to Expose Main Circuit Board.

e) Carefully extract the malfunctioning display digit from its pin sockets as shown in Figure 5.9.

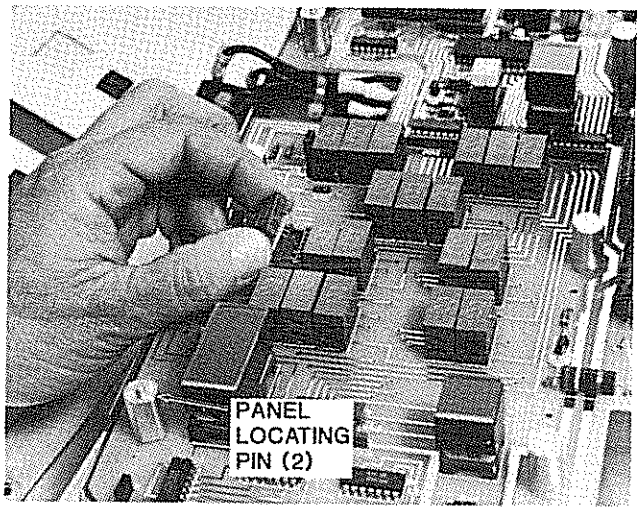


Figure 5.9. Extracting Seven-Segment Display Digit.

f) Using a Catalog No. 2510-621-746 replacement display, orient the decimal dot down and, holding the display pins vertically over the socket, insert the pins of the display straight into the board socket. Do NOT bend or twist the display pins.
g) Reinstall the display panel by replacing but not tightening the two Phillips-head screws in the right corners of the panel (see Figure 5.8A). Adjust the panel so there is no interference between the panel cutouts and the MODE, ENTER and CLEAR switch buttons; then tighten the panel mounting screws.
h) Replace the top cover and microscope grommet.

5.3.4 Reader POWER Switch

If the light in the POWER switch fails or the switch itself malfunctions, replace the switch assembly as described below.
a) DISCONNECT THE POWER CORD.
b) Remove the top cover of the Reader according to the procedures in Paragraph 5.3.1.
c) Lift off the display panel with attached Power switch and push-on wire leads.
d) Pry off the push-on connectors of the 4 wires from their terminals on the POWER switch (Figure 5.10).
e) From the back of the display panel, compress the spring clips on both sides of the switch assembly and force the switch out through the front of the panel.
f) Using a Catalog No. 4460-650-002 Power Switch, press the replacement switch through the front of the panel.

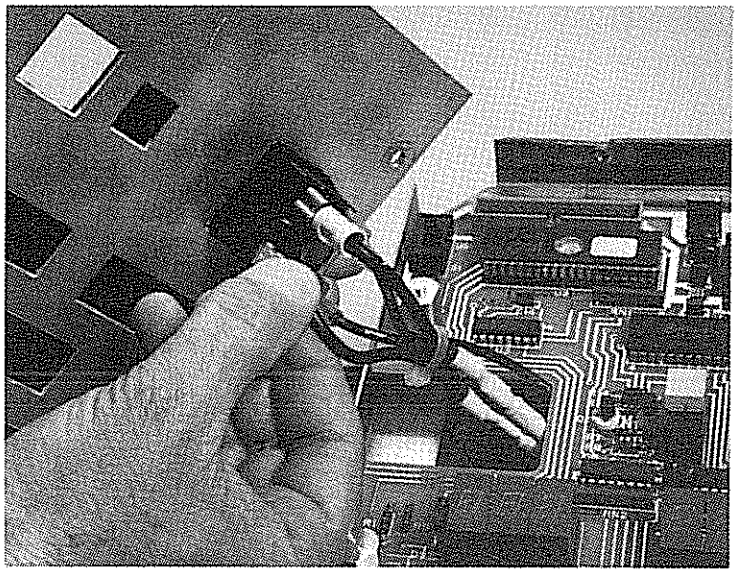


Figure 5.10. Disconnecting POWER Switch Wires from Switch Terminals.

g) Connect the push-on connectors of the 4 switch wires to the switch terminals according to the wiring diagram in Figure 5.11. BE SURE THE WIRES ARE CONNECTED TO THE CORRECT SWITCH TERMINALS AND THE PUSH-ON CONNECTORS ARE PRESSED IN FULLY.
h) Reinstall the display panel following the procedures in Step (g) of Paragraph 5.3.3.
i) Replace the top cover and microscope grommet.

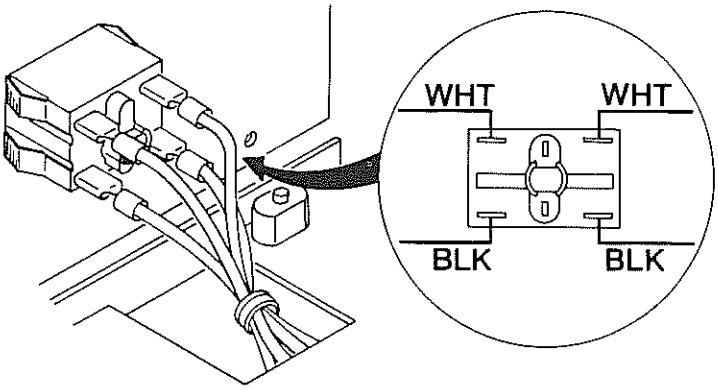


Figure 5.11. Power Switch Wiring Diagram.

5.3.5 Power Fuse

The Model 4452 QBC II Plus Reader incorporates a single main power fuse, located in the back of the instrument (Figure 5.12). The fuse has the following rating: 3 AG 1½ Amp Slo-Blo. Spare fuse are supplied with the Reader; additional fuse can be ordered from Becton Dickinson (Part No. 2510-623-814).

To replace a blown power fuse:

1) DISCONNECT THE LINE CORD.
2) Press the bottom of the white "FUSE" holder button located in the back of the Reader (Figure 5.12). The holder button will release from its housing along with the fuse.
3) Pull the blown fuse out of the holder button and insert the correct replacement fuse.
4) Insert the fuse and holder button into the housing and press to lock the holder in place.

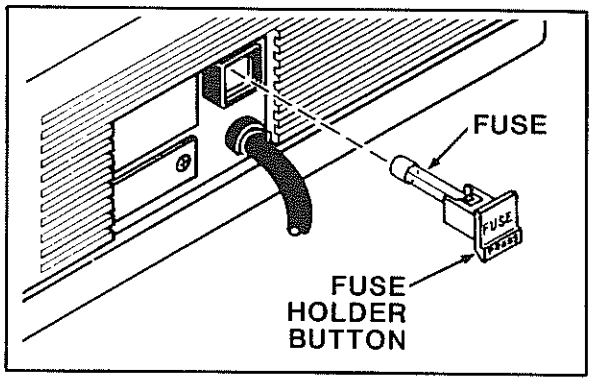


Figure 5.12. Main Power Fuse.

> CAUTION
> WHENEVER A REPLACEMENT FUSE BLOWS OUT, REQUEST TECHNICAL ASSISTANCE TO CORRECT AN INTERNAL ELECTRICAL SHORT CIRCUIT.

5.3.6 Reader Cleaning

a. Exterior Surfaces

Periodically clean the QBC II Plus Reader and QBC Centrifuge with a damp cloth moistened with soap and water or a mild liquid detergent solution. NEVER USE SOLVENTS OR STRONG ABRASIVE CLEANERS. Note: The Centrifuge rotor should only be cleaned only in accordance with specific instructions in the Centrifuge Operator's Manual.

b. Microscope Eyepiece

Clean the surface of the lens with optical tissue, a sable or camel's hair brush, or a liquid cleaner specifically recommended for optical glass.

c. Beam Splitter

With time, the Beam Splitter in the internal optics of the Reader may require cleaning in order to maintain clarity and brightness of the blood tube image. To gain access to the Beam Splitter:

1) Remove the top cover according to procedures in 5.3.1.
2) Loosen and slide up the microscope according to procedures in 5.3.2c in order to gain access to the Beam Splitter Block (Figure 5.13).

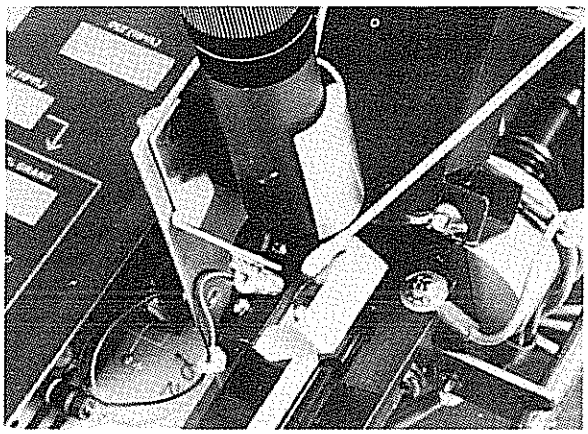


Figure 5.13. Cleaning Beam Splitter Block with Swab.

3) Clean the upper and lower surfaces of the Beam Splitter with a cotton swab. BE CAREFUL NOT TO SCRATCH THE POLISHED SURFACES. DO NOT DISASSEMBLE THE BEAM SPLITTER.
4) Lower the microscope to its correct position and tighten the bracket screws. Re-install the top cover and microscope grommet.

5.3.7 Reader Mechanical and Optical Checks

Operation of the tube holder and optics mechanisms of the Reader should be checked periodically in order to verify smooth movement and correct mechanical and optical alignment.

a. Tube Holder Movement

Turn the transport knob clockwise and counterclockwise several times while observing movement of the tube holder. The holder should travel in and out smoothly without excessive vertical or lateral bouncing or jumping.

Lubrication of the lead screw, extension shaft and guide rod may be necessary (see 5.3.1) if the tube holder mechanism does not move smoothly.

b. Tube Rotation

Insert one of the Calibration Check Tubes and focus the microscope by rotating the eyepiece. Observe the rotating tube through the microscope. There should be minimum blurring of the tube image when viewed through the scope. Externally, the tube should rotate smoothly, without excessive jumping or bouncing.

If the tube jumps or bounces excessively, the rubber drum roller on which the tube rests should be cleaned as follows: With the drum roller spinning, gently wipe the complete length of the roller with a cotton swab that has been dipped in isopropyl alcohol (Figure 5.14).

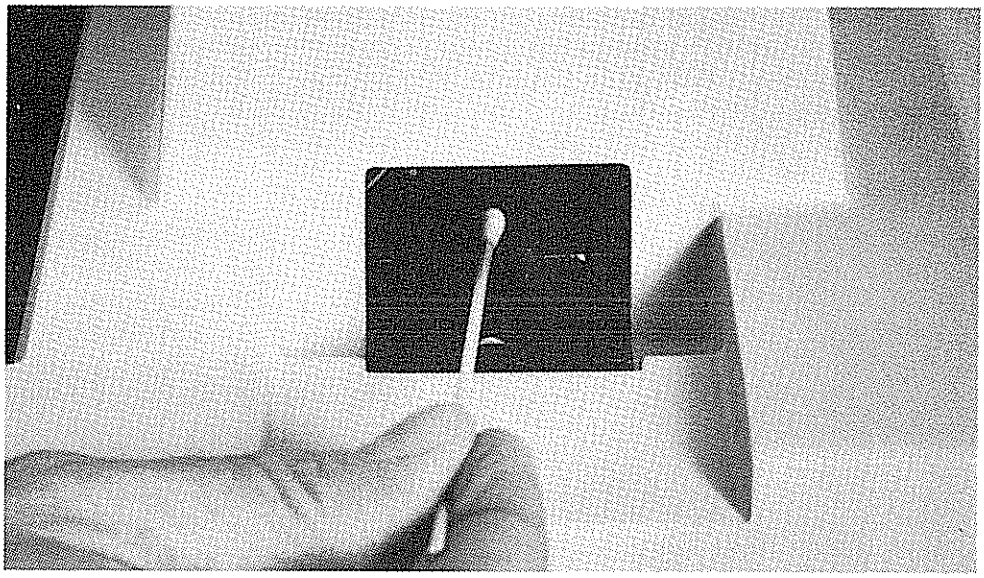


Figure 5.14. Cleaning Rotating Drum Roller with Cotton Swab.

c. Optics and Carriage Alignment

1) Turn the transport knob until the 1st interface of the Check Tube is aligned with the tip of the reticle arrow.
2) Observe the position of the tip of the arrow in relation to the tube. The tip should overlap the tube within the limits shown in Figure 5.15; however the overlap should not exceed 1/4 the diameter of the tube.

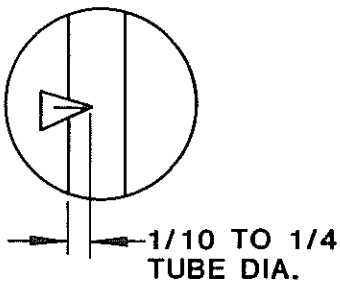


Figure 5.15. Overlap Tolerance of Reticle Arrow.

3) While moving the tube to the other end, observe the overlap of the arrow tip. The overlap should be within the limits shown in Figure 5.15.
4) If overlap is not within the limits shown in Figure 5.15, Request Service for alignment of the reticle arrow and optics.

5.3.8 Repairs to QBC Centrifuge

The Operator's Manual supplied with the QBC Centrifuge contains detailed instructions and procedures for performing the customer-serviceable repairs and parts replacements.

5.3.9 Replacing O-rings in QBC Pipetter

Leakage of blood or failure of the QBC Pipetter to aspirate blood to within ± 1 millimeter of the fill line of the QBC Venous Tube (see discussion in 4.5 of Section 4) indicates that O-ring seals in the Pipetter may be worn and should be replaced. A spare set of three O-rings, and O-ring grease are supplied with the Pipetter.

To replace the O-rings, refer to Figure 5.16 and disassemble the Pipetter as follows:

(a) Unscrew the plastic Barrel, with attached metal Coupling, from the Handle of the Pipetter. Then unscrew the Coupling from the Barrel.
(b) Referring to Figure 5.17, remove shaft O-ring "A", barrel O-ring "B", and coupling O-ring "C".
(c) Using the spare set of O-rings, apply a heavy coat of grease to replacement O-ring "A" and press the O-ring into the shaft cavity of the Barrel.
(d) Lightly grease replacement O-ring "B" and slip the O-ring over the threaded end of the Barrel.
(e) Lightly grease replacement O-ring "C" (small O-ring) and insert into the Coupling.
(f) Reassemble the Coupling to the Barrel.

> CAUTION
>
> When turning the metal Coupling onto the small threaded end of the plastic Barrel, FINGER-TIGHTEN ONLY. Overtightening may cause the threaded end of the Barrel to break.

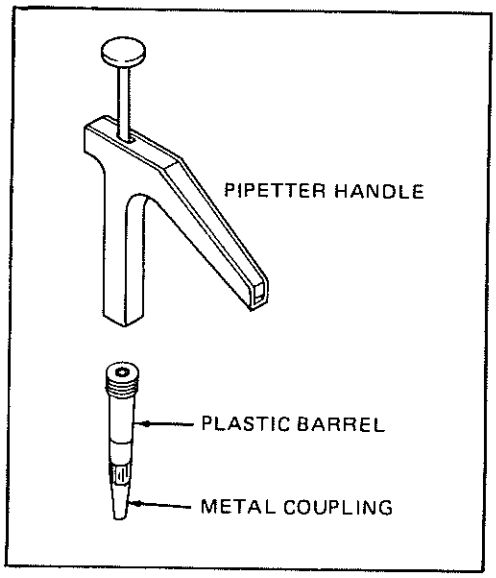


Figure 5.16.
Disassembling Barrel and Coupling From Pipetter Handle.

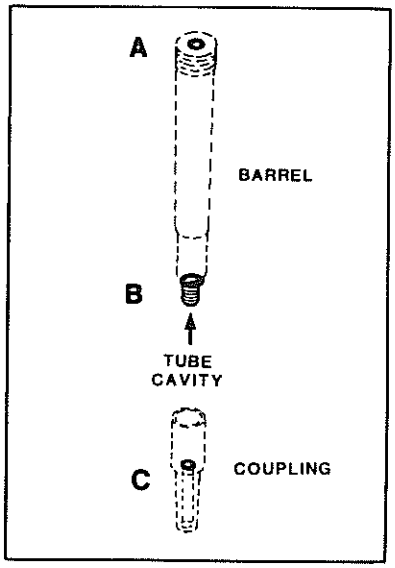


Figure 5.17.
Disassembled Barrel and Coupling O-Rings.

(g) After reassembly, insert the flame-polished end of a QBC Tube (end nearest two red lines) fully into the Coupling and Barrel, then remove and wipe the end of the tube. Repeat several times to remove any excess grease from O-ring "C".

(h) Remove the Coupling from the Barrel and, using a tissue, clean out any grease from the Tube Cavity (see Figure 5.17). IMPORTANT: Excess grease forced inside the bore of a QBC Venous tube can cause the float to stick and fail to descend during centrifugation.

(i) Reassemble the Coupling and Barrel to the Pipetter handle.

5.4 TROUBLESHOOTING

When unexplained difficulties are encountered in obtaining accurate test results, blood tube preparation and reading technique should be reviewed for possible procedural errors as the first step in troubleshooting. Step-by-step blood collection, tube preparation, and assay procedures are detailed in Sections 5 and 6 of this Manual. Special precautions and requirements regarding laboratory temperature (90°F maximum), freshness of sample, tube handling, and assay timing are critical to good cell banding and accurate test results. Once proper technique has been verified, other causes may then be considered.

As discussed in Section 8, certain blood specimens may fail to produce clearly readable cell layers in the QBC tube despite flawless preparation technique. These partially or totally unreadable tubes may be due to pathologic conditions or chemotherapy, where changes in cell density, fragility or morphology may prevent testing by the QBC method. Such specimens must be tested by other means.

The QBC II Plus Reader has been designed for maximum reliability and consistent day-to-day performance when operated and maintained according to specified directions. Malfunctions or out-of-specification performance of the instrument can quickly be detected through daily reading of the Calibration Check Tubes.Other mechanical, electrical and optical malfunctions should be immediately evident during routine use. With the QBC Centrifuge, deviations from design specifications can be identified by performing the Calibration Checks recommended in the Centrifuge Operator's Manual.

In the United States, assistance in correcting equipment malfunctions can be obtained by calling the Technical Service Department of Becton Dickinson Primary Care Diagnostics: 1-800-631-8064. Outside the United States, contact your QBC distributor or nearest Becton Dickinson and Company office.

Section 6
SPECIMEN COLLECTION AND PREPARATION FOR TESTING

> WARNING
> BLOOD SPECIMENS MAY CONTAIN THE HEPATITIS B VIRUS OR HUMAN IMMUNODEFICIENCY VIRUS (HIV). ALWAYS HANDLE BLOOD SPECIMENS AS POTENTIAL BIOHAZARDS CAPABLE OF TRANSMITTING INFECTION.

6.1 VENOUS BLOOD

Venous specimens should be collected only into the anticoagulants disodium or tri-potassium ethylenediamine-tetraacetate (EDTA).

6.1.1 Collection Procedures

(a) Before collecting blood, clean hands thoroughly with a laboratory-approved antiseptic. Use only clean glassware and sterilized collecting instruments. Before venipuncture, clean the skin area with an antiseptic agent.

(b) Draw venous blood with a VACUTAINER® Brand Blood Collection Tube* or other blood-drawing device containing EDTA. To assure an acceptable blood-to-anticoagulant ratio, fill the collection tube to at least 2/3 of its total fill volume. Remove the collection needle and destroy after use.

(c) Thoroughly mix the blood with the EDTA anticoagulant. IF SMALL CLOTS ARE OBSERVED, DISCARD THE SPECIMEN AND OBTAIN A FRESH ONE.

6.1.2 Anticoagulants

Blood for QBC II Plus venous tests must be anticoagulated only with disodium or tri-potassium EDTA. DO NOT USE OTHER ANTICOAGULANTS.

6.1.3 Interfering Substances

- Hemolysis: Tests should not be performed on visibly hemolyzed blood specimens.
- Bilirubin: No effects on test results have been observed at bilirubin concentrations up to 8.5 mg/dl.[8]
- Coumadin: Coumadin anticoagulant therapy has been shown to have no clinically significant effect on performance.[8]
- Doxorubicin: Treatment with the anthracyclic drug Doxorubicin does not appear to interfere with the QBC method.[8]
- Drugs: The effects of other potentially interfering drugs and their metabolites on QBC hematology tests have not yet been established.[9,10]

*Product of Becton Dickinson Vacutainer Systems, Rutherford, N.J.

6.1.4 Specimen Storage and Stability

After blood collection, anticoagulated venous specimens may be held at a room temperature of 68° to 90°F (20° to 32°C) for the times indicated below.

- 90 Minutes from blood collection, provided all QBC hematology parameters, including the Platelet Count, are required. Note: Specimens older than 90 minutes may yield falsely elevated Platelet Counts. After centrifugation, QBC tubes may be tested any time within 4 hours. (See Assay Timing in Section 7.3.4 of Test Procedures for additional details.)

- 4 Hours from blood collection, provided QBC hematology parameters, except the Platelet Count, are required. After centrifugation, tubes may also be held for 4 hours prior to reading.

6.2 CAPILLARY BLOOD

Fill QBC Capillary-Blood Tubes directly from a finger puncture. QBC Capillary-Blood Tubes contain dry anticoagulant coatings and must be mixed after filling as described in Section 7.3.3. of Test Procedures.

6.2.1 Collection Procedures

(a) The finger to be punctured must not be cyanotic or edematous. If cyanotic or cold, immerse in warm water for 3 to 5 minutes or apply a moist compress or warm pack before puncturing.

(2) Clean the finger area with an antiseptic agent and wipe dry.

(3) Puncture the finger with a sterile lancet, wipe away the first drop of blood, and immediately collect the next drop or two directly in the QBC Capillary Tube. Specimens taken after the first several drops may yield lower platelet counts, since the platelets may adhere to the wound site or may aggregate in the blood drop.

(4) Slight pressure may be applied some distance from the finger puncture. Avoid squeezing the puncture area to prevent diluting the blood with tissue fluid.

6.2.2 Anticoagulants

QBC Capillary Tubes are internally coated with sodium heparin and di-potassium EDTA.

6.2.3 Interfering Substances

See Paragraph 6.1.3 under Venous Blood.

6.2.4 Stability of Filled QBC Capillary Tube

Filled QBC Capillary Tubes should be mixed and centrifuged promptly after blood collection. Consult "ASSAY TIMING" in of Section 7 for additional details.

Section 7
TEST PROCEDURES

7.1 MATERIALS PROVIDED

The QBC II Plus System consists of the following instruments and accessories for performing centrifugal hematology tests:

- QBC II Plus Reader;
- QBC Centrifuge;
- QBC Work Station;
- QBC Venous-Blood Pipetter.

7.2 MATERIALS REQUIRED, BUT NOT PROVIDED

The following disposables are required for QBC hematology tests:

- QBC Venous-Blood Tubes;
- QBC Capillary-Blood Tubes.

7.3 CENTRIFUGAL HEMATOLOGY TESTS

7.3.1 Pre-Test Conditions

a) QBC Tube Tray, uncovered and placed in the Work Station. Note: QBC BLOOD TUBES ARE SENSITIVE TO MOISTURE AND LIGHT. REMOVE TUBES ONE BY ONE FROM THEIR OPAQUE VIAL, AND RE-STOPPER THE VIAL EACH TIME A BLOOD TUBE IS REMOVED. QBC Blood Tubes are stable for 30 days after first opening a vial of tubes.

b) Laboratory Temperature: Perform QBC centrifugal hematology tests at 68° to 90°F (20° to 32°C). If blood tubes are tested at temperatures below 68°F (20°C), hematology results may be erroneously high; if tested above 90°F (32°C), interfaces in the blood tube may become blurred and unreadable.

c) Specimen:
- For QBC Venous-Blood Tests: Use well-mixed, EDTA-anticoagulated blood at 68° to 90°F (20°C to 32°C). For venous blood test procedures, see 7.3.2.

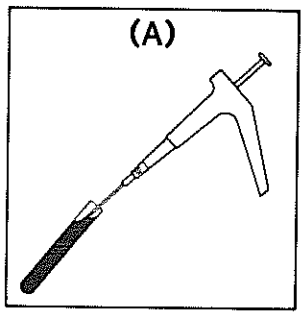
> IMPORTANT
> VENOUS BLOOD TUBES MUST BE PREPARED WITHIN 90 MINUTES OF BLOOD COLLECTION IF ALL QBC PARAMETERS, INCLUDING THE PLATELET COUNT, ARE REQUIRED. When the Platelet Count is not needed, 4 hours can elapse before the blood tube is prepared.

- For QBC Capillary-Blood Tests: use fresh blood collected from a free flowing finger puncture. For capillary blood test procedures, see 7.3.3.

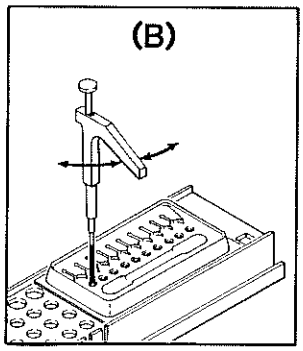
7.3.2 Test Procedures: QBC VENOUS-BLOOD TUBES

STEP 1. FILL AND SEAL BLOOD TUBE

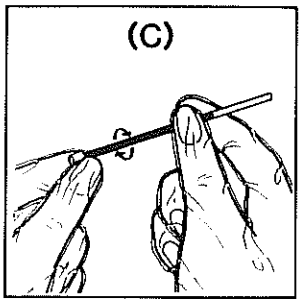
Insert the end of the Tube nearest the red lines into the Pipetter. Push the Tube in until it seats snugly inside Pipetter barrel. Depress the plunger of the Pipetter, then insert the distal end of the Tube into a specimen of well-mixed anticoagulated venous blood (A). Slowly release the plunger of the Pipetter to fill the Tube. With the Tube horizontal, check that the blood level is within ± 1 mm of the black fill line.



Wipe any blood from the surface of the Tube with lint-free tissue. Press the distal end of the Tube firmly into a closure in the tube tray (B). Twist the Pipetter slightly to be sure that the closure remains on the Tube when the Pipetter and Tube are lifted.

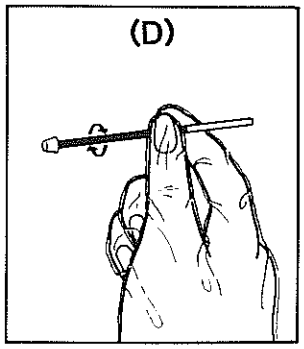


Remove the Tube from the Pipetter. Manually twist and firmly push on the closure to form a leak-tight seal (C). Be sure the closure is on straight. FAILURE TO SEAT THE CLOSURE STRAIGHT MAY RESULT IN BLURRED INTERFACES.



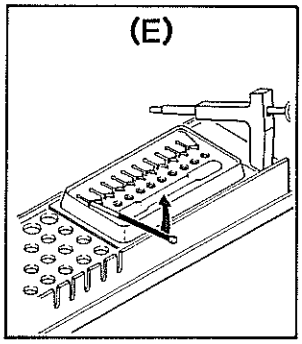
STEP 2. ROLL TUBE BETWEEN FINGERS TO MIX

Gently roll the Tube between the fingers <u>at least 10 times or for at least 5 seconds</u>, keeping the unsealed end slightly above the horizontal (D). PROMPTLY PROCEED TO STEP 3.



STEP 3. INSERT FLOAT INTO BLOOD TUBE

Slide the unsealed end of the Tube over the tip of the pre-positioned float (E) and push until the float is inside the Tube as far as possible. Gently lift the closure end of the Tube until the float releases from its tray slot. Raise the unsealed end of the Tube slightly above horizontal to prevent the float from falling out. If necessary, press the end of the float against a clean surface until it is inside the Tube. NOTE: NEVER TOUCH FLOATS WITH THE FINGERS. USE THE FORCEPS TO HANDLE LOOSE OR DROPPED FLOATS.



Note: After inserting the float, a between-step delay is permitted for batching blood specimens, provided tubes are stored vertically, closure down in the Work Station. A maximum of 20 minutes is allowed between insertion of the float and completion of Centrifugation in Step 4.

STEP 4. CENTRIFUGE FOR 5 MINUTES

Place the blood tube(s) on the rotor of the QBC Centrifuge by inserting the open end under the flange of the rotor nut, then lowering the tube into the rotor slot. Position the tube closure against the outer rim of the rotor. If an odd number of tubes are being centrifuged at one time, use an empty tube (with closure and float) for balancing. Secure the rotor cover and press the centrifuge lid down until it latches. Start the QBC Centrifuge. When centrifugation is complete, PROMPTLY REMOVE THE TUBES FROM THE ROTOR.

Time Delay Between Completion of Centrifugation and Tube Reading: Centrifuged QBC Tubes are stable for up to 4 hours prior to reading, provided they are stored vertically (closure down) in the Work Station and away from heat and intense light.

IMPORTANT:

- Excessive heat may disturb cell layer interfaces in the centrifuged blood tube. Avoid picking up or handling the spun tube below the plasma column. Do not place centrifuged tubes on warm surfaces or under intense light.
- Do NOT leave blood tubes on the rotor after centrifugation. Remove and read immediately, or store in a vertical, closure-down position to preserve distinct cell layers.
- Do not twist or move tube closures after centrifugation.

STEP 5. READ TUBES AND RECORD TEST VALUES

Note: Read the QBC tube as soon as possible after insertion in the Reader, since the cell interfaces may become slightly blurred from prolonged exposure to heat.

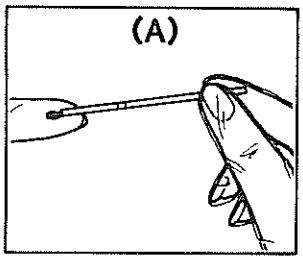
Be sure the "VEN" key is pressed and the "VEN" indicator light is On. Insert the centrifuged tube, closure end first, into the Reader. PROMPTLY read the six interfaces in the blood tube as shown in Section 4.3.2. Record the seven hematology values displayed in the readouts. To obtain the Hemoglobin value, rapidly press the MODE button twice.

Remove the tube and test the next blood tube. Note: Pressing "ENTER" in the next test will erase all values from the previous test.

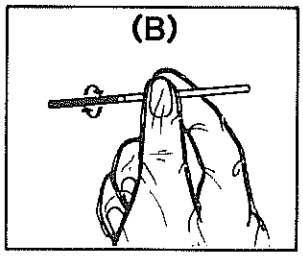
7.3.3 Test Procedures: QBC CAPILLARY-BLOOD TUBES

STEP 1. FILL AND MIX TUBE

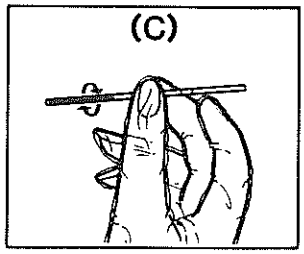
From the end of the tube nearest the two black lines, fill the tube with finger puncture blood to a level between the lines (A). With lint-free tissue wipe any blood on the outside of the tube, being careful not to draw any specimen from the tip of the tube.



Keeping the tube nearly horizontal, roll the tube between the fingers several times to mix the blood with the anticoagulant coating (B).

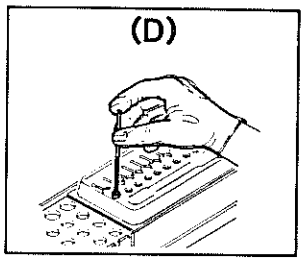


Turn the tube around and tilt, allowing the blood to flow to the opposite end of the Tube (C). Roll the tube between the fingers at least 10 times or for at least 5 seconds to mix the blood with the Potassium Oxalate and Acridine Orange coating. PROMPTLY PROCEED TO STEP 2.

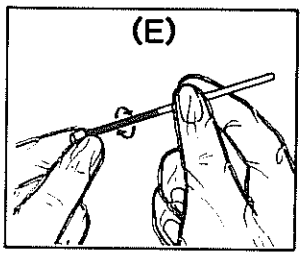


STEP 2. SEAL TUBE AND INSERT FLOAT

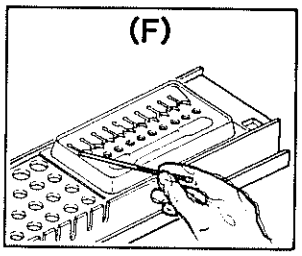
Place the index finger over the end of the Tube nearest the fill lines, and insert the distal end into a Closure in the tube tray (D).



Manually twist and firmly push on the closure to form a leak-tight seal (E). Be sure the closure is on straight. FAILURE TO SEAT THE CLOSURE STRAIGHT MAY RESULT IN BLURRED INTERFACES.



Slide the unsealed end of the Tube over the tip of the pre-positioned float (F) and push until the float is inside the Tube. Gently lift the closure end of the Tube until the float releases from its tray slot. Raise the unsealed end of the Tube slightly above horizontal to prevent the float from falling out. If necessary, press the float against a clean surface to push the end into the Tube. NOTE: NEVER TOUCH FLOATS WITH THE FINGERS. USE THE FORCEPS TO HANDLE LOOSE OR DROPPED FLOATS.



Note: After inserting the float, a between-step delay is permitted for batching blood specimens, provided tubes are stored vertically, closure down in the Work Station. A maximum of 20 minutes is allowed between insertion of the float and completion of Centrifugation in Step 3.

STEP 3. CENTRIFUGE FOR 5 MINUTES

Place the blood tube(s) on the rotor of the QBC Centrifuge by inserting the open end under the flange of the rotor nut, then lowering the tube into the rotor slot. Position the tube closure against the outer rim of the rotor. If an odd number of tubes are being centrifuged at one time, use an empty tube (with closure and float) for balancing. Secure the rotor cover and press the centrifuge lid down until it latches. Start the QBC Centrifuge. When centrifugation is complete, PROMPTLY REMOVE THE TUBES FROM THE ROTOR.

Time Delay Between Completion of Centrifugation and Tube Reading: Centrifuged QBC Tubes are stable for up to 4 hours prior to reading, provided they are stored vertically (closure down) in the Work Station and away from heat and intense light.

IMPORTANT:

- Excessive heat may disturb cell layer interfaces in the centrifuged blood tubes. Avoid picking up or handling spun tubes below the plasma column. Do not place centrifuged tubes on warm surfaces or under intense light.
- Do NOT leave blood tubes on the rotor after centrifugation. Remove and read immediately, or store in a vertical, closure-down position to preserve distinct cell layers.
- Do not twist or move the tube closure after centrifugation.

STEP 4. READ TUBES AND RECORD TEST VALUES

Note: Read the QBC tube as soon as possible after insertion in the Reader, since the cell interfaces may become slightly blurred from prolonged exposure to heat.

Be sure the "CAP" key is pressed and the indicator light is On. Insert the centrifuged tube, closure end first, into the Reader. PROMPTLY read the seven interfaces in the blood tube as shown in Section 4.3.2. Record the seven hematology values displayed in the readouts. To obtain the Hemoglobin value, rapidly press the MODE button twice.

Remove the tube and test the next blood tube. Note: Pressing "ENTER" in the next test will erase all values from the previous test.

7.3.4 Assay Timing (Blood Tube Stability)

To accommodate individual laboratory routines and to permit batch testing, the between-step delays noted previously in 7.3.2 and 7.3.3 and summarized below can be made without affecting test results.

- Venous Blood Tests

a) Between Blood Collection and Completion of Centrifugation:
90 minutes for all hematology parameters, including the Platelet Count and Hemoglobin;
or
4 hours for all hematology parameters, EXCEPT THE PLATELET COUNT.

b) Between Float Insertion and Completion of Centrifugation:
20 minutes maximum, provided the above times are not exceeded.

c) From Completion of Centrifugation to Tube Reading:
4 hours, provided blood tubes are stored vertically with the closure down.

- Capillary Blood Tests

  a) From Finger Puncture Collection into the QBC Capillary-Blood Tube to Insertion of the Float: perform all preparation steps promptly.

  b) Between Float Insertion and Completion of Centrifugation: 20 minutes maximum.

  c) From Completion of Centrifugation to Tube Reading: 4 hours, provided blood tubes are stored vertically with the closure down.

7.3.5 Test Notes

a. Protecting Blood Tubes

KEEP QBC TUBES TIGHTLY STOPPERED IN THEIR OPAQUE GLASS VIAL WHEN NOT IN USE. Remove tubes one by one as needed. Be sure to re-stopper the vial each time. Do NOT remove the strip of desiccant from the vial of tubes.

Store QBC Tubes in their sealed vial in a dark, dry place at 60° to 90°F (16° to 32°C). Protect from moisture, direct light and heat.

b. Fill Level in Venous-Blood Tubes

If the Pipetter fails to aspirate blood to within ± 1 mm of the black fill-line on the QBC Venous Blood Tube, discard the Tube and prepare a fresh Tube. NEVER ATTEMPT TO EMPTY AND REFILL THE SAME BLOOD TUBE. If a fill problem persists, the Pipetter O-rings are most likely worn or faulty. Consult the O-ring replacement procedures in Section 5.3.9. As a temporary measure in the event the Pipetter is defective, Venous Tubes can be filled manually by capillary action.

If the plasma level in a spun QBC Venous Blood Tube is below the lowest red indicator line, blood was lost through leakage or evaporation; if above the top red line, too much blood was probably aspirated during fill. VENOUS BLOOD TUBES SHOULD NOT BE TESTED UNLESS THE PLASMA LEVEL FALLS BETWEEN THE TWO RED INDICATOR LINES.

7.4 CALIBRATION DETAILS

Daily use of the Calibration Check Tubes, as described in Section 4.6.1, will ensure that the QBC II Reader is operating within factory-set tolerances.

7.5 QUALITY CONTROL

Daily testing with QBC Hematology Controls (Catalog No. 4242) is recommended in order to verify performance of the complete QBC II Plus System, including blood tubes. See Section 4.6.2.

The results of QBC II centrifugal hematology tests with whole blood should be compared periodically with those obtained by standard reference methods. The reference procedures on the following page are recommended.

Parameter	Reference Method
HCT	Centrifugal Microhematocrit
WBC	Impedance Cell Counter
GRAN	100-Cell Manual Differential Count*
LYMPH/MONO	100-Cell Manual Differential Count**
PLT	Phase Microscopy or Impedance Cell Counter
HB	Cyanmethemoglobin Method[14]

Note: Request service if the performance is not within acceptable correlation limits.

*Manual differential count of Granulocytes should include the sum of neutrophils, eosinophils and basophils.

**Manual differential count should include the sum of lymphocytes and monocytes.

Section 8
SYSTEM PERFORMANCE

8.1 TEST RESULTS

8.1.1 Digit-Decimal Format

Hematology values generated by the QBC II Plus Reader are displayed on the instrument readouts in the following decimal formats and units:

• Hematocrit (HCT)	XX.X	%	• Grans (rel.)	XX	%
• Hemoglobin (HB)	XX.X	g/dL	• Grans (abs.)	XX.X	$10/^9L$
• Platelets (PLT)	XXX	$10/^9L$	• Lymph/Mono (rel.)	XX	%
• WBC	XX.X	$10/^9L$	• Lymph/Mono (abs.)	XX.X	$10/^9L$

To convert QBC Hematocrit and Hemoglobin test results to S.I. (standard international) units, perform the following:

- Multiply QBC Hematocrit (%) by 0.01 to obtain Hematocrit (ratio);
- Multiply QBC Hemoglobin (g/dL) by 0.155 to obtain Hemoglobin in mmol/L.

When irregularities are detected in length measurements, tube-reading techniques or computed values, the Reader will automatically display a flashing alphanumeric flag and the test will be aborted (see Section 4.3.5). In such cases, no test results or only partial results will be displayed.

8.1.2 Interfaces and Cell Layer Colors

Through the microscope of the QBC II Plus Reader, interfaces between layers in the rotating blood tube should appear well defined and perpendicular to the longitudinal axis of the tube. READINGS SHOULD NOT BE MADE UNLESS THERE ARE CLEAR COLOR DEMARCATIONS BETWEEN EVERY ADJACENT CELL LAYER.

While layer colors may vary somewhat, they should be within the general family of colors previously described.

IMPORTANT: If the three expanded cell layers of the buffy coat appear greenish in color when viewed in the Reader, it usually indicates deterioration of the Acridine Orange coating.

8.1.3 Absent or Unclear Cell Layers

Under certain hematologic and pathologic conditions, the orange-yellow layer of Granulocytes may fail to form, or the lower boundary may be so poorly defined that a clear interface cannot be identified. The condition occurs when the specific gravity of the red cells shifts toward that of the granulocytic leukocytes, causing the red cells and granulocytes to intermingle.

In QBC tubes exhibiting red-cell and granulocyte intermingling, it has been determined that a large proportion exhibit an abnormal MCV, abnormal red cell distribution width (RDW), or other red-cell morphologic anomaly. In some blood specimens, the granulocyte layer may be totally absent or poorly defined despite normal red cell indices and morphology.

A missing granulocyte layer can be easily detected by the transition from the light red layer immediately into the green Lymph/Mono layer, as shown in Figure 8.1.

Should interface readings be inadvertently made where the granulocyte layer is absent, one less than the required number of cell layers (and interfaces) will be present and the Reader will not display test values.

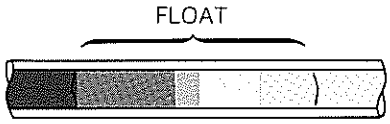


Figure 8.1. QBC Tube With Missing Granulocyte Layer.

8.1.4 Dark Band Formation Between Gran and Lymph/Mono Layers

The appearance of a thin-to-heavy dark red band (Figure 8.2) between the GRAN layer and LYMPH/MONO layer is not uncommon. Blood tubes exhibiting dark banding can be tested, provided a clear demarcation exists between the GRAN layer and the bottom of the dark band. When reading the 4th interface in dark-banded tubes, always align the arrow tip at the bottom of the dark band, i.e., at the interface between the orange-yellow GRAN layer and the dark band.

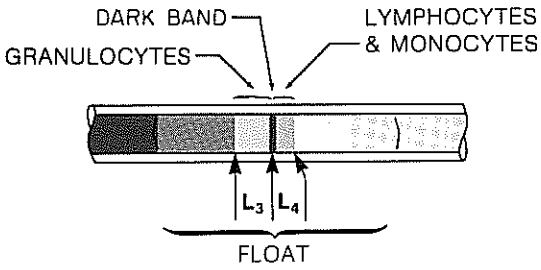


Figure 8.2. QBC Tube With Dark Band Formation Between GRAN and LYMPH/MONO Layers.

8.1.5 Cell Accumulations on Top of Float

In some blood tubes, accumulations of fluorescing cells may be seen adhering to the top and sides of the float while the platelet-to-plasma interface is being read. This appears to be related to the age and conditions of the sample. Studies have shown that the effect is not significant in specimens that are less than 90 minutes old. Therefore, it is important that the limits specified under "Assay Timing" in Section 7 not be exceeded.

8.1.6 Blurred Interfaces

Blurred or fuzzy interfaces—ranging from mild to severe—may result from entrapped lint particles, an improperly-seated closure, or when ambient room temperature exceeds the recommended 90°F (32°C) upper limit. Note: QBC tests must not be run in areas where the temperature exceeds 90°F.

Rotation of the blood tube in the Reader tends to optically average waviness or irregularities that may exist between cell layer boundaries, causing them to appear as straight, "readable" interfaces. As wavy conditions or irregularities increase, the visual effect in the rotating tube is one of color blending between boundaries or blurring. WHEN EXTREMELY FUZZY OR DIFFICULT-TO-READ INTERFACES ARE OBSERVED, THE SPECIMEN SHOULD BE TESTED BY ANOTHER METHOD.

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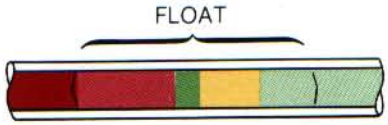
Should interface readings be inadvertently made where the granulocyte layer is absent, one less than the required number of cell layers (and interfaces) will be present and the Reader will not display test values.



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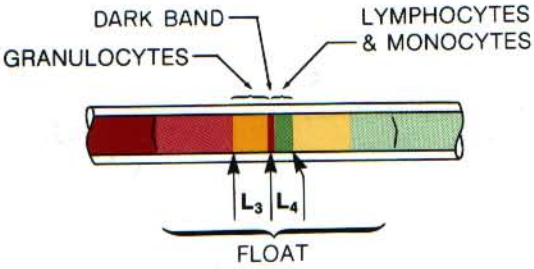

Figure 8.2. QBC Tube With Dark Band Formation Between GRAN and LYMPH/MONO Layers.

8.1.5 Cell Accumulations on Top of Float

In some blood tubes, accumulations of fluorescing cells may be seen adhering to the top and sides of the float while the platelet-to-plasma interface is being read. This appears to be related to the age and conditions of the sample. Studies have shown that the effect is not significant in specimens that are less than 90 minutes old. Therefore, it is important that the limits specified under "Assay Timing" in Section 7 not be exceeded.

8.1.6 Blurred Interfaces

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Rotation of the blood tube in the Reader tends to optically average waviness or irregularities that may exist between cell layer boundaries, causing them to appear as straight, "readable" interfaces. As wavy conditions or irregularities increase, the visual effect in the rotating tube is one of color blending between boundaries or blurring. WHEN EXTREMELY FUZZY OR DIFFICULT-TO-READ INTERFACES ARE OBSERVED, THE SPECIMEN SHOULD BE TESTED BY ANOTHER METHOD.

TABLE VIII-1
EXPECTED VALUES - QBC II PLUS HEMATOLOGY PARAMETERS[8]

Parameter		VENOUS BLOOD Mean Value ($\bar{x}$)	VENOUS BLOOD Range (± 2 S.D.)	CAPILLARY BLOOD Mean Value ($\bar{x}$)	CAPILLARY BLOOD Range (± 2 S.D.)
HCT (%)	Males	44.2	36.8-51.5	43.3	35.4-51.2
	Females	40.4	34.2-46.5	40.7	34.7-46.6
PLT ($x10^9$/L)		268	151-385	261	124-399
WBC ($x10^9$/L)		7.0	4.1-9.9	7.3	3.7-10.9
GRAN (%)		61.6	44.6-78.5	64.8	50.6-79.1
GRAN ($x10^9$/L)		4.5	1.8-7.2	4.5	2.2-6.9
LYMPH/MONO (%)		38.4	21.5-55.4	35.1	20.9-49.4
LYMPH/MONO ($x10^9$/L)		2.7	1.5-3.9	2.4	1.2-3.5

TABLE VIII-2
NORMAL HEMATOLOGY RANGES

HCT (%)[1]	Males	40.0-54.0
	Females	37.0-47.0
PLT ($x10^9$/L)[1]		140-440
WBC ($x10^9$/L)[1]		4.3-10.0
GRAN*	%	44.2-80.2
	($x10^9$/L)	2.0- 8.8
LYMPH/ MONO*	%	28.0-48.0
	($x10^9$/L)	1.2- 5.3

*Note: The normal ranges in Table VIII-2 for Granulocytes and Lymphocytes/ Monocytes were derived from Miale[12]. The reported normals for each white-cell type are grouped as Granulocyte and Lymphocyte/Monocyte sub-populations.

The Hemoglobin range in blood samples from normal adults tested by the QBC II Plus method is virtually identical to the following ranges reported in the literature[1]:

- Males: 14-18 g/dL
- Females: 12-16 g/dL

It is recommended that each laboratory develop normal ranges based on the characteristics of its own patient population.

8.5 SPECIFIC PERFORMANCE CHARACTERISTICS[8]

8.5.1 Precision

Data on within-run reproducibility of QBC II Plus with Venous Tubes and Capillary Tubes at three blood levels are shown in Table VIII-3. The means and ranges listed are based on replicate tests performed on 10 tubes per sample, e.g., 70 tubes where "n=7". The precision studies were conducted over a period of months using several calibrated QBC Readers.

TABLE VIII-3
QBC II PLUS WITHIN-RUN PRECISION

Parameter	QBC Venous Blood Tubes			QBC Capillary Blood Tubes		
	No. of Samples (n=)	Mean Value	Mean C.V.(%)	No. of Samples (n=)	Mean Value	Mean C.V.(%)
HCT (%)	7 16 3	31.3 40.9 47.4	1.34 1.38 1.01	6 16 2	34.6 40.6 45.1	2.06 2.29 2.07
HB (g/dL)	1 1 1	10.9 14.0 16.4	0.8 1.0 1.4	1 1 1	4.9 11.5 17.9	3.0 1.3 0.9
PLT ($x10^9$/L)	13 7 6	128 255 430	10.90 9.48 7.30	12 9 3	136 262 336	15.48 11.67 6.96
WBC ($x10^9$/L)	3 15 8	4.57 6.9 11.93	4.43 5.37 4.33	3 17 4	4.6 6.6 12.8	9.07 8.25 4.96
GRAN (%)*	9 18 31	53.0 64.6 76.3	4.94 3.47 2.90	5 11 8	54.4 64.2 72.9	8.18 6.46 5.28
GRAN ($x10^9$/L)	8 22 28	2.26 4.04 7.16	8.35 5.90 4.90	4 12 8	2.4 3.5 6.8	8.5 7.4 5.2
LYMPH/MONO ($x10^9$/L)	15 33 10	1.42 2.29 3.27	12.60 11.50 7.90	9 9 6	1.7 2.2 2.9	15.3 14.9 11.2

*QBC % Granulocytes and % Lymphocytes/Monocytes always total 100%. Therefore standard deviations for % Granulocytes and % Lymphocytes/Monocytes are identical.

8.5.2 Accuracy

Data on the correlation of QBC II Plus Hematocrit, Hemoglobin, WBC and Platelet parameters with standard reference methods are tabulated in Table VIII-4 and Figures 8.3-8.10. For correlation data on Granulocyte and Lymphocyte/Monocyte counts, see Figures 8.11-8.18.

TABLE VIII-4
QBC II PLUS CORRELATION DATA (HCT, HB, WBC, PLT)

Parameter	Specimen (Reference Method)	n=	Range of Reference Values	Correlation Coefficient	Slope	Intercept
HCT (%)	Venous (Microhematocrit)[11]	200	16.5 - 56.6	0.9884	0.9952	-0.3655
	Capillary (Microhematocrit)[11]	100	34.0 - 50.7	0.9450	1.0000	0.0027
HB (g/dL)	Venous (Cyanmethemoglobin)[14]	206	7.0 - 17.8	0.9905	1.0007	-0.0477
	Capillary (Cyanmethemoglobin)[14]	112	10.1 - 18.2	0.9590	0.9888	-0.0507
PLT (x 10^9/L)	Venous (See Note 1)	492	9 - 733	0.9056	0.9744	-8.2440
	Venous (Phase Microscopy)	101	2 - 869	0.9326	1.0260	-0.0583
	Capillary (UF-100)	99	146 - 383	0.7129	0.9903	0.1430
WBC (x 10^9/L)	Venous (See Note 2)	385	1.8 - 32.0	0.9825	0.9613	0.5059
	Capillary (Coulter ZBI)	100	3.9 - 12.7	0.8652	0.9870	-0.0592

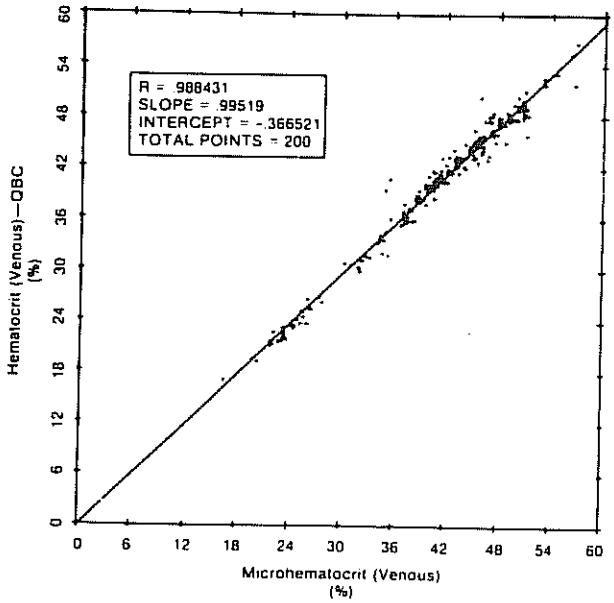

Figure 8.3.
Venous Blood Hematocrit:
QBC II Plus Correlation with Micro-Hematocrit Reference Method.[11]

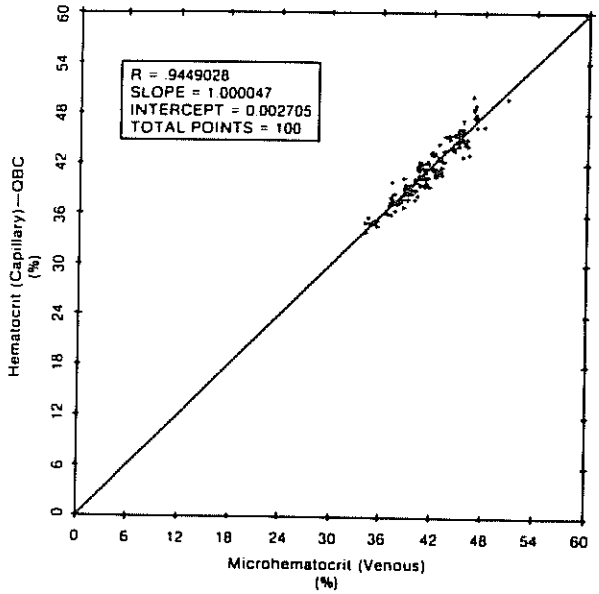

Figure 8.4.
Capillary Blood Hematocrit:
QBC II Plus Correlation with Micro-Hematocrit Reference Method.[11]

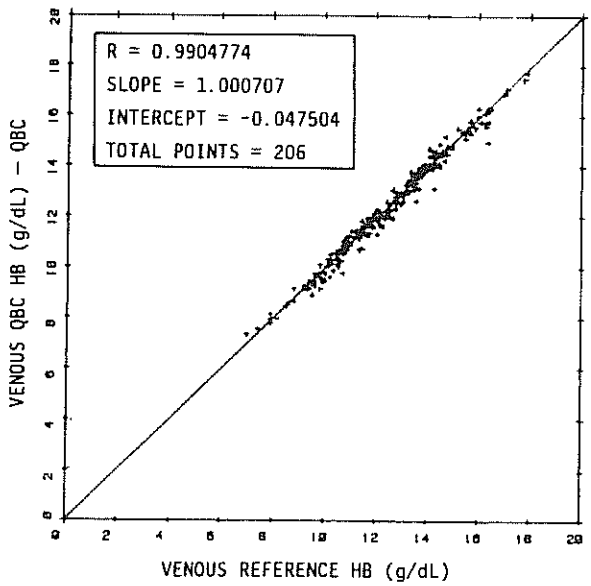

Figure 8.5.
Venous Blood Hemoglobin:
QBC II Plus Correlation with Reference Hemoglobin[14]

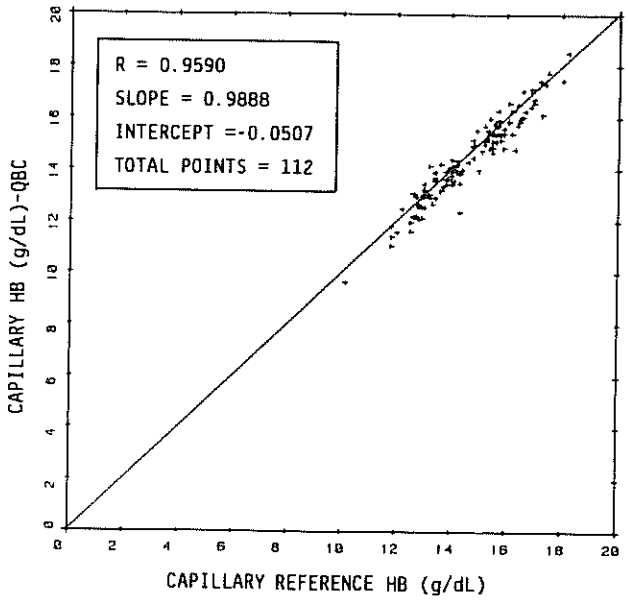

Figure 8.6.
Capillary Blood Hemoglobin:
QBC II Plus Correlation with Reference Hemoglobin[14]

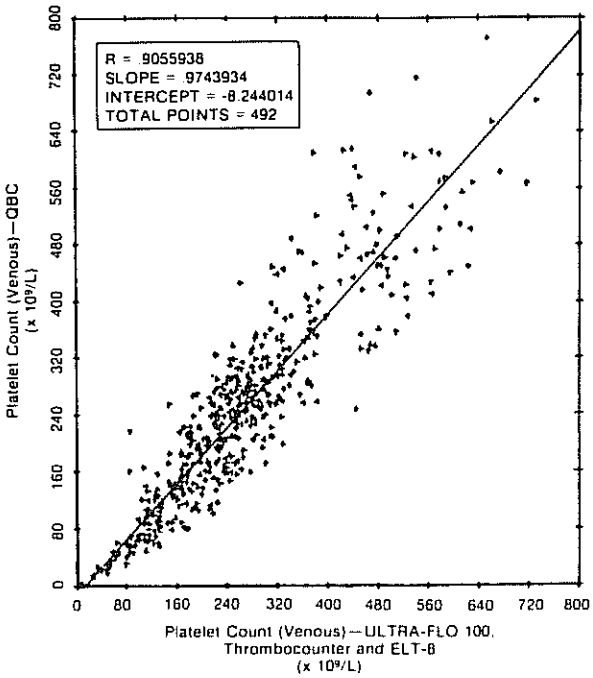

Figure 8.7.
Venous Blood Platelet Count:
QBC II Plus Correlation with ULTRA-FLO 100 and Coulter S+ Platelet Count.

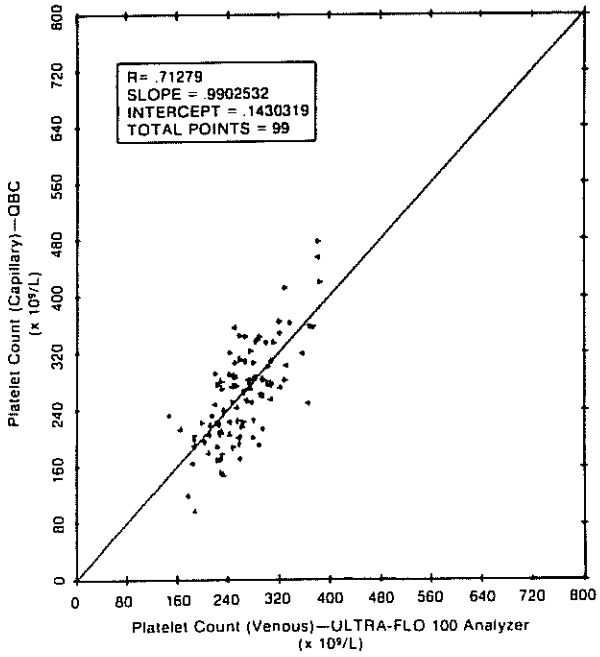

Figure 8.8.
Capillary Blood Platelet Count:
QBC II Plus Correlation with ULTRA-FLO 100 Platelet Count.

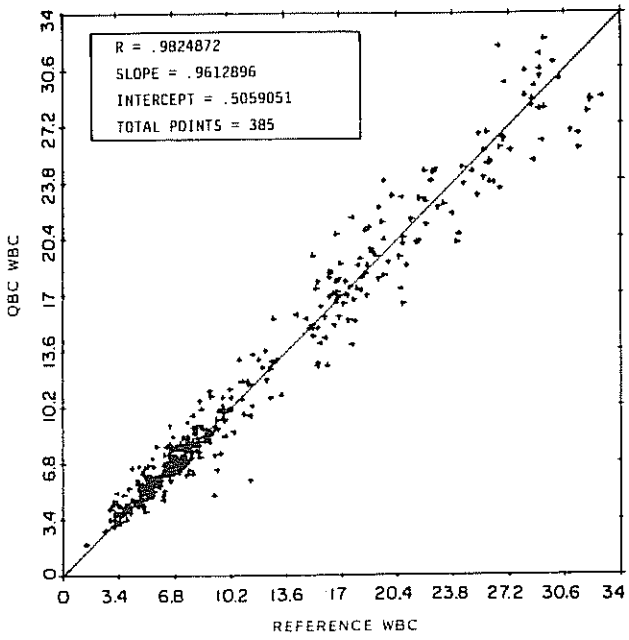

Figure 8.9.
Venous Blood White Cell Count:
QBC II Plus Correlation with Coulter ZBI and Coulter S+ White Cell Count.

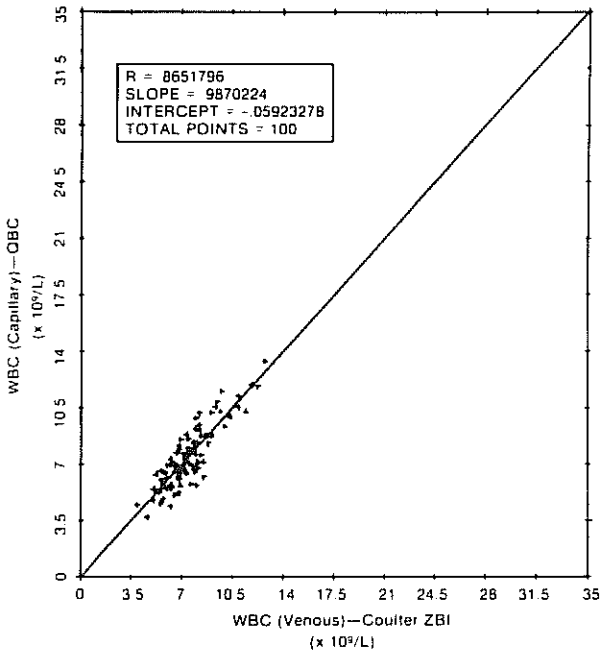

Figure 8.10.
Capillary Blood White Cell Count:
QBC II Plus Correlation with Coulter ZBI White Cell Count.

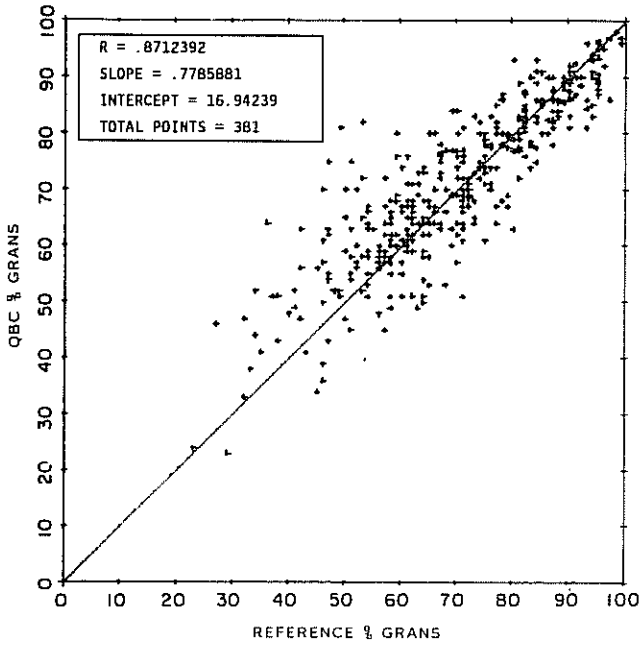

Figure 8.11.
Venous Blood % Granulocytes:
QBC II Plus Correlation with
100-Cell Manual Differential.

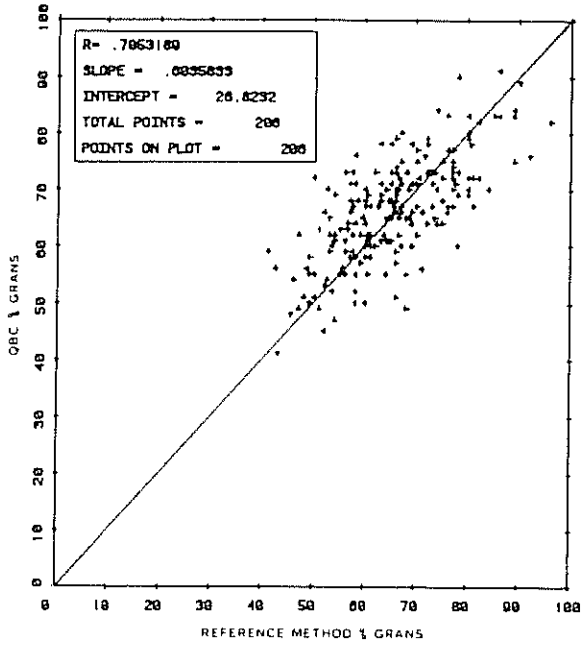

Figure 8.12.
Capillary Blood % Granulocytes:
QBC II Plus Correlation with
100-Cell Manual Differential.

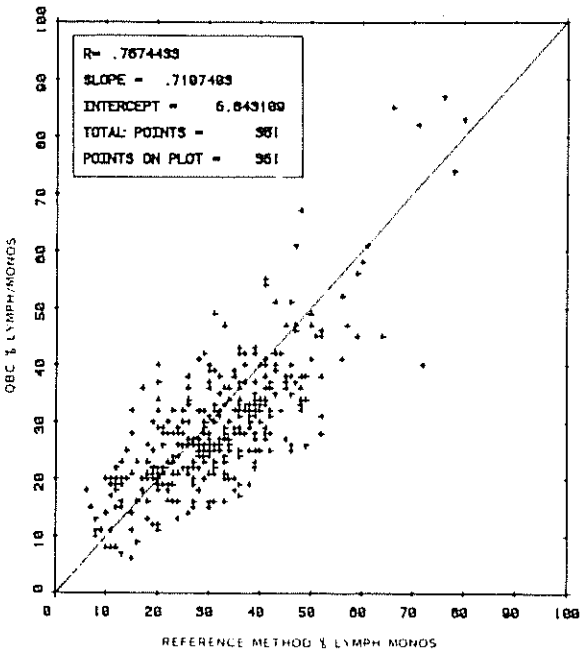

Figure 8.13.
Venous Blood % Lymph/Mono:
QBC II Plus Correlation with
100-Cell Manual Differential.

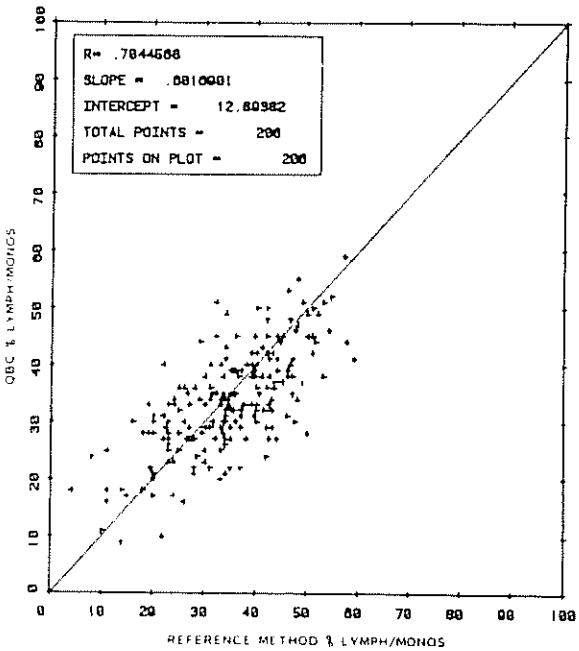

Figure 8.14.
Capillary Blood % Lymph/Mono:
QBC II Plus Correlation with
100-Cell Manual Differential.

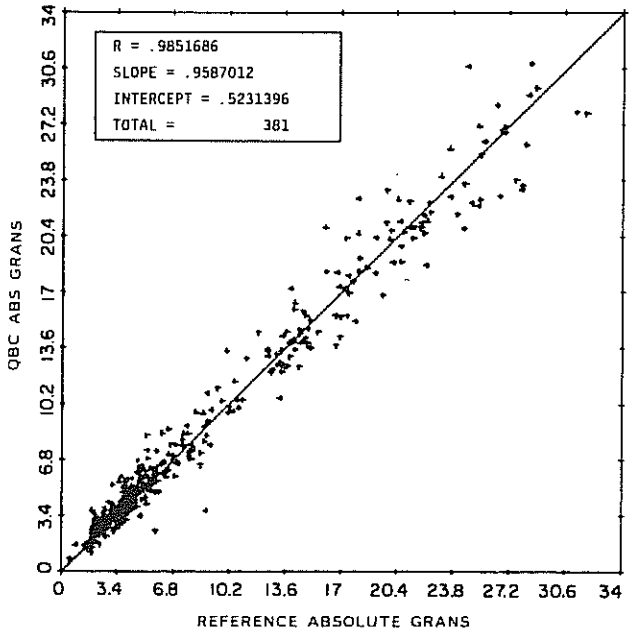

Figure 8.15.
Venous Blood Granulocyte Count: QBC II Plus Correlation with Reference Manual Count.

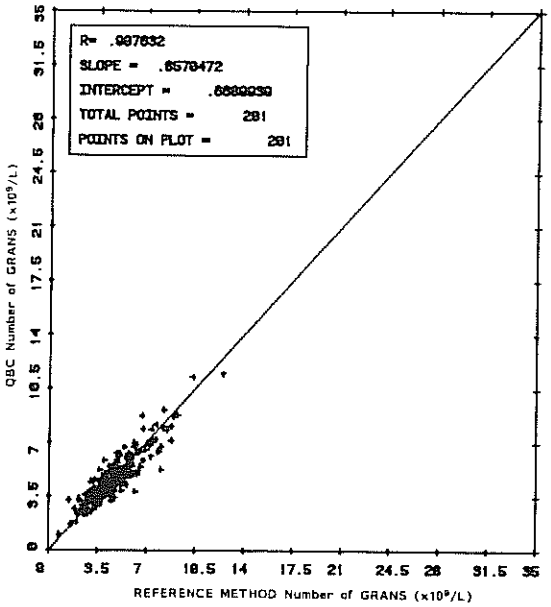

Figure 8.16.
Capillary Blood Granulocyte Count: QBC II Plus Correlation with Reference Manual Count.

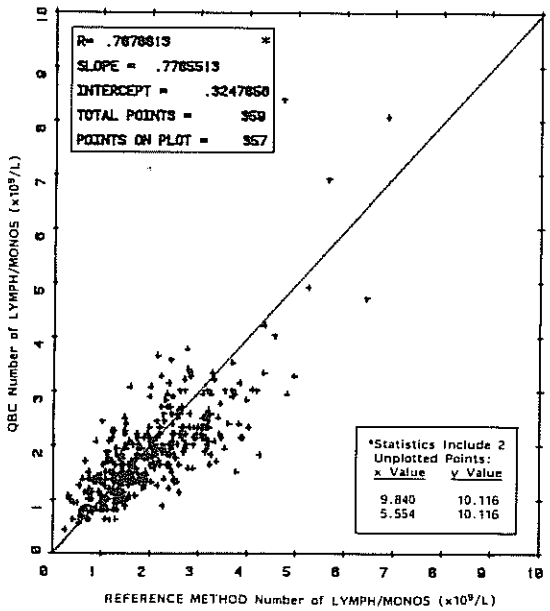

Figure 8.17.
Venous Blood Lymphocyte/Monocyte Count: QBC II Plus Correlation Reference Manual Count.

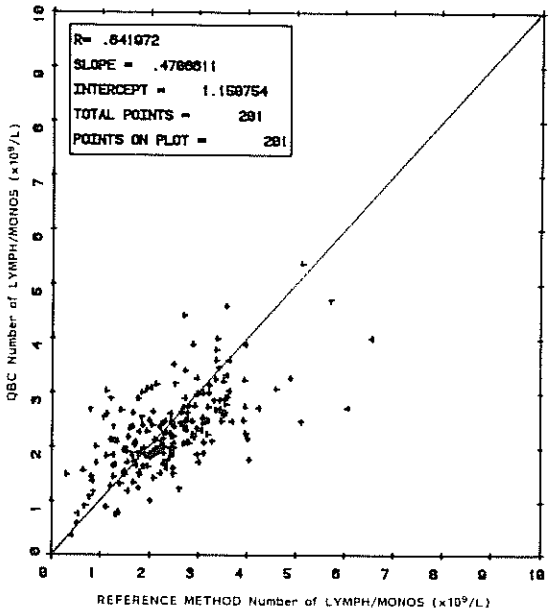

Figure 8.18.
Capillary Blood Lymphocyte/Monocyte Count: QBC II Plus Correlation with Reference Manual Count.

Section 9
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Appendix A
DISCUSSION OF ALERT FLAGS

Table IV-1 in Section 4 lists the alert flags and test result symbols that are programmed into the QBC II Plus Reader, together with brief summaries on probable causes of the flagged conditions. This Appendix provides more detailed descriptions on the test conditions most likely to trigger the flags and symbols.

"-L": Occurs when any interface reading yields a negative or a zero length, e.g., reading the 2nd interface after reading the 3rd interface, or reading the same interface twice.

"H2":* Can appear only after reading the 2nd interface in either the Venous or Capillary modes. For the flag to occur, the cone of the float would be virtually resting on the top of the closure. This condition could arise if: 1) the blood specimen is excessively plasma-rich (Venous Test only), i.e., the tube was filled with unmixed, sedimented blood; 2) the density of the float is too great (out of tolerance); or 3) the tube contains insufficient specimen due to a filling error or blood loss. In all cases, a new tube must be prepared and the test repeated. If the specimen is venous blood, be sure it is well mixed. Reappearance of the flag would suggest an extremely low hematocrit.

"H1":* Can appear only after reading the 3rd interface in either the Venous or Capillary modes. This condition could result from: 1) a defective (out of tolerance) float, causing the light-red erythrocyte layer to extend above the float; or 2) an extremely high hematocrit or other blood abnormality, causing the same condition. The test should be repeated with a new tube and float to eliminate the possibility of a defective float. Reappearance of the "H1" flag indicates that the specimen must be tested by other methods.

"L2":* Can appear after either the 4th, 5th or 6th interface reading in the VENOUS MODE ONLY. It occurs when the top of the cell layer extends above the top of the float. When an "L2" appears after entering the 4th or 5th interface, a valid hematocrit (HCT) test value will be displayed; when it occurs after entering the 6th interface, valid HCT, WBC, GRANS and LYMPH/MONO values will be displayed.

The "L2" flag usually indicates an abnormally large population of white cells or platelets.

"A8":* Can appear ONLY IN THE CAPILLARY MODE. Can occur: 1) if the top of float is read instead of the meniscus; 2) if the Capillary Tube was either grossly over-filled or contains insufficient blood due to a filling error or blood loss; or 3) with a high white cell count, platelet count or blood abnormality, causing a cell layer to extend beyond the top of the float. If another capillary specimen can be obtained, the test should be repeated with a correctly filled tube. Reappearance of the "A8" flag indicates that the specimen must be tested by other methods.

*Always prevents display of hemoglobin value.

Over-range and no value Flags:

The flashing flags "---" for HCT, "99.9" for WBC, and "999" for Platelets appear when the test value exceeds the dynamic capability or display limits of the Reader. In such cases, the specimen must be tested by other methods to determine the flagged paramater.

The "---" flag with no test value will appear in HB in the following cases: if any other test value is flagged; HCT used in the derivation of HB is below 15 % or above 65 %; or the computed HB is below 5 g/dL or above 20 g/dL.

The displayed HB test result will flash on and off whenever the red cell density factor, which was used in the derivation of hemoglobin, is outside pre-programmed limits. In such cases, the blood specimen should be examined more closely, preferably by a peripheral smear, to determine the nature of the abnormality.

"P1"/ "P2" (Service Flag):

Appearance of a flashing Service Flag "P1" or "P2" in the platelet (PLT) display immediately after pressing the POWER or CLEAR button indicates a transient condition or malfunction in the random access memory (RAM) or read only memory (ROM) of the microprocessor. If a Service Flag cannot be cleared by pressing the Power switch off and on, Request Service.

Appendix B
TEST PRINTOUTS

As noted previously, the QBC II Plus Reader incorporates circuitry and a communications port for operation with an Epson LX-series printer. Instructions for connection to a printer are described in Section 2.2.3.

- Obtaining Test Printouts

  Detailed instructions for operating the Epson Printer are provided in the manufacturer's handbook supplied with the Printer.

  When the Reader-to-Printer system is functional, transmission of test results to the printer is initiated within microseconds after pressing "ENTER" at the last interface of the QBC blood tube, i.e., 6th in the "VEN" mode and 7th in the "CAP" mode. Test results will be displayed on the panel of the Reader while data transmission to the printer is in progress.

- Format and Flags:

  Test results are printed on perforated, adhesive-backed 3" x 4" labels supplied in the Catalog 4482 Printer Kit. As shown in Figure B-1, the type of QBC test (i.e., Venous Sample or Capillary Sample) is printed on the label, with space provided for writing in the patient's name and the test date.

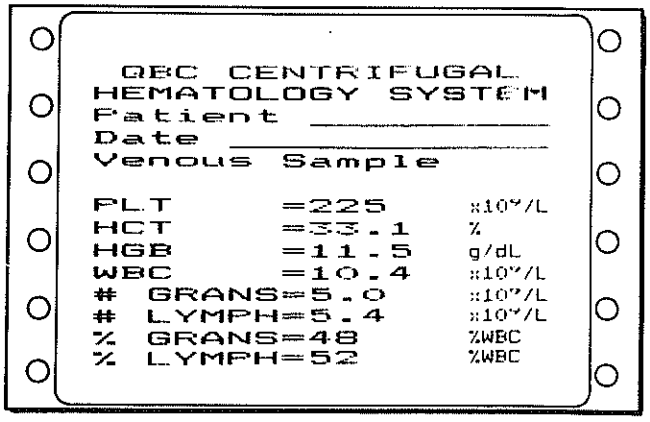

Figure B-1. Printout Format of Typical QBC Venous Blood Test.

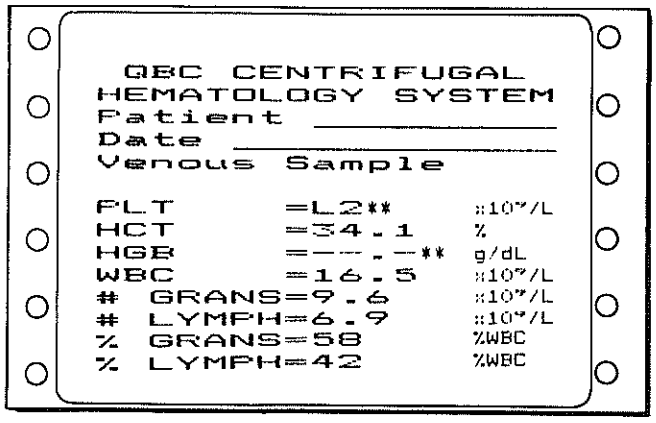

Figure B-2. Sample Printout Showing Error Flag for PLT Parameter.

In an error condition, the Reader will transmit and print an alphanumeric "alert flag" with two asterisks (**) opposite the appropriate parameter and dashes opposite hemoglobin (HB). See the example in Figure B-2. Upon completion of the transmission, the same alert flag will flash on the display panel of the Reader.

As discussed under Alert Flags in Section 4.3.5, further testing depends on the nature of the problem that caused the error condition and will generally involve:

- Repeating the test with the same QBC blood tube;
- Re-testing with a newly prepared QBC blood tube; or
- Obtaining only partial test results (or no results) due to anomalies in the blood that may render the tube unreadable.

- Troubleshooting

If test results are displayed on the QBC II Plus Reader, but are not recorded by the printer, check and correct the following:

a) Printer "Power" switch is OFF.
b) Printer "On Line" light and switch are OFF.
c) "No Paper" light of printer is on, indicating unit is out of label roll stock.
d) Interface cable at printer or Reader is loose or disconnected.

If problems with the printing function persist, request technical service for correction of a circuit malfunction.

Appendix C
PARTS LIST -
QBC II PLUS DISPOSABLES, ACCESSORIES, AND SPARES

	Reorder No.
TEST DISPOSABLES	
QBC Venous-Blood Tubes (100 tests)	4240
QBC Capillary-Blood Tubes (100 tests)	4241
REPLACEMENT ACCESSORIES	
Work Station	4226
QBC Venous-Blood Pipetter (with spare O-rings and grease)	4225
O-rings, Pipetter (set of 3)	4225-603-000
Grease, Pipetter (1 box)	2513-611-000
QBC II/QBC II Plus Venous Cal Check Tube	4235
QBC II/QBC II Plus Capillary Cal Check Tube	4236
Operator's Manual	4247
Forceps	4227-610-000
Spare Parts & Accessories Kit	4239
Dust Cover	4527
SPARE PARTS	
Lamp, Reticle Arrow - 1 ea.	2510-624-513
Lamp, Tube (White) Light - 1 ea.	2510-624-512
Lamp, Illuminator - 1 ea.	4227-602-000
Thrust Pivot, Tube Holder	4460-602-001
Digit Display, Seven Segment Readout	2510-621-746
Fuse, 3AG 1-1/2 Amp. - 5 ea.	2510-623-814
Grease, Lead Screw (1 tube)	4200-600-006
POWER Switch (120 volt)	4460-650-002
PRINTER SYSTEM	
QBC Printer Package	4482
Reader-to-Printer Ribbon Cable	4407
Data Printing Labels (2500 ea.)	2303
REFERENCE CONTROLS	
QBC Hematology Controls, 2 Vials ea., Normal and Abnormal	4242

Appendix D
WARRANTY - QBC II PLUS SYSTEM

Becton Dickinson Primary Care Diagnostics, (hereinafter referred to as Becton Dickinson), warrants the QBC II Plus System to be free from defects in workmanship and materials for a period of one (1) year from date of installation, provided the system is operated in accordance with the QBC II Plus System Operator's Manual. During such period, Becton Dickinson agrees to replace or repair any parts which, in its judgment, are found to be defective, provided the system has not been subjected to misuse or abuse. The warranty stated herein shall extend to the original consumer and not to any subsequent consumer of the System.

Becton Dickinson shall not be liable for any incidental or consequential damages. Becton Dickinson makes no other warranties, expressed or implied, except as stated herein.