OPERATOR'S MANUAL

for the

Centrifugal Hematology System

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CONTENTS

SECTION 1
INTRODUCTION

1.1 INTENDED USE

The Clay Adams QBC II System (Figure 1.1) is a seven-parameter hematology screening device which yields the following quantitative values from a centrifuged blood tube:

- Hematocrit
- Platelet Count
- White Blood Cell Count
- Granulocyte Count (% and number) and
- Lymphocyte-Monocyte Count (% and number).

Figure 1.1. The QBC II Centrifugal Hematology System.

The QBC II Platelet Count, White Blood Cell Counts and counts of the Granulocyte and Lymphocyte/Monocyte white cell subpopulations are estimates 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, but may yield normal quantitative relationships of Granulocytes to Lymphocytes/Monocytes. The QBC II 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.

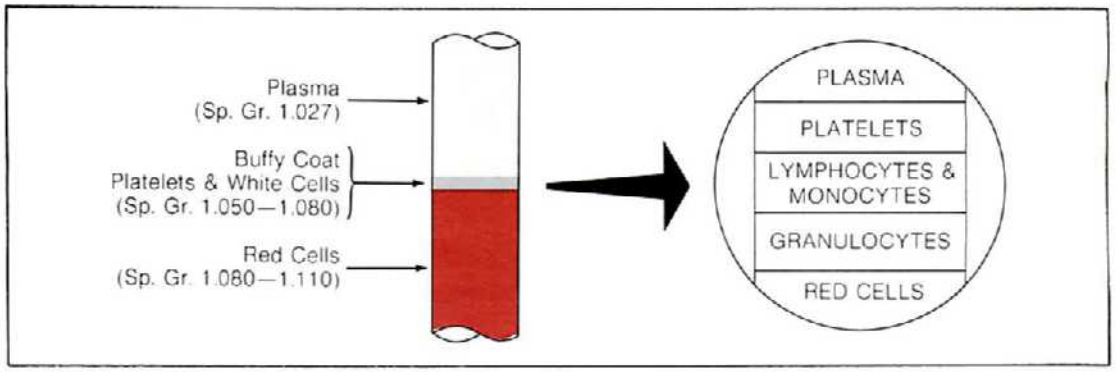


Figure 1.2. Section of Typical Spun Microhematocrit Tube, Showing Relative Densities and Layering of the Formed Elements.

Utilizing mechanical expansion and optical magnification, augmented by supravital cell staining, the QBC II System 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, a hematocrit or PCV is also obtained.

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 CBC or complete blood count is perhaps the most frequently requested and clinically useful test performed on blood. The QBC II System provides the physician with abbreviated 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 II 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.

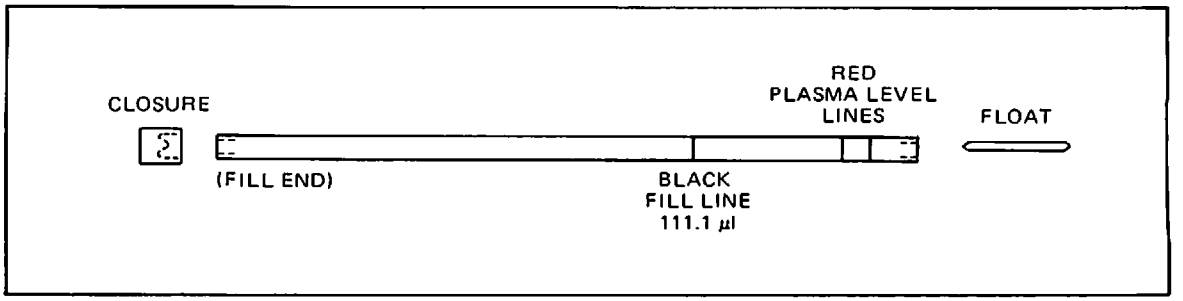


Figure 1.3. QBC Tube for Venous Blood.

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.

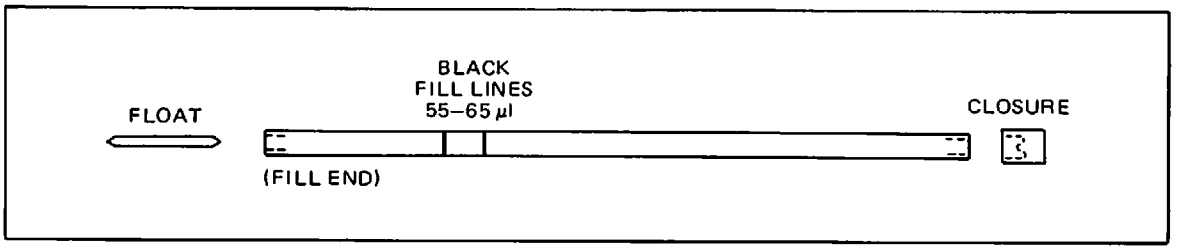


Figure 1.4. QBC Tube for Capillary Blood.

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 creating a clearly visible lighter band of red cells surrounding the bottom portion of the float.

Two red plasma level lines are provided on QBC Venous-Blood Tubes (see Figure 1.3) for checking fill volume in the prepared blood tube prior to testing. Because of the volume of specimen displaced by the float, the plasma level must be between the two red lines after centrifugation of the blood tube. If the plasma is above or below the red lines, the blood tube must be discarded and a new tube prepared. Failure of the plasma level to fall between the red lines may result from a Pipetter malfunction or loss of blood through evaporation or leakage.

Layer lengths (packed cell volumes) are measured in the QBC II Reader. A "MODE" button is provided to program the instrument for reading 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 within the optical system. The length or thickness of each cell layer is fed into the Reader's micro-computer by pressing an "ENTER" button each time an interface is aligned with the arrow. Values for HCT, PLT, WBC, GRANS, and LYMPH/MONO, are displayed on the front panel of the Reader after location of the last interface has been entered.

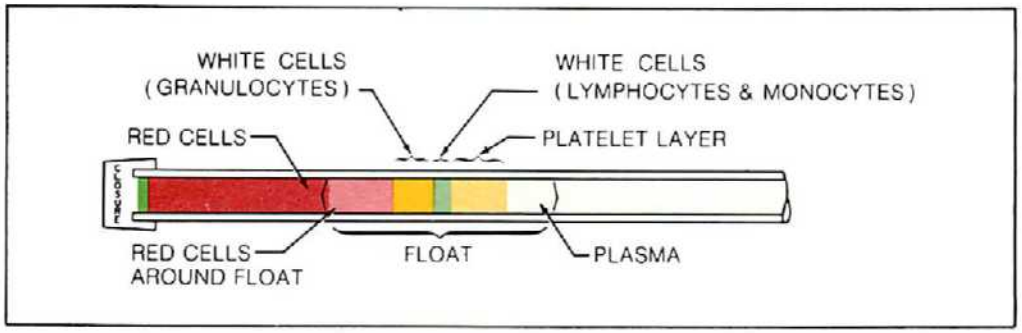


Figure 1.5. Cell Layers and Their Approximate Colors in the Spun QBC Blood Tube. (Note: Closure Fluoresces a Translucent Green.)

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.

1.4 WARNINGS AND PRECAUTIONS

The QBC II 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.

> **WARNING**
> BLOOD SPECIMENS MAY CONTAIN THE HEPATITIS B VIRUS OR HUMAN T-LYMPHOTROPIC VIRUS TYPE III (HTLV-III/LAV). ALWAYS HANDLE BLOOD SPECIMENS AS POTENTIAL BIOHAZARDS.

SECTION 2
INSTALLATION PROCEDURES AND SPECIAL REQUIREMENTS

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

NOTE: In the United States, installation of the System will normally be performed by a Clay Adams Representative. To arrange for installation service or to obtain technical assistance, call the Clay Adams Technical Service Department: 1-(800) 631-8064. Outside the United States, contact your local distributor or Becton Dickinson and Company Office.

2.1 SYSTEMS AND PACKAGING DETAILS

QBC II Systems are available in the electrical ratings and models as listed below.

QBC II System No.	Voltage/ Frequency (Hz)	QBC II Reader Model No.	QBC Centrifuge Model No.
4465	120 V/60 Hz	4460	4207
4476	120 V/60 Hz	4477	4207
. . . . .			
4403	120 V/60 Hz	4477	4207
4404	220 V/50 Hz	4406	4209
4405	100 V/50-60 Hz	4462	4208

Note: All QBC II Readers, except Model 4460, are equipped with circuitry and a rear connector for operation with an accessory Epson printer.

The 4476 QBC II System (120 V/60 Hz) is supplied with a Catalog No. 4482 Printer Package, containing an Epson LX-86 Printer, Reader-to-Printer Ribbon Cable, and accessory equipment. See Section 2.2.5.

In the United States the components of a complete QBC II System are shipped to the customer in separate cartons as follows: the QBC II Reader and accessories (see below); QBC Centrifuge; QBC Work Station; and, where applicable, a QBC Printer Package. Outside the United States, components of the System are shipped in one large container.

The following accessories are packaged with the QBC II 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; and a 5/64" hex key for service and maintenance;
- 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 System is provided in Appendix B of this Manual.

2.2 INSTALLATION REQUIREMENTS

2.2.1 Laboratory Environment

Locate the Reader, Centrifuge and test accessories of the QBC II 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, etc.

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 Cordset Connection to Reader (Model 4406 Only)

All QBC II Readers, with the exception of the 220 volt Model 4406 Reader, are equipped with an integral line cord in the back of the instruments. Model 4406 is shipped with a loose cordset. Before connection to a power source, the female plug of the cordset must be firmly inserted on the 3-prong connector located in the back of the Model 4406 Reader (see Figure 2.1).

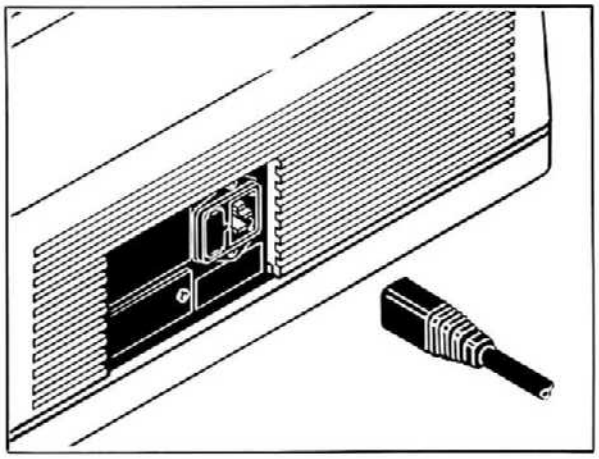


Figure 2.1. Cordset Connection of Plug on Model 4406 Reader.

2.2.3 Power Requirements

Plug the power cords of the QBC II Reader and QBC Centrifuge into grounded electrical receptacles rated for the line voltage and frequency requirements specified on their respective data plates. (See also 2.2.4 below.)

> 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.

2.2.4 Electrical Requirements

For proper functioning of the QBC II Reader and QBC Centrifuge, voltage output of the power source for the System must be between the ranges listed below.

Reader/Centrifuge Model Nos.	Voltage Tolerances
4460 and 4477/4207	105 and 130 Volts
4406/4209	198 and 242 Volts
4462/4208	90 and 110 Volts

If the line voltage is known to fluctuate outside these tolerances, notify the Clay Adams Installer. The use of a special voltage regulator may be required.

2.2.5 Printer Utilization

A Catalog No. 4482 Printer Package or equivalent components are required for automatic recording of QBC II test results on pressure-sensitive labels. The Printer Package contains an Epson LX-86 Printer, Epson Tractor Feed Unit, Printing Labels, Epson Manual, and a special Catalog No. 4407 Reader-to-Printer Ribbon Cable Assembly.

Note: An Epson LX-86 Printer and Tractor Feed Unit can be purchased locally; however, the special Reader-to-Printer Ribbon Cable Assembly (Catalog No. 4407) is required and can be ordered separately from Clay Adams.

a. Connecting Reader-to-Printer Cable

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 2.2 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 QBC II Reader.
2) Secure the plug to the connector by manually tightening the knurled Captive Screws to the Jack sockets 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.

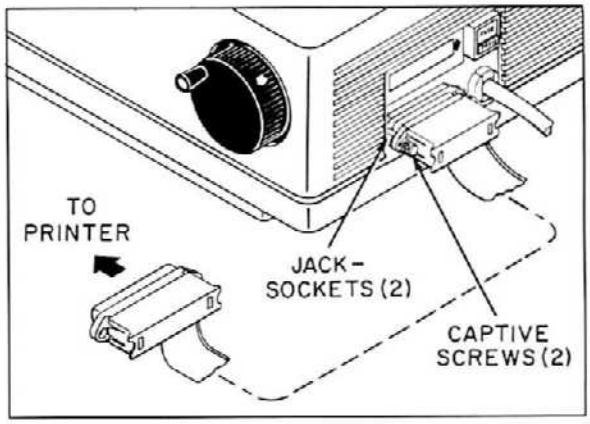


Figure 2.2. Ribbon Cable Connection From Reader to Printer.

b. Printer and Electrical Ratings

Interface circuitry in QBC II Readers equipped for a printer is compatible only with an Epson LX-86 Printer (or older LX-80 model). Do NOT attempt to connect the Reader to any other printer.

If the Epson LX-86 Printer is purchased locally, be sure the electrical rating of the Printer is compatible with the electrical rating of the QBC II Reader.

c. Operating Instructions

See Appendix D of this Manual for operating details on QBC II Readers with printer capability. For printer operation, consult the Epson Manual.

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 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 QBC II 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 QBC II Reader prior to performing hematology tests. 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 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.

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 QBC II Reader after suitable training and under the guidance of the Clay Adams Installer. Note: New calibration tolerance values should be determined when there is a change in primary operators.

SECTION 3
PRINCIPLES OF OPERATION AND SPECIFICATIONS

3.1 QBC II SYSTEM COMPONENTS

As previously described, the QBC II System consists of an electro-optical Reader and high speed QBC Centrifuge for cell packing in blood tubes. 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 READER

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

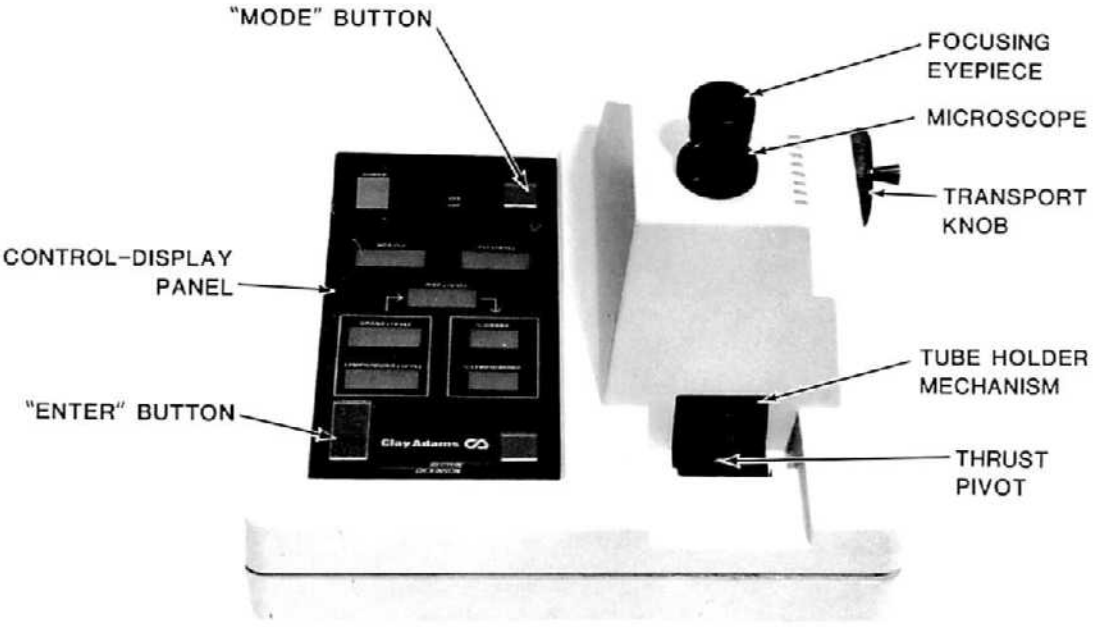


Figure 3.1. External Features of QBC II Reader.

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 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.

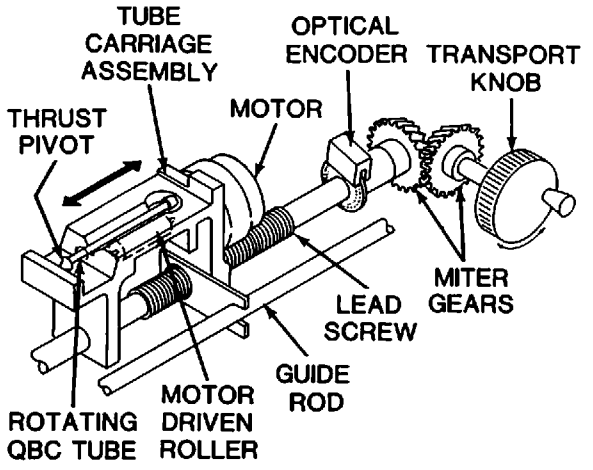


Figure 3.2.
Tube Reader Mechanical System

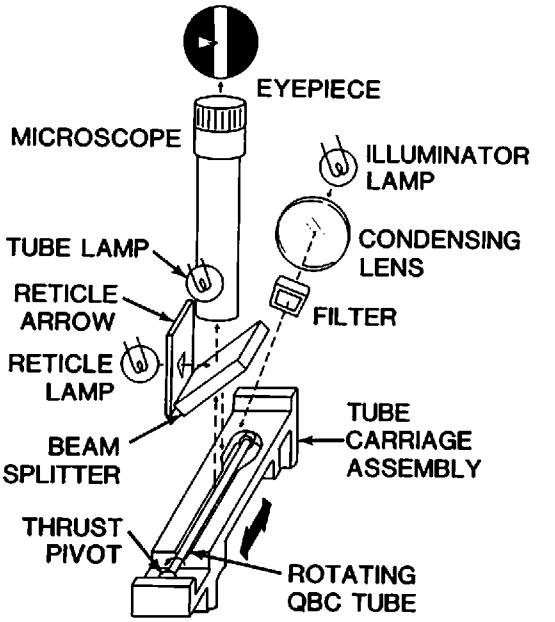


Figure 3.3.
Tube Reader Optical System.

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 auxiliary white light is provided by the Tube Lamp to illuminate the interface between the dark and light layers of red cells (2nd interface).

By imparting rotational movement to the blood tube around its longitudinal centerline, cell layer boundaries are viewed around their entire perimeters, and irregularities at the interfacing boundaries are optically averaged.

A stationary, back-lighted reticle arrow (Figures 3.3 and 3.4) is provided in the optics for aligning and "reading" of 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.

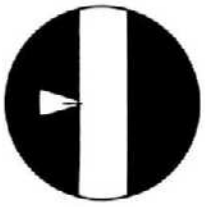


Figure 3.4. Reticle Arrow and QBC Tube Viewed Through Microscope of QBC II Reader.

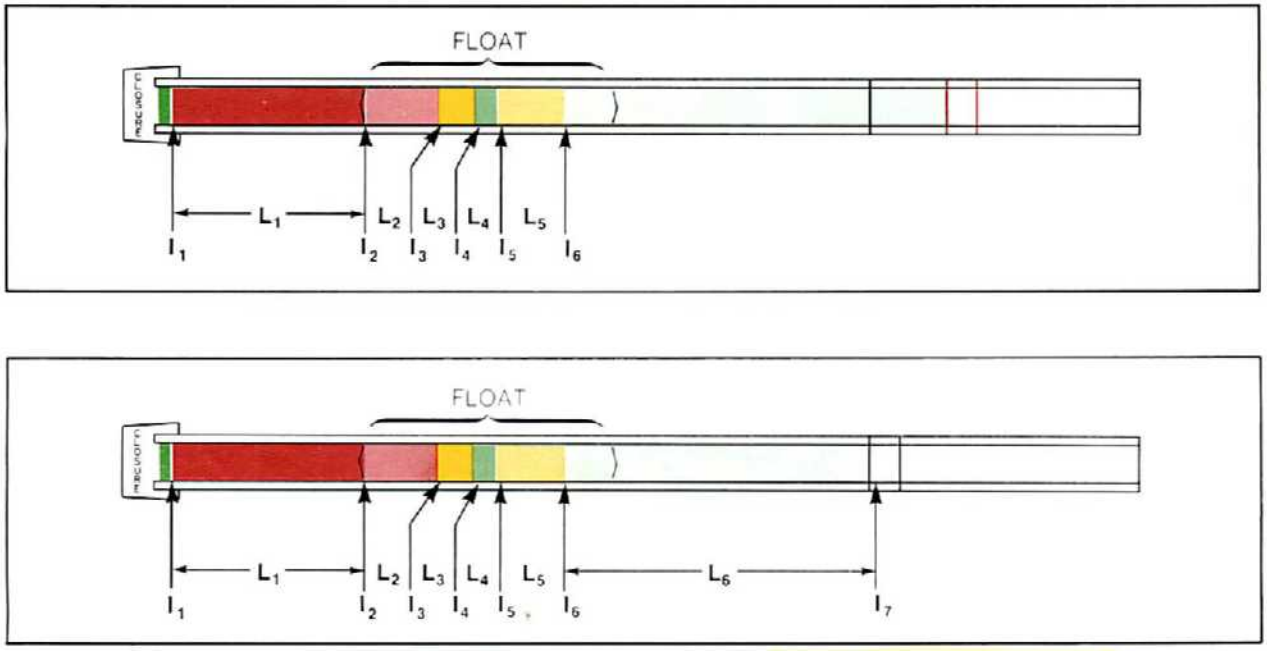


Figure 3.6. Layer Lengths Measured in QBC Capillary-Blood Tube.

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).

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. Pressing "ENTER" again - 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 tubes. Quantitatively, the QBC II hematology parameters are a function 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

Stored constants utilized in the electronic 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. The derivation of test values from QBC Capillary-Blood Tubes utilizes the same length measurements 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). The button is illuminated green when ON.
- MODE: IN position - activates the "VEN" mode indicator light and programs the Reader for venous blood tests. OUT position - activates the "CAP" mode indicator light and programs the Reader for capillary blood tests.
- ENTER: Feeds data to the computer on the beginning and end of each cell layer measurement.
- CLEAR: Erases test values from the readout displays, initiates the self-test sequence, and resets the Reader for a new blood tube test.

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

The seven panel readouts display test values momentarily after pressing "ENTER" at the last interface location. Units and digit-decimal format of test parameters are as follows:

- HCT (%) XX.X
- PLT (10^9/L) XXX
- WBC (10^9/L) XX.X
- GRANS (10^9/L) XX.X
- LYMPH/MONO (10^9/L) XX.X
- GRANS (%) XX
- 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. (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. Clay Adams 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.

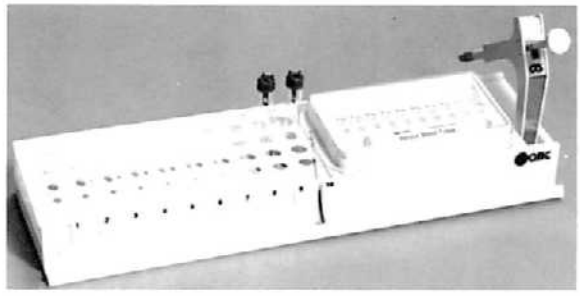


Figure 3.9. QBC Work Station and Venous-Blood Pipetter.

3.5 VENOUS BLOOD PIPETTER

The semi-automatic Pipetter shown in Figure 3.9 is a dedicated device, 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 Pipetter coupling, 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 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
4460,4477	120	60Hz	80	3AG 1-1/2 Amp Slo-Blo
4406	220	50Hz	80	Fast-Acting 1.25 Amp - 2 each Fast-Acting 5 Amp - Circuit Bd.
4462	100	50-60Hz	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
4209	220	50Hz	2
4208	100	50 or 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 System. Maintenance and Service procedures are contained in Section 5. See Appendix D for Printer Operation.

Note: For detailed directions on blood collection, specimen preparation, and test procedures see 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 unless the flashing service flag "P1" appears in the PLT (Platelet) display, in which case the Reader will not function until the problem is corrected. Should the "P1" flag appear, the operator should check for a transient self-clearing condition by pressing the "CLEAR" button several times. If the "P1" flag persists, REQUEST SERVICE.

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 the procedures in 4.6.1 of this Section.

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.

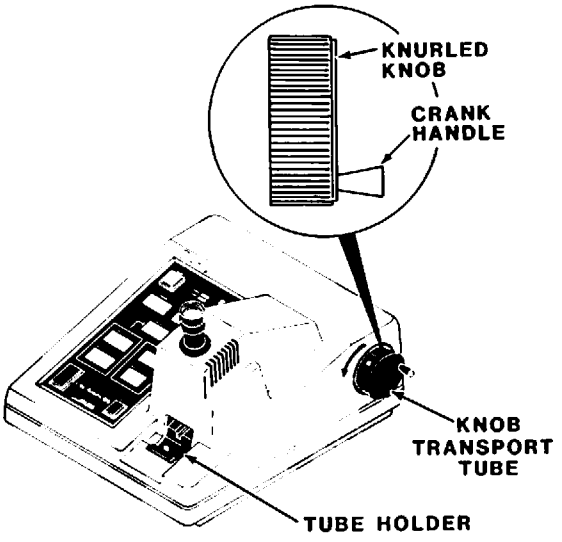


Figure 4.1.
Tube Holder Shown in Down Position.

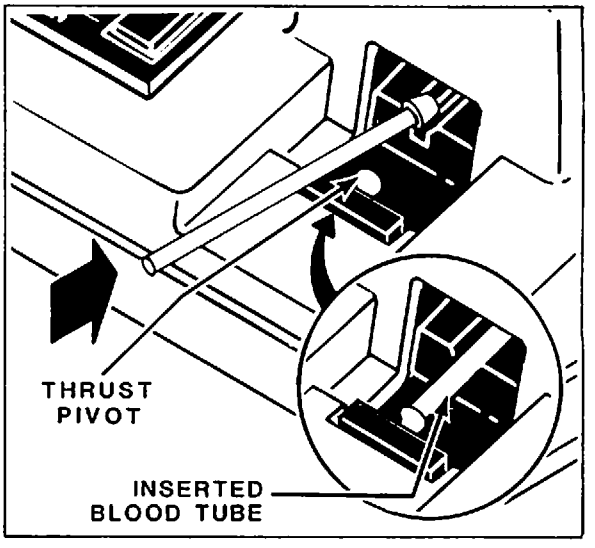


Figure 4.2.
Inserting Blood Tube into Reader.

Referring to the inset in Figure 4.1, the Tube Transport Knob consists of a small protruding 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 begin the reading sequence. For fine adjustment, use the large knurled knob to align a cell interface with the reticle arrow.

Note: Turning the Transport knob excessively fast will trigger a "-L" alert flag in the PLT (Platelet) display. To clear the flag, press the "CLEAR" button, then turn the knob at a slower rate. See Section 4.3.3 for further details.

4.3.2 Blood-Tube Reading Procedures

To read a blood tube, select the desired mode (VEN or CAP), insert the blood tube and follow the Tube-Reading Sequence on Page 4-3. (Note: a full-color, counter-top Test Guide is also supplied with the Reader.)

Test values for all seven QBC parameters 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. 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 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.

TUBE-READING SEQUENCE

QBC Capillary and Venous Blood Tubes

1st Reading

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

Press ENTER. The white tube lamp will light.

2nd Reading

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

Press ENTER. The white tube lamp will turn off.

3rd Reading

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

Press ENTER.

4th Reading

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

Press ENTER.

5th Reading

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

Press ENTER.

6th Reading

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

Press ENTER. In VENOUS mode: Record the seven hematology values.

"CAP" Mode Only

7th (Final) Reading

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

Press ENTER. Record the seven hematology values.

The "Probable Causes" listed in Table IV-1 opposite the H1, H2, L2 and A8 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.

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.

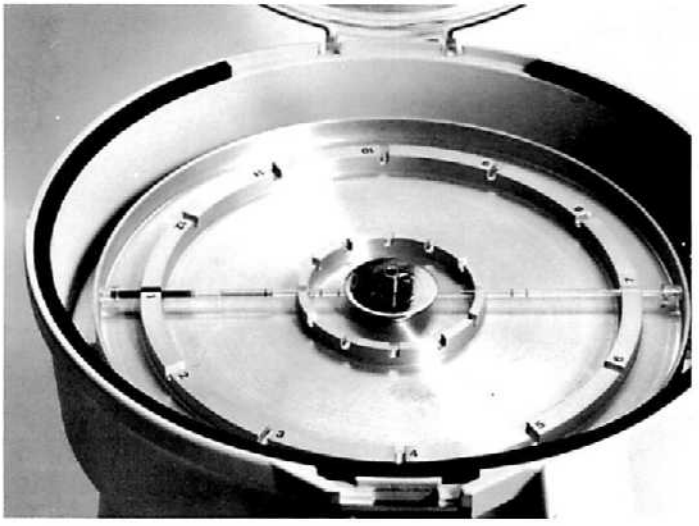


Figure 4.3. Single QBC Tube On Centrifuge Rotor, Showing Balance Tube in Opposite Position.

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 motor 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.

TABLE IV-1. QBC II Reader Alert Flags

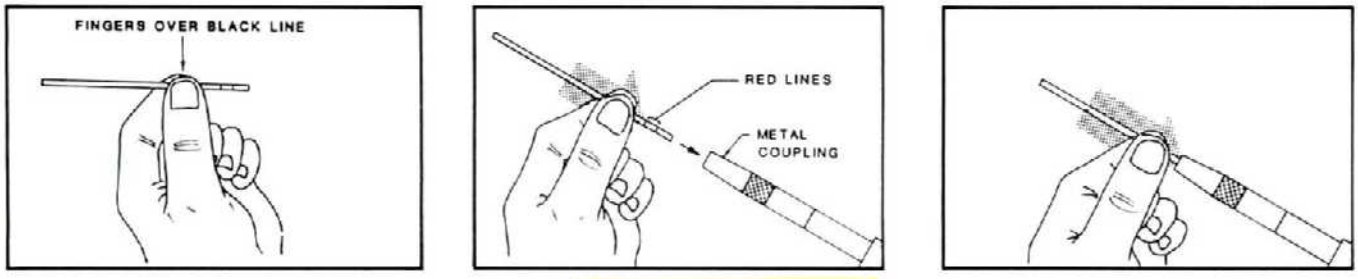
FLASHING TEST FLAG (Mode)	DISPLAY LOCATION OF FLAG	PROBABLE CAUSE(S) OF TEST FLAG	CORRECTIVE OPERATOR ACTION
(VEN and CAP modes)	PLT	1. Tube transport knob was turned too fast between interface readings, moving the blood tube past the encoder too rapidly. 2. Tube was inadvertently moved in wrong direction from last interface reading. 3. "ENTER" was inadvertently pressed twice while blood tube was at the same interface, resulting in a layer measurement of zero. 4. "ENTER" was pressed twice at the same interface to record the length of a *missing* white cell layer or the platelet layer.	1. Press "CLEAR" and repeat from beginning. Turn tube transport knob at slower rate. 2. Press "CLEAR" and repeat test from beginning. Follow proper tube-reading sequence. 3. Press "CLEAR" and repeat correct tube-reading sequence. 4. DISCARD TUBE. Test the specimen by other methods.
 (VEN and CAP modes) AFTER ENTERING 2nd INTERFACE	HCT	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.
 (VEN and CAP modes) AFTER ENTERING 3rd INTERFACE	HCT	1. Float is defective, causing top of light red cell layer (L_2) to extend beyond top of float, preventing an accurate HCT, WBC and PLT. 2. High HCT or blood abnormality.	1. DISCARD TUBE. Prepare new tube and repeat test. 2. DISCARD TUBE. Test specimen by other methods.
 (VEN mode only) AFTER ENTERING 4th INTERFACE	WBC	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 and PLT. **NOTE:** Valid HCT value will be displayed.	1. Test the blood specimen by other methods for WBC and PLT.
 (VEN mode only) AFTER ENTERING 5th INTERFACE	WBC	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 and PLT. **NOTE:** Valid HCT will be displayed.	1. Test the blood specimen by other methods for WBC and PLT.
(VEN mode only) AFTER ENTERING 6th INTERFACE	PLT	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. NOTE: Valid HCT, WBC, GRAN and LYMPH/MONO will be displayed.	1. Test the blood specimen by other methods for PLT.
 (CAP mode Only)	HCT	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 FLAGS — — — (VEN and CAP modes)	HCT	1. High computed value exceeds dynamic capabilities of instrument, preventing display of HCT.	1. DISCARD TUBE. Test the blood specimen by other methods.
 (VEN and CAP modes)	WBC	1. Computed WBC exceeds three digit limitation of Reader display.	1. Test specimen for WBC by other methods.
 (VEN and CAP modes)	PLT	1. Computed PLT exceeds three digit limitation of Reader display.	1. Test specimen for PLT by other methods.

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 4.4 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 4.4. 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 fill 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: In the event of a Pipetter malfunction, QBC Venous-Blood Tubes can be filled by capillary action.

4.6 CALIBRATION

4.6.1 Reader Performance Checks

As previously described, two Calibration Check Tubes are supplied with the System to monitor acceptable performance of the QBC II 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 and Platelet 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.

At the time the QBC II 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 4.5, align the 1st interface (black-to-pale green) with the reticle arrow and press "ENTER".
(3) Continue reading the 2nd through the 6th interfaces in the same manner.
(4) Record the Venous Cal Check values displayed for each of the seven QBC II parameters; then remove the tube.
(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.

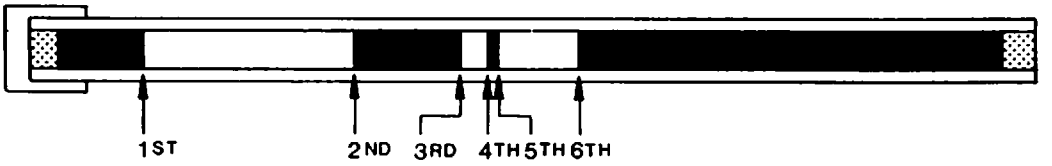


Figure 4.5.
Venous Cal Check Tube, Showing Location of Six Interfaces.

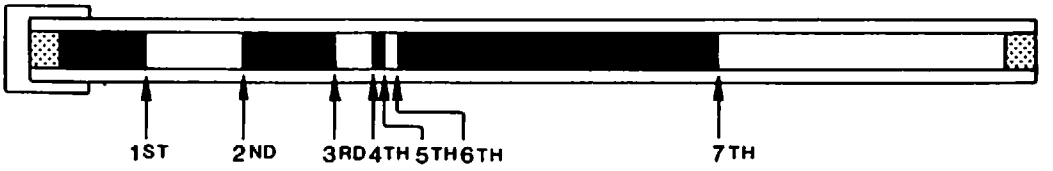


Figure 4.6.
Capillary Cal Check Tube, Showing Location of Seven Interfaces.

(6) Record the Capillary Cal Check values displayed for each of the seven parameters.
(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 whether the apparent alignment changes up or down while refocusing 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 Centrifuge Speed and Timer Checks

When operating at design speed, the QBC Centrifuge generates the centrifugal force required to produce cell packing compatible with QBC test requirements. Nominal speed of the Centrifuge at rated voltage is 12,000 revolutions per minute. Spin time per cycle is fixed at 5 minutes.

Periodic checks of speed and timer accuracy should be performed according to detailed instructions in the QBC Centrifuge Operator's Manual.

4.7 OPERATING PRECAUTIONS

- Power Connections: Connect each component of the QBC II System 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 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.

- Blood specimens may contain the Hepatitis B Virus or Human T-Lymphotropic Virus Type III (HTLV-III/LAV) 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 procedures for the QBC II System and service to malfunctioning components that can be performed by the customer are limited to those described in this Section. DO NOT ATTEMPT ANY OTHER SERVICE OR REPAIRS.

Appendix B contains a complete list of replacement parts and accessories for the QBC II System. 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 Clay Adams Technical Service Department 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, such assistance can be obtained from your local distributor or Becton Dickinson and Company Office.

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

5.3 CUSTOMER-SERVICEABLE ITEMS AND MAINTENANCE

5.3.1 Reader Thrust Pivot Replacement

For a worn, defective or missing thrust pivot (see Figure 4.2), two types of pivots are provided in a Catalog No. 4460-602-001 replacement kit: a thrust pivot with a smooth (unbarbed) stem for early Readers with protruding metal adapters (Figure 5.1A); and a thrust pivot with a barbed stem and inner and outer replacement adapters for Readers with recessed adapters (Figure 5.1B). Detailed installation instructions are provided in the thrust pivot replacement kit.

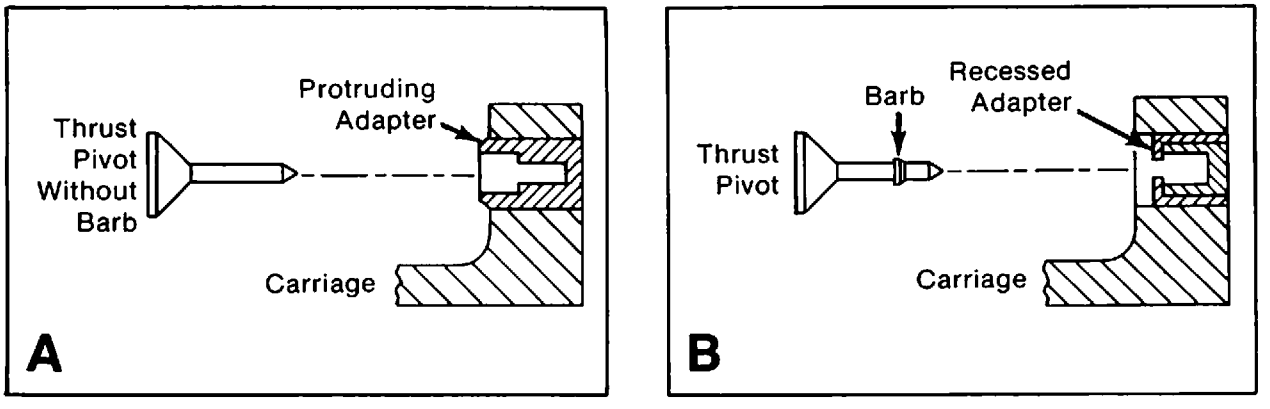


Figure 5.1. Alternate Thrust Pivots and Adapters.

5.3.2 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:

1) DISCONNECT THE POWER CORD.
2) Referring to Figure 5.2A, remove the split rubber grommet surrounding the Microscope.
3) With the 5/64" hex wrench, loosen the two set screws in the transport knob and pull the knob from the shaft (Figure 5.2B).
4) 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.

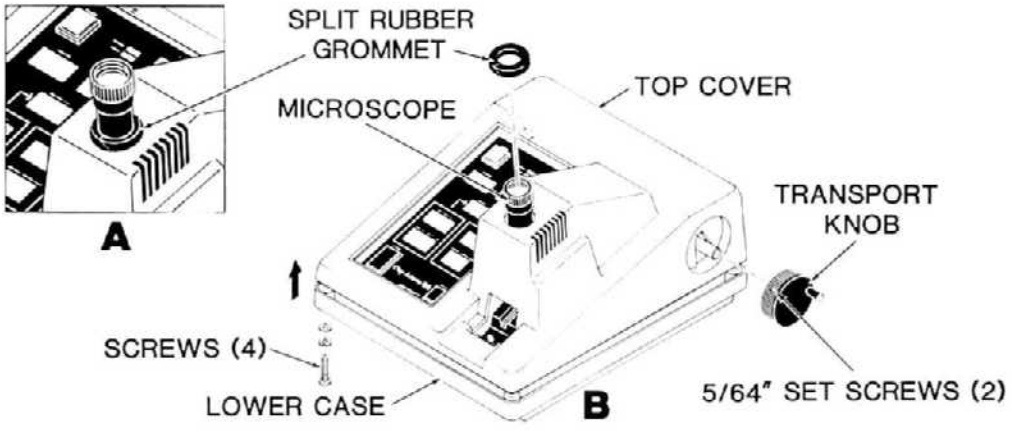


Figure 5.2. Top Cover Removal Details.

Note: Removal of the top cover automatically activates a Safety Interlock Switch (see Figure 5.3) that cuts off electrical power to the Reader.

The Lead Screw, Extension Shaft and Guide Rod are shown in Figure 5.3. The recommended lubricant is Dow Corning Molykote Gn Paste, available from Clay Adams in a tube applicator, Catalog No. 4200-600-006. DO NOT USE OIL OR OTHER LIQUID LUBRICANTS.

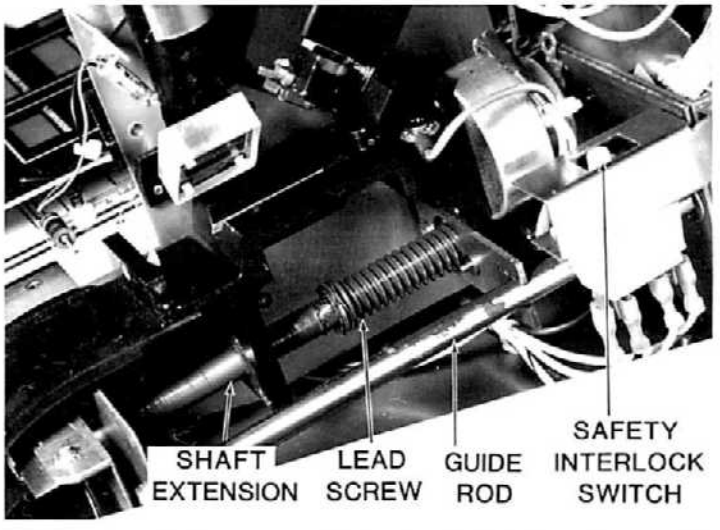


Figure 5.3. Lead Screw and Guide Rod (Top Cover Removed).

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 5.2, re-install the top cover, transport knob and rubber microscope grommet.

5.3.3 Reader Internal Lamps

The Reticle Arrow, Illuminator, and Tube Lamps are rated for continuous, extended service. Burn-out 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.

One 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, transport knob and top cover according to the procedures in Paragraph 5.3.2.

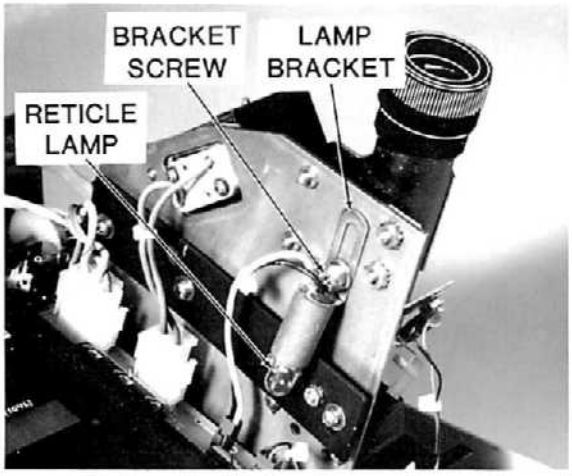


Figure 5.4. Reticle-Arrow Lamp Details.

a. Replacing Reticle Arrow Lamp

Referring to Figure 5.4, 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 of the replacement clean of fingerprints and smudges before installing. Pivot the bracket assembly back. Before re-tightening the bracket screw, adjust the bracket so the filament of the lamp is in line with the reticle arrow.

Temporarily replace the cover. Re-connect the power cord, and press POWER ON. Check for uniform illumination of the reticle arrow, indicating correct adjustment of the lamp filament and bracket. Re-adjust as necessary. Then disconnect the power cord. Re-install the top cover, transport knob and microscope grommet.

b. Replacing Tube Illuminator Lamp

Referring to Figure 5.5A, loosen Wing Nut and remove the cover from the Illuminator Assembly to expose the Illuminator Lamp (Figure 5.5B). 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 Illuminator Assembly cover and re-tighten nut "B". Re-install the top cover, transport knob and microscope grommet.

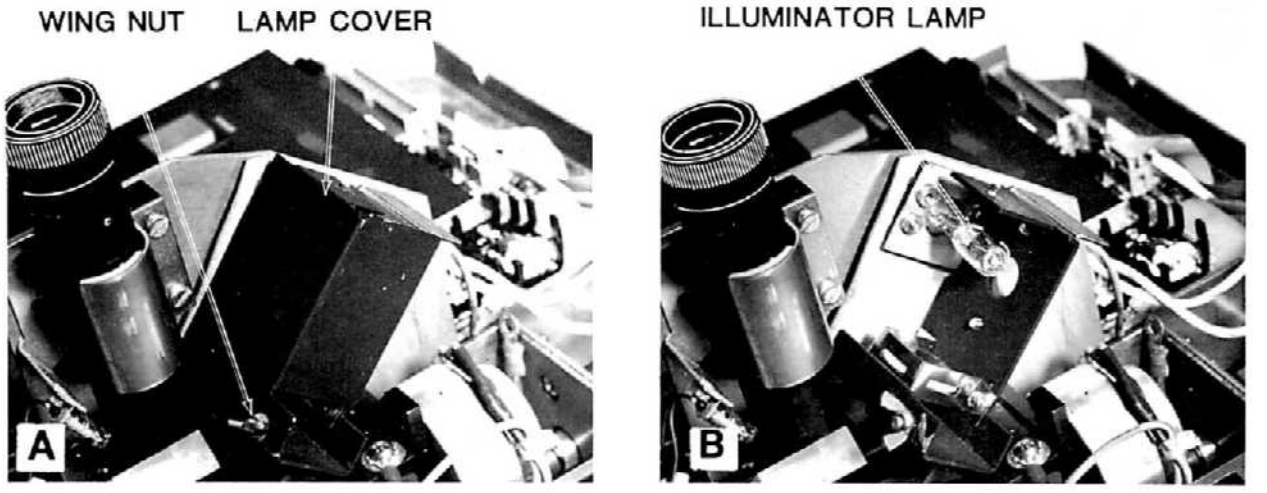


Figure 5.5. Tube Illuminator Lamp Details.

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).

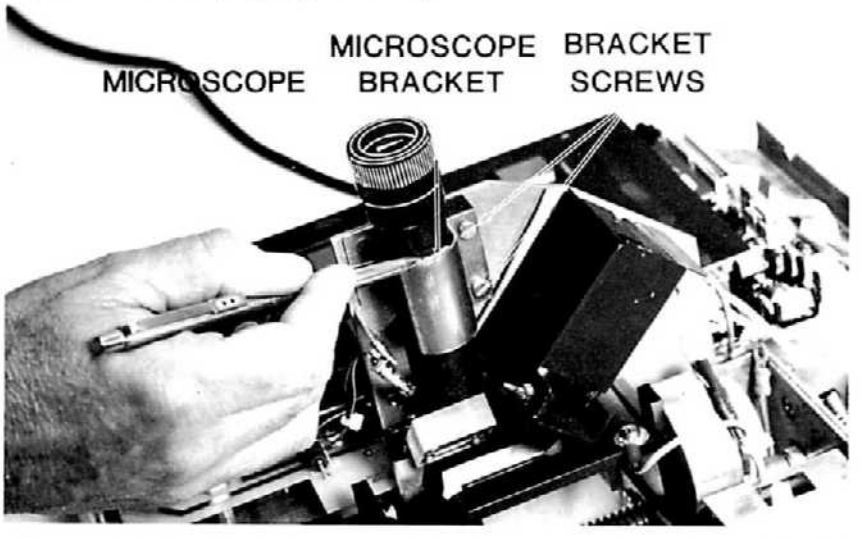


Figure 5.6. Tube Lamp and Microscope Bracket Details.

Before moving the microscope, scribe a pencil mark on the barrel at the top of the clamp as shown in Figure 5.6.

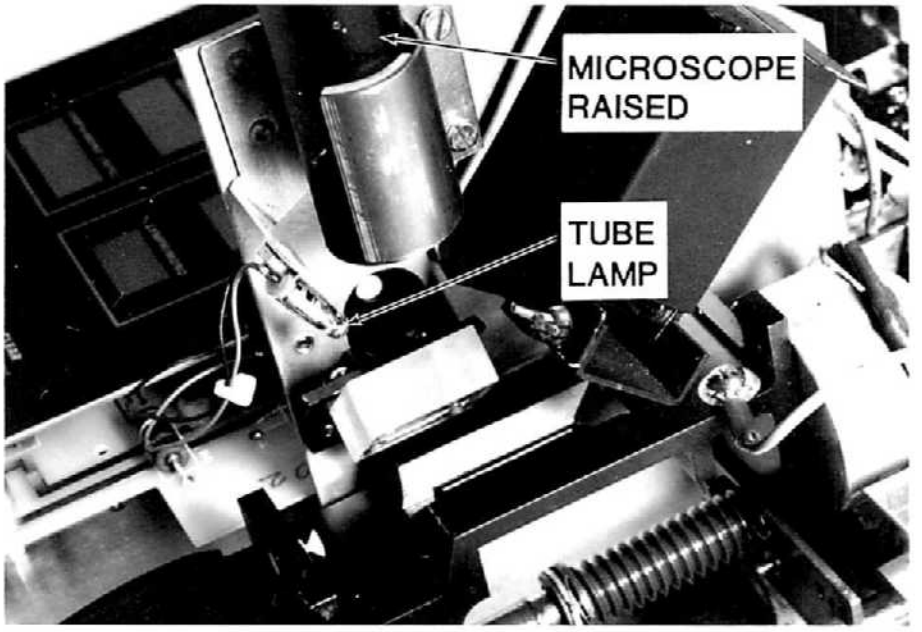


Figure 5.7. Tube Lamp, Showing Microscope in Raised Position.

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 re-tighten the clamp screws. Re-install the top cover, transport knob and microscope grommet.

5.3.4 Reader Seven-Segment Readout Digits

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 5.3.2
c) Lift and lay aside the display panel with attached POWER switch and wiring (Figure 5.8).

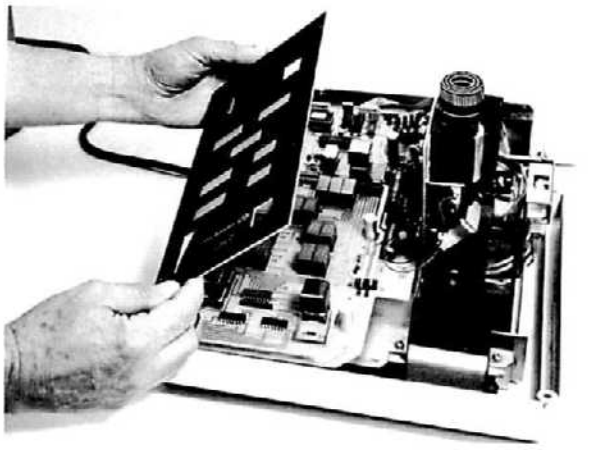


Figure 5.8. Removing Display Panel to Expose Main Circuit Board.

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

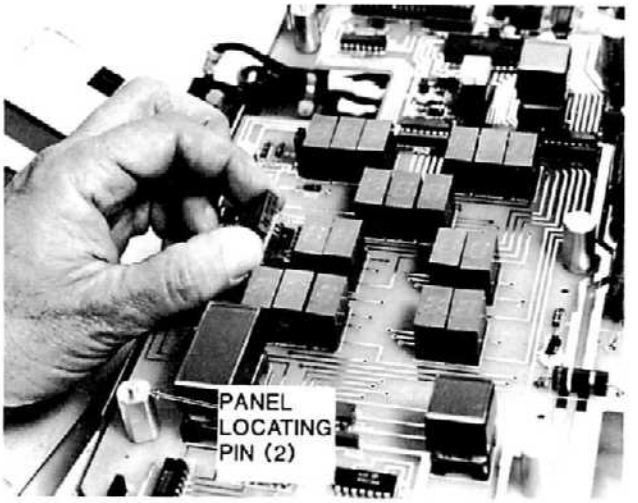


Figure 5.9. Extracting Seven-Segment Display Digit.

e) 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.
f) Re-install the Panel by placing the holes in the left corners of the Panel onto the two left locating pins (see Figure 5.9).
g) Replace the top cover, transport knob and microscope grommet.

5.3.5 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 5.3.2.
c) Lift off the display panel with attached POWER switch and push-on wire leads.

6.1.4 Specimen Storage and Stability

After blood collection, anticoagulated venous specimens may be held at room temperature (20° to 32°C; 68° to 90°F) before preparing QBC Venous-Blood Tubes for the times indicated below.

- 90 Minutes from blood collection, provided all QBC hematology parameters, including the Platelet Count, are required. Note: Specimens more than 90 minutes old may yield falsely elevated Platelet Counts. After centrifugation, QBC tubes may be tested any time within 4 hours. (See Assay Timing, Section 7.3.4 in 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 the test procedures in 7.3.3.

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 (30°C to 40°C) for 3 to 5 minutes before puncture or use a moist compress or warm pack.

(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 the TEST PROCEDURES of Section 7 for additional details.

SECTION 7
TEST PROCEDURES

7.1 MATERIALS PROVIDED

The QBC II System consists of the following instruments and accessories with which to perform centrifugal hematology tests:

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

7.2 MATERIALS REQUIRED, BUT NOT PROVIDED

The following disposables are required for QBC II centrifugal hematology tests:

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

7.3 PERFORMING 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 tube vial.

b) Laboratory Temperature: Perform centrifugal tests at 68° to 90°F (20° to 32°C). If blood tubes are tested at temperatures below 68°F (20°C), the 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 EDTA-anticoagulated blood at 68° to 90°F (20°C to 32°C) and well mixed. See Test Procedures in 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.

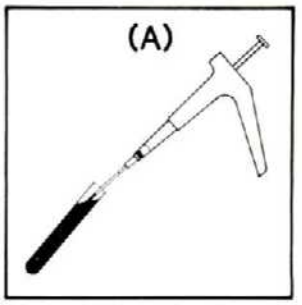
- For QBC Capillary-Blood Tests: use fresh blood collected from a free flowing finger puncture. See Test Procedures in 7.3.3.

end nearest
red lines (insert)

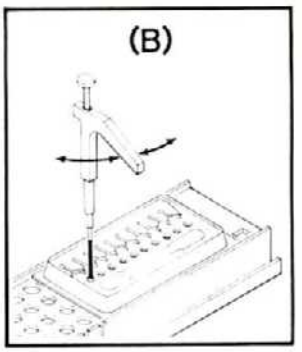
7.3.2 Test Procedures: QBC VENOUS-BLOOD TUBES

STEP 1. FILL AND SEAL BLOOD TUBE

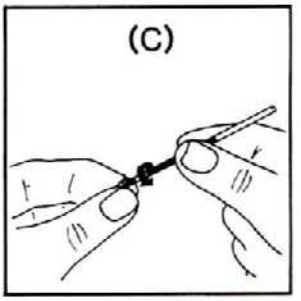
Insert the end of the Tube nearest the red lines into the Pipetter. Push the Tube in until it seats snugly inside Pipetter barrel. Depress the plunger of the Pipetter, then insert the distal end of the Tube into a specimen of well-mixed anticoagulated venous blood (A). Slowly release the plunger of the 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.

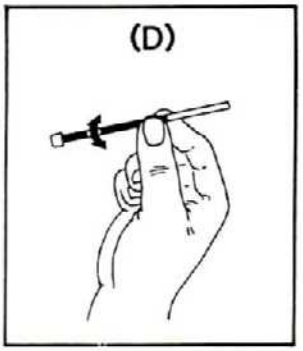


Remove the Tube from the Pipetter. Manually twist and firmly push on the closure to form a leak-tight seal (C). Be sure the closure is on straight. FAILURE TO SEAT THE CLOSURE STRAIGHT MAY RESULT IN BLURRED INTERFACES.



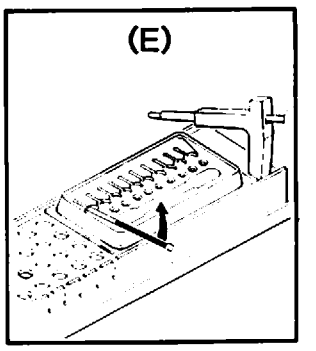
STEP 2. ROLL TUBE BETWEEN FINGERS TO MIX

Gently roll the Tube between the fingers at least 10 times or for at least 5 seconds, keeping the unsealed end slightly above the horizontal (D). PROCEED PROMPTLY 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, 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.

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

Note: Request service if the Reader fails to perform 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
QBC II SYSTEM PERFORMANCE

8.1 TEST RESULTS

8.1.1 Digit-Decimal Format

Hematology test values generated by the QBC II Reader are presented in the following digit-decimal format:

• Hematocrit (%)	XX.X	• Gran (%)	XX
• Platelets (x 10^9/L)	XXX	• Gran (x 10^9/L)	XX.X
• WBC (x 10^9/L)	XX.X	• Lymph/Mono (%)	XX
		• Lymph/Mono (x 10^9/L)	XX.X

When irregularities are detected in length measurements, tube-reading techniques or computed values, the QBC II Reader will automatically display a flashing alphanumeric flag and the test will be aborted (see Section 4.3.3). 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 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. This 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.

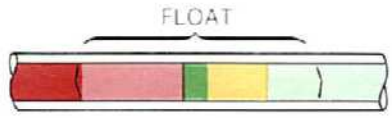


Figure 8.1. QBC Tube With Missing Granulocyte Layer.

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.

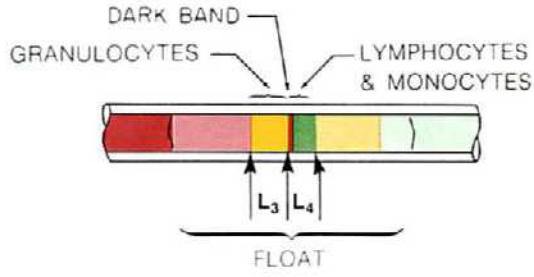


Figure 8.2. QBC Tube With Dark Band Formation Between GRAN and LYMPH/MONO Layers.

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 which are less than 90 minutes old. Therefore, it is important that the limits specified under "Assay Timing" in Section 7.0 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 a blood tube in the QBC II Reader tends to optically average any slight waviness or irregularity that may exist in cell layer boundaries, causing them to appear as straight-line, "readable" interfaces. As wavy conditions or irregularities increase, the visual effect in the rotating tube is one of color blending between boundaries, resulting in blurred interfaces. WHEN EXTREMELY FUZZY OR DIFFICULT-TO-READ INTERFACES ARE OBSERVED, THE SPECIMEN SHOULD BE TESTED BY OTHER METHODS.

8.2 LIMITATIONS OF THE PROCEDURE

The hematology parameters measured by the QBC II System are valid over the following range of values:

- Hematocrit 25 - 55%
- White Cell Count 2.0 - 30.0 (x 10^9/L)
- Gran 1 - 99%; 0.02 - 29.7 x 10^9/L cells (over a WBC of 2.0 - 30.0 x 10^9/L)
- Lymph/Mono 1 - 99%; 0.02 - 29.7 x 10^9/L cells (over a WBC of 2.0 - 30.0 x 10^9/L)
- Platelet Count 80 - 600 (x 10^9/L)

If the specimen yields test values outside these ranges, the results should be confirmed by alternative methods.

QBC II Granulocyte and Lymphocyte/Monocyte counts are not intended to replace the conventional manual differential white cell count. Some disease states are characterized by the presence of abnormal white cell types and yet may display normal quantitative relationships of Granulocytes to Lymphocytes/Monocytes. Due to grouping of the white cell subpopulations by the QBC method, the System cannot discriminate between normal and abnormal cell types and may not indicate the presence of disease states where the number of certain white cell types may be abnormal (e.g., eosinophilia).

QBC II centrifugal hematology tests must always be performed in a temperature environment of 68° to 90°F (20° to 32°C). If blood tubes are tested at temperatures below 68°F (20°C), results may be erroneously high; if tested above 90°F (32°C), interfaces in the blood tube may become blurred and difficult to read.

As indicated under Test Results in 8.1, centrifugal hematology values cannot be obtained by the QBC method unless distinct cell layers with well-defined interfaces form in the blood tube. Non-separation or cell "streaming" can occur under certain hematologic or pathologic conditions, e.g., when an orange-yellow layer of granulocytes fails to form in the QBC tube, or when the lower boundary of granulocytes is so poorly defined that a clear interface cannot be identified. The condition is generally the result of a shift in red-cell specific gravity toward that of the granulocytic leukocytes, causing the red cells and granulocytes to intermingle.

Studies indicate that the frequency of unreadable QBC tubes among office patients of a general practitioner is less than 1%; among clinical outpatients and hospital patients the frequency of unreadable tubes may range from 1.5% to 10%, depending on the pathologies of the patient populations.[8]

8.3 EXPECTED VALUES

The means and ranges listed in Table VIII-1 were determined by the QBC method from specimens taken from ambulatory adult donors working in an industrial environment.

TABLE VIII-1
EXPECTED VALUES - QBC II CENTRIFUGAL 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

Normal ranges reported for the above parameters are listed in Table VIII-2.

TABLE VIII-2
NORMAL HEMATOLOGY RANGES[1]

HCT (%)	Males	40.0-54.0
	Females	37.0-47.0
PLT ($x10^9$/L)		140-440
WBC ($x10^9$/L)		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.

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

8.4 SPECIFIC PERFORMANCE CHARACTERISTICS[8]

8.4.1 Precision

Data on within-run reproducibility of the QBC II System at three venous- and capillary-blood levels are shown in Table VIII-3.

TABLE VIII-3
QBC II WITHIN-RUN PRECISION

Parameter	VENOUS Blood n=	Mean Value	Mean C.V.(%)	C.V. Range(%)	CAPILLARY Blood n=	Mean Value	Mean C.V.(%)	C.V. Range(%)
HCT (%)	7	31.3	1.34	0.76 - 1.69	6	34.6	2.06	1.73 - 2.57
	16	40.9	1.38	0.74 - 1.99	16	40.6	2.29	1.29 - 3.80
	3	47.4	1.01	0.90 - 1.22	2	45.1	2.07	1.71 - 2.43
PLT ($x10^9$/L)	13	128	10.90	7.09 - 17.20	12	136	15.48	8.22 - 26.72
	7	255	9.48	4.46 - 15.04	9	262	11.67	8.73 - 14.61
	6	430	7.30	5.49 - 11.81	3	336	6.96	6.56 - 7.43
WBC ($x10^9$/L)	3	4.57	4.43	3.43 - 5.32	3	4.6	9.07	3.48 - 12.35
	15	6.9	5.37	2.50 - 7.99	17	6.6	8.25	4.12 - 14.60
	8	11.93	4.33	2.53 - 6.89	4	12.8	4.96	3.56 - 6.10
GRAN (%)*	9	53.0	4.94	1.79 - 8.53	5	54.4	8.18	4.5 - 9.7
	18	64.6	3.47	1.33 - 5.90	11	64.2	6.46	3.0 - 10.5
	31	76.3	2.90	1.0 - 9.8	8	72.9	5.28	2.8 - 7.8
GRAN ($x10^9$/L)	8	2.26	8.35	4.7 - 14.6	4	2.4	8.5	5.1 - 10.8
	22	4.04	5.90	3.8 - 8.9	12	3.5	7.4	3.1 - 11.1
	28	7.16	4.90	3.1 - 7.1	8	6.8	5.2	4.5 - 6.5
LYMPH/MONO ($x10^9$/L)	15	1.42	12.60	7.8 - 19.4	9	1.7	15.3	12.0 - 18.5
	33	2.29	11.50	4.9 - 16.5	9	2.2	14.9	7.9 - 19.0
	10	3.27	7.90	3.2 - 13.9	6	2.9	11.2	6.1 - 13.4

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

8.4.2 Accuracy

Data on the correlation of QBC II Hematocrit, WBC and Platelet Count with those from standard reference methods are tabulated in Table VIII-4 and Figures 8.3-8.8. For correlation data on QBC II Granulocyte and Lymphocyte/Monocyte counts, see Figures 8.9-8.16.

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

Parameter	Specimen (Reference Method)	n=	Range of Reference Values	Correlation Coefficient	Slope	Intercept
HCT (%)	Venous (Microhematocrit)[12]	200	16.5 - 56.6	0.9884	0.9952	-0.3665
	Capillary (Microhematocrit)	100	34.0 - 50.7	0.9450	1.0000	0.0027
PLT (x 10^9/L)	Venous (See Note 2)	492	9 - 733	0.9056	0.9744	-8.2440
	Venous (Phase Microscopy)	101	2 - 869	0.9326	1.0260	-0.0583
	Capillary (Clay Adams UF-100)	99	146 - 383	0.7129	0.9903	0.1430
WBC (x 10^9/L)	Venous (See Note 1)	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

Notes: 1. Reference methods - Coulter ZBI, Coulter Model S, and Ortho ELT-8
2. Reference methods - Clay Adams ULTRA-FLO 100 Platelet Analyzer, Coulter Thrombocounter, and Ortho ELT-8.

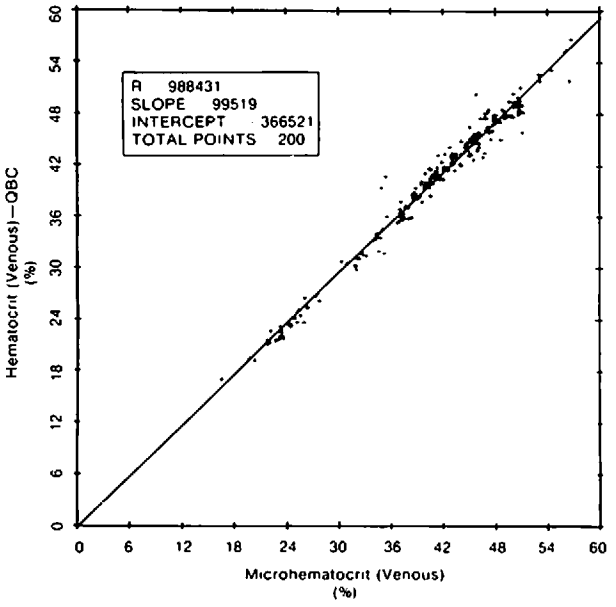


Figure 8.3.
Venous Blood Correlation Graph: QBC II Hematocrit vs Microhematocrit Reference Method.

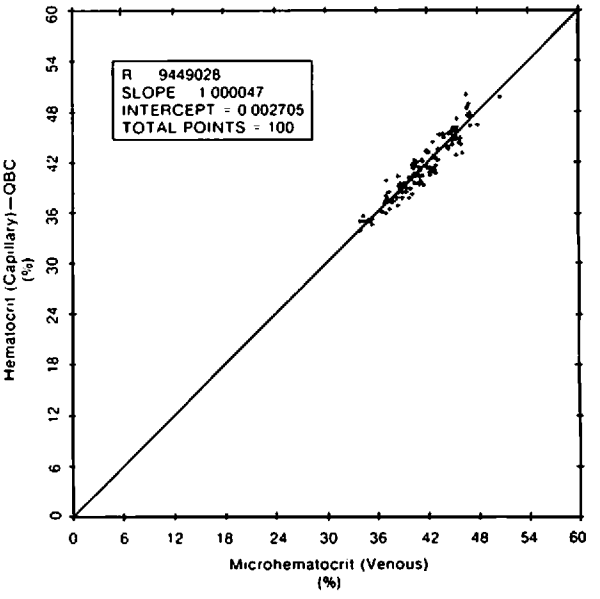


Figure 8.4.
Capillary Blood Correlation Graph: QBC II Hematocrit vs Microhematocrit Reference Method.

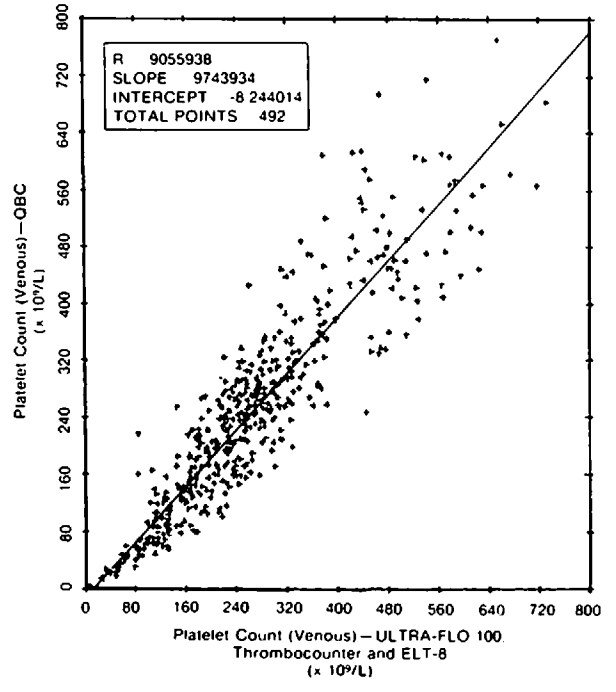


Figure 8.5.
Venous Blood Correlation Graph: QBC II Platelet Count vs ULTRA-FLO 100, Thrombocounter and ELT-8 Platelet Counts.

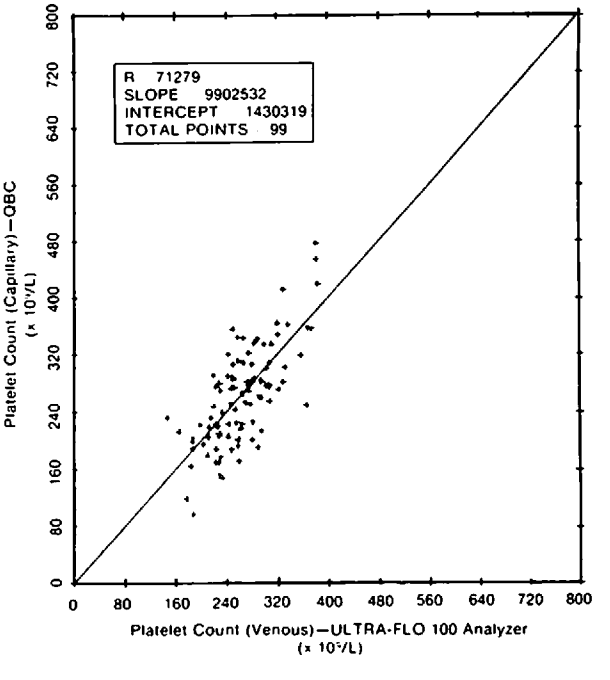


Figure 8.6
Capillary Blood Correlation Graph: QBC II Platelet Count vs ULTRA-FLO 100 Platelet Counts.

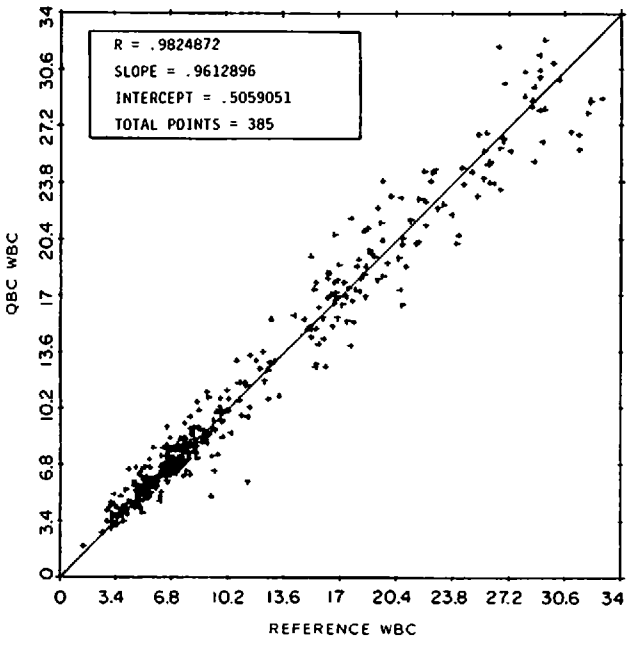


Figure 8.7.
Venous Blood Correlation Graph: QBC II White Cell Count vs Coulter ZBI, Coulter Model S and Ortho ELT-8 White Cell Counts.

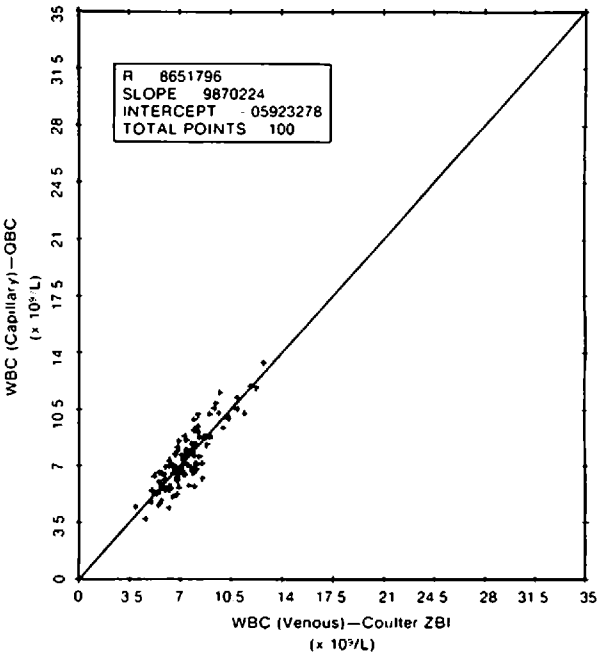


Figure 8.8.
Capillary Blood Correlation Graph: QBC II White Cell Count vs Coulter ZBI, White Cell Counts.

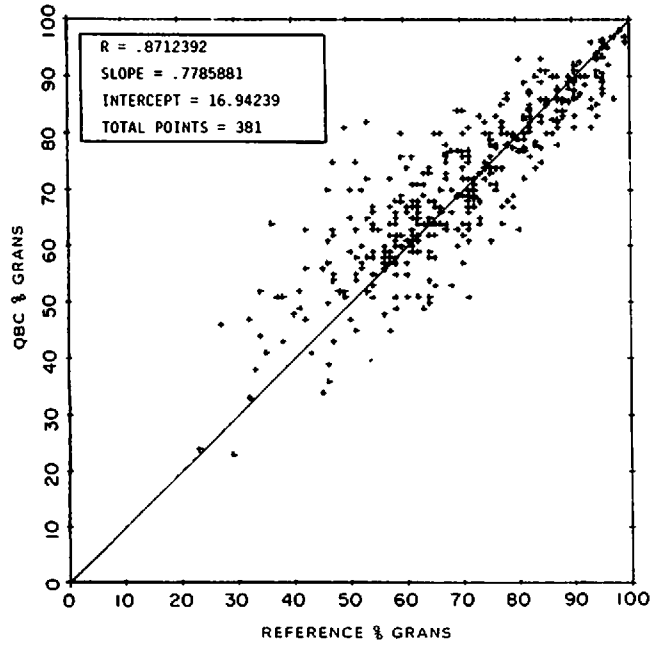


Figure 8.9.
Venous Blood Correlation Graph: QBC II % Granulocytes vs 100-Cell Manual Differential.

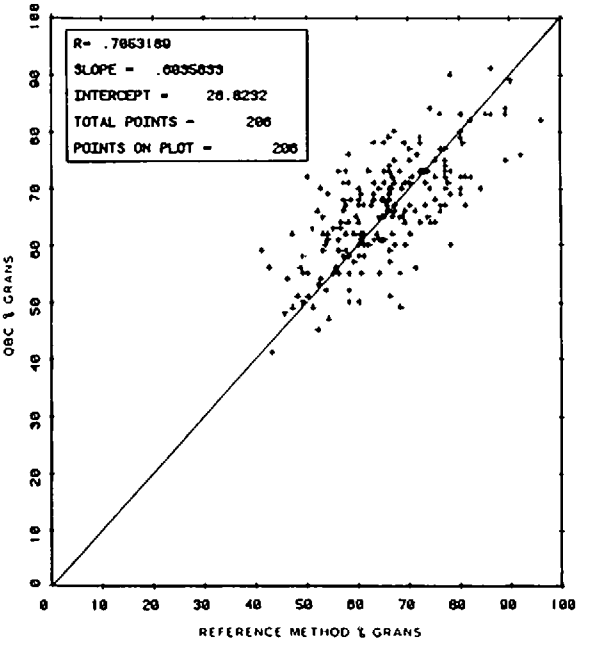


Figure 8.10.
Capillary Blood Correlation Graph: QBC II % Granulocytes vs 100-Cell Manual Differential.

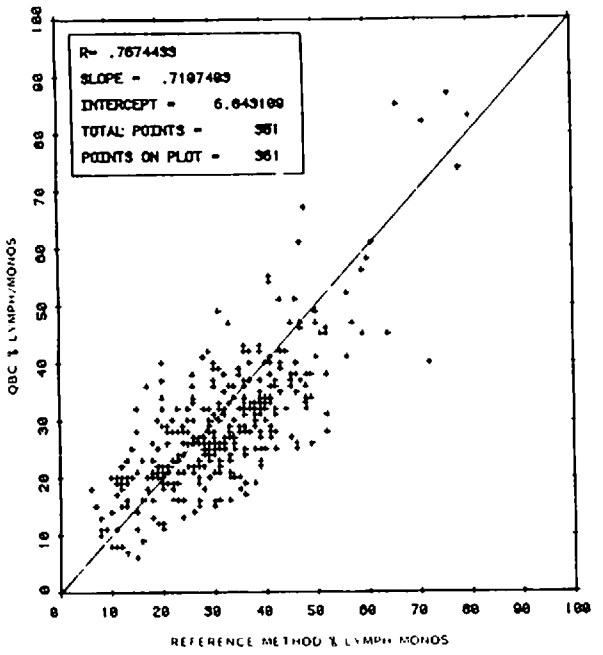


Figure 8.11.
Venous Blood Correlation Graph: QBC II % Lymph/Mono vs 100-Cell Manual Differential.

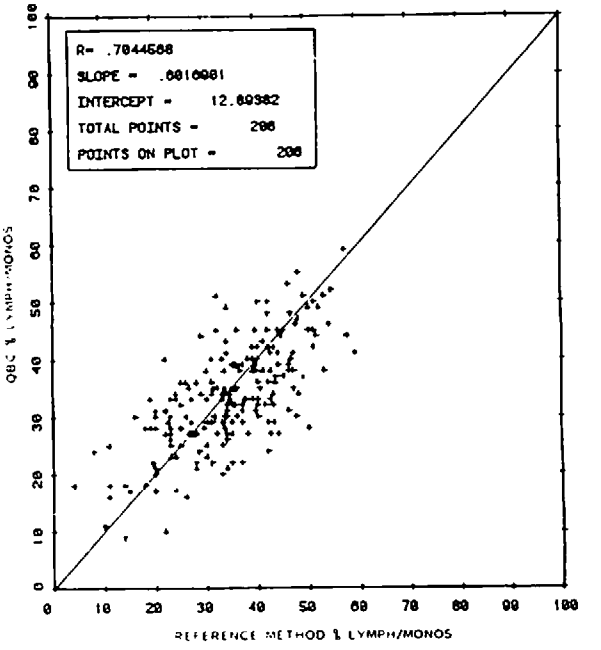


Figure 8.12.
Capillary Blood Correlation Graph: QBC II % Lymph/Mono vs 100-Cell Manual Differential.

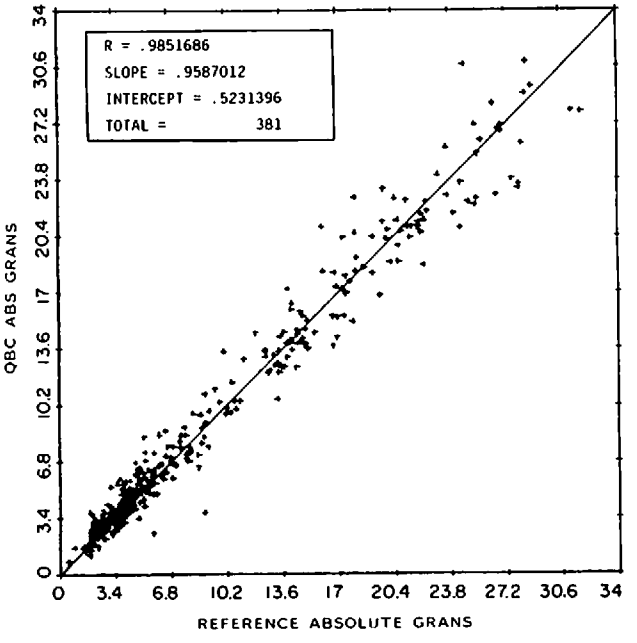


Figure 8.13.
Venous Blood Correlation Graph: QBC II Granulocyte Count vs Reference Manual Count.

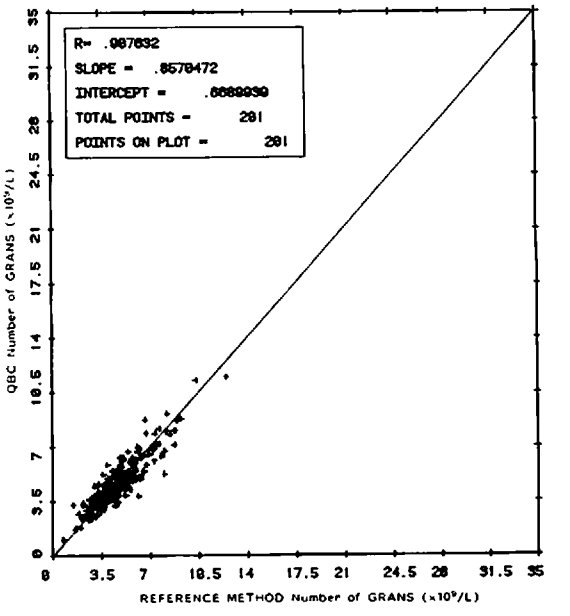


Figure 8.14.
Capillary Blood Correlation Graph: QBC II Granulocyte Count vs Reference Manual Count.

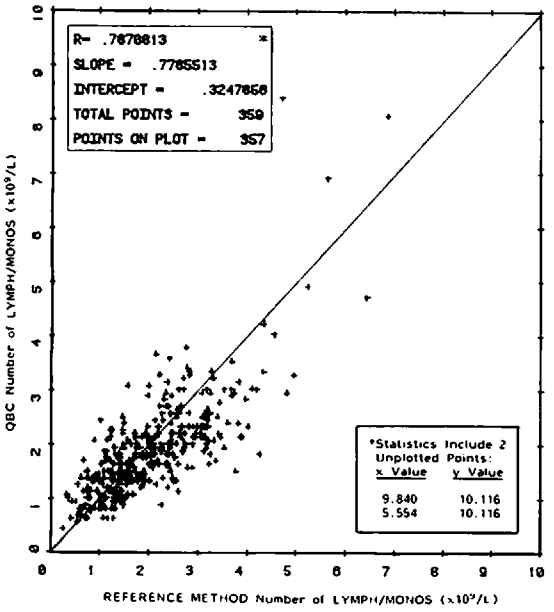


Figure 8.15.
Venous Blood Correlation Graph: QBC II Lymphocyte/Monocyte Count vs Reference Manual Count.

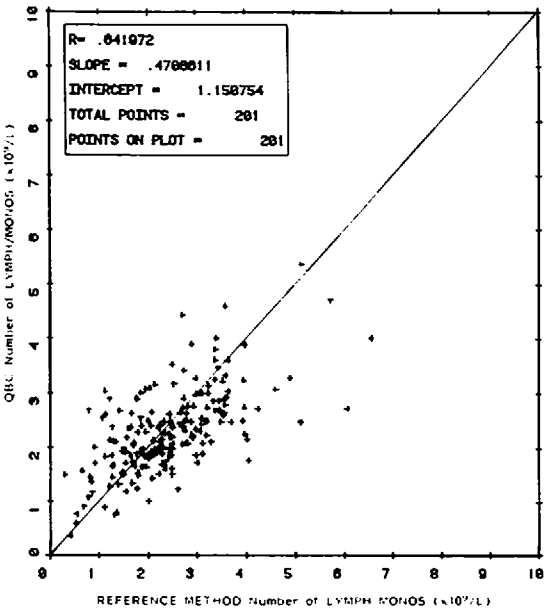


Figure 8.16.
Capillary Blood Correlation Graph: QBC II Lymphocyte/Monocyte Count vs Reference Manual Count.

SECTION 9
BIBLIOGRAPHY

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APPENDIX A
DISCUSSION OF READER FLAGS

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

"-L": Usually triggered when the transport knob is turned too rapidly in any direction. It will also occur when any interface reading yields a zero or negative length, e.g., from reading the 2nd interface after reading the 3rd interface.

"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 last-measured 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. It could occur: 1) if top of float is read instead of 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) 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.

Over-range Flags: The flashing overrange flags ("---" for HCT; "99.9" for WBC and "999" for Platelets) can appear when the test value either exceeds the dynamic capability or readout limits of the Reader. In such cases, the specimen must be tested by other methods to determine the overrange parameter.

"P1" (Service Flag): Appearance of the non-flashing Service Flag "P1" in the platelet (PLT) display immediately after pressing the POWER or CLEAR button indicates a transient condition or malfunction in the ramdom access memory (RAM) of the microprocessor. If the "P1" Flag cannot be cleared by pressing POWER OFF and re-energizing, Request Service.

APPENDIX B
PARTS LIST -
QBC II SYSTEM DISPOSABLES, ACCESSORIES, AND SPARES

	Reorder No.
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
Calibration Check Tube - Venous Mode	4235
Calibration Check Tube - Capillary Mode	4236
Operator's Manual	4440
Forceps	4227-610-000
Spare Parts & Accessories Kit (for 120 Volt and 100 Volt Readers)	4239
Spare Parts & Accessories Kit (for 220 Volt Reader)	4243
Dust Cover	4527

SPARE PARTS	Reorder No.
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., for Models 4460, 4462,4477 - 5 ea.	2510-623-814
Power Module Fuse, 1.25 Amp., for Reader Model 4406 - 5 ea.	2510-623-822
Circuit Board Fuse, 5.0 Amp., for Reader Model 4406 - 5 ea.	2510-623-825
Grease, Lead Screw (1 tube)	4200-600-006
POWER Switch, for Reader Models 4460, 4462, 4477	4460-650-002
POWER Switch, for Reader Model 4406	4461-650-002
PRINTER SYSTEM	
QBC Printer Package	4482
Reader-to-Printer Ribbon Cable	4407
Data Printing Labels (2500 ea.)	2303

APPENDIX C
WARRANTY - QBC II SYSTEM

CLAY ADAMS, Division of Becton Dickinson and Company, (herein after referred to as CLAY ADAMS) warrants the QBC II 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 System Operator's Manual. During such period, CLAY ADAMS 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.

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

APPENDIX D
OPTIONAL PRINTER SYSTEM

As described in Section 2.2.4 of the Manual, QBC II Readers equipped for operation with an Epson Printer provide a permanent patient record of each QBC test. Operating instructions and label format are discussed below.

- Reader/Printer Operation

  Complete instructions for operating the Epson Printer are contained in the manufacturer's handbook supplied with the Printer.

  When the QBC II/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 Venous Tube or 7th in the Capillary Tube. IMPORTANT: Test results are not displayed on the panel of the Reader until the data transmission message to the Printer is complete. Transmission and printing require approximately 20 seconds before test results are displayed on the Reader panel.

  IMPORTANT: During the printing function, NEVER depress the "CLEAR" key. Pressing "CLEAR" during printing will interrupt further data transmission and "erase" all remaining test results from the computer.

  Printing can be discontinued by turning the power switch of the Printer off or disconnecting the ribbon cable plug.

- Format and Flags:

  Test results are printed on perforated, adhesive-backed 3" x 4" labels for patient record purposes. As shown in Figure D-1 the printing format of the patient label identifies the type of QBC blood test (i.e., Capillary or Venous Sample) and provides space for entering the patient's name and date of test.

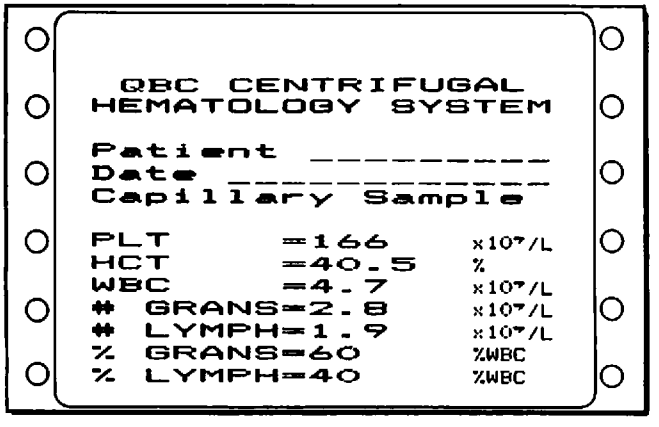

Figure D-1. Printout Format of Typical QBC Capillary Blood Test.

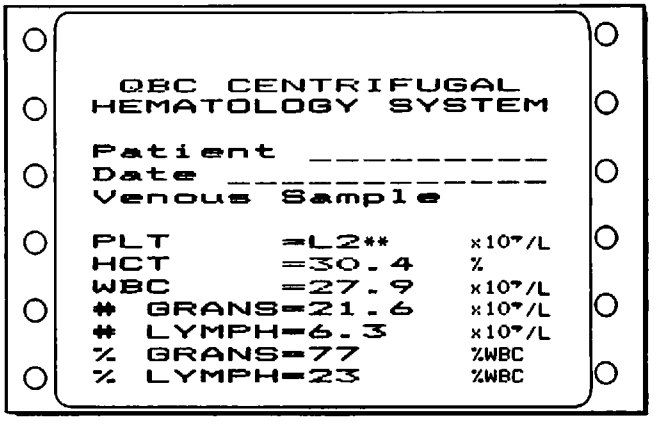

Figure D-2. Sample Printout Showing Error Flag for PLT Parameter.

In an error condition, the Reader will transmit and print an alphanumeric "alert flag" with two asterisks (**) opposite the appropriate parameter. See the example in Figure D-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 4.3.3, 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
- Recording 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 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.

IMPORTANT: Once the test results appear on the panel of the QBC Reader, the same test data cannot be re-transmitted to print a patient label. The blood tube must be read again to obtain a printout.

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

QBC® Venous Blood Tubes

Product Information and Test Procedures

For Testing With Becton Dickinson QBC-Series Centrifugal Hematology Systems

INTRODUCTION

NOTICE

USE THESE TUBES ONLY WITH VENOUS BLOOD. WITH CAPILLARY BLOOD USE CATALOG NO. 4241 QBC TUBES.

Intended Use

QBC Venous-Blood Tubes are designed exclusively for use with the Becton Dickinson series of QBC Centrifugal Hematology Systems. QBC is a blood screening method which yields the following hematology values from a centrifuged blood tube:

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

The QBC Platelet Count, White Cell Count and counts of the white-cell subgroups are estimates derived from measurements of packed cell volumes in the centrifuged QBC blood tube. Some disease states are characterized by the presence of abnormal WBC types and yet may yield normal quantitative relationships of Granulocytes to Lymphocytes/Monocytes. The QBC method cannot discriminate between normal and abnormal cell types.

Hemoglobin (HB) is displayed only on the **QBC® II Plus Reader and on Readers specially converted to compute hemoglobin.*

Summary and Explanation

It has been known for many years that the grayish-white buffy coat in the hematocrit tube (Figure 1) contained packed layers of leukocytes and platelets.[1]

In color and thickness, the gross appearance of the buffy coat has long been of interest to clinical hematologists. Wintrobe[1,2] reported approximate correlations between the thickness of the included packed cell masses and the total leukocyte and platelet counts. Olef[3] additionally found that the buffy coat thickness provided an index to the total number of platelets circulating in the blood.

Bessis[4] and Davidson[5] subsequently identified discrete white cell layers within the total leukocyte mass of the buffy coat, which formed according to the different densities of the included white cell types. Zucker and Cassen[6] later confirmed that the layering out of leukocytes occurred in their order of increasing density, namely, monocytes, lymphocytes, and granulocytes.

Histochemical studies by Jackson[7] and others established the metachromatic fluorescence of certain blood cells and their ultrastructures when treated with the supravital fluorochrome Acridine Orange (AO). It was observed that white cells and platelets could be readily distinguished from each other by virtue of their characteristic fluorescence. Mature red cells, however, showed no up-take of the stain and, under blue-violet light, retained their characteristic dark red appearance.

The QBC method utilizes differential metachromatic fluorescence of AO-treated blood cells and density gradient cell layering within the buffy coat to measure the separated packed volumes of red cells, white cells and platelets. Layer measurements are made in an electro-optical QBC Reader instrument, which then computes and displays the Hematocrit, Platelet Count, WBC, and subgroup counts of Granulocytes and Lymphocytes/Monocytes.[10]

Hemoglobin concentration (in applicable Readers only) is derived from the hematocrit and measurements of red cell density. In traditional hemoglobinometry, the absorbance of cyanmethemoglobin is measured to determine HB.

Principles

QBC Venous-Blood Tubes are 75 mm glass capillaries. Fill volume to a black calibration line on the tube is 111.1 µl. Tubes are internally coated with controlled amounts of Acridine Orange (to stain the white cells and platelets) and Potassium Oxalate. The Potassium Oxalate, by osmotically removing water from the red cells, increases their density. Otherwise, the nearly similar densities of granulocytes and young red cells (including reticulocytes) could cause intermingling of these cells at their interfacing boundary.

A closure and an insertable plastic float are supplied with each QBC tube. The float settles within the buffy coat during centrifugation, axially expanding the stained white cell and platelet layers by a factor of 10. Two red indicators are imprinted on the blood tube, between which the plasma level should rise during tube centrifugation because of specimen displacement by the float.

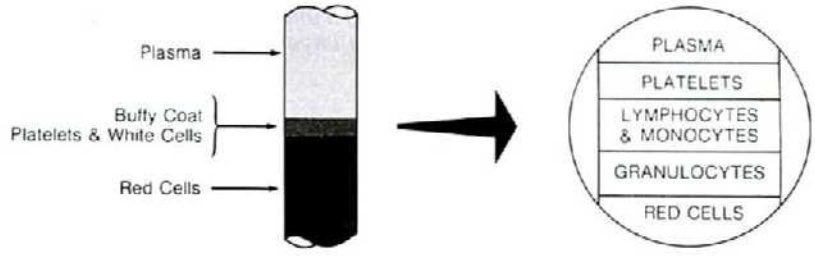

Figure 1. Section of Typical Spun Microhematocrit Tube, Indicating Relative Densities of the Formed Blood Elements.

INTRODUCTION (Continued)

In the QBC Reader the blood tube is illuminated by blue-violet light. Interfaces or boundaries between dark and light red-cell layers and between differentially fluorescing layers of granulocytes, lymphocytes/monocytes and platelets become clearly visible under the microscope of the Reader (Figure 2).

By means of an external knob, the operator can sequentially align the cell interfaces (a total of six) with a stationary cursor in the microscope viewer. Inputs on interface locations are supplied to the microprocessor of the Reader via an "ENTER" switch, pressed each time an interface has been aligned with the cursor. Packed cell volumes and test values are then automatically computed from the five lengths (L_1 through L_5) shown in Figure 3.

Hemoglobin is derived from known and measured forces affecting float depth in the red cells, from which red cell density is computed. The latter quantity is then multiplied by hematocrit to yield the hemoglobin concentration.

Test values are displayed by the Reader after the 6th or last interface is entered.

Reagents

Each QBC Venous-Blood Tube is internally coated with Acridine Orange, Potassium Oxalate, Agglutinating Agent and Stabilizers. See label on blood tube vial for concentrations.

Warnings and Precautions

- QBC Venous-Blood Tubes are intended for In Vitro Diagnostic Use.

WARNING

ACRIDINE ORANGE REAGENT MAY BE TOXIC. DO NOT INGEST. AVOID CONTACT WITH SKIN, EYES AND CLOTHING.

- Blood tubes in this pack must be used only with EDTA-anticoagulated venous blood.
- QBC tests must be performed in an ambient temperature of 68° to 90°F (20° to 32°C).
- QBC blood tubes are designed exclusively for testing only in a QBC Reader. Hematocrit or cell count values from spun QBC blood tubes cannot be obtained on mechanical tube-reading devices or from direct-reading scales.

Storage and Stability of QBC 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.

- Storage

  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.

CAUTION

EXPOSURE TO EXCESSIVE HUMIDITY, LIGHT AND HEAT CAN CAUSE THE COATING REAGENTS IN QBC TUBES TO DETERIORATE.

- Stability

  Unopened Vial Expiration: This printed date on the vial label applies only to tubes in the **unopened** vial. See instruction on "Opened Vial Expiration" below.

  Opened Vial Expiration: Tubes can be used for **30 days** after first opening the vial. Record the opening date of the vial in the space provided on the label. Do NOT use QBC tubes after 30 days from opening.

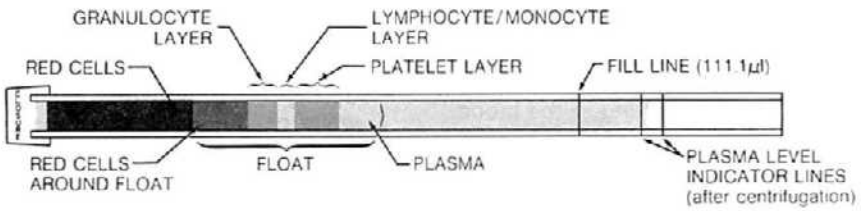

Figure 2. Spun QBC Venous-Blood Tube, Showing Differentiated Packed Cell Layers.

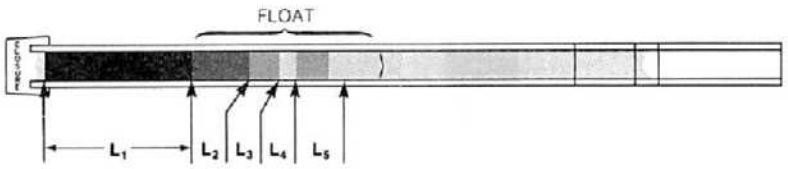

Figure 3. Packed Cell Lengths Used in the Computation of HCT and WBC, GRAN, LYMPH/MONO, and PLT Counts.

PERFORMANCE (Continued)

Accuracy

Graphs and statistical data on the correlation of QBC Venous Blood Parameters with those of reference methods are shown in Figures 4-11.

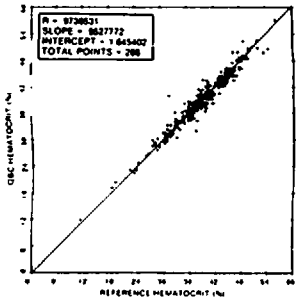

Figure 4. Venous Blood Correlation: QBC Hematocrit vs Microhematocrit Reference Method.

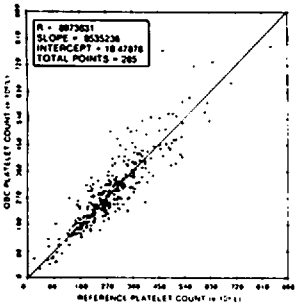

Figure 5. Venous Blood Correlation: QBC Platelet Count vs ULTRA-FLOW 100 and Coulter S+ Platelet Counts.

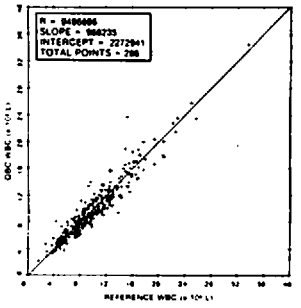

Figure 6. Venous Blood Correlation: QBC White Cell Count vs Coulter ZBI and Coulter Model S+ White Cell Counts.

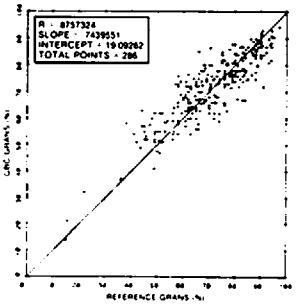

Figure 7. Venous Blood Correlation: QBC % Granulocytes vs 100-Cell Manual Differential.

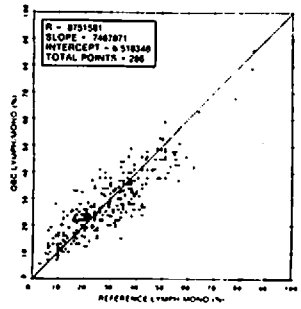

Figure 8. Venous Blood Correlation: QBC % Lymph/ Mono vs 100-Cell Manual Differential.

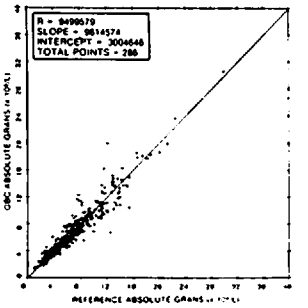

Figure 9. Venous Blood Correlation: QBC Granulocyte Count vs Reference Manual Count.

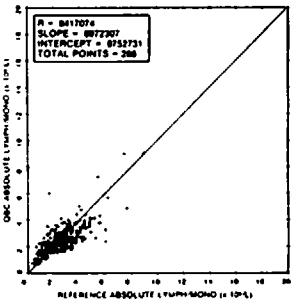

Figure 10. Venous Blood Correlation: QBC Lymphocyte/ Monocyte Count vs Reference Manual Count.

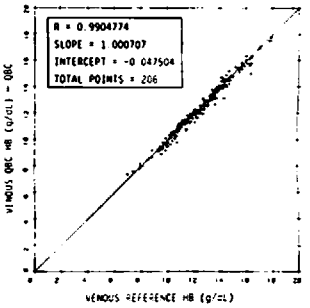

Figure 11. Venous Blood Correlation: QBC Hemoglobin vs Cyanmethemoglobin Method.[11]

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Ordering Information

QBC Tubes for Venous Blood: Package of 10 Trays — 10 Tubes, Closures and Floats Per Tray — **Reorder No. 4240.**

Becton Dickinson
Primary Care Diagnostics
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SPECIMEN COLLECTION

Specimen Collection and Preparation For Analysis

WARNING

BLOOD SPECIMENS MAY CONTAIN THE HEPATITIS B VIRUS OR HUMAN IMMUNODEFICIENCY VIRUS (HIV). TREAT BLOOD SPECIMENS AS POTENTIAL BIOHAZARDS CAPABLE OF TRANSMITTING INFECTION. ALWAYS USE PROTECTIVE LABORATORY GLOVES WHEN HANDLING BLOOD.

Venous Blood Collection

1. Draw venous blood specimens 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 with blood to at least 2/3 of its total fill volume. Remove the collection needle and destroy after use.
2. Thoroughly mix the specimen with the EDTA anticoagulant. If hemolysis or small clots are observed, discard the specimen.

Anticoagulants

Venous blood specimens for QBC tests must be anticoagulated only with disodium or tri-potassium EDTA. Do NOT use other anticoagulants.

Interfering Substances

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

Stability and Storage

Anticoagulated venous blood must not be held more than 90 minutes at room temperature before filling and centrifuging QBC tubes. Consult "Assay Timing" in the TEST PROCEDURES section for additional details.

TEST PROCEDURES

Material Provided

The items below are supplied in the Catalog No. 4240 QBC tube pack.

- 100 QBC Venous-Blood Tubes;
- Tube Closures and Floats (100 ea);
- Package Insert.

Note: QBC tubes and floats are matched by production lot to yield optimum performance. To insure this optimum performance, it is recommended that leftover tubes or floats from this pack not be used with parts from other packs **with different lot numbers**.

Materials Required, But Not Provided

A Becton Dickinson QBC Reader System is required for testing QBC Venous-Blood Tubes.

For blood tube preparation, each QBC Reader System is supplied with a Centrifuge, Work Station Organizer, and Venous-Blood Pipetter. With the **Model No. 4200 QBC Reader only**, a 43° C Incubator is included for warming the blood tubes prior to centrifugation. Incubation of blood tubes at 43° C is NOT required when testing with other Reader models due to modifications in their electro-optical components.

Pre-Test Conditions

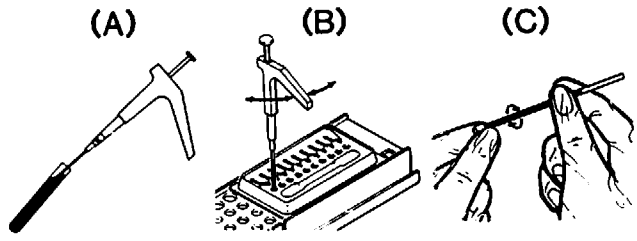
- Reader instrument turned ON and warmed for at least 5 minutes, and "VEN" (Venous) mode activated.
- QBC Tube Tray placed in holder of Work Station. Note: QBC blood tubes are sensitive to moisture and light. Remove tubes one by one, and re-stopper the vial each time.
- EDTA-anticoagulated venous blood, well mixed and at room temperature (68° to 90° F; 20° to 32° C).
- **With Model No. 4200 QBC System Only:** Incubator ON and warmed for at least 15 minutes.

IMPORTANT:

VENOUS SPECIMENS MUST BE CENTRIFUGED WITHIN 90 MINUTES OF BLOOD DRAW TO OBTAIN THE FULL PANEL OF QBC PARAMETERS. If a Platelet Count is NOT required, the specimen may be up to 4 hours old before completion of centrifugation.

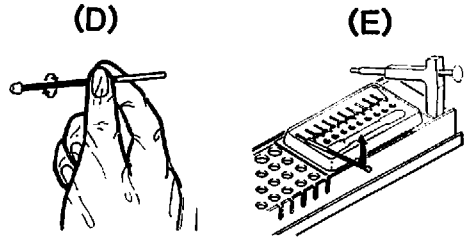
Procedure Steps

1. FILL AND SEAL TUBE



Insert the end of the Tube nearest the red lines into the Pipetter. Press the tube fully into the Pipetter barrel. Depress the plunger of the Pipetter, then insert the Tube into a specimen of well-mixed anticoagulated blood (A). Release the plunger slowly to fill the Tube. Check that the blood level is within approximately ± 1 mm of the black fill line. With a lint-free tissue, carefully wipe excess blood from the surface of the Tube. Press the distal end of the Tube into a closure in the tube tray (B). Twist the Pipetter slightly to be sure that the closure remains on the Tube while lifting the Pipetter and Tube. Remove the Tube from the Pipetter. Manually twist and push the closure onto the tube to form a leak-tight seal (C). Be sure the closure is on straight and tight. Failure to seat the closure straight may result in blurred interfaces.

2. MIX TUBE AND INSERT FLOAT



Gently roll the Tube between the fingers AT LEAST 10 TIMES OR FOR AT LEAST 5 SECONDS TO MIX THE BLOOD WITH THE TUBE COATINGS (D). Keep the unsealed end of the Tube slightly above the horizontal while rolling between the fingers. Slide the unsealed end of the Tube over the tip of the pre-positioned float (E) and push until the float is as far as possible 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 sliding out. Press the end of the float against a clean surface until the float is inside the tube. NOTE: NEVER TOUCH THE FLOAT WITH THE FINGERS. Use the forceps supplied with the Reader.

Promptly proceed to Step 3 or Step 4.

3. **(WITH MODEL 4200 QBC READER ONLY)** — INCUBATE FOR 5 MINUTES

Insert the Tube, unsealed end first, into a well of the QBC Incubator and set the timer dial for 5 minutes. When the timer bell rings, PROMPTLY REMOVE THE TUBE FROM THE INCUBATOR. CENTRIFUGE IMMEDIATELY.

4. CENTRIFUGE FOR 5 MINUTES

Place the QBC Tube(s) on the rotor of the Centrifuge according to procedures in the applicable Operator's Manual. 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. Centrifuge for 5 minutes according to instructions in the Operator's Manual.

PROMPTLY REMOVE THE TUBES FROM THE CENTRIFUGE. Check that the plasma level in the spun tube is between the two red lines. If above or below the lines, discard the tube and prepare a fresh tube.

CAUTION

- Excessive heat may disturb cell layer interfaces in the centrifuged blood tube. Avoid picking up or handling the spun tube below the red indicator lines or placing them on warm surfaces or under intense light.
- Do not twist or move the closure after centrifugation.
- If not read immediately, tubes must be removed from the centrifuge and stored in a vertical, closure-down position to maintain cell layer boundaries (see following).

Centrifuged tubes are stable for up to **4 hours before reading**, provided they are stored vertically (closure down) away from heat and direct light. Slots for storing the tubes are provided on the QBC Work Station.

5. READ LAYER LENGTHS AND RECORD TEST VALUES

Insert the centrifuged tube into the QBC Reader according to directions in the applicable Operator's Manual. Be sure the Reader is in the "VEN" mode. Read the 6 interfaces in the QBC venous tube; then record all test values as directed in the Operator's Manual. Note: Since cell interfaces may become slightly blurred from prolonged exposure to heat, read QBC blood tubes as soon as possible after inserting in the Reader.

Assay Timing (Blood Tube Stability)

To accommodate individual lab routines and to permit batch testing, between-step delays can be made in the tube preparation procedures. QBC test results will not be affected, provided the *following times* are not exceeded:

- Between Blood Draw and Completion of Centrifugation:

  90 minutes (maximum): for a full panel of QBC parameters; or
  4 hours (maximum): for all QBC parameters **except Platelet Count**.

- Once the float is inserted (end of Step 2), tubes should be centrifuged as soon as possible. However, not more than 20 minutes should elapse between insertion of the *float and the completion of* centrifugation.

- From Completion of Centrifugation (Step 4) to Tube Reading:

  4 hours (maximum), provided tubes are stored in a vertical closure-down position.

Test Note

If problems are experienced with filling the tubes, the color of cell layers, or the readability of any interface, refer to the applicable Operator's Manual.

Calibration and Quality Control

Test results obtained by the QBC method should be compared periodically with results obtained by other methods. The following reference procedures are recommended.

Parameter	Ref. Method
HCT	Centrifuged Microhematocrit
HB	Cyanmethemoglobin Method
WBC	Impedance Cell Counter
Gran	100-Cell Manual Differential
Lymph/Mono	100-Cell Manual Differential
Platelet Count	Phase Microscopy or Impedance Cell Counter

A daily pre-test calibration check of the QBC Reader is recommended with the Venous Calibration Check Tube supplied with the Instrument. Procedures are fully described in the applicable Operator's Manual.

Test Results

Test values displayed by the QBC Readers are presented in the following digital/decimal format.

Hematocrit (%)	XX.X
Hemoglobin (g/dL)	XX.X
Platelet Count (x 10^9/L)	XXX
White Cell Count (x 10^9/L)	XX.X
Gran (%)	XX
Lymph/Mono (%)	XX
Gran (x 10^9/L)*	XX.X
Lymph/Mono (x 10^9/L)*	XX.X

*To compute the number of Granulocytes and number of Lymphocytes/Monocytes when testing with the **Model No. 4200 QBC Reader,** multiply the percent values of the parameters by the WBC.

When irregularities are detected in layer length measurements or in tube reading techniques, the Reader will automatically display an alphanumeric Alert Flag and the test will be aborted. In such cases, no test results (or partial results) will be displayed. Consult the applicable Operator's Manual for a description of Alert Flags.

Limitations

1. The hematologic parameters measured by the QBC method are valid over the following range of values:

Hematocrit	25-55%
Hemoglobin	5-20 g/dL
Platelet Count	80-600 (x 10^9/L)
Gran	1 - 99%; 0.02 - 29.7 x 10^9/L cells (over a WBC of 2.0 - 30.0 x 10^9/L)
Lymph/Mono	1 - 99%; 0.02 - 29.7 x 10^9/L cells (over a WBC of 2.0 - 30.0 x 10^9/L)

   If the specimen yields values outside these ranges, results should be confirmed by alternate methods.

   QBC Granulocyte and Lymphocyte/Monocyte counts are not intended to replace the conventional manual differential white cell count. Some disease states are characterized by the presence of abnormal white cell types and yet may display normal quantitative relationships of Granulocytes to Lymphocytes/Monocytes. Due to grouping of the white cell subpopulations, the QBC method cannot discriminate between normal and abnormal cell types and may not indicate the presence of disease states where the number of certain white cell types may be abnormal (e.g., eosinophilia).

2. QBC tests must always be performed in a temperature environment of 68° to 90°F (20° to 32°C). If blood tubes are tested at temperatures below 68°F (20°C), results may be erroneously high; if tested above 90°F (32°C), interfaces in the blood tube may become blurred and unreadable.

3. QBC Blood Tubes must be prepared from specimens less than 90 minutes old from blood draw to obtain a full panel of hematology parameters. Specimens older than 90 minutes may yield falsely elevated platelet counts. Note: Once blood specimens have been centrifuged, tubes may be stored an additional 4 hours prior to reading (see Assay Timing).

4. VALUES CANNOT BE OBTAINED BY THE QBC METHOD WHEN DISTINCT CELL LAYERS AND WELL-DEFINED INTERFACES FAIL TO FORM IN THE CENTRIFUGED BLOOD TUBE. Note: Non-separation or cell "streaming" can occur under certain hematologic or pathologic conditions, e.g., when an orange-yellow layer of granulocytes fails to form, or the lower boundary is so poorly defined that a clear interface cannot be identified. The condition is generally the result of a shift in red-cell specific gravity toward that of the granulocytic leukocytes, causing the red cells and granulocytes to intermingle.

5. Hemolyzed specimens, anticoagulants other than disodium or tri-potassium EDTA, and certain drugs may affect the accuracy of QBC test results.

Expected Values

The means and ranges listed in the following table were determined from venous specimens drawn from adult donors working in an industrial environment and tested by the QBC method.

EXPECTED VALUES
QBC CENTRIFUGAL HEMATOLOGY PARAMETERS[8]
(Venous Blood)

Mean Value Parameter		Mean Value	Range (± 2 S.D.)
HCT (%)	Males	44.2	36.8- 51.5
	Females	40.4	34.2- 46.5
PLT (x 10^9/L)		268	151 -385
WBC (x 10^9/L)		7.0	4.1- 9.9
GRAN (%)		61.6	44.6- 78.5
GRAN (x 10^9/L)		4.5	1.8- 7.2
LYMPH/MONO (%)		38.4	21.5- 55.4
LYMPH/MONO (x 10^9/L)		2.7	1.5- 3.9

Normal hemoglobin ranges obtained on applicable QBC Readers should be virtually identical to the following normal ranges reported in the literature:[2]

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

In accordance with good laboratory practice, each laboratory should develop normal values based upon the geographical area, age, sex, and other factors specific to the population being tested.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision (Within-Run Reproducibility)

	MEAN VALUE	MEAN C.V. (%)
HCT (%)	40.9	1.38
HB (g/dL)	13.5	1.09
PLT (10^9/L)	255	9.48
WBC (10^9/L)	6.9	5.37
GRAN (%)*	64.6	3.47
GRAN (10^9/L)	4.0	5.9
LYMPH/MONO (10^9/L)	2.3	11.5

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

Quantitative Buffy Coat Analysis

A New Laboratory Tool Functioning as a Screening Complete Blood Cell Count

Stephen C. Wardlaw, MD, Robert A. Levine, MD

• **We have developed a system for the quantitative analysis of the buffy coat in centrifuged whole blood samples. This analysis, performed in a modified microhematocrit tube, provides a hematocrit value, total WBC count, platelet count, and a separation of the leukocyte population into granulocytes and nongranulocytes. All results are available within 15 minutes and correlate well with existing methods. The system is expected to provide a rapid means of performing a complete blood cell count in a physician's office.**

(*JAMA* 1983;249:617-620)

THE COMPLETE blood cell (CBC) count is the most widely requested and, perhaps, the single most important laboratory test performed on blood, and, in the majority of cases, it is performed to obtain general information rather than a specific diagnosis. In these instances, the CBC count functions as a screening test, and the maximum use of the test is obtained when the results are immediately available to the physician. In conjunction with James V. Massey III, president of Columbia Medical Laboratories, Bridgeport, Conn, we have developed a novel means of physically expanding and separating the buffy coat into three distinct layers that consist of granulocytes, nongranulocytes (lymphocytes and monocytes), and platelets. These expanded separate layers may then be readily quantitated, providing a hematocrit value, total WBC count, platelet count, and a clinically useful partial differential cell count.[1]

MATERIALS AND METHODS

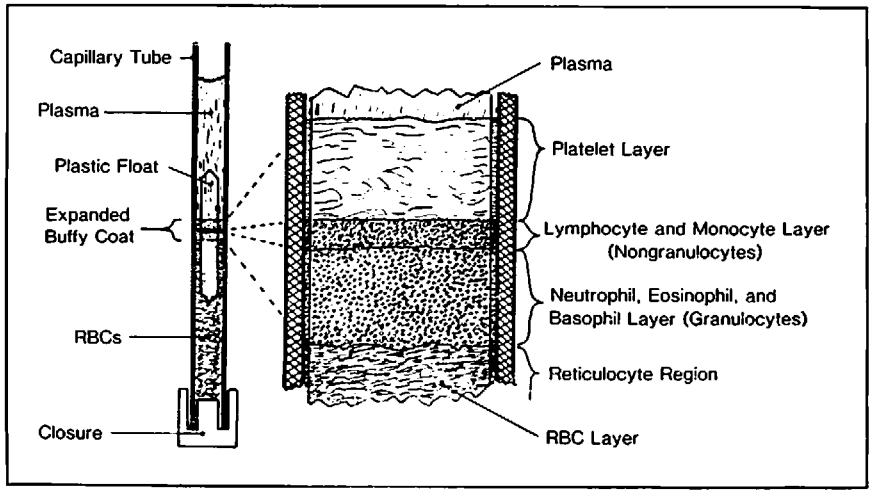
The heart of the system is a precision-bored glass capillary tube that contains a solid cylindrical plastic float (Fig 1). The original tubes were fashioned from 200-μL disposable glass pipettes that had inner diameters of 1.677 mm. After drawing up 111 μL of potassium edetate (K,EDTA) anticoagulated blood and sealing the end of the tube with a plastic cap, the tube is incubated at 42 °C for five minutes. The injection-molded plastic cylinder is inserted, and the tube is spun in a standard microhematocrit centrifuge at 10,500 rpm for five minutes. As the RBCs sediment under centrifugation, the plastic cylinder, having a specific gravity (1.055) that is midway between that of plasma (1.028) and RBCs (1.090),[2] becomes positioned, floating on top of the RBCs and surrounded by the expanded buffy coat. This cylinder occupies 90.66% of the cross-sectional area of the tube and, thus, expands the lengths of the buffy coat layers by a factor of 10.71. With this expansion, the space between the capillary wall and the plastic float is only 40 μm. This expansion factor seems to be the optimum; since the expanded region is only two to three cells thick, further expansion does not allow free movement of the float, and less expansion leaves the layers too small to be easily measured if the WBC count or platelet count is low.

See also pp 613, 633, 636, 639, and 640.

To distinguish the buffy coat layers, 9.9 μg of acridine orange is precoated in the capillary tube and acts as a supravital stain. The dye is taken up by the nucleoproteins of the WBCs, where it fluoresces green when excited by violet light (460 nm).[3] The WBCs of the granulocytic series, however, also have numerous granules that contain glycosaminoglycans. The acridine orange adsorbed on these molecules fluoresces at 680 nm,[3] which, when combined with the nuclear fluorescence, makes this part of the WBC layer appear bright orange (Fig 1). These cells are the heaviest component of the buffy coat and layer immediately on top of the RBCs. Cells lacking these granules (monocytes and lymphocytes) layer above the granulocytes in a single layer and fluoresce a brilliant emerald green. The platelets, fluorescing yellow, form the third, uppermost band beneath the plasma, which fluoresces green.

A viewer holding a ×10 magnifier and a light source filtered to transmit violet light was used for initial macroscopic examination of the centrifuged tube. A blocking filter in the magnifier removed the violet light, allowing viewing of the

Fig 1.—Quantitative buffy coat analysis tube after centrifugation. Enlarged view, taken near center of float, shows linearly expanded buffy coat.



From the Department of Laboratory Medicine, Yale University School of Medicine, New Haven, Conn.

This material is the result of research carried out in the offices and laboratory of the authors and is in no way connected with Yale University.

Reprint requests to 960 Main St, Branford, CT 06405 (Dr Levine).

Reprinted from the Journal of the American Medical Association
February 4, 1983, Volume 249

Table 1.—Conversion of Layer Lengths to Cell Counts*

Hematocrit value, %	2.64 × layer height†
Granulocyte count	4.25 × layer height
Nongranulocyte count	4.96 × layer height up to 1.21 mm, 8.97 × layer height for that part over 1.21 mm
WBC count	Granulocyte count plus nongranulocyte count
Platelet count	175.8 × layer height

*Lengths of layers in millimeters and cell counts ×1,000/μL (assumes 111-μL sample of blood).

†The RBC layer height is the height of the unexpanded layer plus 0.066 times the expanded portion of the RBC layer.

Table 2.—Precision of Replicate Determinations*

Value	Mean of Mean Sample Values	Mean Coefficient of Variation, %
Hematocrit	40.9%	1.4
WBC	6.9 (×1,000/μL)	5.4
Platelet	225 (×1,000/μL)	9.5

*Ten replicate determinations of 26 samples.

fluorescent colors. A micrometer measured the tube's longitudinal movement underneath a cursor, allowing precise measurement of the band lengths. This instrument was used during the initial phase of the study to determine the factors to be used for conversion of the band lengths into count equivalents.

Microscopic inspection of the components of the buffy coat cell layers may be performed directly through the tube wall, using a fluorescence microscope or by fracturing the tube and extracting cells. Using either method, the layers are found to be relatively homogeneous, except for some RBC admixture with the granulocyte layer. Immature cells or the granulocytic series migrate to the upper portion of the lower (granulocyte) band, and, in the case of blasts or promyelocytes, the band borders lose distinction because of the intermixing of these cells with the nongranulocyte (lymphocyte/monocyte) layer.

One of the early problems encountered was the failure of the lower granulocyte layer. Immature cells of the granulocytic series migrate to the upper portion of the density of the RBCs. Certain organic salts of alkali metals, eg, potassium oxalate, or low-molecular-weight sugars, eg, erythritol, selectively remove a portion of the water from the RBCs without affecting the WBCs.[4,5] This increases the density of the RBCs to the extent that when centrifuged, virtually all of the WBCs and platelets in the blood sample separate from the RBCs. For this study, the capillary tubes contained 0.81 mg of potassium

Table 3.—Clinical Composition of Study Group

No. of Patients	Primary Disease Category
59	General Medical (noninflammatory/nonneoplastic)
	Inflammatory
10	Viral
12	Bacterial
15	Allergic/autoimmune
	Neoplastic/Hematologic
108	Carcinoma
2	Sarcoma
25	Lymphoma
4	Myelogenous leukemia
10	Lymphocytic leukemia
13	Miscellaneous malignancies

Table 4.—Chemotherapeutic Agents Used in Study Group

No. of Patients	Agent
48	Fluorouracil
43	Cyclophosphamide
41	Doxorubicin hydrochloride
30	Methotrexate
25	Vincristine sulfate
14	Tamoxifen citrate
13	Prednisone
9	Bleomycin sulfate
5	Vinblastine sulfate
4	Lomustine
4	Chlorambucil
3	Cisplatin
3	Dacarbazine
2	Mitomycin
2	Melphalan
3	Miscellaneous

oxalate. Because of the unequal partitioning of oxalate between the RBCs and the plasma, the plasma concentration is dependent on the hematocrit value but is typically 86 mM.

For the correlation portion of the study, a special instrument was designed to read the tubes. This reader is essentially an electronic micrometer connected to a simple fluorescence microscope. A microprocessor built into the reader converts the band lengths into cell counts by multiplying the length by predetermined factors and calculates the hematocrit value by correcting for the RBC shrinkage induced by the potassium oxalate (Table 1). The reader's performance is checked by measuring a standard tube with inscribed lines of known spacing, and centrifuge performance is monitored by periodic checks of its revolutions per minute. Studies of the system's precision, using blood from normal volunteers, are given in Table 2.

The performance of quantitative buffy coat analysis (QBCA) in an outpatient setting was compared with that of standard hematologic testing methods at two different sites in New Haven County, Connecticut. The first site was a rural/suburban group general medical practice with four internists; the second was a four-partner hematology and oncology

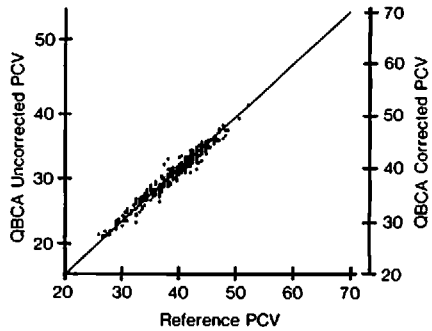


Fig 2.—Reference packed-cell volume (PCV) correlated with quantitative buffy coat analysis (QBCA) PCV, both as initially measured and after correction for potassium oxalate-induced shrinkage. Identity line is for reference PCV and corrected QBCA PCV. Packed-cell measurement is in vol %.

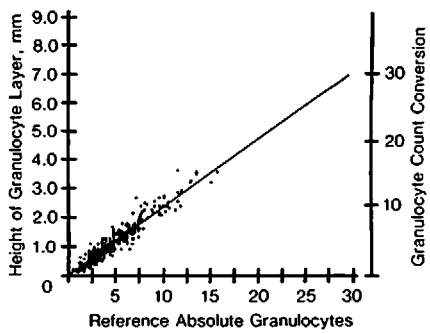


Fig 3.—Correlation between reference absolute granulocyte count and height of granulocyte layer in quantitative buffy coat analysis (QBC) tube. Identity line is for reference count and QBCA count conversion (n=307, r=.947). Absolute granulocyte counts, ×1,000/μL.

group practice. A total of 318 blood samples from 279 patients were analyzed during the 30-day study period, and the charts of 224 patients were reviewed in detail. A summary of the diagnoses and chemotherapeutic medications current at the time of phlebotomy are given in Tables 3 and 4.

Anticoagulated venous blood was analyzed by QBCA within two hours of phlebotomy. Spun microhematocrit values were used for the reference packed-cell volume (PCV); the reference WBC count, and the platelet counts were determined using electrical impedance cell counters (Coulter "S" and Thrombocounter). Manual 100-cell differential cell counts were performed on all samples.

RESULTS

Figure 2 shows the correlation between the measured percent volume of RBCs and the reference PCV. Because the relationship is uniform and linear, the reader's microprocessor can correct for the oxalate-induced shrinkage and reconstruct the true PCV, as shown on the right ordinate scale.

The reference absolute granulocyte

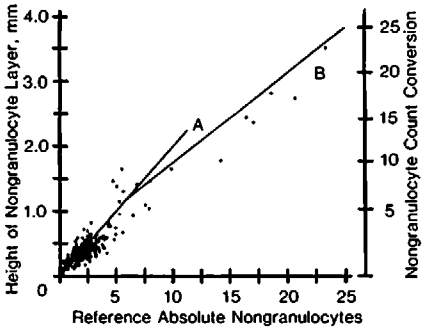


Fig 4.—Nonlinear height/count relationship of the nongranulocyte layer. Line A represents best fit for "average" samples, and line B shows that samples with absolute nongranulocyte counts greater than 6,000/μL have greater percentage of smaller cells. Quantitative buffy coat analysis count conversion is shown on right ordinate (n=307, r=.950). Absolute nongranulocyte counts, ×1,000/μL.

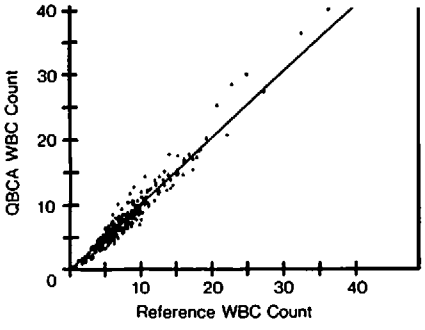


Fig 5.—Quantitative buffy coat analysis (QBCA) total WBC count, as determined by adding absolute granulocyte and nongranulocyte counts, plotted with identity line against reference total WBC count (×1,000/μL) (n=316, r=.971).

count was calculated by multiplying the percentage of granulocytes (neutrophils, eosinophils, and basophils) by the total WBC count. The correlation of this absolute count with the length of the granulocyte band is shown in Fig 3. The right ordinate scale gives the cell count conversion as determined by the reader's microprocessor. Since the granulocytes are a relatively homogeneous group of cells, the relationship between the length and the cell count is linear over the entire range of measurement.

The nongranulocytic cells are a mixture of small lymphocytes, large lymphocytes, and monocytes, and the average mixture is consistent enough to allow a reasonably accurate length-count conversion. In cases where there is a preponderance of abnormal cells, however, the "average" relationship does not hold. Figure 4 shows the relationship between the non-

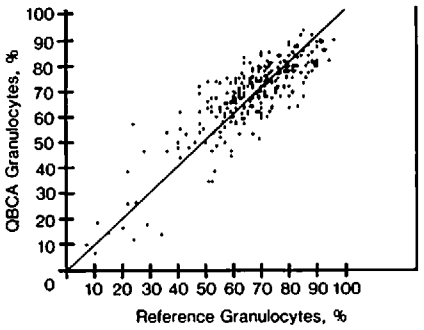


Fig 6.—Quantitative buffy coat analysis percent of granulocytes, plotted with identity line reference value, as obtained from 100-cell manual differential cell count (n=307, r=.848).

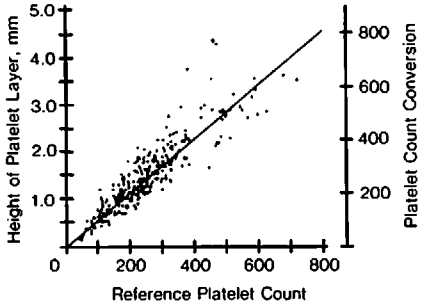


Fig 7.—Correlation of reference platelet count (×1,000/μL) with height of quantitative buffy coat analysis (QBCA) platelet layer. Identity line is for right ordinate scale's QBCA platelet count conversion (n=317, r=.900).

granulocyte count and the length of the cell layer. Up to an absolute nongranulocyte count of about 6,000 cells per microliter, the length/count relationship can be considered average, and the calculation reflected by regression line A can be used. In cases characterized by notably increased total nongranulocyte counts, the cells are generally smaller than average, especially in the case of chronic lymphocytic leukemia, and the calculation line B is used. The total WBC count is the sum of the absolute granulocyte count and absolute nongranulocyte count. Figure 5 represents the correlation between the QBCA total WBC count and the results of the reference method.

Figure 6 presents the differential cell count data in the more familiar percentage format. Here, the scatter reflects, to a large degree, the imprecision inherent in the performance of a 100-cell differential cell count.[6] Although the percentage presentation is the most widely used means of reporting the data, we prefer to know the absolute counts and believe that this is the more valid way of presenting the information. Wintrobe and

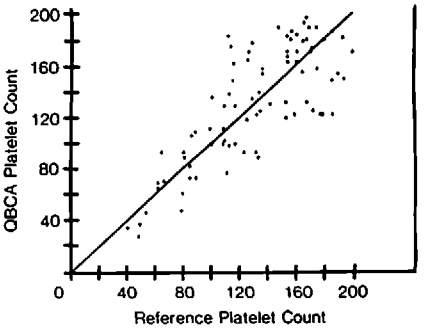


Fig 8.—Eighty-four samples with platelet counts (×1,000/μL) in clinically important range below 200,000.

others' have made pleas for reporting the absolute cell counts.

The platelet count is the least precise QBCA measurement, and this is reflected in the smoothly widening envelope of the scattergram of Fig 7. In looking at the lower ranges, however (Fig 8), it can be seen that clinically important outliers do not occur. We recommend that when using this, or any other method, platelet counts below 80,000/cu mm be confirmed by an independent method, eg, examination of the peripheral blood smear. Variation in platelet size may account for part of the discrepancy between QBCA and the reference method. Although there is no definitive evidence, it has been suggested that circulating platelet mass, which is the quantity actually measured by QBCA, is a better indicator of hemostatic capability than the platelet count.[8,9]

COMMENT

Based on this comparison of QBCA results with those obtained using standard methods, it seems that QBCA can provide an accurate, rapid means of performing a screening CBC count. This study used venous blood samples because the collection of capillary samples would have required an additional invasive procedure for the patient; however, QBCA tubes, with the addition of heparin sodium and sodium edetate, have been successfully used to collect and analyze capillary blood samples in a small number of volunteers. This ability to use capillary blood samples should render the system especially useful for pediatric and chemotherapy patients, where venipunctures may not be desirable.

The limitations of the system must, however, be appreciated; examination

Fig 9.—Appearance of quantitative buffy coat analysis tube in normal and in some specific diseases. Tubes were illuminated with violet light (460 nm), and camera used an orange blocking filter. From right to left, normal sample, granulocytosis, pancytopenia after chemotherapy, acute myelogenous leukemia (large number of blasts in nongranulocyte band have displaced platelets into unexpanded region), and nonseparation in patient with microcytosis.

of the peripheral blood smear is essential if a hematologic dyscrasia is suspected or if the physician desires to quantitate eosinophilia. Morphological RBC abnormalities cannot be evaluated either, but a phenomenon that we call "nonseparation" may alert the user to their presence in some specific cases.

This nonseparation, or the loss of a distinct interface between the RBC and granulocyte layer, was seen in approximately 2% of the chemotherapy patients and 4% of the general internal medicine patients. These nonseparating samples were associated with clinical conditions that caused microcytosis (iron deficiency, thalassemia, or certain hemoglobinopathies), microangiopathic hemolytic anemia, or mechanical RBC trauma. In general, samples with a mean corpuscular volume less than 70 cu μmL demonstrated nonseparation. Such specimens must be examined by standard methods.

Without the 42 °C incubation, about 5% of the centrifuged samples will have granulocytes adherent to the side of the glass capillary tube throughout the entire RBC region. This phenomenon occurs independently of the nonseparation phenomenon but may present a similar appearance. When samples of anticoagulated blood are allowed to remain at room temperature for several hours or are incubated at 42 °C for five minutes, the granulocyte adherence is substantially diminished. This decrement in adhesiveness with time or with incubation may be caused by a decrease in the glycolytic activity necessary for this phenomenon[10] or simply to an overall loss of cellular vitality. The leukocyte adherence phenomenon, observed in the absence of incubation, may prove to be a useful marker of an acute-phase reaction.

A unique feature of the device as a research tool is that it separates the cells into groups and presents them as an easily visible sheet, two to three cells thick. In the 111-μL sample, within the tube are approximately 1 million WBCs, each of which is visible through the wall of the tube. Specific immunofluorescent stains could efficiently detect specific, single cells, if present.

In preliminary studies using animal models, it was found that blood-borne parasites, eg, malarial trophozoites, the trypanosomes of Chagas-Cruz disease and the microfilaria of canine heartworm, were detectable within the expanded area. These can be detected either by a general stain, eg, acridine orange, or, more specifically, by immunofluorescent means. As a result of this, we believe that QBCA may have considerable use as a diagnostic tool in studies of parasitic diseases.

An additional useful feature of QBCA is that it allows visualization of the actual cell layers. Quantitative abnormalities can be graphically appreciated, and additional qualitative information can be obtained by careful inspection of the expanded buffy coat layers. For example, a red-black line, probably composed of RBCs damaged by their contact with the dry oxalate tube coating, may be seen at the granulocyte/nongranulocyte interface. In samples from normal persons, this line is extremely fine, but in patients who have undergone splenectomies, and others, this band may increase to 0.5 mm, presumably because of an increased population of abnormally fragile RBCs. Unusual band coloration may also point to an underlying abnormality. Bilirubin alters the acridine orange binding, causing all bands, although still well defined, to appear faint green. During this study, bilirubinemia was first discovered in two patients by this observation. The user quickly gets a feel for what is normal, and diagnoses can be suggested by the macroscopic appearance of the tube; Fig 9 shows some of the more commonly encountered conditions.

CONCLUSION

Dr Maxwell Wintrobe was the first physician to detect the separation of the buffy coat into platelet and leukocyte layers. In 1933, he published a formula for converting buffy coat layer lengths into approximate cell counts and stated that macroscopic examination of a centrifuged blood sample was a useful first step in the evaluation of a patient's status.[11] The well-known color plate I in his book entitled *Clinical Hematology*[7] has several examples where this inspection would be of benefit.

We believe that QBCA is an extension of this basic observation. Its ease and rapidity of use as well as its ability to allow visual assessment and quantitation of results should make QBCA extremely useful to the practitioner and of interest to research physicians.

Clay Adams, Division of Becton-Dickinson Inc, Parsippany, NJ, transformed the ideas and prototype system into a finished product. Special high-precision glass capillary tubes and their associated plastic inserts were also provided by Clay Adams.

Samuel N. Bobrow, MD; Leonard R. Farber, MD; Richard E. Kaufman, MD; Arthur L. Levy, MD; W. Bruce Lundberg, MD; Edward S. Scherr, MD; and Marvin P. Zimmerman, MD, assisted during the clinical portion of the study.

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ERROR CODES 4-5

Blood-Tube Reading Sequence

- To test QBC Venous Tubes perform Steps 1-6
- To test QBC Capillary Tubes perform Steps 1-7

QBC®
Centrifugal Hematology System

LIMITS 8-3
NORMALS 8-4

1

Turn the transport knob to advance the tube into the Reader. Position the tube so that the tip of the cursor points directly to the center of the GREEN closure and RED cell interface (1st Reading).

Press ENTER. Prompt Display number will advance to "2" and white lamp will light.

2

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

Press ENTER. Prompt Display number will advance to "3" and white lamp will go out.

3

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

Press ENTER. Prompt Display number will advance to "4."

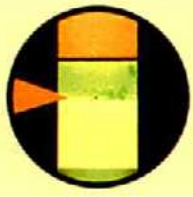
4

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

Press ENTER. Prompt Display number will advance to "5."

5

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



Press ENTER. Prompt Display number will advance to "6."

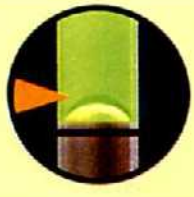
6

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

Press ENTER. Record Venous Blood hematology parameters. Note: In "CAP" mode, proceed to Step 7.

7

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



Press ENTER. Record Capillary Blood hematology parameters.

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BECTON DICKINSON

Dear QBC® Customer:

In an effort to help you offset the cost of daily quality control, we have provided the QBC control subsidy. Under this program, valuable coupons are included with control shipments and may be redeemed for free QBC reagent kits.

We are pleased to announce the continuation of the QBC control subsidy program with a few minor revisions.

Here is how the program will work:

- Starting August 1993, coupons will have expiration dates.
- To receive a free kit, collect and mail three coupons. All three coupons must be received by the earliest expiration date printed on any individual coupon. December 1993 controls will contain a regular coupon plus a bonus coupon. The bonus coupon may be used to obtain one additional free kit.
- When redeeming coupons for free kits, you may select standard QBC reagent tubes or the new E-Z Prep™ tubes.

If you currently have old coupons in your possession, you may redeem them up to December 31, 1993. If you have only one of the old coupons, you may combine it with two new coupons for a free kit if redeemed by December 31, 1993. It should be combined with the August and September coupons. (In other words, the old coupon may count as one of the required three.) Your August coupon will be contained in the control shipment the week of August 16th.

With the implementation of CLIA '88 and the requirement for running daily controls, our goal is to deliver a high quality, low cost product which will have minimal financial impact on you. When compared to the benefit of in-office hematology testing and the enhanced work flow efficiencies, the cost of daily controls is small.

If you have any comments, questions, or suggestions, please call our Technical Service Department at 1-800-631-8064. Thank you for being a QBC customer.

Sincerely,

Jay E. Baum

Jay E. Baum
Associate Product Manager
Hematology

Attachment

EXAMPLE

COUPON MONTH	EXPIRATION DATE
August '93	December 31, 1993
September '93	January 31, 1994
October '93	February 28, 1994
December Bonus	February 28, 1994

- To receive one free kit, the customer should redeem coupons for August, September and October by December 31, 1993 since this is the earliest expiration date.

- To receive a free bonus kit, the customer should redeem the December bonus coupon by February 28, 1994.

QBC HEMATOLOGY CONTROLS

TIPS ON HANDLING

o STORE THE VIALS IN THE REFRIGERATOR.

Always keep your control vials in the refrigerator when not in use. Temperature should be 2° - 8°C (35° - 46° F). Keep away from the freezer compartment area.

o WARM THE VIALS TO ROOM TEMPERATURE BEFORE MIXING.

Remove only the vials you need to run the daily QC check. Check that the expiration date and 11 day open vial stability have not been exceeded. Warm these vials to room temperature (about 15 minutes) before mixing. Promptly return the vials to the refrigerator when testing is complete.

o MIX THE VIALS WELL.

Proper mixing of the control vials is <u>very important.</u> Vigorously roll the vials between the palms of your hands for 30 - 45 seconds, and then mix by gently inverting 5 - 10 times. Do not use a mechanical mixer or nutator. It is important to mix the vials just before filling the QBC tube.

o CHECK YOUR RESULTS AGAINST THE CORRECT RANGES.

The insert sheet must correspond to the lot number on the control vials. Select venous or capillary ranges, as appropriate, and verify your results against the range shown for your QBC instrument.

QBC Control Product
Shipment Schedule
ALL Customers

Please note the following shipment dates through
September, 1993

LOT#	Ship Dates	Expiration Date	Lot Life
Q81	08/17-18/93	09/04/93	2 Weeks
Q82	08/31-9/1/93	09/18/93	2 Weeks
Q83	09/14-15/93	10/02/93	2 Weeks
Q84	09/28-29/93	10/16/93	2 Weeks

NEXT SHIP DATES
Cycles A & C : 08/17/93
Cycles B & D : 08/18/93