

QBC™ Centrifuge System Operator's/Service Manual



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The QBC™ System is protected by one or more of the following U.S. Patent Numbers: 4,027,660; 4,082,085; 4,007,396; 4,159,896; 4,156,570; 4,091,659; 4,141,654; 4,137,755; 4,181,609; 4,209,226; 4,190,328; 4,558,947; 4,567,754; 4,594,165; 4,683,579; 4,695,553; and 4,779,976 as well as many foreign patents. Other patents pending.

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Section □ 1 INTRODUCTION

1.1 INTENDED USE

The QBC[™] Centrifuge (Figure 1-1) is an ultra-compact instrument, designed to spin down blood specimens for QBC[™] Centrifugal Hematology tests or QBC[™] Malaria tests.



Figure 1-1. QBC™ Centrifuge, Model 425740.

1.2 SUMMARY AND EXPLANATION

1.2.1□**QBCTM** Centrifugal Hematology Tests

QBCTM centrifugal hematology tests are based on a high-precision glass capillary tube containing an equally precise plastic float. When the tube is filled with blood, sealed, and centrifuged at high speed for five minutes, the float is buoyed by the packed red cells, automatically positioning the float within the buffy coat layer, between the packed red cells and the plasma. QBCTM tubes for hematology are produced in a standard design (ie., with an unassembled float and tube closure) and in an E-Z PrepTM tube design, with a preassembled float and a stopper.

Under centrifugation, blood cells in the buffy coat layer separate according to their densities, forming visibly discrete bands as shown in Figure 1-2. Platelets constitute the topmost band, lymphocytes and monocytes the center band, while granulocytes, the heaviest band, form immediately above the packed red cells.

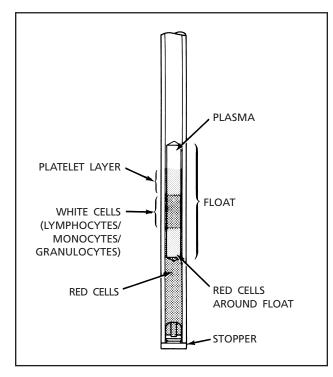


Figure 1-2. Cell layers in Centrifuged QBC™ E-Z Prep™ Hematology Tube.

1

1.2.1□**QBC**TM□**Centrifugal**□**Hematology**□**Tests** (continued)

Coated reagents in the QBCTM blood tube enhance the visual separation between cell layers and provide differential staining so that tubes can be read by non-automatic and automatic QBCTM Analyzers.

1.2.2□QBC™□Malaria□Detection□Tests

The centrifugal test for detecting malaria parasites is based on a high precision glass capillary tube containing an equally precise plastic float. When the blood-filled tube is centrifuged at high speed for five minutes, the float is buoyed by the packed red cells, automatically positioning the float within the buffy coat layer, between the packed red cells and the plasma.

During centrifugation, blood cells in the buffy coat separate according to their densities, forming visibly discrete bands (Figure 1-3). Platelets constitute the topmost layer, lymphocytes and monocytes the middle layer, and granulocytes, being the heaviest of the buffy coat cells, concentrate immediately above the packed red cells. Reagents coated in the QBCTM tube promote separation and metachromatic staining of these cells.

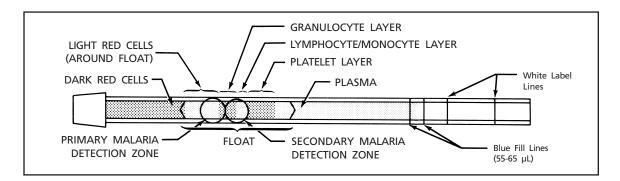


Figure 1-3. Differentiated Cell Layers in Spun QBC™ Malaria Tube.

Examination of the centrifuged blood under a fluorescence microscope readily permits the detection of malaria in the infected cells and plasma. Direct malaria detection by the QBCTM test method is therefore more rapid than conventional blood-film microscopy.

1.3 PRINCIPLES OF THE PROCEDURES

1.3.1□QBC™□Centrifugal□Hematology□Tests

The QBCTM Centrifuge is designed to spin up to 20 QBCTM blood tubes at the force-time requirements needed to produce optimally packed cell layers for cell counting and analyses. QBCTM blood tubes are 75 mm glass tubes, internally coated with potassium oxalate, acridine orange, anticoagulants, and an agglutinating agent. The tubes are sealed with a plastic closure or rubber stopper and contain a precision-molded float within the blood-filled tube. Rotor speed and timing of the centrifuge are computer controlled for maximum consistency in the formation of packed cell layers in spun QBCTM tubes.

1.3.1□QBCTM□Centrifugal□Hematology□Tests (continued)

For technical assistance with QBC™ hematology tests contact:1-866-265-1486

QBC Diagnostics Inc.

200 Innovation Blvd., Suite 212, State College, PA 16801

1.3.2□QBC™□Malaria□Detection□Tests

The QBC™ Centrifuge is designed to spin up to 20 QBC™ malaria tubes at the force-time requirements needed to cause the infected cells to concentrate in a narrow area of the tube for easy identification. QBC™ malaria tubes are 75 mm glass capillaries, internally coated with potassium oxalate, acridine orange stain and anticoagulants. Expansion of the separated cell layers is achieved with a plastic float, which is inserted into the tube prior to centrifugation. Rotor speed and timing of the centrifuge are computer controlled for consistent performance. For malaria detection in the centrifuged sample, the tube is examined under a fluorescence microscope in the region between the light red blood cells and granulocytes and lymphocytes/monocytes, where the parasites are most abundant.

For technical assistance with QBC™ malaria tests contact: 1-866-265-1486

QBC Diagnostics Inc. 200 Innovation Blvd., Suite 212, State College, PA 16801

1.4¬WARNINGS¬AND¬PRECAUTIONS

Always observe good laboratory procedures when handling patient specimens.



WARNING

BLOOD SPECIMENS USED FOR THESE PROCEDURES MAY CONTAIN THE HEPATITIS B AND CVIRUS, HUMAN IMMUNODEFICIENCY VIRUS (HIV), OR OTHER::INFECTIOUS::DISEASES.::|HANDLE::BLOOD::AS::A::POTENTIAL::BIOHAZARD Capable of transmitting infection. Always wear gloves and OTHER APPROPRIATE BLOOD BARRIER PROTECTION WHEN COLLECTING AND□PREPARING□BLOOD.



WARNING

QBCTM::TUBES:::ARE::MADE::OF::GLASS.::EXERCISE::CARE WHEN HANDLING AND PREPARING TUBES TO PREVENT_BREAKAGE_AND_POSSIBLE_INJURY.

Consult Section 4.6 of this manual for detailed safety precautions.

IMPORTANT: The coating ingredients in QBC™ tubes for hematology differ from those in QBC™ tubes for malaria. Accordingly, do not interchange QBC™ Hematology Tubes with QBC™ Malaria Tubes, since erroneous test results will be obtained.

1.5 SYMBOL DEFINITIONS

Direct Current (non-alternating)



Not for use in the presence of flammable gases.



Attention! Read the attached note!

Section□2 SYSTEM□DESCRIPTION

2.1 COMPONENTS

The QBC[™] Centrifuge is shipped with an external plug-in power pack that supplies the required direct current (D.C.) voltage to power the motor, circuit board and other internal systems of the instrument.

2.2 CENTRIFUGE DESCRIPTION

The QBCTM Centrifuge is a compact, low-profile unit measuring less than 13 centimeters (5.1 in.) high with cover down, and housed in a sturdy plastic case. As shown in Figure 2-1, the centrifuge incorporates a 20-place rotor, mounted to the shaft of a brushless D.C. motor. In addition to shock-mounting of the motor to minimize vibration, the centrifuge rests on four suction feet for added stability. A protective metal cover, which threads onto the motor shaft, keeps the spinning tubes snugly in place on the rotor. The hinged top lid with safety latch provides a housing or shield around the rotor during operation.

Electrical power to the centrifuge is controlled by a momentary ON/OFF power button located on the front deck. Before the motor will start, the top lid must be closed and latched. Once a spin cycle has started, a safety interlock prevents the lid from being opened until the rotor brakes to a stop. The spin cycle is controlled by an electronic timer on the main circuit board. Spin time is fixed at 5 min.

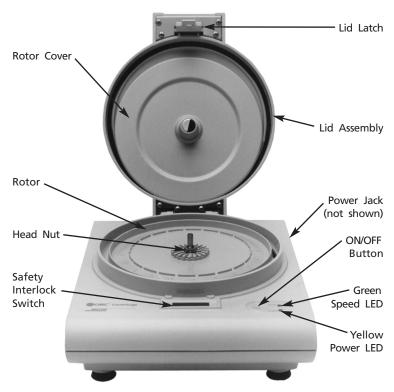


Figure 2-1. Features and Controls of QBC™ Centrifuge.

2.2 CENTRIFUGE DESCRIPTION (Continued)

A green light emitting diode (LED) for "SPEED" and a yellow LED for "POWER" adjacent to the "ON/OFF" button provide visual indicators of power circuit status. Condition of each LED (On, Off, or Flashing) based on the status of power, lid latching, rotor speed, etc., is described in Sections 4.5 and 9.5.

2.3 POWER PACK

The Power Pack for the QBC™ Centrifuge is a table-top, 100 watt, switched-mode power supply, with a universal input range (90-265 VAC) and a 47 VDC output. The unit is equipped with an on/off switch and a user-serviceable primary fuse.

2.4 SPECIFICATIONS

2.4.1□QBC™□Centrifuge

□ Rotor Capacity: 1 to 20 QBC™ tubes.
□ Rotor Speed: 12,000 rpm ± 80 rpm.
□ Nominal Relative Centrifugal Force (RCF): 14,387 x g.
☐ Timer: Electronic, 300 s spin, 15-20 s deceleration.
☐ Electro-Mechanical Safety Interlock: Lid must be closed and latched
before motor can be energized. Lid remains locked until rotor stops.
□ Operating Temperatures:
• For QBC™ Hematology: 20 to 32 °C (68 to 90 °F).*
• For Parasite Detection: 16 to 37 °C (60 to 99 °F).*
□ Functional Range:
• Centrifuge Operation: 2 to 40 °C (36 to 104 °F).*
☐ Operating Relative Humidity: 0% to 80% for temperatures between +2 and 31 °C,
derating linearly to 50% between 31 and 40 °C.
□ Non-Operating Storage Temperature Limits: -26 to 66 °C (-15 to 150 °F)
□ Maximum Altitude: 2000 m (6562 ft).
☐ Weight (with rotor and cover installed): 2.8 kg (6.2 lbs).
□ Dimensions (with lid closed) 23.5 cm W x 29.8 cm D x 12.7 cm H. (9.25 in. W x 11.75 in. D x 5 in. H.)
☐ Transient Overvoltage Category I.
□ Indoor or under-cover use only.
□ Pollution Degree I.
☐ Electrical: 47 VDC ± 3 VDC, 3 ADC Maximum, Steady State.
·

2.4.2□QBC™□Power□Pack

The power supply accompanying or sold with the QBC[™] Centrifuge complies with IEC 1010-2-020 and bears the GS mark.

```
□ Input: 100-240 ± 10% VAC, 50-60 Hz.
□ Output: 47 ± 3 VDC, 3 amps steady state, 5 amps surge.
□ DC Output Cord: 0.46 m (1.5 ft.).
□ AC Line Cord (unassembled):

• Standard Cord: 2.3 m (7.5 ft).
• Continental European Cord: 2.5 m (8.2 ft).

□ Fuse: 5.0 Amp, 250V, F-type.
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^{*}For temperature specifications: consult the package insert of the disposables in use in your laboratory.

Section□3 INSTALLATION□AND□SET-UP

3.1 PACKAGING AND PARTS

The QBC[™] Centrifuge and Power Pack are shipped in a single container, together with the following parts, test accessories and instructions (Figure 3-1):

- Rotor Cover Assembly
- Head Nut Wrench
- Rotor Removal Wire
- Spare Fuse for Power Pack
- Two Power Pack Line Cords (see below)
- Operating Instructions (this Manual)

Note: For use of the centrifuge in Continental Europe, an alternate line cord is provided with the Power Pack. Select the appropriate line cord and discard the unused cord.

3.2 INSTALLATION AND SERVICE

For first-time users of the QBC M System, a representative of QBC Diagnostics Inc. or your local QBC System distributor will normally install the required equipment; the installer will also train operating personnel in proper use of the equipment. If necessary, contact your nearest QBC Diagnostics Inc. office to arrange for installation service.



Figure 3-1. QBCTM Centrifuge, Showing Parts and Accessories. (Note: Centrifuge is supplied with rotor installed.)

3.3 CONNECTING POWER UNIT

Be sure the Power Pack switch is OFF. Insert the plug of the Power Pack output into the jack on the right side of the centrifuge (Figure 3-2). Using the appropriate line cord, connect the female plug to the receptacle in the side of the Power Pack (Figure 3-3); connect the male plug to a grounded A.C. power receptacle; then turn ON the Power Pack switch. Failure to turn the Power Pack OFF before inserting the plug may result in an electrical arc which can damage the Power Pack or centrifuge. When disconnecting the Power Pack from the centrifuge, turn OFF the Power Pack switch and allow_at_least_(30)_s before unplugging the output plug. Failure_to_wait_at_least_(30)_s after_turning_the_Power_Pack_OFF_may_result_in_an_electrical_arc_which_can damage_the_Power_Pack_Or_centrifuge.



Figure 3-2. Connecting Output Cord of Power Unit to Centrifuge Jack.



Figure 3-3. Connecting AC Line Cord to Power Pack Plug.



CAUTION

To avoid electrical hazards and equipment damage, connect the power cord only to grounded receptacles delivering the voltage and frequency specified on the data plate of the power supply, with a switch or other means of circuit disconnection ocated outside the dearance envelopedefined in Section 3.4 of this manual. When only a 2-wire receptacle and/or an unswitched line is available, have the receptacle and/or the supply line modified by a qualified service technician, in accordance with applicable electrical codes, to conform to this note.

3.4 PLACEMENT AND OPERATING EQUIPMENT

Place the centrifuge on a smooth, level working surface in a location where it will not be exposed to direct sunlight. Centrifugations in direct sunlight can elevate the rotor compartment temperature and may adversely affect the formation of readable cell layers in QBC™ blood tubes. For stability, be sure the unit rests on its suction feet.

Mark an envelope 300 mm (~12 inches) wider than the body of the centrifuge around the area in which the centrifuge is to be used. Keep all personnel and hazardous materials outside this envelope when the centrifuge is operating.

3.4 PLACEMENT AND OPERATING EQUIPMENT (continued)



WARNING

IFO THISO EQUIPMENTO ISO USEDO INO AO MANNERO INCONSISTENTO WITHO THE MANUFACTURER'SO SPECIFICATIONS,O THEO PROTECTIONO AGAINST HAZARDSOTHISODEVICEOPROVIDESOMAYOBEOIMPAIRED.

Be sure to keep the operating area within the temperatures listed below.

- For QBC[™] Centrifugal Hematology tests: operating temperature should be maintained at 20 to 32 °C (68 to 90 °F) to assure proper cell layering in QBC[™] blood tubes.
- For QBC[™] Blood Parasite Detection tests: operating temperature should be maintained at 16 to 37 °C (60 to 99 °F) to assure the concentration of parasitic organisms.

3.5 ROTOR ASSEMBLY

The QBC[™] Centrifuge is shipped with the rotor assembly completely installed.

If the rotor is removed, for example for cleaning (see Section 9.2), it can be reinstalled as follows:

- a) Position the rotor so that the slots on the underside of the rotor hub are aligned with the drive pin in the motor shaft (Figure 3-4).
- b) Press the rotor down until the drive pin is seated in the hub slots and 3-5 threads of the shaft protrude above the hub, about 6 mm (1/4").

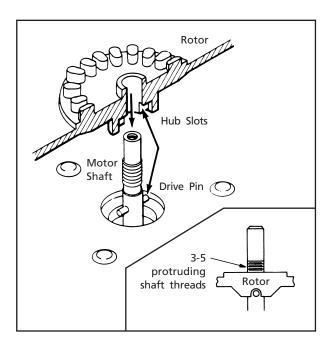


Figure 3-4. Installing Rotor Assembly.



CAUTION

TOO PREVENTO DAMAGEO TOO ROTORO COVER ANDO CENTRIFUGEO LID,O BEO SUREO ROTORO IS CORRECTLYOSEATEDOONODRIVEOPIN.

c) Thread the head nut onto the shaft finger-tight, by turning it clockwise. Tighten with a light torque using the head nut wrench supplied with the centrifuge (Figure 3-5). DO NOT OVERTIGHTEN. Turn nut 1-2 tube positions to tighten.



Figure 3-5. Tightening Rotor with Head Nut Wrench

Section□4 CENTRIFUGE□OPERATION

4.1 GENERAL PROCEDURES

 $Before \verb|| starting \verb|| the \verb|| QBC^{\texttt{M}} \verb|| Centrifuge, \verb|| be \verb|| sure \verb|| the \verb|| rotor \verb|| cover \verb|| is \verb|| installed \verb|| and \verb|| the \verb|| lid \verb|| is \verb|| closed \verb|| and \verb|| latched.$ The \verb|| centrifuge \verb|| will \verb|| not \verb|| start \verb|| unless \verb|| the \verb|| lid \verb|| is \verb|| latched.

 To start the 5-min spin, press and release the "ON/OFF" button on the front deck of the centrifuge (Figure 4-1). The rotor will begin accelerating until it stabilizes at the design speed. See Section 4.5 for sequencing of 'POWER' and 'SPEED' indicator lights.



CAUTION

TOO PREVENTO PERSONALO INJURYO OR DAMAGE, ONEVEROLEANON, OPICKOUP, OR TILTO THEO CENTRIFUGEO WHILEO ITO IS OPERATING. ONEVERO REMAINO WITHIN THEOCLEARANCE ENVELOPEODEFINED ON SECTIONO 3.400FOTHIS OMANUALONGER THANO NECESSARYO FOR OPERATIONALOREASONS.



Figure 4-1. Detail of ON/OFF Button and POWER/SPEED LED's.

- Spin time is fixed at 5 min and is not adjustable. After 5-min spin, 15-20 s are required for the rotor to decelerate to a full stop, at which time the lid latch unlocks.
- To stop the centrifuge any time during a spin, press and release the "ON/OFF" button. Note: After completing any spin cycle (full or interrupted) the timer is automatically reset to zero.

4.2 BETWEEN-SPIN TIME DELAY

Since the QBCTM test method depends upon proper cell layering in the hematology and malaria tubes, blood sampled must be protected from excessive heat buildup in the rotor compartment, which may adversely affect cell layer formation. Accordingly, between successive spins be sure to wait the appropriate time specified below. IMPORTANT: During each between-spin rest, be sure the rotor cover is removed and the rotor empty.

4.2.1□QBC™□Hematology□Tubes

- If room temperature is 24 °C or less (\leq 75 °F), wait 1 min between spins.
- If room temperature is 25 28°C (75 82 °F), wait 3 min between spins.
- If room temperature is 29 30°C (84 86 °F), refer to the table below.

Between	Between	Between	Between	Above 5 Spins
1st & 2nd Spins	2nd & 3rd Spins	3rd & 4th Spins	4th & 5th Spins	
3 min.	6 min.	9 min.	12 min.	15 min.

• If room temperature is 31 - 32 °C (88 - 90 °F), wait 30 min between spins.

Note: During QBC[™] Hematology tests using standard or E-Z Prep[™] tubes, room temperature should not exceed 32 °C (90 °F).*

^{*}Important: For room temperature specifications: consult the package insert of the disposables in use in your laboratory.

4.2 BETWEEN-SPIN TIME DELAY (continued)

4.2.2□QBC™□Malaria□Tubes

- If room temperature is less than 33 °C (< 91 °F), wait 1 min between spins.
- If room temperature is 33 35 °C (91 95 °F), wait 3 min between spins.
- If room temperature is 36 37 °C (97 99 °F):
 - With 1 to 5 consecutive spins, wait 6 min between spins.
 - With consecutive spins above 5, wait 9 min between spins.

Note: During QBC™ Malaria tests, room temperature should not exceed 37 °C (99 °F).

4.3 TUBE LOADING AND BALANCING

The top lid is spring-loaded and is automatically released when the Power switch of the centrifuge is off, provided the Power Pack is on and connected to the centrifuge. When a spin cycle is completed, the latch releases after a momentary delay and the lid pops up (Figure 4-2).



Figure 4-2. Spring-Loaded Lid Latch Mechanism

Place tubes on the rotor in a balanced array, with the□tube□closures□or□stoppers□(in□E-Z□PrepTM□ tubes)□against□the□outer□rim□of□the□rotor. To maintain balance, insert the tubes consecutively, starting at slot #1.

When spinning an odd number of tubes (e.g., three), BE SURE TO BALANCE THE ROTOR BY PLACING AN UNFILLED QBCTM TUBE IN THE OPPOSITE SLOT (e.g., #4 as shown in Figure 4-3). Use a closure or stopper and a float in the balance tube.



Figure 4-3. Typical Placement of Blood and Balance Tubes.

Note: If using an E-Z $Prep^{TM}$ Tube for balancing, do not attempt to re-use the balance tube for a patient sample. Re-use for balancing only.

4.3 TUBE LOADING AND BALANCING (continued)

Before closing the lid, INSTALL THE ROTOR COVER. To secure the cover, turn the cover knob **clockwise** onto the motor shaft (Figure 4-4). Continue turning the knob until the cover is snug. DO NOT OVERTIGHTEN.



CAUTION

NEVERO ATTEMPTO TOO CENTRIFUGE QBCTMOTUBESOUNLESSOTHEOCOVEROIS INSTALLEDOVEROTHEOROTOR, OSINCE TUBEO BREAKAGEO ANDO LOSSO OF SAMPLEOWILLOCCUR.



Figure 4-4. Tightening Knob of Rotor Cover.

4.40EMERGENCYOUNLATCHINGOFOLID

An electric interlock prevents the operator from manually opening the centrifuge lid once it is closed and latched. In case the latched lid must be opened, <u>and the cover was installed over the rotor</u>, press the ON/OFF button twice to start and stop the Centrifuge. The lid will then open.

In case the latched lid must be opened, <u>but the rotor cover was inadvertently left off</u>, **DO**NOT attempt to start and stop the centrifuge with the ON/OFF button; instead, turn off the Power Pack switch and wait for the yellow LED to turn off; then turn on the Power Pack switch. This will disengage the electric latch interlock and cause the lid to open.

Note: For procedures on opening the lid in the event that main power to the centrifuge is lost through a fuse or main electrical failure, see Section 9.3.

4.5 SPEED/POWER LED MONITORS

The yellow 'POWER' and green 'SPEED' LED lights are used for monitoring the status of the centrifuge. When both lights are on steadily, the centrifuge is at design speed (12,000 \pm 80 rpm). When the yellow light is on steadily but the green light is flashing, the centrifuge is below (but accelerating to) design speed; and when both lights are <u>flashing</u> the unit is above design speed. If speed exceeds 14,800 rpm, the centrifuge will automatically shut down.

A detailed table of LED Status Indicators is presented in Section 9.5, TROUBLESHOOTING.

4.6 PRECAUTIONS AND HAZARDS

The QBC[™] Centrifuge is intended for *in vitro* diagnostic tests. In order to obtain properly centrifuged specimens and to avoid damage or hazards, the basic operating precautions below should be observed.

- For smooth operation and long service life, always place blood tubes on the rotor in a balanced array.
- Always install the rotor cover before closing the top lid.
- Never attempt to override the lid safety interlock.
- Never attempt to pick up or move the centrifuge while the rotor is spinning.
- "Universal Precautions" should be followed in handling all items contaminated with blood or other body fluids.
- Exercise care when using QBC™ tubes. The tubes are made of glass and may break, possibly causing injury and exposure.
- If a tube breaks, carefully remove broken glass with a hemostat or other device, using puncture-resistant utility gloves, and dispose of properly.
- Disinfect rotor after a tube break. See Section 9.2.2.
- For continued safety, periodically inspect the rotor for signs of wear or defects as described in Section 9.2 of this manual.
- Blood products and other biological materials should always be disposed of in accordance with laws, regulations, and institutional guidelines applicable to your facility.

¹Recommendations for Prevention of HIV Transmission in Health Care Settings. MMWR 1987; 36 (Supplement #25).

Section□5 SPECIMEN□COLLECTION

5.1□**GENERAL**

The QBCTM Centrifuge is designed for the preparation of specimen tubes for QBCTM Hematology and Malaria tests. Detailed directions on blood collection, preparation, and stability for each type of test are contained in the package insert supplied with QBCTM hematology tubes and malaria tubes. Handling precautions and collection procedures are summarized below.

5.2 HANDLING PRECAUTIONS

Exercise good laboratory procedures when collecting and handling patient specimens.



WARNING

BLOOD: SPECIMENS: USED: FOR: THESE: PROCEDURES: MAY: CONTAIN: THE HEPATITIS: B: AND: C: VIRUS,: HUMAN: IMMUNODEFICIENCY: VIRUS: (HIV),: OR OTHER: INFECTIOUS: DISEASES.: HANDLE: BLOOD: ALWAYS: WEAR: GLOVES: AND OTHER: APPROPRIATE: BLOOD: BARRIER: PROTECTION: WHEN: COLLECTING AND: PREPARING: BLOOD.

- Be sure to clean the skin area with an antiseptic agent; dry the area with a sterile wipe. Puncture only with a **sterile** lancet.
- Always use sterile needles and collection tubes.

5.3 SPECIMENS FOR QBC MOHEMATOLOGY TESTS

Venous blood for QBC[™] hematology test analysis can be collected in Vacutainer[™] brand tubes containing EDTA anticoagulant. QBC[™] tubes for venous blood are filled by means of a semi-automatic pipetter supplied with the QBC[™] System. QBC[™] capillary-blood tubes are pre-coated with anticoagulants and are filled with blood directly from a finger puncture.

After filling with blood, the tubes are sealed with a rubber stopper or plastic closure. The float in QBC™ tubes expands the buffy-coat cell layers during centrifugation, as previously described.

Stability: For stability specifications, consult the package insert of the disposables in use in your laboratory.

5.4\(\text{SPECIMENS}\)\(\text{FOR}\(\text{QBC}^\mathbf{m}\)\(\text{MALARIA}\)\(\text{TESTS}\)

Collect capillary blood from the finger or foot, directly into the malaria tube; or draw venous blood and collect into the malaria tube. Fill the tube with 55 to 65 μL of blood. Malaria tubes are pre-coated with sodium heparin and dipotassium EDTA anticoagulants.

<u>Stability:</u> Centrifuge the blood-filled malaria tubes as soon as possible after filling. See 6.4.4 for extended stability of malaria tubes prior to microscopic examination.

Section□6 CENTRIFUGATION□PROCEDURES

6.1□MATERIALS□PROVIDED

The QBC[™] Centrifuge is designed to spin up to 20 QBC[™]-type blood tubes over a fixed time of 5 min. The centrifuge is supplied with a Power Pack and the test accessories listed in Section 3.1.

6.2 MATERIALS REQUIRED BUT NOT PROVIDED

6.2.1□QBC™□Hematology□Tests

In addition to a QBCTM Reader or Analyzer, the following disposables and test accessories are required for QBCTM hematology tests:

- QBC[™] E-Z Prep[™] Venous Tubes 100 Tests: Cat. No. 424640
- QBC[™] E-Z Prep[™] Capillary Tubes 100 Tests: Cat. No. 424641
- QBC[™] E-Z Prep[™] Pipetter for venous blood, Cat. No. 424225
- Work Station, Cat. No. 424226
- Sterile wipes.

- Standard QBC[™] Venous Tubes 100 Tests: Cat. No. 424240 100 Tests: Cat. No. 424245* 1000 Tests: Cat. No. 424237*
- Standard QBCTM Capillary Tubes 100 Tests: Cat. No. 424241 100 Tests: Cat. No. 424246* 1000 Tests: Cat. No. 424238*

6.2.2□QBC™□Malaria□Tests

The following disposables and test accessories are required for QBCTM malaria detection tests:

- QBC[™] Malaria Kit 100 Tests: Cat. No. 253037 2000 Tests: Cat. No. 253005
- Fluorescence Microscope or Standard White Light Microscope with ParaLens™ Microscope Adapter.
- Sterile wipes.

6.3□**TEMPERATURE**□**REQUIREMENTS**

<u>For QBC™ Hematology Tests*:</u> Optimum results are obtained when the laboratory temperature is maintained between 20 to 32 °C (68 to 90 °F).* To avoid excessive heating of blood tubes during spinning, locate the centrifuge away from direct sunlight.

<u>For Malaria Detection Tests:</u> Optimum results are obtained when test procedures are performed at temperatures between 16 to 37 °C (60 to 99 °F).

*IMPORTANT: For room temperature specifications: Consult the package insert of the disposables in use in your laboratory.

^{*}With multi-language instructions.

6.4 CENTRIFUGATION INSTRUCTIONS



CAUTION

DOO NOTO USED THISO CENTRIFUGED FORD SPINNINGD MICROHEMATOCRITO ORD OTHER CAPILLARY OTUBES. OTHEOROTOR AND OCOVERDARE DESIGNED TOO ACCOMMODATED ONLY QBCTMD TUBES. OTHEROTOPES OF CAPILLARIES MAY BREAK, CAUSINGD BLOOD SPILLS AND OLOSSOF SPECIMEN.

6.4.1□Affixing□Identification□Labels (Malaria□Tubes□Only)

Before Placing QBC[™] malaria tubes on the centrifuge rotor, a correctly marked patient identification label should be affixed on each tube between the two white lines scribed near one end of the tube (Figure 6-1).

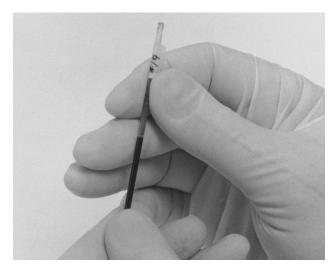


Figure 6-1. Placement of ID Label on QBC™ Malaria Tube.

6.4.2□Loading□and□Balancing□Rotor

Position QBCTM specimen tubes in the holder slots of the rotor, with the stopper against the outer rim of the rotor. Arrange the tubes in a balanced array, i.e., #2 tube opposite #1 tube, #4 opposite #3, etc. When centrifuging an odd number of tubes, balance the rotor with an empty QBCTM hematology tube or malaria tube. Note: Do not attempt to re-use the balance tube for patient samples.

6.4.3 □ Centrifugation □ Procedures

- a) Secure the cover to the rotor; then close and firmly latch the lid.
- b) Press and release the ON button to start the spin cycle.
- c) After the five-min spin cycle is complete and the lid pops up, open the lid and REMOVE THE TUBES.

IMPORTANT: Failure to remove tubes promptly after centrifugation may affect cell layer boundaries and subsequent test results.

6.4.3 Centrifugation Procedures (continued)

d) If not read promptly, the centrifuged tube should be stored temporarily, stopper or closure end down, in the QBC™ tube rack (see Figure 6-2 or QBC™ work station.

Note: See Test Timing in 6.4.4.

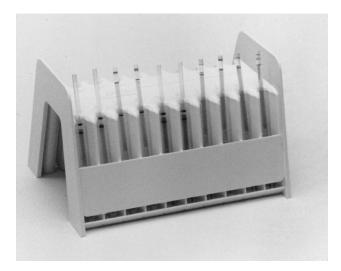


Figure 6-2. Centrifuged Tubes Sorted in QBC™ Rack.

6.4.4□Testing□Time

Testing of QBC[™] Hematology tubes and Malaria tubes promptly after centrifugation is recommended. The delays below, however, will not affect test results.

- QBC[™] Hematology Tubes: To obtain accurate cell counts, test hematology tubes in the QBC[™] Analyzer 4 hours after centrifugation. Store the tubes vertically, stopper down in the tube rack, away from heat and intense light. Consult the applicable QBC[™] System Operator's Manual for test instructions.
- QBC[™] Malaria Tubes: After centrifugation, malaria tubes can be held for as long as 3 days unrefrigerated, at temperatures up to 37 °C (99 °F), before microscopic examination. Store tubes vertically, closure down in the tube rack.

Section□7 LIMITATIONS□OF□PROCEDURES

7.1 QBCTMCCENTRIFUGALCHEMATOLOGYCTESTS

QBCTM tests should be performed at temperatures between 20 and 32 °C (68 and 90 °F).* If tubes are run at temperatures below 20 °C, test results may be erroneously high; if tested above 32 °C, interfaces may become blurred and difficult to detect visually or automatically, depending on the model of QBCTM Analyzer performing the test.

7.20QBCTM0MALARIADETECTION0TESTS

The QBCTM Malaria test is a qualitative method for diagnosing "positive" or "negative" patients. While numerous reports have demonstrated that the QBCTM test is significantly more sensitive for detecting malaria than stained blood films, QBCTM may not detect very low levels of parasitemia.

Experienced microscopists can discriminate between various species of malarial parasites using the QBCTM test. Examination of a thin blood smear may be required to differentiate species in some cases.

See the package insert in the Malaria Kit for a list of literature references.

*IMPORTANT: For room temperature specifications: consult the package insert of the disposables in use in your laboratory.

Section□8 CALIBRATION□CHECKS

According to Federal Regulations, centrifuges, such as the QBC[™] Centrifuge, require verification or calibration as follows: 1) before initial use; 2) after repair or adjustments; and 3) annually after use. The centrifuge timer, however, should be checked for accuracy at least every 3 months.

The QBC[™] Centrifuge has been fully **calibrated**□**at**□**the**□**factory** and is ready to deliver consistent, accurate test results upon first use. For subsequent calibration checks, follow the procedures in 8.1 and 8.2 below.

8.1□CHECKING□ROTOR□SPEED

The rotor of the QBCTM Centrifuge is designed to spin at 12,000 \pm 80 rpm. Atpleastpeveryp6pmonthsporpafterpany adjustmentsporprepairs, check the rotor speed with a non-contact strobe tachometer to assure that speed is sufficient to produce visibly distinct and differentiated cell layers in the QBCTM tube. A window in the top lid and a reference line on the knob of the rotor cover are provided for speed checks with a non-contact tachometer.

8.2 CHECKING TIMER ACCURACY

The electronic timer of the Centrifuge is designed to be accurate to 300 \pm 15 s. Check the timer for accuracy against a reliable stopwatch or quartz timer at least every **3** \square **months** as follows:

- a) Install the rotor cover.
- b) Close the latch and top lid.
- c) Press and release the ON button, and simultaneously start the stopwatch.
- d) Stop the **stopwatch** when you audibly detect cutoff of power to the motor and the centrifuge begins to decelerate.
- e) The stopwatch reading should be 5 min \pm 15 s.

If the 15-s tolerance is exceeded, repeat the check to eliminate the possibility of procedural errors. Request service if the accuracy check is unsatisfactory.

Section□9 MAINTENANCE□AND□SERVICE

9.1□GENERAL□CLEANING



CAUTION

 $TO \square AVOID \square ELECTRICAL \square HAZARDS, \square ALWAYS \square DISCONNECT \square THE POWER \square CORD \square BEFORE \square CLEANING.$

Use soap or a mild detergent and water to clean the lid, housing and most parts of the QBC™ Centrifuge. (See below for special instructions on cleaning the rotor.) To prevent marring or scratching the finish, avoid solvents or strong abrasives. Dry all surfaces with soft paper towels or cloth.

Important: When cleaning the inside of the centrifuge, do not allow any fluids to run down into housing beneath the rotor. Fluid in this area can damage the centrifuge.

Cleaning and decontamination may be necessary as a safeguard before the centrifuge or rotor is maintained, repaired, or transferred. The user should attach a label or tag to the unit before it is moved or serviced, certifying that cleaning and decontamination were performed.

9.2 ROTOR MAINTENANCE

9.2.1 Periodic Inspection

Remove and inspect the rotor for defects at least every 12 months and each time the rotor is removed for cleaning.

To remove the rotor:

- a) Turn the head nut **counterclockwise** with the wrench to remove.
- b) Insert the removal wire under the rotor. Lift both sides of the wire to pry up the rotor (Figure 9-1).



Figure 9-1. Prying Rotor From Motor Shaft with Removal Wire.

Carefully inspect the rotor for defects that could impair its continued safe use. Check top and bottom surfaces for the following:

- Cracks, especially hairline cracks in the region adjacent to the hub;
- Surface corrosion, particularly in the region of the hub;
- Deep scratches or severe dents.

If any of the above defects are found, replace the rotor with a new assembly. See Section 9.6 for catalog numbers.

Also inspect the motor shaft, shaft pin and head nut for signs of wear, corrosion or damage. Replace any defective parts or request repair service. Use the centrifuge only if all parts are in good condition.

9.2.1 Periodic Inspection (continued)

To replace the rotor: refer to Figures 3-4 and 3-5. Position the rotor hub on the motor shaft so that the slots on the underside of the hub are in line with the shaft pin. Press the rotor down until the shaft pin is seated in the hub slots and 3-5 threads on the shaft protrude above the hub, about 6 mm (¼"). Secure the rotor to the motor shaft with the head nut. Lightly tighten the nut with the wrench.

Also inspect the centrifuge housing and lid for cracks, missing pieces, or deformations.

Extended service life of the rotor requires that the assembly be cleaned only by the procedures and with the approved agents specified in 9.2.2. Before using any cleaning or decontamination methods other than those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment.

9.2.2 Rotor Cleaning Procedures

To clean, always remove the rotor from the centrifuge so that the procedure can be performed properly.

a. Cleaning Agents

The rotor assembly can be damaged by certain chemicals and disinfecting agents. Clean and disinfect the rotor only with a solution containing a 1:10 dilution of commercial sodium hypochlorite (5%).



CAUTION

DOO NOTO USED ANYO OTHERD CLEANINGD ANDO DISINFECTINGD AGENTS, SINCE THEYDCANDCORRODEDANDDAMAGEDTHEDROTOR. BEDSURED TO THOROUGHLY RINSEDANDDRYDTHEDROTORDBEFOREDRE-INSTALLING.

A 1:10 dilution is prepared by adding one (1) part of household bleach to nine (9) parts of water. Soak the rotor in the dilute bleach for atpleastptenp(10) min to destroy any viral and bacterial contaminants. BE SURE TO REMOVE THE ROTOR PROMPTLY AFTER 10 MIN OF SOAKING IN THE BLEACH SOLUTION SINCE EXTENDED EXPOSURE TO THE BLEACH CAN CORRODE THE ROTOR.

b. Rinsing and Drying

After soaking in the dilute bleach solution specified above, completely immerse the rotor in clean water. Rinse again under running water to remove all traces of bleach.

Thoroughly dry the top and bottom surfaces of the rotor. Oven drying may be used, provided the temperature DOES NOT EXCEED 53 ℃ (126 ℃).

IMPORTANT: The motor shaft, shaft pins and attaching hardware must also be dean and dry before reassembly.

If the rotor is cleaned without removing it from the centrifuge (not a recommended procedure), wipe it with a doth moistened with water only. DO NOT USE THE ABOVE DILUTE BLEACH SOLUTION. Do NOT wipe the rotor with any other cleaning agent, since it cannot be sufficiently rinsed off while the rotor is installed.

9.3 RELEASING LID LATCH

If the lid is latched and there is a loss of main power to the centrifuge – i.e., a blown fuse in the Power Pack or interruption of primary electrical power – the lid will remain latched. A jammed plunger in the latch solenoid can also cause the lid to remain latched. If you cannot wait for the restoration of power or the replacement of a fuse, the lid can be opened as follows:

- a) Disconnect the Power Pack plug from the centrifuge.
- b) Turn the centrifuge upside-down.
 Using a Flat-head screwdriver,
 locate in the center: the emergency lidopen slot.
- c) Push gently on the end of the solenoid plunger until the latch is released (Figure 9-1, 9-2).



Figure 9-1.

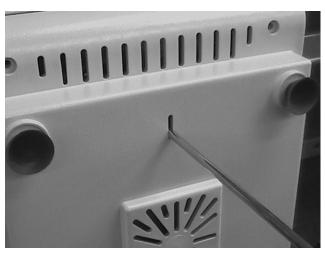


Figure 9-2.

- d) Turn the centrifuge upright. Reconnect the plug of the Power Pack to the centrifuge.
- e) When the power problem is corrected, check by closing and latching the lid; then turn power on and off to verify that the lid unlatches properly.

9.40REPLACINGOPOWEROPACKOFUSES

- a) Unplug the line cord of the Power Pack from the wall receptacle.
- b) Remove the fuse cover from the Power Pack.
- c) Remove the blown fuse(s) and install a 5 amp replacement fuse.
- d) Replace the fuse cover.
- e) Reconnect line cord of Power Pack.

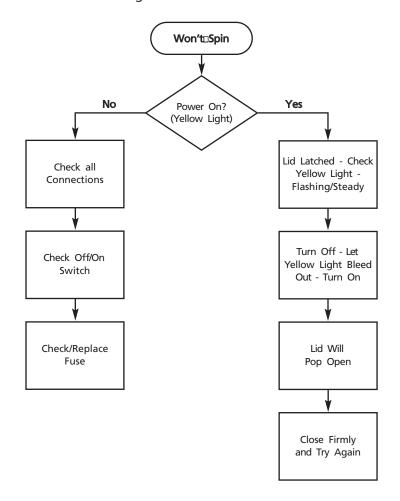
9.5 TROUBLESHOOTING

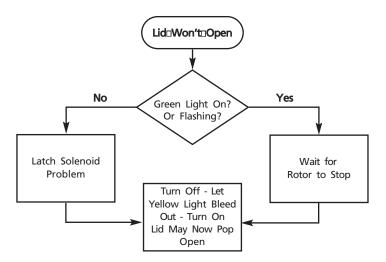
A reference guide to common operating problems with the centrifuge is presented below.

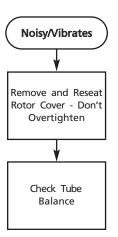
PROBLEM CAUTION		ACTION	
Centrifuge shows no sign of power, but primary	Fuse in Power Pack is blown.	See Section 9.4 and replace fuse.	
electrical supply is available.	Loose power connection.	Check all power plugs.	
Centrifuge does not operate	Lid is not latched.	Close and latch lid.	
when the ON button is pressed.	Failure of micro-switch in latch mechanism.	Request service.	
Centrifuge lid will not open, but primary electrical supply is available.	Centrifuge rotor is spinning.	An electrical interlock prevents the lid from opening until rotor stops spinning. Wait until all motion ceases.	
	Latch release delay.	Wait 4-5 s after rotor stops.	
	Plunger of latch solenoid is jammed.	See Section 9.3 and release solenoid plunger.	
Centrifuge vibrates excessively. (Note: momentary vibration is normal during acceleration, but should disappear upon reaching full speed.)	Press power button OFF to stop rotation. See Action steps. (Note: Centrifuge is capable of 30° tilt without causing excessive vibrations.)	 a) Be sure tube load is properly balanced. b) Tighten rotor nut with wrench, replace and tighten rotor cover. Close top lid and re-check for vibration. c) Check that surface does exceed 30° tilt limit. 	

9.5 TROUBLESHOOTING (continued)

Troubleshooting Guide for 425740 Centrifuge







Note: Momentary vibration (rumble) is normal during acceleration and deceleration.

9.5 TROUBLESHOOTING (continued)

The combinations of On, Off and Flashing status of the 'POWER' and 'SPEED' LED's shown below provide visual indicators of the current operating condition.

Yellow□LED 'POWER'	Green□LED 'SPEED'	Centrifuge: Status Operator: Action		
Off	Off	Power off, no rotor motion.	Turn on power switch.	
Flashing	Off	Ready to spin, lid latched. Press ON button		
On	Off	Power on, no rotor motion, lid not latched.	Load or unload tubes.	
On	Flashing	Power on, lid latched, rotor□under□speed.		
On	On	Power on, lid latched, rotor at design speed.	No action.	
Flashing	Flashing	Power on, lid latched, overspeed shutdown.	Request service.	

9.6□PARTS□LIST

The following spare parts and accessories for the QBC™ Centrifuge are available from your QBC™ System distributor or through the nearest QBC Diagnostics Inc. office:

Part Description	Catalog _□ No.	Formerly
Rotor Head	421289	42022001
Head Nut	421290	42022002
Rotor Cover	421291	42022003
 Head Nut Wrench 	421292	42022004
 Rotor Removal Wire 	4277-020-006	-
Line Cords, Power Pack:		
United States	421634	42432612
Europe	421551	42251012
United Kingdom	421554	42251015
• Fuse, 5A (2/pk)	421565	42251026
Power Pack	421763	42474004
 Operator's Manual, QBC[™] Centrifuge 	422928	42474020

WARRANTY QBC™□Centrifuge

QBC Diagnostics Inc., (herein after referred to as QBC Diagnostics Inc.), warrants the QBCTM Centrifuge to be free from defects in workmanship and materials for a period of one (1) year from date of installation, provided the centrifuge is operated in accordance with the Operator's Manual. During such period, QBC Diagnostics Inc. agrees to replace or repair any parts which, in its judgment, are found to be defective, provided the centrifuge 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 centrifuge.

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

NationalContact

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