QBC STAR™
Centrifugal Hematology System

CLIA COMPLIANCE ASSISTANCE MANUAL

Review and modify this program, if necessary, to meet your own office needs and to accommodate any future changes to CLIA or other applicable regulations. This material is not a substitute for legal advice rendered by someone familiar with your particular laboratory and with the comprehensive laws governing laboratory operations. For this reason, you should consult with competent legal counsel if you have questions about your obligations under CLIA.

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QBC® Diagnostics
Innovative Solutions for a Healthier World

QBC Diagnostics, Inc.
168 Bradford Drive
Port Matilda, PA 16870

QBC Diagnostics, Inc.

GOOD LABORATORY PRACTICES

INTRODUCTION

This CLIA COMPLIANCE ASSISTANCE MANUAL is intended to help you manage your office laboratory according to current laboratory quality standards. Implementing these practices will assist you in ensuring that the tests performed in your office laboratory are reliable. This information will also support your efforts to comply with any federal or state regulatory requirements that may affect the operation of your laboratory.

This CLIA COMPLIANCE ASSISTANCE MANUAL is divided into thirteen sections.

Good Laboratory Practices:

The first ten sections provide information to help your laboratory meet the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88): laboratory certification, laboratory safety, personnel, specimen collection and handling instructions, patient test management requirements, quality control, proficiency testing, instrument maintenance, and quality assurance. Section 11 contains a step-by-step procedure manual for the QBC STAR™ Centrifugal Hematology System using QBC STAR™ Blood Collection Tubes. Once customized with information pertaining to your laboratory, this Procedure Manual can be used to help you fulfill the requirements of CLIA'88.

Master Record Forms:

All forms referred to in the first eleven sections are included in section 12. Because these record forms are master copies, they should be photocopied before use.

Appendix:

1. Section 13 is the Appendix, which includes Levey-Jennings Charts.

We hope this manual becomes a valuable tool for you and your laboratory staff. Because procedures are subject to occasional change, always refer to the test package insert for the most current information and modify your Procedure Manual accordingly. If you have any comments or any suggestions for future editions, please send to:

QBC Diagnostics, Inc
Attention: Technical Services
168 Bradford Drive
Port Matilda, PA 16870

LABORATORY CERTIFICATION

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Obtaining a CLIA Certificate:

Call or write the appropriate regional office of the Center for Medicare / Medicaid Services (CMS) listed below, and request the forms required to register your laboratory under CLIA'88. Complete and return the forms. You will be assessed a registration fee depending on your annual test volume. Registration fees are expected to be collected every two years.

CMS REGIONAL OFFICES

REGION I (CT, MA, ME, NH, RI, VT)	617-565-1188
REGION II (NY, NJ, PR, VI)	212-616-2205
REGION III (DE, DC, MD, PA, VA, WV)	215-861-4140
REGION IV (AL, FL, GA, KY, MS, NC, SC, TN)	404-562-7500
REGION V (IL, IN, MI, MN, OH, WI)	312-886-6432
REGION VI (AR, LA, NM, OK, TX)	214-767-6423
REGION VII (IA, KS, MO, NE)	816-426-5233
REGION VIII (CO, MT, ND, SD, UT, WY)	303-844-2111
REGION IX (AZ, CA, HI, NV, GUAM, SAMOA)	415-744-3501
REGION X (AK, ID, OR, WA)	266-615-2306

www.cms.hhs.gov/regionaloffices

CLIA Test Classification:

Hematology tests using the QBC™ Hematology Systems are classified under CLIA'88 as moderately complex tests. This can be verified in the Federal Register; February 28, 1992, Volume 57 No. 40.

Calculating Annual Test Volume:

To calculate your annual test volume, the following rules apply:

- Do not count waived tests (dipstick urinalysis, urine pregnancy tests, sedimentation rates, etc.).
- Do not count calculated parameters (LDL, hematology indices such as MCHC, etc.). Each QBC determination counts as 5 tests: WBC, HCT, HGB, PLT, and DIFF.
- Count each chemistry test separately, even if performed in profiles or panels.
- Antibiotic susceptibility tests are counted as one per panel of antibiotics.
- Do not count tests performed for QC, QA, or proficiency testing.

Notification Requirements:

☞ Notify CMS within 30 days of any change in ownership, name, location, director, or for high complexity laboratories, supervisor.

☞ Notify CMS within 6 months after beginning to perform any new test that does not fall within a specialty for which your laboratory is certified.

LABORATORY SAFETY

LABORATORY SAFETY

Safety is vitally important for the physician's office. It is imperative that the entire laboratory staff understand the importance of safety training and the proper implementation of safety policies and procedures. By following a few simple precautions, potentially dangerous accidents can be prevented. Maintain training records demonstrating that all laboratory staff have been trained in safety procedures, including fire safety, infectious waste disposal, electrical hazards, and general personal and technical safety procedures. A sample training record is located at the end of this section as well as in Section 12 of this CLIA COMPLIANCE ASSISTANCE MANUAL. When training is completed, sign the certificate and retain copies in the employee's personnel file.

Post safety rules in the laboratory. A sample Laboratory Safety Poster is located at the end of this section as well as in Section 12 of this CLIA COMPLIANCE ASSISTANCE MANUAL.

General Precautions for Specimen Handling:

Use barrier protection to prevent skin and mucous membrane contamination while handling the following human body fluids:

- blood
- unfixed tissues or organs
- body fluids (cerebrospinal, synovial, pleural, peritoneal, pericardial, amniotic)
- semen and vaginal secretions
- saliva (ONLY in dental procedures)
- any body fluid visibly contaminated by blood
- any body fluid in situations where it is difficult or impossible to differentiate between body fluids

In accordance with the Occupational Safety and Health Administration (OSHA) regulations, "all such specimens must be assumed to be infectious."

General Laboratory Safety:

☞ Handwashing is the single most important safety practice in the laboratory. Wash hands:
- After removing gloves or other personal protective equipment.
- Before touching your eyes or mouth.
- Immediately, if a specimen or reagent has been spilled on your bare hands.
- Before eating, drinking, or smoking.

☞ Wear gloves whenever you:
- Handle blood, body fluids, mucous membranes, or open wounds.
- Touch items or surfaces soiled with blood or body fluids, including dried blood and body fluids.
- Perform venipuncture, fingersticks, and other vascular access procedures.
- Have cuts, scratches, dermatitis, or other breaks in your skin.
- Universal Precaution: No glove should be re-used. Replace when damaged.

☞ Wear protective clothing and equipment while performing laboratory procedures involving potentially infectious materials. Remove protective clothing and equipment before leaving the laboratory.

☞ DO NOT recap, bend, or break needles after drawing blood.

☞ Do not eat, drink, smoke, handle contact lenses, or apply cosmetics or lip balm in the laboratory.

☞ Employers must offer the Hepatitis B vaccine series (free of charge) to any employee that is exposed on the job to the potentially infectious materials listed above. Employees who choose not to receive the Hepatitis B vaccination must sign a declination form.

☞ Use laboratory refrigerators ONLY for storage of reagents, controls, or specimens. No food or drink is allowed in laboratory refrigerators.

☞ Clean laboratory countertops daily. Clean spills immediately. Effective disinfectants include a 10 percent household bleach solution, phenols, and gluteral dehydes. Wear utility gloves when cleaning.

☞ Pipette reagents with a mechanical pipette or a bulb. NEVER PIPETTE BY MOUTH!

☞ If blood or glass should escape the plastic protective tube, clean and disinfect the QBC STAR instrument as follows:

1. Put on puncture-resistant gloves. Use a hemostat or other device to pick up any glass or plastic fragments. Dispose of in a biohazard sharps container.

2. Clean any contaminated surfaces with 10% solution of household bleach (1 part bleach to 9 parts water). Allow to stand 5 minutes, then wipe thoroughly with water and dry. Household bleach is effective against bacteria, spores, and viruses. However, it is an oxidizing agent, and is corrosive to metal alloys. Bleach must be thoroughly rinsed off the instrument and dried. It should never be used if there is surface damage to any metal parts.

☞ Never open a running QBC STAR or slow its rotor down using your hands, a pencil, or similar device.

☞ Inspect QBC STAR Tubes before centrifugation. Do not use cracked, scratched or broken tubes.

☞ Pick up broken glass using a hemostat or other device, wearing puncture-resistant gloves. Do not simply use gloved hands to pick up potentially contaminated sharps.

☞ Clearly label all reagents and other materials. If caustic or volatile materials are used, store only minimal quantities on the premises. Establish a clean-up procedure to be followed in case of a spill or broken container. Sand or other absorbent material may be used to clean up chemical spills. Keep Material Safety Data Sheets (MSDS) for all hazardous chemicals used in your practice and train employees in their proper use.

♦☞ Be sure your office laboratory follows all federal, state, and local requirements for safe operation.

Electrical Equipment:

☞ Have an adequate number of grounded electrical outlets and enough lighting for safe laboratory operations. Be familiar with the location of circuit breakers for your laboratory. Electrical equipment must have safe cords and three prong grounded plugs.

☞ Maintain equipment properly to avoid electrical hazards. If an electrical problem with a piece of equipment is suspected, immediately turn the equipment off, disconnect it from the outlet, and have it repaired.

Fire Safety:

- ☞ Mount a small, multi-use (ABC) fire extinguisher on the laboratory wall. The fire extinguisher should be tested and maintained according to local fire regulations, and all laboratory staff should know how to use it.

- ☞ Clearly mark exits from the building. All office personnel should know how to leave the building quickly in case of fire.

Hazardous and Infectious Waste Disposal:

- ☞ Contact local and state authorities about specific policies and regulations for laboratory waste disposal and disposal via the sanitary sewer.

- ☞ Discard all needles and sharp objects into a sharps container that is spillproof, tamperproof, and punctureproof. DO NOT recap, bend, or break needles after drawing blood.

In Case of Accident:

Notify the laboratory director as soon as possible after the incident. If an accident involves exposure to potentially infectious materials (e.g., a needle stick), follow the OSHA requirements for post-exposure monitoring in the Bloodborne Pathogens standard (29 CFR Part 1910.1030).

For More Information:

Contact your state health department or write to:

OSHA, Office of Publications
Labor Department, Room N3101
200 Constitution Avenue N. W.
Washington, D. C. 20210
Phone: 202-693-1880
Fax: 202-693-2498
www.osha.gov

Much of the information from this Safety Section was derived from the following publication, which is an excellent reference for physician office laboratories:

Physician's Office Laboratory Guidelines, NCCLS POL1/2-T3

Clinical and Laboratory Standards Institute
940 West Valley Rd. Ste 1400
Wayne, PA 19087-6886
Phone: 610-688-0100
Fax: 610-688-0700
www.CLSI.org

LABORATORY SAFETY TRAINING CERTIFICATE

Facility Name:_____

This Is To Certify That

(Employee Name)_____

Has Read And Understands All Safety Procedures For This Laboratory, Has Reviewed The Location Of Any Safety Equipment, And Has Demonstrated Ability To Use Safety Equipment.

Employee Signature:_____Date:_____

Laboratory Director Signature:_____Date:_____

LABORATORY SAFETY

- **Wear gloves for each phlebotomy and when handling laboratory specimens.**
- **Wash hands after removing gloves.**
- **Never break or shear contaminated needles.**
- **Do not recap, bend or break needles after drawing blood.**
- **Wear protective clothing when necessary and remove before leaving the laboratory area.**
- **No food or drinks in laboratory refrigerator.**
- **Never pipette by mouth.**
- **Report electrical problems and accidents immediately.**
- **Do not eat, smoke, drink, handle contact lenses, or apply cosmetics in this area.**

PERSONNEL TRAINING AND QUALIFICATIONS

PERSONNEL TRAINING AND QUALIFICATIONS

All specific guidelines for training and requirement can be found at www.phppo.cdc.gov/clia/regs

The Laboratory Director:

The laboratory director is responsible for the overall performance and administration of the laboratory. Any situation that could affect laboratory performance or compromise employee safety is reported to the laboratory director. The laboratory director ensures that all laboratory personnel are competent to perform test procedures and record and report test results accurately. In moderately complex laboratories, the educational requirements for laboratory director vary from a bachelor's degree to a medical degree, although different experience is required in each case. CLIA specifies that a physician (MD, DO, or DPM) laboratory director must have at least one year of experience supervising moderately or high complex testing OR must have completed a 20 credit educational course. One possible place to find programs is www.quality-america.com.

In addition, the director must comply with any state licensing requirements applicable in the state where the laboratory is located.

Laboratory Personnel:

Besides the laboratory director, three other positions are specified by CLIA for a moderately complex laboratory: the clinical consultant, the technical consultant, and the testing analyst(s). Many physicians designate themselves to fulfill the positions of clinical consultant and technical consultant, since, like the laboratory director position, both require one year of experience directing or supervising moderately complex testing.

Personnel who actually perform moderately complex tests (e.g., use the QBC STARCentrifugal Hematology System) are referred to as testing analysts by CLIA and must have at least a high school diploma or equivalent. It is imperative that training is documented for the tests that personnel are authorized to perform. Training can be provided by the physician or under the physician's supervision, a manufacturer's representative, a technical consultant, or a professional group. Although QBC Diagnostics, Inc. does offer employee training upon initial installation of the QBC STAR Centrifugal Hematology System, a Training Checklist is provided at the end of this section as well as in Section 12 (Master Record Forms) of this CLIA COMPLIANCE ASSISTANCE MANUAL in the event that a physician office laboratory needs to train a new employee. Laboratory personnel must carefully follow the instructions for test performance and trou-

bleshooting located in the Procedure Manual. The Procedure Manual for the QBC STAR Centrifugal Hematology System is provided in section 11 in this CLIA COMPLIANCE ASSISTANCE MANUAL.

Personnel Evaluation:

Personnel must be evaluated by the technical consultant at least semiannually during the first year of employment. Thereafter, testing personnel are evaluated yearly. When a new method is initiated, evaluations must be performed prior to reporting test results. The physician director may perform the evaluations if he or she is acting as technical consultant. A Laboratory Personnel Evaluation Checklist is provided at the end of this section as well as in Section 12 (Master Record Forms) of this CLIA COMPLIANCE ASSISTANCE MANUAL.

LABORATORY PERSONNEL TRAINING CHECKLIST

TECH: _____ **DATE: _____**

Test Name(s) : _____

	YES/NO NOT APPLICABLE
Knows how equipment, reagents, and necessary supplies are stored and where they are located.	
Can perform QC using necessary materials.	
Knows where procedure manual is located and follows it as written, for test performance.	
Performs quality control at the required frequency, documents such actions, and knows what to do when quality control is unacceptable.	
Documents all corrective actions associated with quality control, quality assurance, instrumentation, and proficiency testing.	
Performs correct calculations to obtain reportable results.	
Knows and uses proper reporting systems (including panic results).	
Can recognize system failures, unacceptable quality control and calibration checks, and inconsistent or erroneous patient results.	
Knows whom to contact in the event of questions concerning testing or reporting.	

Trainer:_____ Date:_____

Title:_____

LABORATORY PERSONNEL EVALUATION

TECH: _____ DATE: _____

	YES/NO NOT APPLICABLE
Observation of all phases of testing show that all written steps of the procedure are followed without deviation.	
Instrument maintenance and function checks are performed and documented according to written procedures.	
Patient test results are recorded and reported according to protocol.	
Quality control and proficiency test records are reviewed and acted upon when necessary.	
When problems arise, the testing analyst knows how to assess the situation and does what is required to resolve the problem.	
Accurate test performance has been proven by internal blind test samples, external proficiency testing, or analyzing previously tested specimens.	
The testing analyst does not report out patient test results when quality control is not acceptable.	
The testing analyst documents all remedial actions associated with QC, QA, instrumentation, and proficiency testing.	
The testing analyst recognizes all system failures, unacceptable QC and calibration checks, and inconsistent or erroneous patient test results.	
The testing analyst contacts the appropriate person when questions arise concerning testing and/or reporting results.	

Reviewed by:_____

Title:_____ Date:_____

SPECIMEN COLLECTION AND HANDLING

SPECIMEN COLLECTION AND HANDLING

The quality of a test is only as good as the quality of the specimen. The following guidelines help ensure the quality of specimens collected in your laboratory, as well as the safety of the staff performing the tests.

REMINDER: UNIVERSAL PRECAUTIONS FOR SPECIMEN HANDLING

- ☞ Wear gloves when collecting every blood specimen!
- ☞ Handle **all** patient specimens (especially blood and body fluid samples) as though they are infectious!

For more information, contact CLSI at:

Clinical and Laboratory Standards Institute
940 West Valley Rd. Ste 1400
Wayne, PA 19087-6886
Phone: 610-688-0100
Fax: 610-688-0700
www.CLSI.org

VENOUS BLOOD COLLECTION (VENIPUNCTURE)

Supplies:

Disposable Gloves	Needle holder/adapter
Tourniquet	Needles
Alcohol pads	VACUTAINER™ Brand (or other) evacuated blood collection tubes
Sterile gauze	Sharps Container
Bandage	Marking pen

Procedure:

1. Identify the patient by having him or her (or a guardian) state his full name.

2. Select the appropriate blood collection supplies and establish the order to draw multiple specimens. Use non-additive tubes before additive tubes to prevent contamination of non-additive tubes.

3. Label all evacuated blood collection tubes with the patient's name and the time and date the specimen is drawn.

4. Reassure the patient that although the venipuncture may be slightly painful, it won't last long. Position the patient with the elbow extended and the arm supported. Have the patient make a fist, but avoid vigorous hand exercise ("pumping").

5. Apply the tourniquet about 3-4 inches above the venipuncture site. Do not stop the blood flow for more than one minute before the blood is drawn. If necessary, release and reapply the tourniquet.

6. Select the venipuncture site. The median antecubital and cephalic veins are most commonly used.

7. Clean the venipuncture site with an alcohol pad, making one smooth, circular pass of the venipuncture site. Allow the skin to dry, to prevent hemolysis and to prevent the patient from having a burning sensation when the needle is inserted. Do not touch the vein site after cleaning it.

8. Perform the venipuncture:

    a. Wearing gloves, gently grasp the patient's arm near the venipuncture site, using the thumb to draw the skin tight.

b. With the needle bevel facing up, line up the needle with the vein. Penetrate the skin and enter the vein at an angle of approximately 15-30 degrees. Holding the flange of the needle adapter, push the evacuated tube forward, allowing the back end of the needle to puncture the stopper to engage the vacuum.

c. As the blood begins to flow into the tube, release the tourniquet and open the patient's fist to avoid bleeding at the puncture site.

d. Keep constant, forward pressure on the tube to prevent the shutoff valve from closing and stopping the flow of blood.

e. Allow tubes containing an anticoagulant to fill until the vacuum is exhausted and blood flow ceases, assuring the correct ratio of blood to anticoagulant.

f. If a blood sample cannot be obtained, change the position of the needle. If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, move it further into the vein, but do not probe with the needle. You may need to try another tube.

g. Remove the tube from the needle adapter when the blood stops flowing. The automatic shut-off valve will stop any blood from flowing into the adapter. If necessary, insert other tubes in the proper order and repeat the collection procedure.

h. Gently remove the needle from the venipuncture site. Apply sterile gauze to the site, while keeping the arm extended. Keep pressure on the site for at least 2 minutes. Ensure that bleeding has stopped, and apply a bandage over the site. Instruct the patient to wear the bandage for at least 15 minutes.

i. Gently invert any tube(s) containing anticoagulant or clot activators, as in SST™ Brand tubes, five to ten times to mix the blood with anticoagulant. Do not shake the tube vigorously, because this will damage the blood cells and possibly lead to erroneous test results.

9. Dispose of needle(s) in a Sharps Container. Dispose of gloves and gauze in an appropriate biological hazard container. Wash hands.

Collecting Multiple Specimens:

When drawing more than one tube of blood from a single venipuncture using an evacuated tube, use the tubes in this order:

1. Red Stopper or Red/Gray (SST™ Brand) tube
2. Blue Stopper
3. Green Stopper
4. Lavender Stopper
5. Gray Stopper

TUBE STOPPER COLOR	ADDITIVE	SPECIMEN	TESTS USED FOR
red	none	serum	chemistry, serology
red/gray (marble)	serum separator	serum	chemistry
blue*	citrate	citrate plasma, whole blood	coagulation
green	heparin	plasma, whole blood	some chemistry tests
lavender	EDTA	plasma, whole blood	hematology
gray	oxalate-fluoride	plasma, whole blood	some glucose tests

* If only a blue stopper (citrate additive) tube is required, first draw 2-3 ml blood into a non-additive tube to prevent tissue fluid from contaminating the specimen.

Areas to Avoid When Drawing Venous Specimens:

- Scarred areas, such as healed burns.
- Thrombosed veins. These veins feel thick and cord-like and tend to roll.
- Bruised areas. If you cannot avoid collecting from a bruise site, then draw the specimen from the site farthest away from the bruised area.
- The arm on the side of a prior mastectomy. Because this surgery results in lymphostasis, specimen collection may be difficult.
- The arm that has the A-V shunt in a dialysis patient.
- A recent IV site, or the same side of the body as the IV site.

Errors to Avoid in Venous Blood Collection:

- Do not underfill the tube. This may result in excess anticoagulant interfering with the test result, or cause hemolysis of the specimen.

- Completely mix the tube to avoid clot formation in specimens collected in tubes containing anticoagulants.

- Do not mix the specimen too vigorously. Overly vigorous mixing may result in cell damage and hemolysis.

- Do not overfill evacuated tubes when adding blood with a syringe. This could adversely affect the ratio of blood to anticoagulant. Overfilling anticoagulant tubes can also lead to excess pressure, causing the stoppers to come off.

CAPILLARY BLOOD COLLECTION

Supplies:

Disposable Gloves
Alcohol swab or pad
Sterile gauze
Bandage
Marking pen
Sharps Container
Lancet with blade no longer than 2.0-2.4 mm
Collection device: QBC STAR Blood Collection Tube

Procedure:

1. Identify the patient by having him or her (or a guardian) state his full name.

2. Select and organize the appropriate blood collection supplies.

3. Select a puncture site. With older children and adults, use the third or fourth finger of the non-dominant hand. Choose a puncture site halfway between the center of the finger pad and the outer edge of the finger. [For infants, punctures may be performed on the outer or inner portion of the plantar surface of the heel.]

4. Make sure the site to be punctured is not cyanotic, edematous, or cold. If cyanotic or cold, cover the puncture site with a warm, moist towel for at least three minutes before puncture.

5. Clean the puncture site with an alcohol pad. To prevent hemolysis, allow the site to dry.

6. Wearing gloves, puncture the finger with a sterile lancet. Wipe away the first drop of blood to avoid diluting the specimen with excess tissue fluid.

7. To fill the collection device, apply slight pressure above the puncture site. Avoid squeezing directly at the puncture area, because that may cause cell damage as well as dilute the specimen with tissue fluid.

8. When collection is complete, apply slight pressure with sterile gauze and elevate the puncture site. Bandage, if necessary.

9. Prepare and cap **QBC STAR Tubes** per package insert instructions with cap located on the other end.

10. Label the specimen: Indicate on the Laboratory Specimen Log the patient name and identification number, the date and time of specimen collection, and the initials of the person who performed the test.

11. Dispose of lancet(s) in a Sharps Container. Dispose of gloves and gauze in an appropriate biological hazard container. Wash hands.

To Avoid Hemolysis in Capillary Blood Collection:

- ☞ Allow the site to dry after cleaning with alcohol.
- ☞ Do not squeeze the puncture site excessively.
- ☞ Do not press or scrape the collection device on the skin.

To Avoid Clotting in Capillary Blood Collection:

- ☞ Keep the puncture site clean by wiping off excess blood on skin around puncture.
- ☞ Touch collection device only to drop of blood as it exits the puncture site. Do not scoop off skin.

Responding to Patient Problems during Specimen Collection:

Fainting

- ☞ Lower the head and arms of a fainting victim who is seated.
- ☞ Loosen any tight clothing.
- ☞ Record pulse and blood pressure, and observe for respiration.
- ☞ Call the physician if the patient does not respond.

Nausea

- ☞ Have the patient take slow, deep breaths.
- ☞ Lower the patient's head.

Vomiting

- ☞ Provide a basin and tissues or a damp cloth.
- ☞ Provide water to rinse the mouth.
- ☞ If prone, roll the patient to one side.
- ☞ Call the physician.

Excessive Bleeding from the Venipuncture Site

- ☞ Continue pressure on the venipuncture site until bleeding stops.
- ☞ If bleeding continues for five minutes, call the physician.

Convulsions

- ☞ Gently restrain the patient to prevent self-injury.
- ☞ Place soft material between the patient's teeth.
- ☞ Call the physician.

PATIENT TEST MANAGEMENT AND RECORD KEEPING

PATIENT TEST MANAGEMENT (RECORD KEEPING)

A patient test management system insures that specimens from one patient are not confused with those of another and that laboratory test reports reach the ordering physician and are retrievable. Patient test management refers to such actions as labeling patient specimens, recording the time and date of testing, using written (instead of verbal) test orders from the physician, and assigning each patient a unique identification number. Under CLIA, the laboratory must have available and follow written policies and procedures for test management.

The patient chart or a requisition form may be used to document the physician's test order for a particular patient. Once the patient's specimen arrives in the laboratory for testing, record it on the Laboratory Specimen Log. A sample Laboratory Specimen Log is located at the end of this section as well as in Section 12 (Master Record Forms) of this CLIA COMPLIANCE ASSISTANCE MANUAL. The Laboratory Specimen Log is helpful for accessing past patient testing information as well as for calculating yearly test volume for CLIA'88 fee schedule purposes. According to CLIA regulations, waived tests do not need to be recorded on a master laboratory log, although it is good laboratory practice to maintain a log for all tests performed.

Laboratories must state in writing exactly HOW patient test results are reported to the physician. For the QBC™ system, patient test management is included in the Procedure Manual. See the "Procedure Manual" section in this CLIA COMPLIANCE ASSISTANCE MANUAL for the section to record your result reporting procedure.

Patient test results will not be reported by the QBC STAR if outside the patient reportable range (e.g., operating range) of the analyzer. The specimen, or patient may then be sent to a commercial laboratory for further testing.

Retest Panic values (also called "Action" or "Critical" values) as soon as possible and report to the ordering physician immediately. A section to record your panic value policy is also included in the Procedure Manual.

Keep a record of any specimen that is unsuitable for analysis. Use the Specimen Rejection Log for this purpose. A copy is located at the end of this section as well as in Section 12 (Master Record Forms) in this CLIA COMPLIANCE ASSISTANCE MANUAL. The reason for rejection, physician notification, and the consequences are documented on this log.

Physicians should question any patient test result that appears inconsistent with clinically relevant criteria or previous test results. If an incorrect patient test result is accidentally reported, notify the physician of the correction and submit a corrected report. Keep both reports for two years.

Keep patient test results as well as Quality Assurance, Quality Control, and proficiency testing records in a location where they are accessible to inspectors for at least two years. If your office laboratory performs immunohematology procedures (e.g., blood grouping and typing), keep these records for at least five years.

If your office laboratory staff is large enough so that communication problems could develop concerning testing or reporting patient specimens, the laboratory director can resolve the problem with the technical consultant and/or the testing personnel. Retain a written report of any communication problems.

LABORATORY SPECIMEN LOG

DATE/TIME REC'D	PATIENT NAME	PATIENT ID#	TEST(S) ORDERED	TECH INITIALS

DATE/TIME REC'D	PATIENT NAME	PATIENT ID#	REASON FOR REJECTION/ PERSON NOTIFIED	NEW SPEC? Y/N DATE/TIME	TECH INITIALS

CALIBRATION AND QUALITY CONTROL

CALIBRATION AND QUALITY CONTROL

Calibration:

CLIA recommends that the end-user perform calibration check every six months or as often as the manufacturer recommends. The QBC STAR Centrifugal Hematology System is factory calibrated and does not require end user calibration. Power on self tests are performed when the unit is turned on or every 8 hours. For more detailed information on requirements of Calibration Verification please see the CLIA Updated Regulations Brochure #3.

Controls:

Analytical Quality Control

The QBC STAR Centrifugal Hematology System has multiple built-in analytical quality control (QC) systems that maintain the overall system integrity and the quality of the test results it produces. The QBC STAR System has five analytical quality control elements:

1. Factory calibration. System calibration is set during manufacture and cannot be altered by the user.

2. Instrument Power On Self-Test. This test assures that each time the instrument is turned on, the computer, memory, optics, and motors are fully functional. Should you choose to leave the system on continuously; the test will automatically be repeated every 8 hours if the door is closed. A tri-level quality control label (QC label), designed to simulate 3 hematology specimens (simulating low cell counts, normal cell counts, and elevated cell counts) tests the system's optics against values established at the time of manufacture. At the end of the power on self-test, the instrument prints the values obtained from reading the QC label. The values may be plotted to evaluate for shifts or trends in the data. The instrument will flag any results that are outside the set limits, print an error code, and automatically shut down operation of the instrument until the problem is corrected and a valid power on self-test is performed.

3. Electronic QC (during each sample run). The built-in electronic checks during each sample run confirm the proper centrifuge speed, centrifugation profile, system communications, and internal temperature.

4. Sample Preparation QC (during each sample run). The built in checks confirm that the QBC STAR tube has not been previously processed. Tests confirm that the tube assembly is the proper length, the float is present and the correct length, and the tube is filled with the correct amount of blood.

5. Reagent QC (during each sample run). These built-in checks evaluate sample and reagent integrity using the data from the optical scan. This includes tests for fluorescent signal intensity, proper number, size and location of the cell layers and interface sharpness.

When these analytical quality control checks are successfully completed, the status of the instrument's analytical QC is printed on the patient record as "STAR Analytical QC: Passed." Results are reported only if all of the analytical quality control requirements have been satisfied.

Tri-Level Quality Control Label

A tri-level quality control label, designed to simulate 3 hematology specimens, is automatically read every 8 hours if the door is closed as part of the instrument power on self-test. The instrument prints the hematology values obtained from reading the QC label at the end of the power on self-test. These values are available to plot and evaluate shifts and trends.

The instrument compares the QC label's values measured (during power on self-test and during patient sample runs) to factory established limits. Results of any value outside of the established limits will result in an instrument shutdown until the problem is corrected and a valid power on self-test is performed.

The QC label tolerances are shown in the table below.

Electronic QC Ranges										
	Level 1				Level 2				Level 3	
	MIN	Target	Max		Min	Target	Max		Min	Target	Max
HCT (%)	36.9	37.9	38.9		44.9	45.9	46.9		65.1	66.1	67.1
HGB (g/dL)	12.3	12.9	13.5		14.8	15.6	16.4		20.6	21.7	22.8
MCHC (g/dL)	31.6	34.0	36.6		31.6	34.0	36.5		30.7	32.8	35.0
PLT ($x10^9$/L)	90	100	110		342	360	378		615	647	679
WBC ($x10^9$/L)	4.6	5.7	6.8		9.5	10.6	11.7		48.5	53.5	58.5
Gran ($x10^9$/L)	2.2	2.7	3.2		6.0	6.5	7.0		28.3	31.3	34.3
%Gran	38	47	57		56	61	67		54	59	63
L/M ($x10^9$/L)	2.4	3.0	3.6		3.5	4.1	4.7		20.2	22.2	24.2
%L/M	43	53	62		33	39	44		37	41	46

External liquid controls

QBC Controls are available for additional performance monitoring of the QBC STAR system. You must run liquid controls and document the results before you begin testing with a new lot or newly received shipment of QBC STAR Tubes. You must run liquid controls and document the results with each instance of instrument relocation or repair. Consult the package insert accompanying the controls for preparation instructions and expected results. You must also follow any quality control requirements from your regulatory or accreditation agencies.

Compare external control results to the expected results listed in the package insert accompanying the control material to ascertain whether or not they are acceptable. You may record results on the Quality Control Log (and then discard the instrument printout) or retain the instrument printout for the quality control samples. A sample Quality Control Log is located at the end of this section as well as in Section 12 (Master Record Forms) of this CLIA COMPLIANCE ASSISTANCE MANUAL. If the printout is used as the permanent QC record, be sure to indicate the initials of the person performing the QC sample tests and whether or not the results are acceptable.

Retain QC results even if a control value does not fall within the acceptable range. Retain all QC results for at least two years. Document any repeat control testing or corrective action taken on the instrument printout or on the Quality Control Log. Periodically evaluate control results on an ongoing basis to determine if results are consistently running high or low.

Under normal or “in control” situations, QC results will occasionally be outside acceptable limits. When a result exceeds QC limits, do not begin testing patient samples. Follow the troubleshooting flowchart on the following page.

Plotting control results is not required by CLIA for QBC Hematology Systems testing. Some states or accrediting organizations may have more stringent laboratory regulations than CLIA’88. You should determine if such regulations apply to your laboratory. If your laboratory wishes to construct Levey-Jennings plots for QC data, the Appendix of this CLIA COMPLIANCE ASSISTANCE MANUAL provides blank Levey-Jennings graphs.

STEP 1. Check QBC tube and control expiration date and open vial stability date. If acceptable, prepare and read a new control tube from the same vial of control. If results are within range, QC requirements are met. Be sure to note on the Quality Control Log that a new control tube was tested. If the control is still outside of the acceptable range, go to STEP 2.

STEP 2. Repeat the control test using a fresh vial of control. If the controls are within acceptable ranges, QC requirements are met. Again, note on the control log sheet what was done. If either control is outside the acceptable range, go to STEP 3.

STEP 3. Complete the Checklist for Responding to Out of Control QC Results located at the end of this section and in Section 12 of this CLIA COMPLIANCE ASSISTANCE MANUAL.

STEP 4. Contact QBC DIAGNOSTICS, INC. for technical assistance at 1.866.265.1486

QBC QUALITY CONTROL TROUBLESHOOTING

CHECKLIST FOR RESPONDING TO OUT-OF-CONTROL QC RESULTS

DATE	TECH	TUBE (QBC STAR)	CONTROL LOT #	CONTROL LEVEL

DESCRIPTION OF FAILURE

_____
_____
_____
_____
_____
_____

	YES/NO
Were controls cool and in good condition when received?	
Were controls promptly refrigerated upon arrival?	
Are controls stored at the proper refrigerator temperature (2-8°C or 36-46°F)?	
Is the control within the lot expiration date noted on the vial?	
Is only one vial each of level 1 and level 2 control open and in use at any time?	
Is the date opened written on the control vials in use and are they within the open vial stability period?	
Do the lot numbers on the control assay sheet and the control vials agree?	
Are results being compared to the correct range for your QBC model and tube type?	
Are controls handled and prepared *exactly* as described in the package insert?	

UNKNOWN

Explain any “no” responses. Is this the likely reason for the out-of-control result?

QBC™ QC LOG

CONTROL LEVEL _____

PERIOD COVERED: FROM _____ TO _____

QBC TUBES: QBC STAR

CONTROL LOT NO. _____

EXPIRATION DATE _____

PARAMETER				HCT (%)	HB (g/dL)	WBC (x 10^9/L)	GRAN (x 10^9/L)	LY/MO (x 10^9/L)	PLT (10^9/L)	Internal QC OK (✓)	CORRECTIVE ACTION
MEAN											
RANGE											
TUBE LOT	EXP. DATE	DATE	TECH								

REVIEWED BY: _____

DATE REVIEWED: _____

PROFICIENCY TESTING

PROFICIENCY TESTING

Proficiency Testing (PT) is an external evaluation of the quality of a laboratory's performance. When a laboratory enrolls in PT, it will receive five "unknown" samples three times a year for the tests ordered. PT samples are tested in the same way as patient samples. The PT organization compares a laboratory's results to the established "correct" value and compiles them by test method and instrument type to provide information on how well a laboratory performs.

CLIA'88 requires enrollment in proficiency testing for all non-waived analytes. Laboratories must document how PT samples are handled, tested, and reported. Refer to the instructions from the PT program you use to determine how samples are handled and prepared for use in the QBC STAR system.

PT results may not be discussed with other laboratories, including another laboratory owned by the same entity, until after the deadline for reporting PT results. Never send PT samples to a commercial laboratory for analysis. Keep PT results for a period of at least two years.

A laboratory must pass four of five challenges for each analyte in a shipment, for a minimum score of 80%. If your laboratory receives a "not graded" score, it is not considered a failure under CLIA. It is required that you use result ranges in the booklet to determine if you would have passed or failed. If there were a failure it still must be reviewed and corrective action taken. If your laboratory receives a failing score on an individual PT event, take action to identify and correct the problem. To assist QBC™ Hematology Systems customers in successful proficiency testing, a "Checklist for Proficiency Testing Success" and a "Proficiency Testing Failure Investigation Report" are located at the end of this section. The Investigation Report is also located in Section 12 (Master Record Forms) of this CLIA COMPLIANCE ASSISTANCE MANUAL.

Laboratories that fail two consecutive shipments or two of three shipments will receive some type of sanction from HCFA. A laboratory with serious quality problems may have its certificate limited or suspended.

PROFICIENCY TEST PROGRAMS

A partial list of organizations that may offer Proficiency Testing for the QBC STAR System is shown below:

American Association of Bioanalysts
205 West Levee Street
Brownsville, TX 78520-5596
1-800-234-5315

American Academy of Family Physicians
8880 Ward Parkway
Kansas City, MO 64114-2797
1-800-274-2237

College of American Pathologists
(EXCEL)
325 Waukegan Road
Northfield, IL 60093-2750

American Academy of Family Physicians (AAFP)
PT Program Coordinator
11400 Tomahawk Creek Parkway
Leawood, KS 66211

College of American Pathologists (CAP)
Surveys Department
325 Waukegan Road
Northfield, IL 60093

American Proficiency Institute (API)
1159 Business Park Drive
Traverse City, MI 49686
800-333-0958

American College of Physicians (ACP)
2011 Pennsylvania Ave. NW Suite 800
Washington, D.C. 20006
800-338-2746

American Association of Bioanalysts (AAB)
205 West Levee
Brownsville, TX 78520
800-234-5615

CHECKLIST FOR PROFICIENCY TESTING SUCCESS

- ✓ Mark the calendar to know when the PT shipment will arrive.
- ✓ Once the PT shipment has arrived, mark the arrival date and the condition of PT samples. Notify the PT provider immediately if any problems are noted.
- ✓ Check the instructions in the PT kit for any special storage or handling require ments (e.g., refrigeration requirements).
- ✓ Carefully review the instructions in the PT kit for preparation and testing of the PT samples.
- ✓ Test the PT samples within 1-2 days of receipt.
- ✓ Follow your normal routine: test quality control samples before testing patient samples and PT samples. Test PT samples in the same manner as patient samples. In other words, test PT samples with the regular patient workload using a staff member who routinely performs QBC testing. Do not test PT samples more than once unless it is your regular laboratory procedure for testing patient samples. For example, if patient samples with abnormal results are retested, PT samples that are abnormal should also be retested.
- ✓ Be sure that PT result forms are correctly completed. Be certain to select the correct test method for your laboratory to ensure your results will be compared to the appropriate peer group. Have a second person in the practice review the results form for clerical errors before submitting it to the PT provider.
- ✓ Keep a copy of all records associated with PT testing, including a copy of the results form sent to the PT provider. Keep the original QBC™ System printouts for the quality control, and PT sample testing. Retain these records for at least two years from the PT event date.

PROFICIENCY TESTING FAILURE INVESTIGATION REPORT

Background Information:

PT Program_____ Failures_____
Test Method_____ Result_____
Date Received_____ Accepted Range _____
Date Tested_____

Investigation:

Gather all PT records and answer the following:	**YES/NO**
Were the PT samples received cold and in good condition?	
Were the PT samples stored at the proper storage temperature until testing?	
Was the refrigerator temperature in the correct range on the days that PT samples were stored and tested?	
Were the PT samples in good condition on the test day? *For example, no hemolysis?*	
Did you follow exactly the handling and preparation instructions that accompanied the PT samples?	
Did you correctly enter the numerical data on the PT results forms?	
Were all self checks acceptable the day PT was tested?	
Were the Quality Control results acceptable on the day PT samples were tested?	
Did you select the correct method code for the QBC™ instrument and QBC tubes? *For example QBC STAR system and tubes.*	

PROFICIENCY TESTING FAILURE INVESTIGATION REPORT (Cont'd)

1. If any "no" responses resulted from PT failure investigation, note the appropriate corrective action taken.

   _____
   _____
   _____
   _____

2. Verify that current QBC™ System performance is acceptable:

   Quality Control Results Acceptable Yes/No

3. If applicable, review specimen preparation and handling with staff.

   Name: _____ Date Reviewed: _____
   Name: _____ Date Reviewed: _____
   Name: _____ Date Reviewed: _____
   Name: _____ Date Reviewed: _____

4. If needed, contact QBC DIAGNOSTICS, INC.1-866-265-1486 for assistance.

   Date Called: _____ Contact: _____

   Results of Call:

   _____
   _____
   _____
   _____
   _____
   _____

Corrective Actions:

Laboratory Director: _____ Date: _____

INSTRUMENT MAINTENANCE

INSTRUMENT MAINTENANCE

Instrument maintenance involves keeping laboratory equipment in good working order. Although every laboratory performs these duties as a matter of course, federal laboratory regulations require that this maintenance be scheduled and documented.

There is no daily or scheduled maintenance nor are there any user-serviceable parts on the QBC STAR™ Centrifugal Hematology System except for fuses in the power entry module. For all service and repairs please contact Technical Services at 1.866.265.1486.

Instrument Cleaning:

Periodically clean the exterior surface of the QBC Analyzer with a damp cloth moistened with soap and water or a mild detergent solution. Never use strong abrasive cleaners or solvents.

Disinfection:

If a **QBC STAR Tube** breaks, the spread of blood and glass is substantially contained by the capped tube carrier. This device design provides a high degree of user and instrument protection from exposure to blood and aerosols.

If blood or glass should escape the plastic protective tube, clean and disinfect the QBC STAR instrument as follows:

1. Put on puncture-resistant gloves. Use a hemostat or other device to pick up any glass or plastic fragments. Dispose of in a biohazard sharps container.

2. Clean any contaminated surfaces with 10% solution of household bleach (1 part bleach to 9 parts water). Allow to stand 5 minutes, then rinse thoroughly with water and dry. Household bleach is effective against bacteria, spores, and viruses. However, it is an oxidizing agent, and is corrosive to metal alloys. Bleach must be thoroughly rinsed off the instrument and dried. It should never be used if there is surface damage to any metal parts.

For any other cleaning methods, you must contact QBC DIAGNOSTICS, INC. to verify that the proposed method does not damage the QBC STAR Centrifugal Hematology System.

CAUTION

Do not immerse the QBC STAR instrument in water or other liquid.

Temperature:

The QBC™ system operates optimally between 16-32°C. At 33-37°C use may be limited by instrument temperature shutdown. QBC controls are stored refrigerated between 2-8°C. Therefore, temperatures of the laboratory and the laboratory refrigerator where reagents are stored must be recorded daily. Use the Temperature Charts located at the end of this section as well as in Section 12 (Master Record Forms) of this CLIA COMPLIANCE ASSISTANCE MANUAL. For your convenience, the temperature charts contain pre-printed temperature ranges. Adjust temperatures that are out of range and include any remedial action in the appropriate section on the bottom of the Temperature Chart.

QBC™ SYSTEM MAINTENANCE LOG

Reviewed by _____
Date Reviewed _____
Month _____ **Year** _____

_____ -
QBC STAR Analyzer:

Model #_____ **SN #** _____

Clean exterior surfaces as required with a damp cloth moistened with soap and water or a mild detergent. There are no user-serviceable parts on the QBC STAR except for fuses in the power entry module. For all service or repairs please contact Technical Service at 866.265.1486.

Clean Housing	Date/Tech	Date/Tech	Date/Tech	Date/Tech	Date/Tech	Date/Tech	Date/Tech	Date/Tech

CALLS TO TECHNICAL SERVICE

Date/Tech	**Problem**	**Resolution**

REFRIGERATOR TEMPERATURE RECORD

Reviewed by_____

Date Reviewed_____

Refrigerator ID_____

Year_____

ACCEPTABLE RANGE: 2-8°C

Action Taken:

	Month		Month		Month	
	Temp	Tech	Temp	Tech	Temp	Tech
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

ROOM TEMPERATURE RECORD

Reviewed by _____

Date Reviewed _____

Year_____ACCEPTABLE RANGE FOR QBC STAR OPERATION : 16-32°C

Action Taken:

	Month		Month		Month	
	Temp	Tech	Temp	Tech	Temp	Tech
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
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21						
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24						
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26						
27						
28						
29						
30						
31						

_____

_____

_____

QUALITY ASSURANCE

QUALITY ASSURANCE

Quality Assurance (QA) consists of the steps taken to assure the quality of laboratory services provided. Unlike Quality Control which monitors the test system only, QA involves the entire test process including the pre-analytic phase (specimen collection and handling), the analytic phase (performing the test), and the post-analytic testing phase (reporting patient test results).

The laboratory director oversees the implementation of the QA plan and helps identify and correct problems as they occur. The QA plan is periodically reviewed to minimize the possibility of recurrence of problems. When problems are identified, areas for improvement to the QA plan may be implemented.

Quality Assurance includes the following components:

- ☞ Personnel Training and Qualifications
- ☞ Proficiency Testing
- ☞ Procedure Manual
- ☞ Specimen Collection and Handling Specifications
- ☞ Patient Test Management/Record Keeping
- ☞ Quality Control Program
- ☞ Instrument Maintenance Program
- ☞ Laboratory Safety

A sample Quality Assurance Program for an office laboratory follows. The Laboratory Director should indicate approval by signing the Monthly Quality Assurance Assessment (see page 5). Review it to be sure your laboratory has implemented these policies. If you have questions regarding any of the components of the Quality Assurance Program, consult the appropriate tabbed section in this CLIA COMPLIANCE ASSISTANCE MANUAL.

A sample Monthly Quality Assurance Checklist is also provided so that your laboratory can evaluate the effectiveness of your policies and procedures, i.e., your Quality Assurance Program. As necessary, revise your Quality Assurance Program based on the results of the monthly evaluations and communicate any revisions to the laboratory staff.

PROFICIENCY TESTING

- PT samples are tested, to the extent possible, exactly like patient specimens, i.e., the same number of times and using the same personnel and methods as for patient testing.

- PT results are reviewed and retained for a period of at least two years. PT failures are investigated and remedial action is taken.

- Tests for which no PT exists are verified twice per year for accuracy using the split-sample method.

SPECIMEN COLLECTION AND HANDLING

- Specimens are collected and handled according to manufacturer's instructions (located in the Procedure Manual, section 11) for each particular test.

- Patients are questioned to ascertain their correct identification and to ensure that specimen collection instructions, where applicable, have been followed.

- Specimen labels are legible, indelible, and firmly affixed to the specimen container.

- If there is a delay in testing, specimens are preserved according to manufacturer's instructions to ensure their integrity.

PATIENT TEST MANAGEMENT/ RECORD KEEPING

- A Laboratory Specimen Log is used to record specimens received. A copy of the Laboratory Specimen Log is located in Section 12 of this CLIA COMPLIANCE ASSISTANCE MANUAL. Copies of all test reports are readily accessible.

- Panic (also called "Action" or "Critical") values are retested as soon as possible. Confirmed panic values are reported to the authorized individuals immediately. Panic values are included in the respective procedure for each method, where applicable.

REPORTING PATIENT TEST RESULTS

- All routine laboratory records are kept for at least two years.

- Patient test results that fall outside the patient reportable range (i.e., operating range) of an analyzer are reported to the requesting individual as “outside the reportable range of the instrument.” The specimen may then be sent to a commercial laboratory for confirmation.

- Physicians will question any patient test result that appears inconsistent with clinically relevant criteria or previous test results.

- If communication problems develop with the laboratory concerning testing or reporting patient specimens, the laboratory director will resolve the problem with the technical consultant and the testing personnel. A written report will be retained.

- If an incorrect patient test result is reported, the laboratory notifies the authorized individual (usually the physician who ordered the test) of the correction and submits a corrected report. Both reports are kept for at least two years.

QUALITY CONTROL

- A procedure manual is readily available to the lab staff at all times for non-waived tests.

- Quality Control (QC) is documented each day of testing for non-waived tests, as specified in the procedure manual. Control results are within acceptable limits before patient samples are reported.

- QC results are recorded, even if a particular control value does not fall within the acceptable range. Any repeat controls or corrective actions taken are documented.

- New lot numbers of reagents, test kits, and media are verified for quality using QC material before use.

- Test materials are stored as stated in the package insert. All outdated materials are discarded.

- Equipment is maintained and calibrated according to the users manual.

- Daily temperature checks of room temperature, refrigerators, freezers, heating blocks, and incubators, if applicable, are documented.

MONTHLY QUALITY ASSURANCE ASSESSMENT

This Quality Assurance program is assessed monthly to evaluate and monitor the ongoing and overall quality of the total testing process. A sample Monthly Quality Assurance Checklist is located in Section 12 of this CLIA COMPLIANCE ASSISTANCE MANUAL. In this way, the effectiveness of policies and procedures may be evaluated. As necessary, these procedures will be revised based on the results of the monthly evaluations and revisions will be communicated to the lab staff.

_____ _____

LABORATORY DIRECTOR SIGNATURE DATE

MONTHLY QUALITY ASSURANCE CHECKLIST

	YES/NO NOT APPLICABLE
Our **LABORATORY SAFETY POLICIES** were followed:	
The laboratory director was notified of any situation that could affect the laboratory's performance or the safety of employees.	
All new laboratory personnel have read the safety guidelines in this Manual.	
All new laboratory personnel have been offered the Hepatitis B vaccine.	
Our **PERSONNEL POLICIES** were followed:	
All personnel who perform tests have documented training for these tests.	
All personnel who perform tests have read the procedure manual for those tests.	
Personnel evaluations were performed as necessary.	
Our **PROFICIENCY TESTING POLICIES** have been followed:	
Proficiency tests were handled in the same manner as patient specimens.	
Proficiency test results were evaluated, failures were investigated, and remedial action was taken.	
Our **PATIENT TEST MANAGEMENT SYSTEM** was followed as written:	
Patient specimens were collected and handled according to our protocol.	
All blood collection tubes were labeled legibly.	
Specimens were logged correctly on the Laboratory Specimen Log.	
All lab reports contain correct information.	
Our **QUALITY CONTROL POLICIES** were performed as specified:	
All required temperatures were taken and recorded.	
All reagents, controls, kits, etc. that exceeded their expiration date were discarded.	

MONTHLY QUALITY ASSURANCE CHECKLIST (CONT'D)

	YES/NO NOT APPLICABLE
Any required instrument maintenance was performed and documented.	
Any necessary remedial action was performed and documented.	
Our **QUALITY ASSURANCE PROGRAM** is monitored for compliance:	
The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies or procedures.	
If you answered "No" to any of the above, explain the problem and how it was resolved:	

Tech: _____ **Date:_____**

Laboratory Director: _____ **Date: _____**

QBC STAR SYSTEM PROCEDURE MANUAL

HOW TO USE THIS PROCEDURE MANUAL

A procedure manual contains step by step instructions for test performance. Use it to train new employees and to ensure that all employees perform patient tests in the exact same manner. In this way, you can be confident that reliable, consistent test reports are generated from the office laboratory.

CLIA'88 requires that a procedure manual be present for all non-waived tests and that laboratory personnel follow its instructions. A procedure manual for the QBC STAR Blood Collection Tube on the QBC STAR System follows. Note that this Procedure Manual must be customized in several places so that a particular laboratory can document Laboratory Director approval, how results are reported, etc. Areas that require customization are:

Laboratory Director Approval
Normal Ranges (optional)
Results Reporting
Panic Values

PROCEDURE MANUAL
QBC STAR SYSTEM

Blood Collection Tube Testing

_____

FACILITY NAME

Sign and date to indicate that the QBC STAR Procedure Manual has been approved for use in this laboratory. Reprove, sign and date if procedure changes are instituted or if the laboratory directorship changes.

Laboratory Director:_____

Approval Date:_____

Date Reviewed	Laboratory Director Signature	Page Changed

QBC STAR SYSTEM PROCEDURE MANUAL

QBC STAR Blood Collection Tube Testing

TABLE OF CONTENTS

BACKGROUND

The thin, grayish-white buffy coat in the hematocrit tube consists of packed leukocytes and platelets. Platelets, being less dense, settle in a separate layer above the leukocytes. In the 1930s, Wintrobe and Olef described methods for estimating elevated white cell and platelet populations, based on the milky appearance and thickness of the buffy coat. In later studies of cell density gradients, further subdivision or layering was found to occur between two subpopulations of leukocytes by virtue of their different specific gravities. The upper layer was reported to contain predominantly lymphocytes and monocytes; the lower, predominately the granulocytes or neutrophils (i.e., segmented, band), eosinophils, and basophils.

The QBC™ System hematocrit, platelet count, white cell count, and counts of the white-cell subgroups are derived from measurements of packed cell volumes in the centrifuged QBC blood tube. The QBC System utilizes differential metachromatic fluorescence of Acridine Orange 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 taken at the interfaces of the density gradients in the QBC reader which then computes and displays the hematocrit, platelet count, WBC, and subgroups of granulocytes and lymphocytes/monocytes. Hemoglobin concentration is derived from the hematocrit and measurements of red cell density. Mean corpuscular hemoglobin concentration, or MCHC, is derived by dividing the hemoglobin by the hematocrit and multiplying by 100.

BLOOD COMPONENTS TESTED

The QBC STAR™ Centrifugal Hematology System performs the following tests:

Hematocrit (HCT in %)
Hemoglobin (HB in g/dL)
Mean Corpuscular Hemoglobin Concentration (MCHC in g/dL)
Total White Blood Cell count (WBC in 10^9/L)
Granulocyte count (% and number in 10^9/L)
Lymphocyte/monocyte count (% and number in 10^9/L)
Platelets (PLT in 10^9/L)

SPECIMEN COLLECTION AND HANDLING

Treat all blood specimens as potential biohazards capable of transmitting infection. Always wear gloves when handling blood specimens.

Review the Specimen Collection and Handling Section in Section 5 of this CLIA COMPLIANCE ASSISTANCE MANUAL.

Venous Blood

Draw venous blood specimens into a VACUTAINER™ Brand blood collection tube or other blood drawing device containing EDTA (lavender top tube). Label the tube with the patient name and/or identification number, date, and time of collection. Fill the collection tube with blood to its total fill volume. Thoroughly mix the blood specimen with the anticoagulant by inverting the tube gently 12-15 times. If clots are observed, discard the specimen.

Venous blood samples may be stored at room temperatures 20-25°C for up to 8 hours prior to preparation of the **QBC STAR Tube**.

Samples that cannot be tested immediately must be refrigerated if the room temperature is above 77°F (25°C). Refrigerated samples stored at 2-8°C are stable for up to 8 hours. Bring samples back to room temperature before you prepare **QBC STAR Collection Tube**.

Capillary Blood

Collect capillary blood directly into the **QBC STAR Tube**. To avoid sampling errors, the blood must be free-flowing and collected with minimum delay.

Puncture the finger with a sterile lancet, wipe away the first drop of blood, and collect the remaining blood into the open end of the **QBC STAR Tube**. Fill the tube beyond the first black line and up to the second black line. Do not allow the QBC STAR plastic sleeve to contact the blood. Specimens taken after the first several drops may yield lower counts, since platelets may adhere to the wound site and may aggregate in the drop of blood. The tube should be placed in the QBC STAR Analyzer promptly after filling, mixing, and capping, and no later than 15 minutes after filling with blood.

CRITERIA FOR SPECIMEN REJECTION

Do not test the following specimens:

- ☞ Unlabeled or mislabeled blood collection tube
- ☞ Non-lavender stoppered blood collection tube
- ☞ Lavender tube less than expected fill volume (1/2 total volume) or clotted
- ☞ Lavender tube not processed within the 8 hour time limit
- ☞ **QBC STAR Tube** overfilled (above the two black lines) or underfilled (below the two black lines)
- ☞ Venous samples which are not at room temperature
- ☞ Visibly hemolyzed patient specimen
- ☞ Capillary sample is visibly clotted
- ☞ Any miscellaneous event that may effect specimen integrity has occurred

Document specimen rejection on the Specimen Rejection Log. A copy of this log is located in Section 12 (Master Record Forms) of this CLIA COMPLIANCE ASSISTANCE MANUAL.

SPECIMEN STORAGE AND PRESERVATION

QBC STAR™ Tube tests should be run at room temperature 20-32°C.

Once the **QBC STAR Tube** is filled, mixed and capped, insert into the QBC STAR Hematology System promptly. Do not allow more than 15 minutes to elapse between capping and insertion into the analyzer.

MATERIALS

QBC STAR System Components:

QBC STAR™ Centrifugal Hematology System
User's Manual

Reagents and Controls:

QBC STAR Tubes - Catalog No. 429625 (100 tubes/test)
QBC Hematology Controls - Catalog No. 424304

REAGENT AND CONTROL STORAGE

QBC STAR Blood Collection Tubes:

QBC STAR Tubes are shipped in a box containing 100 tubes. Store box in a dry cupboard or drawer, at 16-32°C. Do not store in bright light. The tubes are individually packaged in a foil-plastic blister that also contains a desiccant sachet. Do not open or remove the tube from the unitized package until needed.

An expiration date is printed on the box and the unitized package. Do not use tubes that are past the expiration date. The tube must be used after opening the unitized package; do not remove the tube from the unitized package until needed

QBC™ Hematology Controls:

Refrigerate QBC Hematology Controls at 2-8°C. The expiration date is printed on the vial label and the outer package. Do not use controls after the expiration date. Once the vial is opened, the open vial stability printed on the control assay sheet should not be exceeded. Store tightly capped, in the refrigerator, when not in used. Do not freeze or place near a freezer compartment. Repeated warming and cooling or prolonged mixing will damage blood cells in the material and shorten the life of the controls. For best results, a fresh set of control vials should be opened every four days.

TEST PROCEDURE

Daily Start Up:

☞ Power on the QBC STAR Hematology System and before processing samples allow the analyzer to complete the self-check.

Instrument Power On Self-Test and Analytical Quality Control Checks

When the instrument is powered on and the door is closed, the system software performs a power on self-test to verify proper operation (or once every 8 hours if power is left on continuously). The power on self-test checks such things as: centrifuge motor at various speeds, emission filter assembly, optics assembly, light source, optical clarity and focus, internal printer and setup keypad.

The instrument runs a built-in analytical quality control checks every time a sample is processed. Sample integrity checks include: statistical matching of band lengths, ratios and absolute values for signal levels, ratios that are used to evaluate the quality of interfaces, measurement of float length, verification of optics and sensors, measurement and evaluation of sample fill volume. Additional tests performed as part of each assay cycle include centrifuge speed and electro-optical verification. Results are reported on tube tests only if all analytical quality control checks pass.

The power-on self-test and analytical quality control checks provide verification of instrument parameters including but not limited to timing, speed, disposable integrity, and reagent stability.

In addition to these checks, the system monitors the temperature inside and outside the instrument before and during each test. The system will allow operation of the instrument if the temperature is higher than 32° C, but with limited reports. If the sample temperature exceeds 45° C, the unit will become too hot to operate.

Since the QBC STAR instrument contains a centrifuge, centrifuge speed measurements are verified each time a sample is processed.

If any part of the power on self-testing or analytical quality control checks fails, a message is displayed. Confirmation of the success of power on self-tests is provided by the “Ready” message. In addition, each results printout indicates the outcome of analytical quality control checks.

☞After acceptable system verification/QC checks, begin testing patient samples. If system verification checks are not satisfactory, troubleshooting is required. Refer to the "Remedial Action/Troubleshooting" Section of this Procedure Manual for guidance.

Testing Patient Samples:

1. LOG PATIENT SPECIMENS

   Log patient specimens on the Laboratory Specimen Log. A sample Laboratory Specimen Log is in Section 12 (Master Record Forms) of this CLIA COMPLIANCE ASSISTANCE MANUAL.

2. PREPARE TUBES FOR TESTING
   (Refer to the QBC STAR Quick Reference Guide for illustrations of these steps)

   Step 1: Fill the Tube

   Anticoagulated Venous Blood
   Gently mix the sample at least 12-15 times by inversion before filling the tube.
   Tilt the sample vial and place the collection tip of the **QBC STAR Tube** in contact with the blood tube. Do not allow the **QBC STAR** plastic sleeve to contact the blood.
   Fill the tube beyond the first black line, and up to the second black line

   Capillary Blood
   Place the collection tip of the **QBC STAR Tube** in contact with the blood droplet at the finger puncture site. Do not allow the **QBC STAR** plastic sleeve to contact the blood.
   Fill the tube beyond the first black line up to the second black line.
   Rock the tube to mix.
   DO NOT ALLOW THE BLOOD TO TOUCH THE TUBE PLUG WHILE PERFORMING THIS STEP.
   If blood stops mixing, discard tube and fill a new tube.
   Rock the tube back and forth at least 4 times to mix the blood with the orange coating. For each complete rock, allow the blood to move from the open end to the bottom (plug) end and back to the open end.
   Hold the tube at an angle allowing the blood to move down the tube towards the center of the tube.

   STEP 2. CAP THE TUBE

   Remove the cap from the tube by pulling the cap straight off the bottom of the tube.
   Place the cap over the collection end of the tube by guiding the glass end of the tube into the center of the cap.
   Push the cap on firmly.

   STEP 3. READ THE TUBE

   Promptly insert the tube into the QBC STAR analyzer oriented with the top of the tube (capped end) pointing into the analyzer.
   Close the analyzer door.
   Press the "start" button.
   When the test is complete, the results are automatically displayed and printed.

DO NOT OPEN THE DOOR UNTIL THE RESULTS ARE REVIEWED AND PRINTED.
Test results are cleared from the display when the analyzer door is opened.
Indicate on the printout the patient name, date of birth (if desired), accession number (or identification number), and the initials of the person performing the test.

INTERPRETATION OF TEST RESULTS

Patient Reportable Ranges

The hematological parameters measured by the QBC™ method are valid over a certain range of values, referred to as the "patient reportable range." The reportable ranges for the QBC STAR Hematology System are:

PATIENT REPORTABLE RANGES: QBC STAR

Hematocrit	15-65%
Hemoglobin	5.0-20.0 g/dL
MCHC	25.0-37.3 g/dL
Platelet Count	20-999 (x 10^9/L)
WBC Count	1.6-99.9 (x 10^9/L)
Granulocyte Count	0.8-70.0 (x 10^9/L)
Lymph/Mono Count	0.8-99.9 (x 10^9/L

Test results that fall outside these ranges are reported as: "outside the reportable range of the instrument." Results may be confirmed by alternate methods.

Error Messages

When the QBC STAR Hematology System detects an error or irregular condition, a message or code is displayed to identify the problem. A list of error messages is provided in the QBC STAR Hematology System Operator's/Service manual.

Normal Ranges

Typical normal ranges reported in the literature are shown below. Reference ranges may differ by age and sex of patients.

ESTABLISHED NORMAL HEMATOLOGY RANGES (ADULT):

HCT(%) males	42 - 50
HCT (%) females	36 - 45
HB (g/dL) males	14 - 18
HB (g/dL) females	12 - 16
MCHC(g/dl)	31.7 - 36
PLT (x 10^9/L)	140 - 440
WBC (x 10^9/L)	4.3 - 10.0
Gran (x 10^9/L)	1.8 - 7.2
Lymph/mono (x 10^9/L)	1.7 - 4.9

Normal range references:

Williams, W.J., Beutler, El, Lichtman, M.A., Coller, B.S., Kipps, T.J., Ed. Hematology, 5th ed., New York: McGraw Hill Co., 1995 p. 9.

Wintrobe, M.M. (1981) Clinical Hematology, 8th ed., Lea & Febiger, Phila., PA, 1981 p. 1885-1889.

If your office laboratory has established its own normal ranges based on the characteristics of your patient population, fill them in below.

PARAMETER	NORMAL RANGE	UNITS
HCT Males		%
HCT Females		%
HB Males		g/dL
HB Females		g/dL
MCHC		g/dL
PLT		X10^9/L
WBC		X10^9/L
Gran		X10^9/L
Lymph/mono		X10^9/L

TEST LIMITATIONS

The following have been tested for their effects on hematology test results using the QBC STAR System:

Hemolysis: QBC tests should not be performed on visibly hemolyzed patient specimens.
Bilirubin: No effects with concentrations up to 20 mg/dL.
Coumadin: No clinical effect.
Doxorubicin: Does not appear to interfere.
Triglycerides : No effects with concentrations up to 1,800 mg/dL.
Other Drugs: The effects of other potentially interfering drugs and their metabolites on QBC test results have not yet been established.

Interfering Substances:

Values cannot be obtained by the QBC STAR Hematology System when distinct layers and well defined interfaces have not formed in the centrifuged tube. Non-separation can occur under certain hematologic or pathologic conditions. Contact Technical Service with any questions at 866-265-1486.

Detecting Abnormal Cell Types:

Granulocyte and lymphocyte/monocyte counts obtained with any hematology instrument 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 or nucleated red blood cells and yet may display total white cell counts in the normal range as well as normal quantitative relationships of granulocytes to lymphocytes/monocytes. Due to grouping by density of the cell subpopulations by the QBC STAR method, the system cannot discriminate between normal and abnormal cell types and may not indicate the presence of disease states in patients with these conditions.

Quality medical care requires that laboratory values always be correlated with the clinical state. In patients with hematological or other malignancies or bone marrow infiltration, in particular, verification by alternative methods is indicated.

RESULTS REPORTING

Test Reports:

Review test results as soon as possible after the test is completed. Once test results are obtained, indicate exactly how they are reported to the physician. Include any steps such as logging in, attaching the result to the patient's chart, etc.:

_____
_____
_____
_____
_____
_____
_____

Abnormal Results:
If abnormal results are reported differently than normal results in your laboratory (e.g., verbally notifying the physician, designating in red ink, etc.), indicate below exactly how they are reported:

_____
_____
_____
_____
_____
_____
_____
_____

Results that Exceed the Reportable Range of the QBC STAR System:

When a patient's test result exceeds the reportable range of the QBC STAR System, indicate on the test report that the result exceeds the reportable range of the analyzer. The patient specimen may be sent to a commercial laboratory for confirmation.

Panic Values:

Critical laboratory results (panic or action values) must be immediately reported to a physician, preferably the patient's physician. The chart below lists results outside the QBC analyzer reportable range. Fill in your laboratory panic values if different from these limits, or write "same" if they are used.

Analyte	QBC STAR Analyzer Range Limits	Laboratory Panic Values
Hematocrit	<15 or > 65%	_____
Hemoglobin	< 5 or >20 g/dL)	_____
Platelets	<20 or >999 x 10^9/L	_____
WBC	< 1.6 or > 99.9 x 10^9/L	_____
Grans	< 0.8 or > 70.0 x 10^9/L	_____
Lymph/Mono	< 0.8 or > 99.9 x 10^9/L	_____

NOTE: Verify all panic value results by repeat collection and testing. Designate on the test report the person notified, the time and date, and the person who notified the physician. Indicate any further action taken regarding panic values in your practice:

_____

_____

Results Reported in Error:

Immediately after recognizing an erroneous result has been reported in error:

1. Contact the individual who received the original report and notify whether or not a corrected result will be forthcoming.

2. When possible, retest the original specimen to obtain the correct result.

3. Report the corrected result, noting on the report the original result and that this is a corrected result. If the original report is available, document on the report that the original result was in error. Have the physician re-sign the report indicating awareness of the error.

4. Document on the monthly quality assurance checklist all the actions associated with the erroneous result, including: all patient information, dates, times, individuals involved, original and corrected results, why the erroneous result was reported and what will be done to prevent it from recurring.

5. Maintain all original and corrected reports for at least two years.

QUALITY CONTROL

Analytical Quality Control

The QBC STAR Centrifugal Hematology System has multiple built-in analytical quality control (QC) systems that maintain the overall system integrity and the quality of the test results it produces. The QBC STAR System has five analytical quality control elements:

1. Factory calibration. System calibration is set during manufacture and cannot be altered by the user.

2. Instrument Power On Self-Test. This test assures that each time the instrument is turned on, the computer, memory, optics, and motors are fully functional. Should you choose to leave the system on continuously; the test will automatically be repeated every 8 hours if the door is closed. A tri-level quality control label (QC label), designed to simulate 3 hematology specimens (simulating low cell counts, normal cell counts, and elevated cell counts) tests the system's optics against values established at the time of manufacture. At the end of the power on self-test, the instrument prints the values obtained from reading the QC label. The values may be plotted to evaluate for shifts or trends in the data. The instrument will flag any results that are outside the set limits, print an error code, and automatically shut down operation of the instrument until the problem is corrected and a valid power on self-test is performed.

3. Electronic QC (during each sample run). The built-in electronic checks during each sample run confirm the proper centrifuge speed, centrifugation profile, system communications, and internal temperature.

4. Sample Preparation QC (during each sample run). The built in checks confirm that the QBC STAR tube has not been previously processed. . Tests confirm that the tube assembly is the proper length, the float is present and the correct length, and the tube is filled with the correct amount of blood.

5. Reagent QC (during each sample run). These built-in checks evaluate sample and reagent integrity using the data from the optical scan. This includes tests for fluorescent signal intensity, proper number, size and location of the cell layers and interface sharpness.

When these analytical quality control checks are successfully completed, the status of the instrument's analytical QC is printed on the patient record as "STAR Analytical QC: Passed." Results are reported only if all of the analytical quality control requirements have been satisfied.

Tri-Level Quality Control Label

A tri-level quality control label, designed to simulate 3 hematology specimens, is automatically read every 8 hours if the door is closed as part of the instrument power on self-test. The instrument prints the hematology values obtained from reading the QC label at the end of the power on self-test. These values are available to plot and evaluate shifts and trends.

The instrument compares the QC label's values measured (during power on self-test and during patient sample runs) to factory established limits. Results of any value outside of the established limits will result in an instrument shutdown until the problem is corrected and a valid power on self-test is performed.

The QC label tolerances are shown in the table below.

Electronic QC Ranges										
	Level 1				Level 2				Level 3	
	MIN	Target	Max		Min	Target	Max		Min	Target	Max
HCT (%)	36.9	37.9	38.9		44.9	45.9	46.9		65.1	66.1	67.1
HGB (g/dL)	12.3	12.9	13.5		14.8	15.6	16.4		20.6	21.7	22.8
MCHC (g/dL)	31.6	34.0	36.6		31.6	34.0	36.5		30.7	32.8	35.0
PLT ($x10^9$/L)	90	100	110		342	360	378		615	647	679
WBC ($x10^9$/L)	4.6	5.7	6.8		9.5	10.6	11.7		48.5	53.5	58.5
Gran ($x10^9$/L)	2.2	2.7	3.2		6.0	6.5	7.0		28.3	31.3	34.3
%Gran	38	47	57		56	61	67		54	59	63
L/M ($x10^9$/L)	2.4	3.0	3.6		3.5	4.1	4.7		20.2	22.2	24.2
%L/M	43	53	62		33	39	44		37	41	46

External liquid controls

QBC Controls are available for additional performance monitoring of the QBC STAR system. You must run liquid controls and document the results before you begin testing with a new lot or newly received shipment of QBC STAR Tubes. You must run liquid controls and document the results with each instance of instrument relocation or repair. Consult the package insert accompanying the controls for preparation instructions and expected results. You must also follow any quality control requirements from your regulatory or accreditation agencies.

New lots of QBC Hematology Controls (#424304) are available every three weeks and contain a 22 day supply of two levels of control material.

QBC CONTROL PREPARATION:

- ☞ Only remove one vial of each level of control from the refrigerator. Before using, check that controls have not exceeded their expiration date and the open vial stability.

- ☞ When first opened date each vial with date opened and date of expiration.

- ☞ Roll between palms of the hands for at least 45 seconds. Mix by gently inverting the vials 5-10 times. Be sure to mix the vial immediately prior to aspirating a sample. Do not use a mechanical rotator to mix the vials.

- ☞ For control testing, fill and prepare tubes in the same way that patient specimens are prepared.

QBC CONTROL TESTING:

- ☞ Test controls in the same manner as patient specimens.

- ☞ Compare control results to the assayed ranges located in the control material package insert sheet. If both controls are within the acceptable range for all hematology parameters, patient samples may be tested and reported.

- ☞ Save control test results (actual printouts or QBC QC Logs) for at least two years.

- ☞ When controls do not fall within expected ranges, the control value(s) in question should be circled or otherwise indicated, and troubleshooting is required. Save the “out-of control” result with all other control records and document any corrective (remedial) action taken.

QBC QUALITY CONTROL TROUBLESHOOTING

STEP 1. Check QBC tube and control expiration date and open vial stability date. If acceptable, prepare and read a new control tube from the same vial of control. If results are within range, QC requirements are met. Be sure to note on the Quality Control Log that a new control tube was tested. If the control is still outside of the acceptable range, go to STEP 2.

STEP 2. Repeat the control test using a fresh vial of control. If the controls are within acceptable ranges, QC requirements are met. Again, note on the control log she what was done. If either control is outside the acceptable range, go to STEP 3.

STEP 3. Complete the Checklist for Responding to Out of Control QC Results located in Section 12 of this CLIA COMPLIANCE ASSISTANCE MANUAL.

STEP 4. Contact QBC Diagnostics, Inc. for technical assistance at 1-866-265-1486.

LITERATURE REFERENCES

1. Stevenson, G.F. "The Small Office Laboratory in the Cycle of Laboratory Medicine: Reinventing the Magic Box." JAMA 254 (1985): 2949-2951.

2. Fischer, P.M. and Addison, L.A. "The Office Laboratory Director's Guide." JAMA 254 (1985): 2491-2495.

3. Belsey, R.; Greene, M.; and Baer, D. "Managing Liability Risk in the Office Laboratory." JAMA 256 (1986): 1338-1341.

4. National Committee for Clinical Laboratory Standards: Physician Office Laboratory Guidelines: Tentative Guidelines. Villanova, Pa.: NCCLS Publications, POL 1/2-T3 and POL 3-R, 1995. WWW.NCCLS.ORG

5. Fischer, Paul M., Addison, L.A., Curtis, P., Michell, J.M., et al: The Office Laboratory. Norwalk, CT.: Appleton-Century-Crofts, 1983.

6. Belsey, R.E., Baer, D.M., Statland, B.E., Sewell, D.L.: The Physician's Office Laboratory. Oradell, N.J.: Medical Economics Books, 1986.

7. Butler, C.L., Gross, M.C., Butler, R.C.: How to Avoid Mistakes in a Physician's Office Laboratory. Bethesda, Md.: Health and Education Resources, 1989.

8. Office Laboratory Reference Manual. Auburn Hills, MI.: Health Marketing Resources, Inc., 1989.

9. Henry, J.B.: Clinical Diagnosis and Management by Laboratory Methods. New York, N.Y.: W.B. Saunders, 1984.

10. QBC STAR™ Blood Collection Tube Package Insert, QBC DIAGNOSTICS, INC.

11. QBC STAR™ Centrifugal Hematology System User's Manual, QBC DIAGNOS TICS, INC.

12. NCCLS: Clinical Laboratory Safety; Approved Guideline. Villanova, PA; NCCLS Publications. GP17-A, Vol. 14, No. 5, April 1996.

MASTER RECORD FORMS

These forms are masters and should be copied before use.

LABORATORY SAFETY TRAINING CERTIFICATE

Facility Name:_____

This Is To Certify That

(Employee Name)_____

Has Read And Understands All Safety Procedures For This Laboratory, Has Reviewed The Location Of Any Safety Equipment, And Has Demonstrated Ability To Use Safety Equipment.

Employee Signature:_____Date:_____

Laboratory Director's Signature:_____Date:_____

LABORATORY SAFETY

- **Wear gloves for each phlebotomy and when handling laboratory specimens.**
- **Wash hands after removing gloves.**
- **Never break or shear contaminated needles.**
- **Do not recap, bend or break needles after drawing blood.**
- **Wear protective clothing when necessary and remove before leaving the laboratory area.**
- **No food or drinks in laboratory refrigerator.**
- **Never pipette by mouth.**
- **Report electrical problems and accidents immediately.**
- **Do not eat, smoke, drink, handle contact lenses, or apply cosmetics in this area.**

LABORATORY PERSONNEL TRAINING CHECKLIST

TECH: _____ **DATE: _____**

Test Name(s): _____

	YES/NO NOT APPLICABLE
Knows how equipment, reagents, and necessary supplies are stored and where they are located.	
Can perform QC using necessary materials.	
Knows where procedure manual is located and follows it as written, for test performance.	
Performs quality control at the required frequency, documents such actions, and knows what to do when quality control is unacceptable.	
Documents all corrective actions associated with quality control, quality assurance, instrumentation, and proficiency testing.	
Performs correct calculations to obtain reportable results.	
Knows and uses proper reporting systems (including panic results).	
Can recognize system failures, unacceptable quality control and calibration checks, and inconsistent or erroneous patient results.	
Knows whom to contact in the event of questions concerning testing or reporting.	

Trainer:_____ Date:_____

Title:_____

LABORATORY PERSONNEL EVALUATION

TECH: _____ DATE: _____

	YES/NO NOT APPLICABLE
Observation of all phases of testing show that all written steps of the procedure are followed without deviation.	
Instrument maintenance and function checks are performed and documented according to written procedures.	
Patient test results are recorded and reported according to protocol.	
Quality control and proficiency test records are reviewed and acted upon when necessary.	
When problems arise, the testing analyst knows how to assess the situation and does what is required to resolve the problem.	
Accurate test performance has been proven by internal blind test samples, external proficiency testing, or analyzing previously tested specimens.	
The testing analyst does not report out patient test results when quality control is not acceptable.	
The testing analyst documents all remedial actions associated with QC, QA, instrumentation, and proficiency testing.	
The testing analyst recognizes all system failures, unacceptable QC and calibration checks, and inconsistent or erroneous patient test results.	
The testing analyst contacts the appropriate person when questions arise concerning testing and/or reporting results.	

Reviewed by:_____

Title:_____ Date:_____

LABORATORY SPECIMEN LOG

DATE/TIME REC'D	PATIENT NAME	PATIENT ID#	TEST(S) ORDERED	TECH INITIALS

SPECIMEN REJECTION LOG

Reviewed by _____
Date Reviewed _____
Month Year _____

DATE/TIME REC'D	PATIENT NAME	PATIENT ID#	REASON FOR REJECTION/ PERSON NOTIFIED	NEW SPEC? Y/N DATE/TIME	TECH INITIALS

EXTERNAL LIQUID CONTROLS CHECKLIST FOR RESPONDING TO OUT-OF-CONTROL QC RESULTS

DATE	TECH	TUBE (QBC STAR)	CONTROL LOT #	CONTROL LEVEL

DESCRIPTION OF FAILURE

_____
_____
_____
_____
_____
_____

UNKNOWN

	YES/NO
Were controls cool and in good condition when received?	
Were controls promptly refrigerated upon arrival?	
Are controls stored at the proper refrigerator temperature (2-8°C or 36-46°F)?	
Is the control within the lot expiration date noted on the vial?	
Is only one vial each of level 1 and level 2 control open and in use at any time?	
Is the date opened written on the control vials in use and are they within the open vial stability period?	
Do the lot numbers on the control assay sheet and the control vials agree?	
Are results being compared to the correct range for your QBC model and tube type?	
Are controls handled and prepared *exactly* as described in the package insert?	

Explain any “no” responses. Is this the likely reason for the out-of-control result?

_____

_____

QBC™ QC LOG
EXTERNAL CONTROLS

PERIOD COVERED: FROM _____ TO _____

CONTROL LEVEL _____

QBC TUBES: QBC STAR CONTROL LOT NO. _____ EXPIRATION DATE _____

PARAMETER				HCT (%)	HB (g/dL)	WBC (x 10^9/L)	GRAN (x 10^9/L)	LY/MO (x 10^9/L)	PLT (10^9/L)	Internal QC OK (✓)	CORRECTIVE ACTION
MEAN											
RANGE											
TUBE LOT	EXP. DATE	DATE	TECH								

REVIEWED BY: _____ DATE REVIEWED: _____

Internal Electronic QC for L/M ($x10^9$) QBC STAR

	Level 1			Level 2			Level 3				
	Min	Target	Max	Min	Target	Max	Min	Target	Max	Comments	Tech
Values	2.4	3	3.6	3.5	4.1	4.7	20.2	22.2	24.2		
Date											

REVIEWED BY: _____ DATE REVIEWED: _____

Internal Electronic QC for Grans ($x10^9$) QBC STAR

	Level 1			Level 2			Level 3				
	Min	Target	Max	Min	Target	Max	Min	Target	Max	Comments	Tech
Values	2.2	2.7	3.2	6	6.5	7	28.3	31.3	34.3		
Date											

REVIEWED BY: _____ DATE REVIEWED: _____

Internal Electronic QC for WBC ($x10^9$) QBC STAR

	Level 1			Level 2			Level 3				
	Min	Target	Max	Min	Target	Max	Min	Target	Max	Comments	Tech
Values	4.6	5.7	6.8	9.5	10.6	11.7	48.5	53.5	58.5		
Date											

REVIEWED BY: _____ DATE REVIEWED: _____

Internal Electronic QC for PLT QBC STAR

	Level 1			Level 2			Level 3				
	Min	Target	Max	Min	Target	Max	Min	Target	Max	Comments	Tech
Values	90	100	110	342	360	378	615	647	679		
Date											

REVIEWED BY: _____ DATE REVIEWED: _____

Internal Electronic QC for MCHC (g/dL) QBC STAR

	Level 1			Level 2			Level 3				
	Min	Target	Max	Min	Target	Max	Min	Target	Max	Comments	Tech
Values	31.6	34	36.6	31.6	34	36.5	30.7	32.8	35		
Date											

REVIEWED BY: _____ DATE REVIEWED: _____

Internal Electronic QC for HGB (g/dL) QBC STAR

	Level 1			Level 2			Level 3				
	Min	Target	Max	Min	Target	Max	Min	Target	Max	Comments	Tech
Values	12.3	12.9	13.5	14.8	15.6	16.4	20.6	21.7	22.8		
Date											

REVIEWED BY: _____ DATE REVIEWED: _____

Internal Electronic QC for HCT (%) QBC STAR

	Level 1			Level 2			Level 3				
	Min	Target	Max	Min	Target	Max	Min	Target	Max	Comments	Tech
Values	36.9	37.9	38.9	44.9	45.9	46.9	65.1	66.1	67.1		
Date											

REVIEWED BY: _____ DATE REVIEWED: _____

PROFICIENCY TESTING FAILURE INVESTIGATION REPORT

Background Information:

PT Program_____ Failures_____
Test Method_____ Result_____
Date Received_____ Accepted Range _____
Date Tested_____

Investigation:

Gather all PT records and answer the following:	**YES/NO**
Were the PT samples received cold and in good condition?	
Were the PT samples stored at the proper storage temperature until testing?	
Was the refrigerator temperature in the correct range on the days that PT samples were stored and tested?	
Were the PT samples in good condition on the test day? *For example, no hemolysis?*	
Did you follow exactly the handling and preparation instructions that accompanied the PT samples?	
Did you correctly enter the numerical data on the PT results forms?	
Were all self checks acceptable the day PT was tested?	
Were the Quality Control results acceptable on the day PT samples were tested?	
Did you select the correct method code for the QBC™ instrument and QBC tubes? *For example QBC STAR system and tubes.*	

PROFICIENCY TESTING FAILURE INVESTIGATION REPORT (Cont'd)

Corrective Actions:

1. If any "no" responses resulted from PT failure investigation, note the appropriate corrective action taken.

   _____
   _____
   _____
   _____

2. Verify that current QBC™ System performance is acceptable:

   Quality Control Results Acceptable Yes/No

3. If applicable, review specimen preparation and handling with staff.

   Name: _____ Date Reviewed: _____
   Name: _____ Date Reviewed: _____
   Name: _____ Date Reviewed: _____
   Name: _____ Date Reviewed: _____

4. If needed, contact QBC DIAGNOSTICS, INC. at 866.265.1486 for assistance.

   Date Called: _____ Contact: _____

   Results of Call:

   _____
   _____
   _____
   _____
   _____
   _____

Laboratory Director: _____ Date: _____

QBC SYSTEM MAINTENANCE LOG

Reviewed by _____
Date Reviewed _____
Month _____ **Year** _____

_____
QBC STAR Analyzer:

Model #_____ **SN #** _____

Clean exterior surfaces as required with a damp cloth moistened with soap and water or a mild detergent. There are no user-serviceable parts on the QBC STAR except for fuses in the power entry module. For all service or repairs please contact Technical Service at 1-866-265-1486.

Clean Housing	Date/Tech	Date/Tech	Date/Tech	Date/Tech	Date/Tech	Date/Tech	Date/Tech	Date/Tech

CALLS TO TECHNICAL SERVICE

Date/Tech	**Problem**	**Resolution**

REFRIGERATOR TEMPERATURE RECORD_____

Reviewed by_____

Date Reviewed_____

Refrigerator ID_____

	Month		Month		Month	
	Temp	Tech	Temp	Tech	Temp	Tech
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
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31						

Year_____ ACCEPTABLE RANGE: 2-8°C OR 36-46°F

Action Taken:_____

ROOM TEMPERATURE RECORD

Reviewed by _____

Date Reviewed _____

Year_____ACCEPTABLE RANGE FOR QBC STAR OPERATION : 16-32°C OR 61-90°F

Action Taken:

	Month		Month		Month	
	Temp	Tech	Temp	Tech	Temp	Tech
1						
2						
3						
4						
5						
6						
7						
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MONTHLY QUALITY ASSURANCE CHECKLIST

	YES/NO NOT APPLICABLE
Our **LABORATORY SAFETY POLICIES** were followed:	
The laboratory director was notified of any situation that could affect the laboratory's performance or the safety of employees.	
All new laboratory personnel have read the safety guidelines in this Manual.	
All new laboratory personnel have been offered the Hepatitis B vaccine.	
Our **PERSONNEL POLICIES** were followed:	
All personnel who perform tests have documented training for these tests.	
All personnel who perform tests have read the procedure manual for those tests.	
Personnel evaluations were performed as necessary.	
Our **PROFICIENCY TESTING POLICIES** have been followed:	
Proficiency tests were handled in the same manner as patient specimens.	
Proficiency test results were evaluated, failures were investigated, and remedial action was taken.	
Our **PATIENT TEST MANAGEMENT SYSTEM** was followed as written:	
Patient specimens were collected and handled according to our protocol.	
All blood collection tubes were labeled legibly.	
Specimens were logged correctly on the Laboratory Specimen Log.	
All lab reports contain correct information.	
Our **QUALITY CONTROL POLICIES** were performed as specified:	
All required temperatures were taken and recorded.	
All reagents, controls, kits, etc. that exceeded their expiration date were discarded.	

MONTHLY QUALITY ASSURANCE CHECKLIST (CONT'D)

	YES/NO NOT APPLICABLE
Any required instrument maintenance was performed and documented.	
Any necessary remedial action was performed and documented.	
Our **QUALITY ASSURANCE PROGRAM** is monitored for compliance:	
The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies or procedures.	
If you answered "No" to any of the above, explain the problem and how it was resolved:	

Tech: _____ **Date:_____**

Laboratory Director: _____ **Date: _____**

RESULTS OF PATIENTS RUN

QBC Tubes
Catalog#: _____

Lot#: _____

Expiration: _____

Date	Oper	Patient

Parameter	HB (g/dL)	HCT %	PLT (10^9/L)	WBC (10^9/L)	% Grans	% Lymph monos	Total Grans (10^9/L)	Total Lymphs & Mono (10^9/L)	MCHC(g/dL)	Comments
*Operating Ranges										
Lab Panic Values										

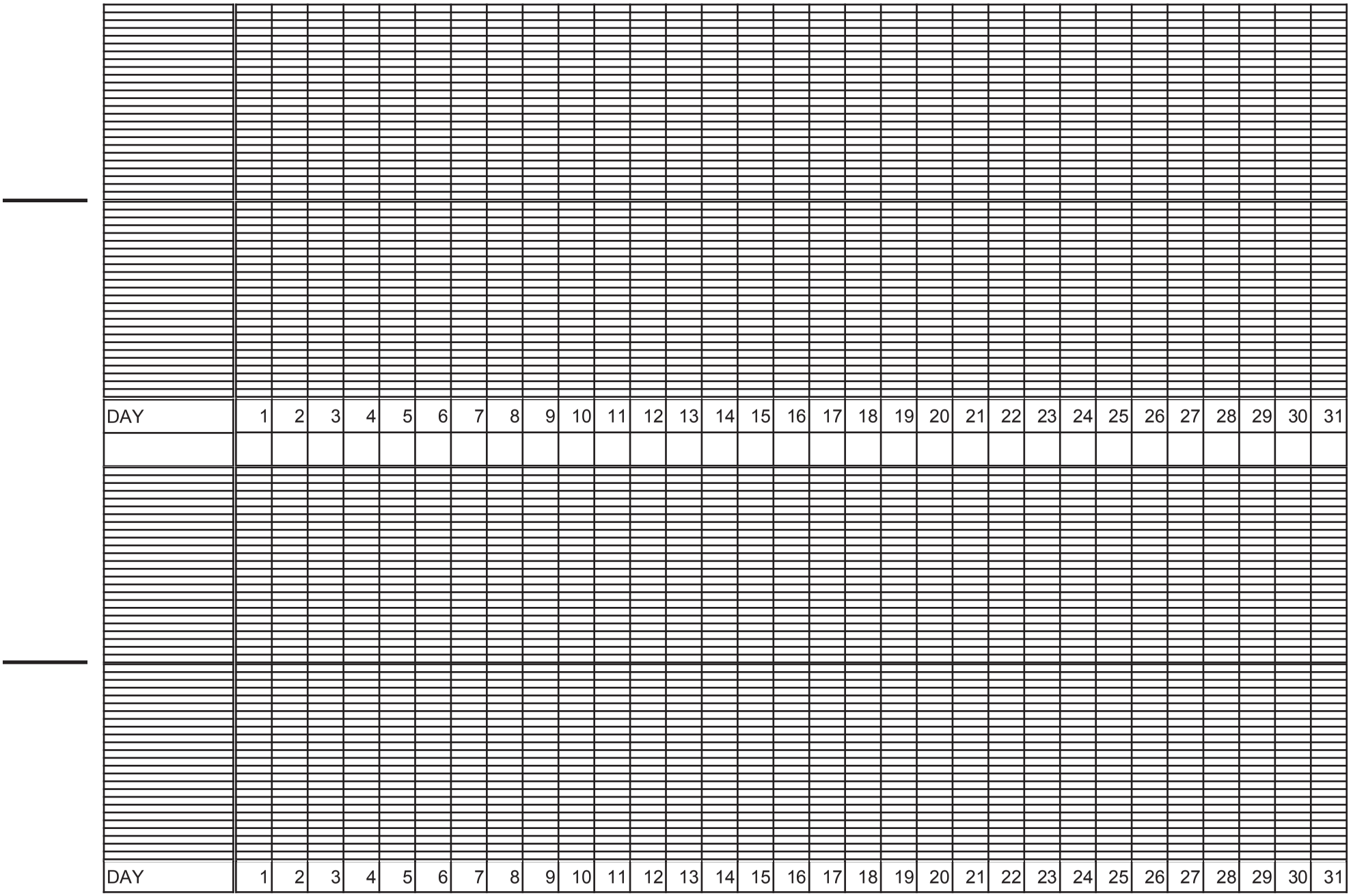
* If the specimen yields test values outside these ranges, results should be confirmed by alternative methods.

Appendix
Levey-Jennings

LEVEY-JENNINGS CHART

Control Lot # _____ **Reviewed by** _____

Expiration Date _____ **Date Reviewed** _____



DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

LEVEY-JENNINGS CHART

Control Lot # ______________

Expiration Date ____________

Reviewed by ________________

Date Reviewed ________________

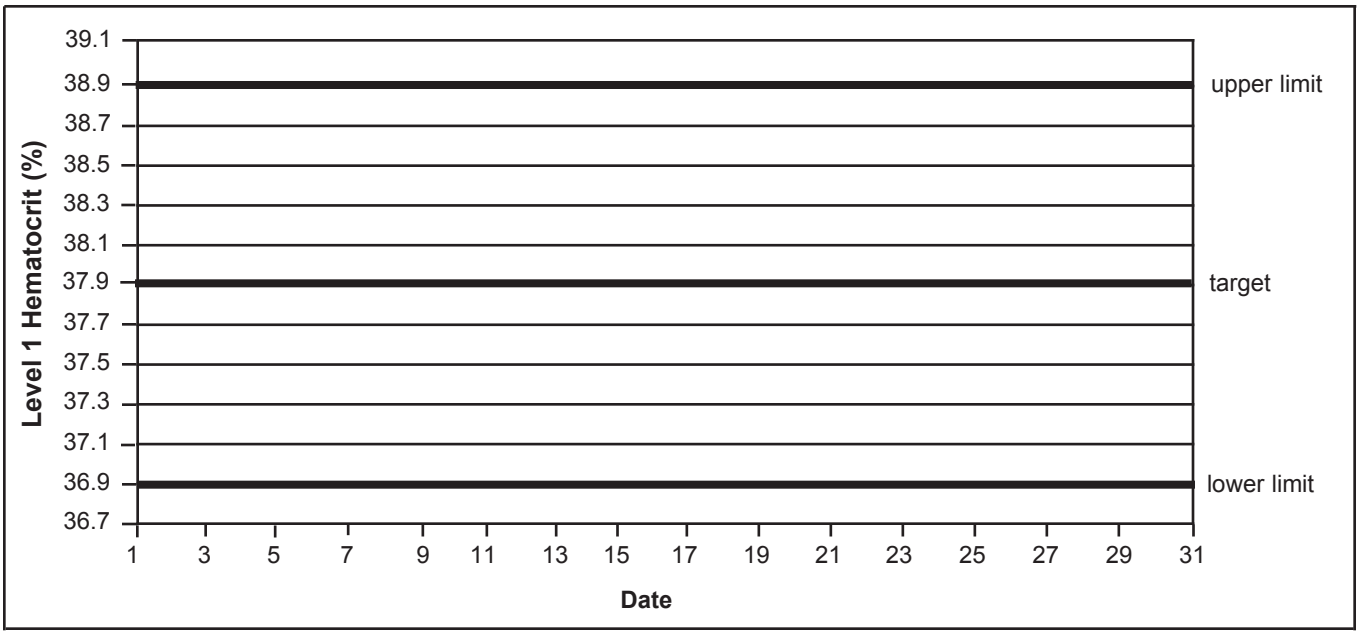
DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

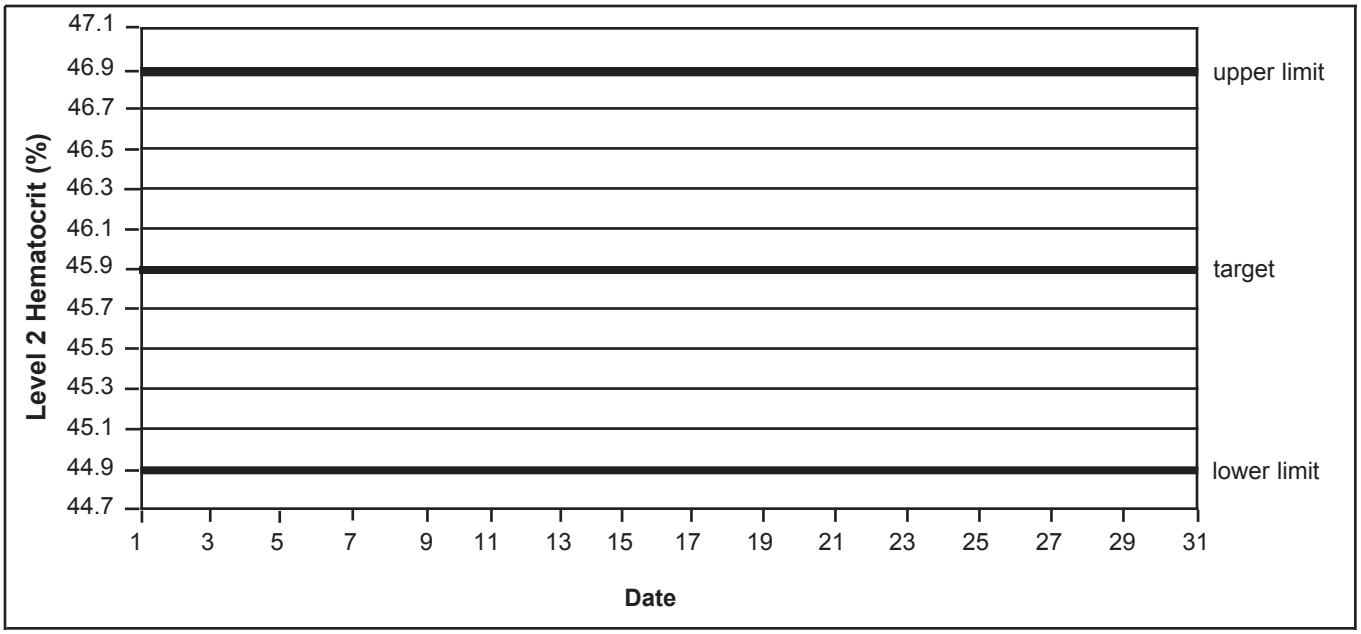
DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

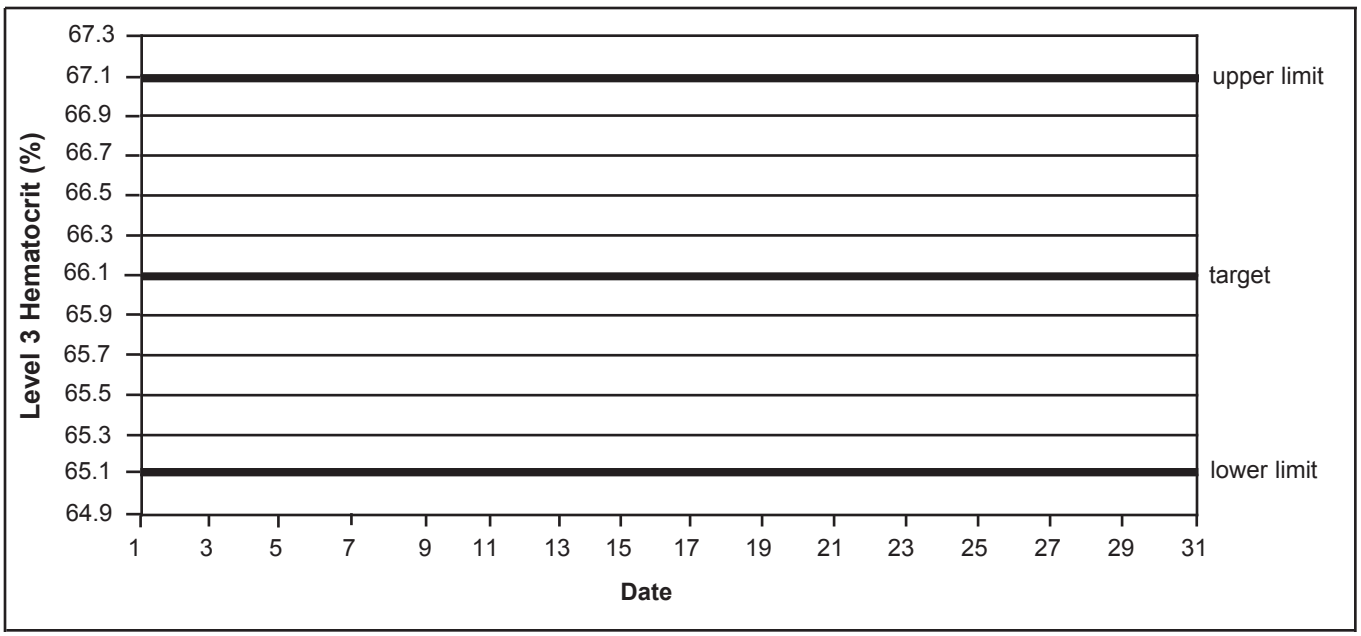
DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

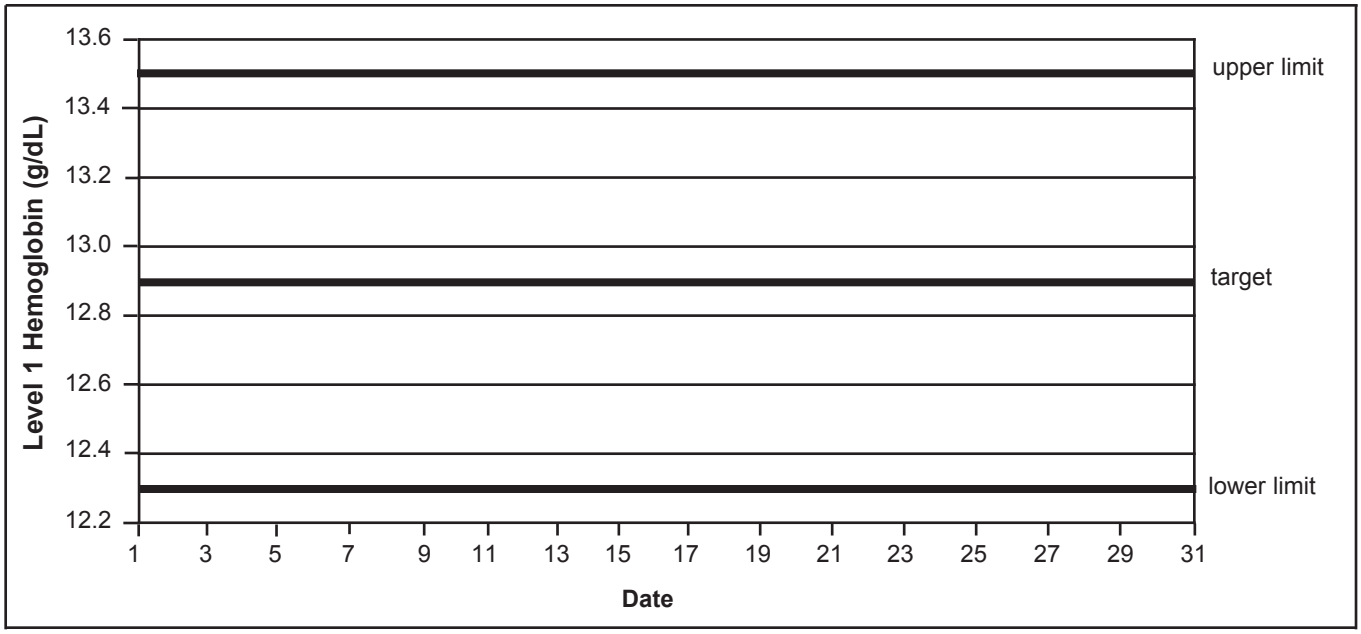
QBC STAR Electronic QC, Hematocrit **Month:** _____

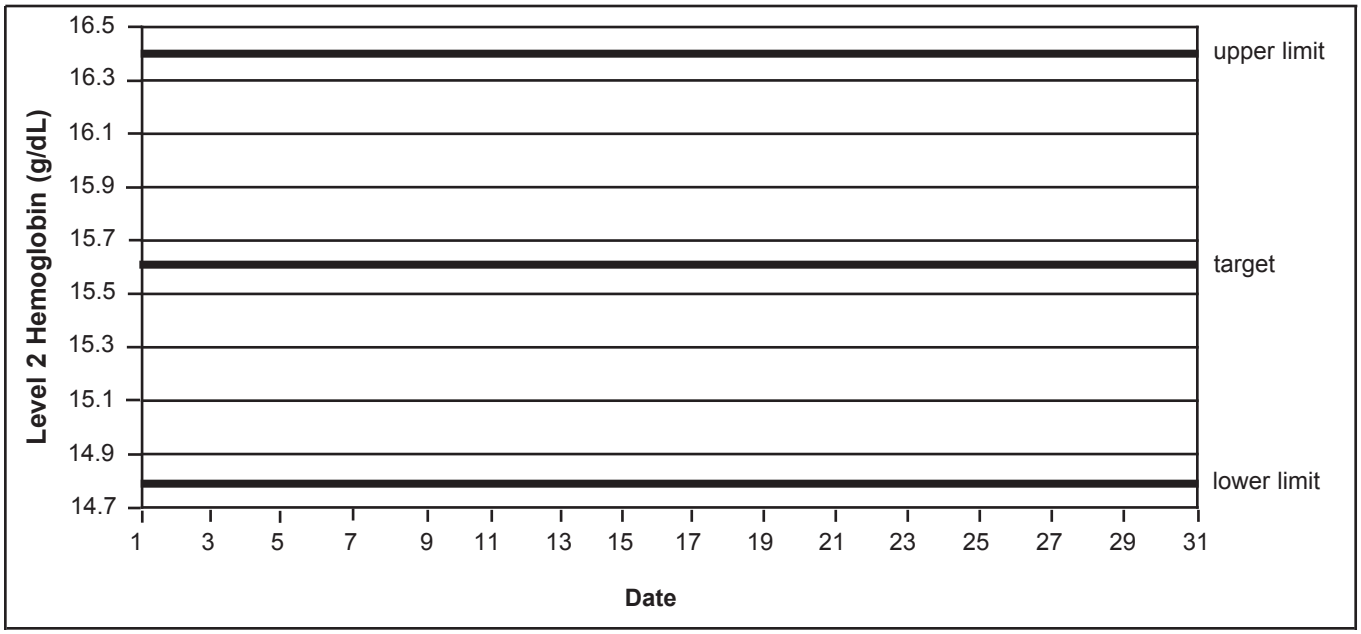


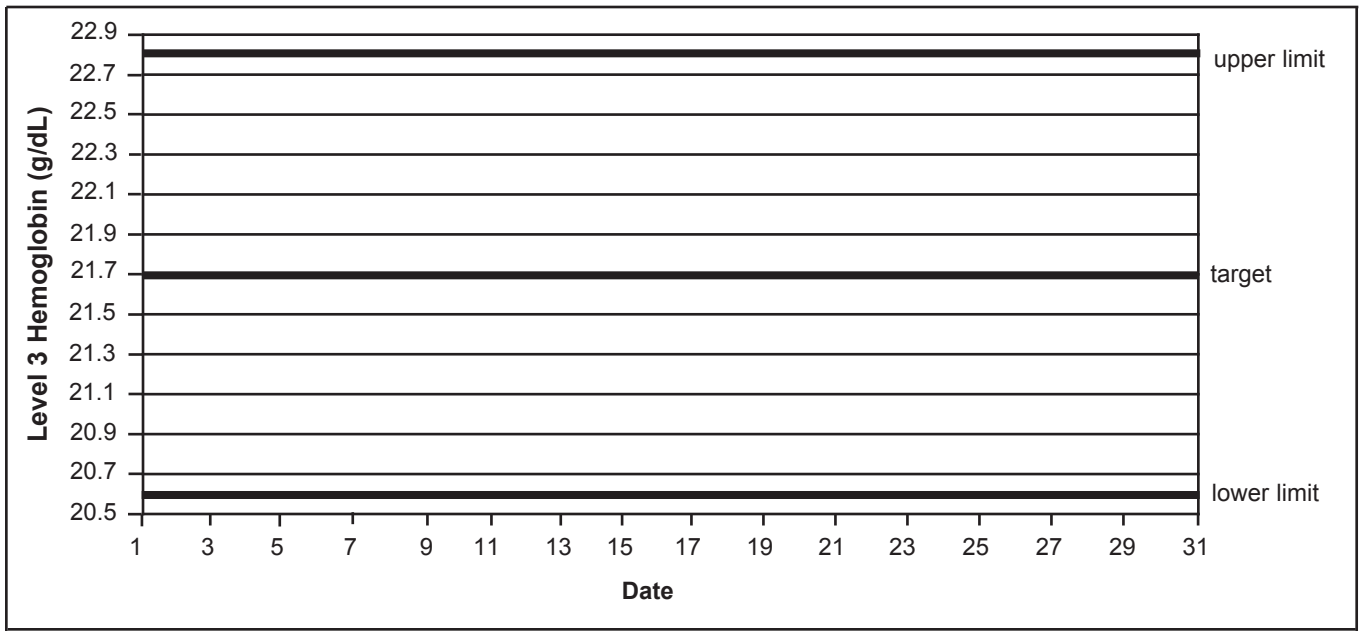




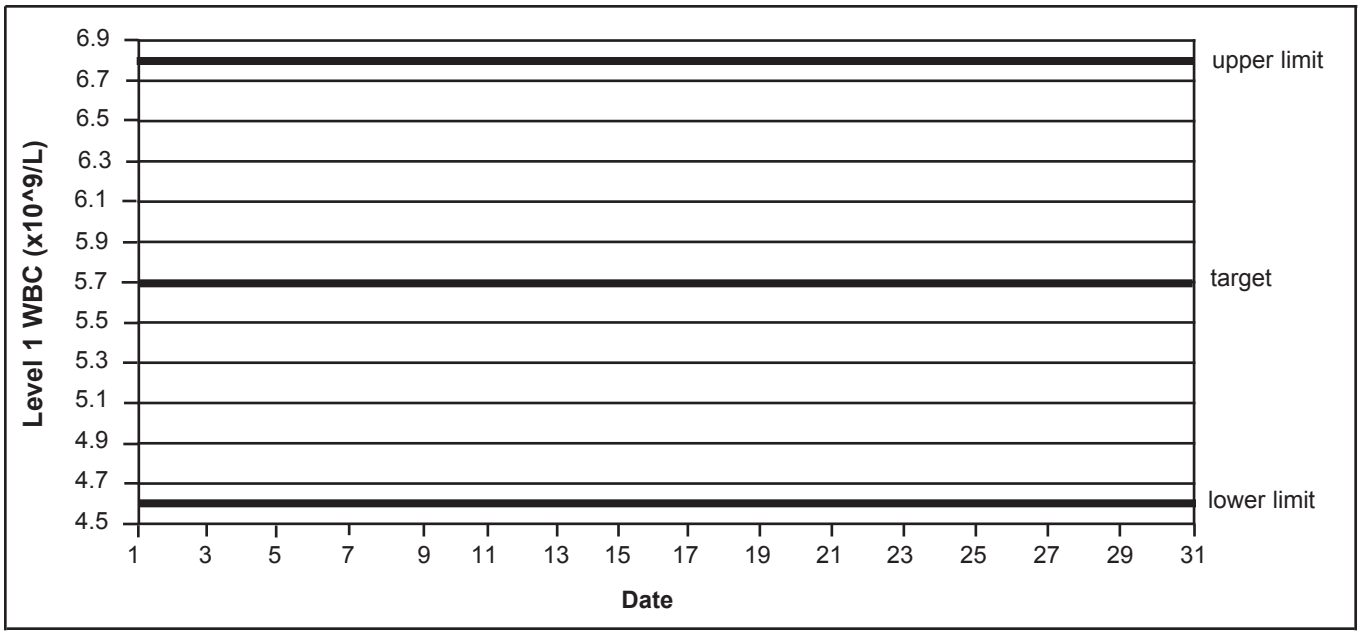
QBC STAR Electronic QC, Hemoglobin **Month:**_____

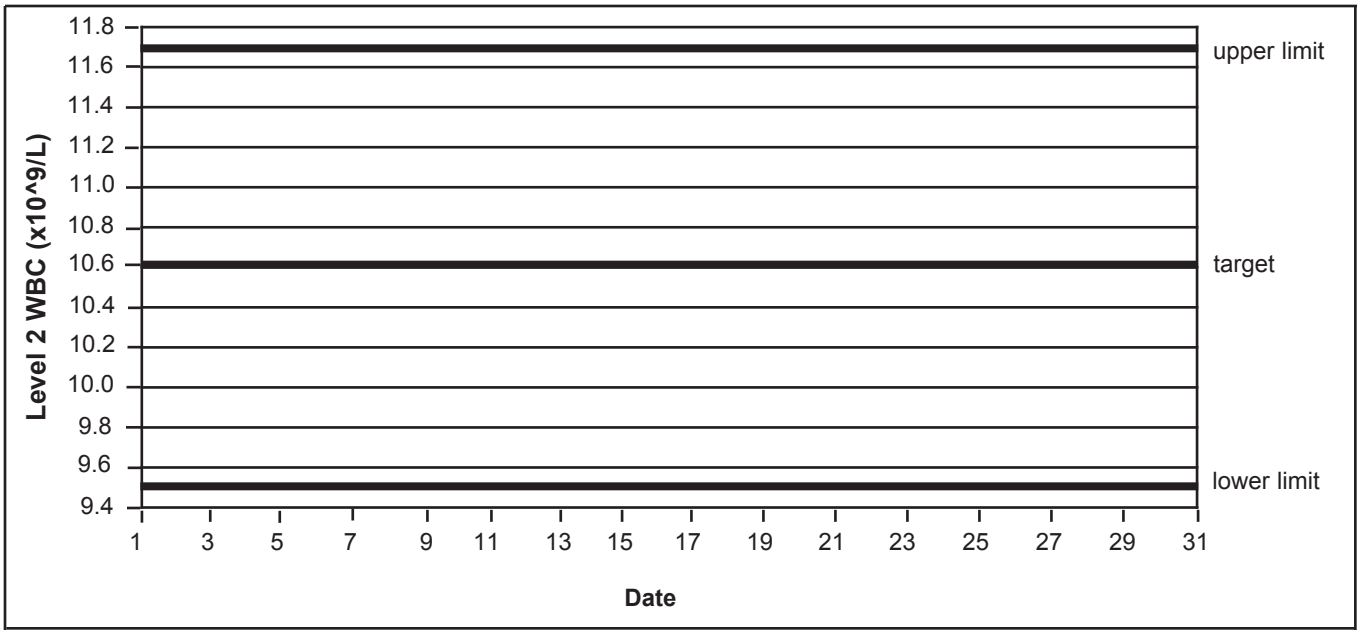


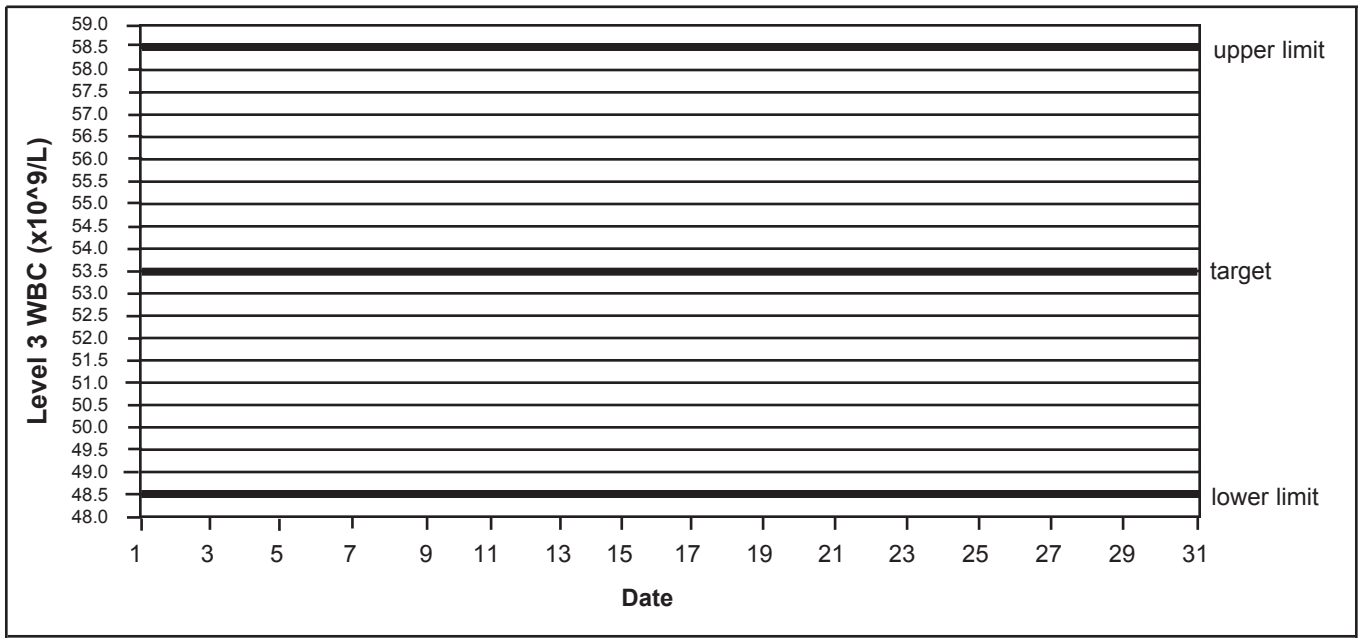




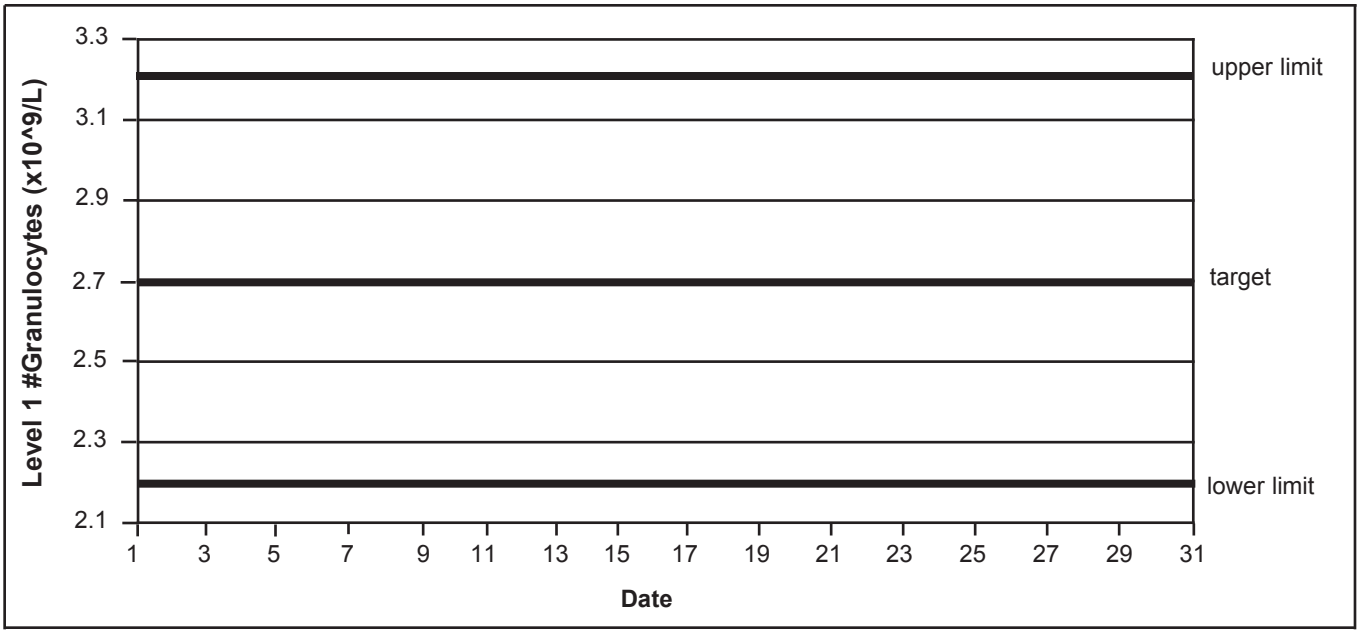
QBC STAR Electronic QC, WBC **Month:** _____

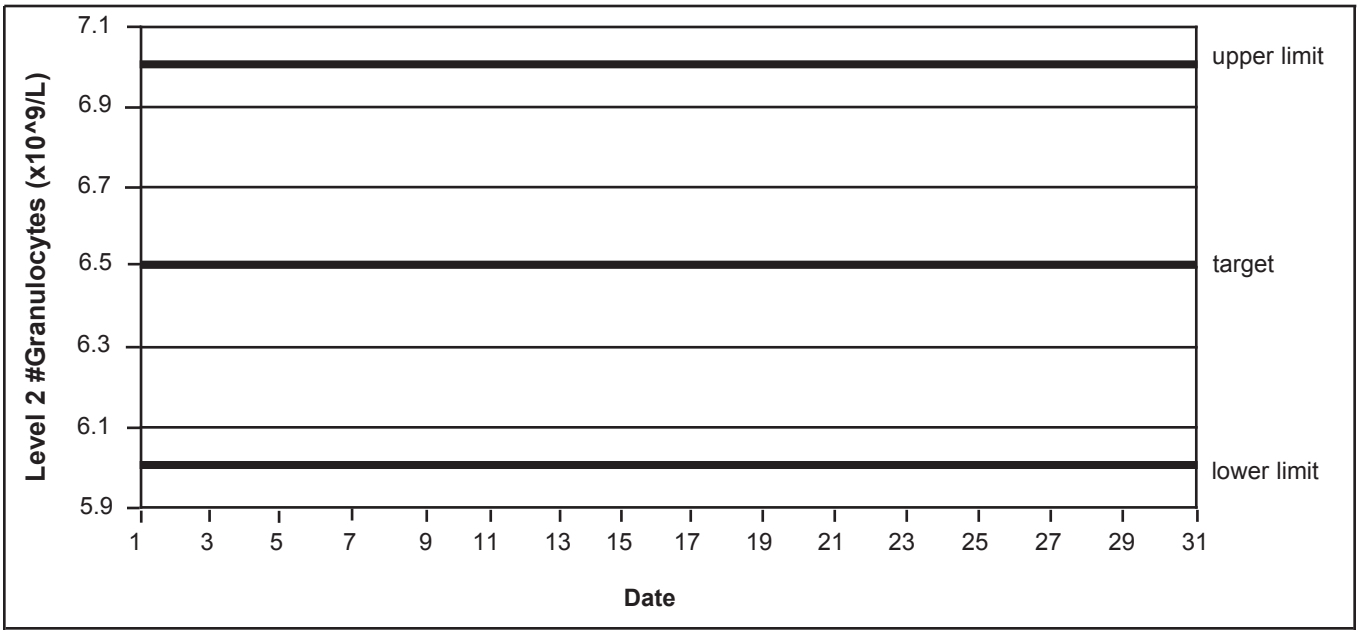


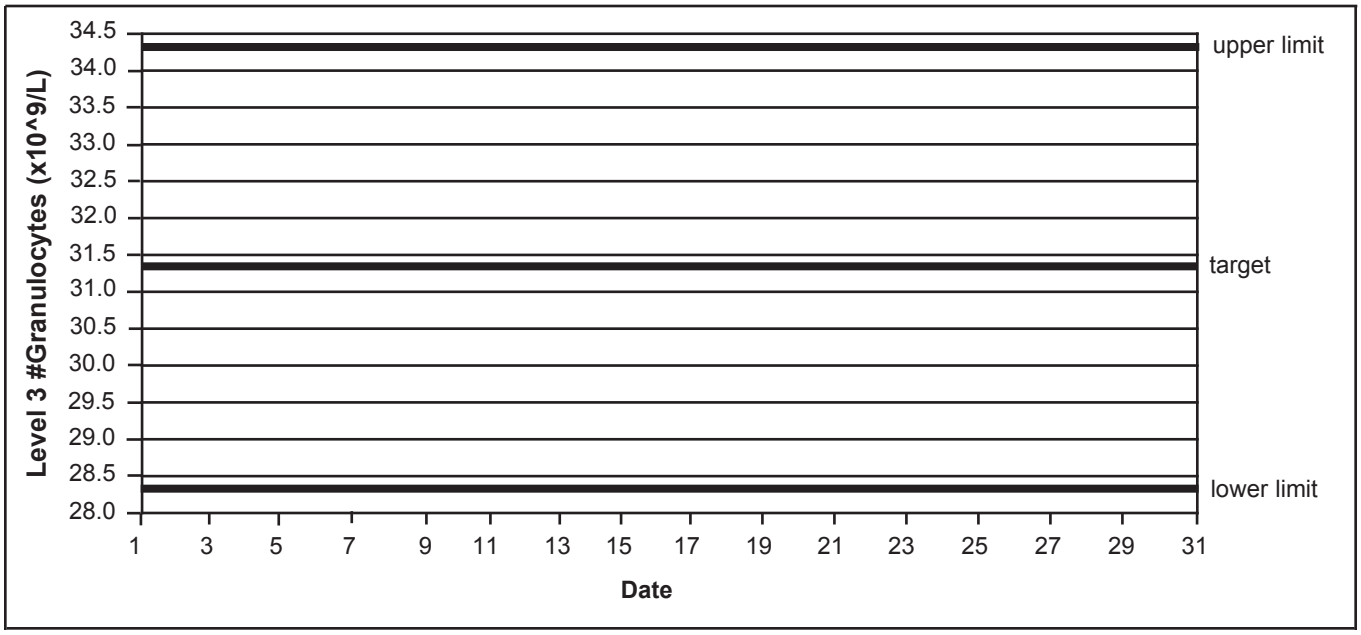




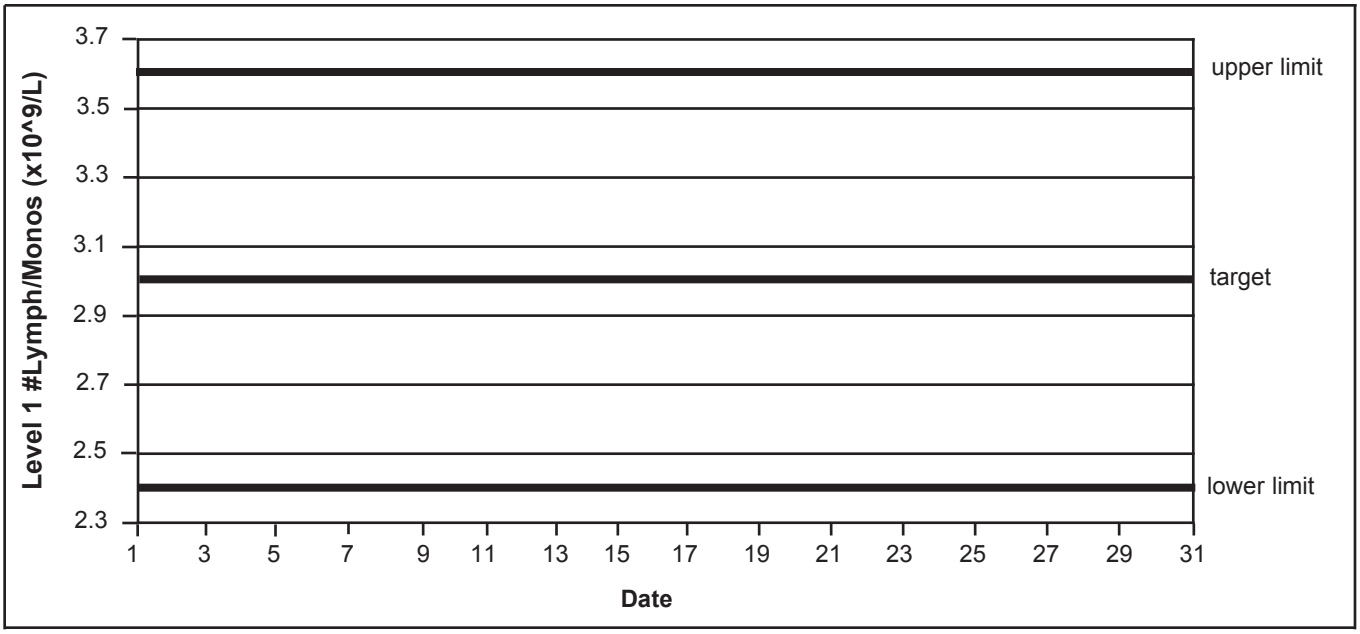
QBC STAR Electronic QC, #Granulocytes **Month:**_____

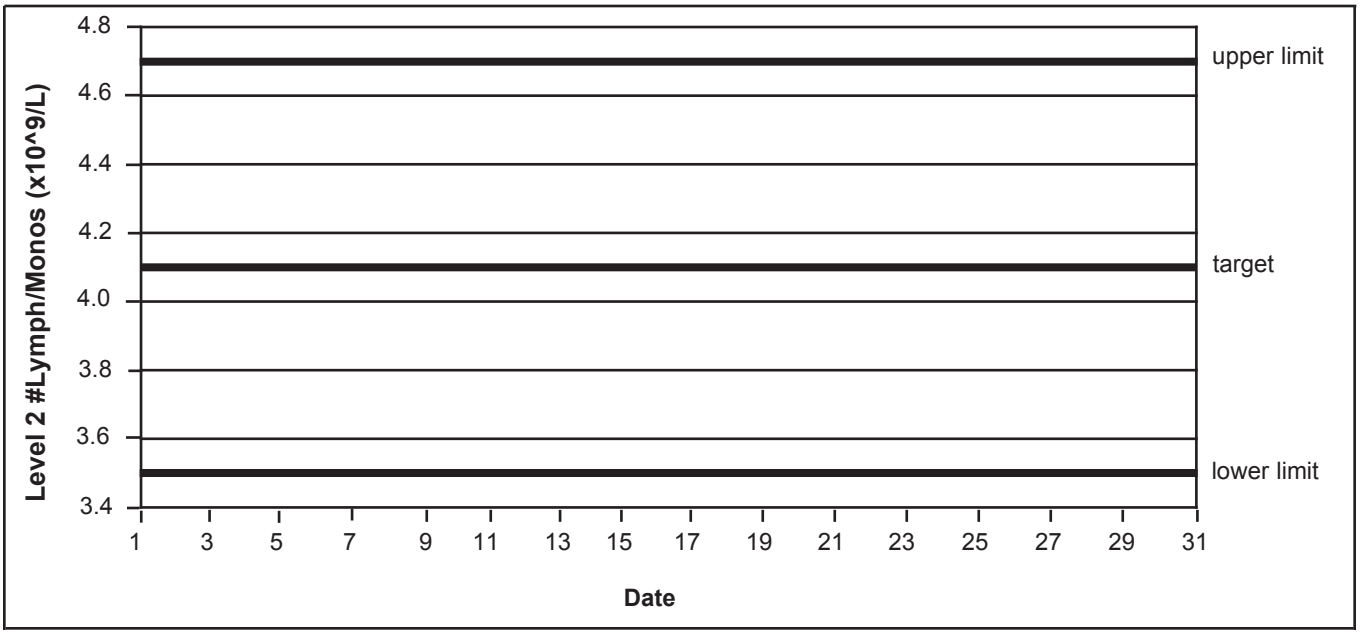


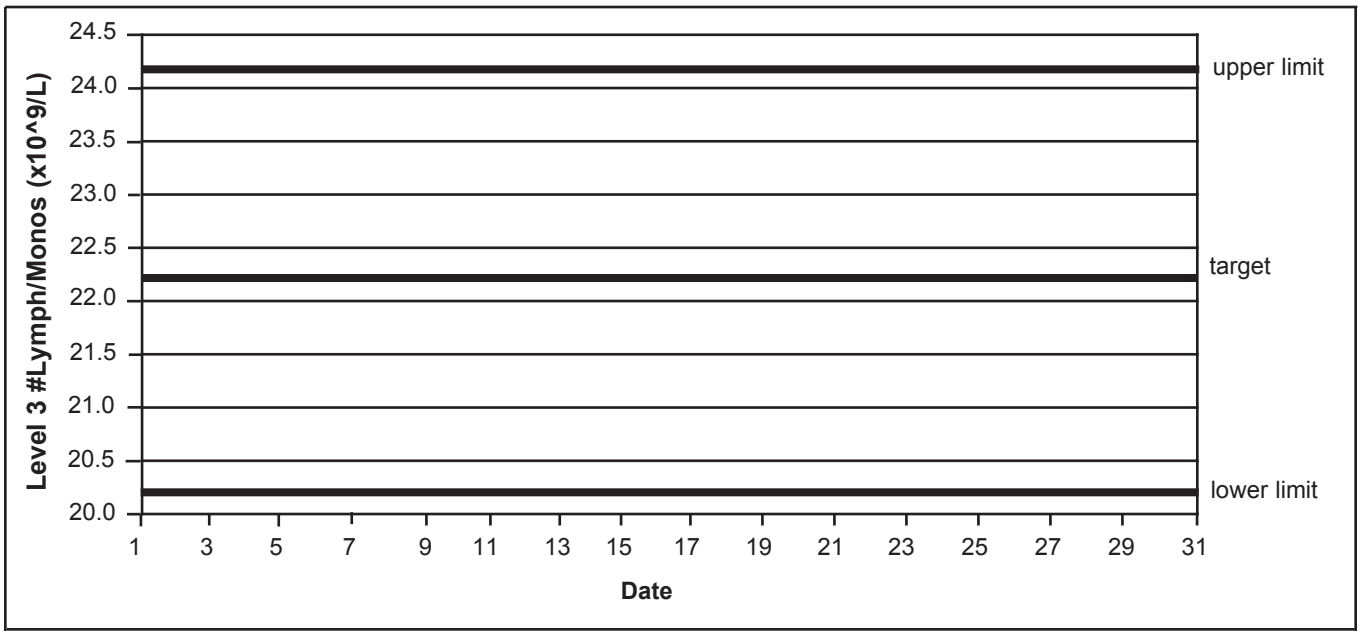




QBC STAR Electronic QC, #Lymph/Monos **Month:**_____







QBC STAR Electronic QC, Platelet **Month:** _____