

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

**Activated Clotting Time (ACT), Whole Blood
by Hemochron Response using P214/ P215 tube**

Principle

The Hemochron Response Whole Blood Coagulation System is a dual-well microprocessor controlled coagulation testing instrument capable of performing the Activated Clot Time (ACT). The ACT is the method of choice for monitoring heparin therapy in the near patient environment. Administration of heparin to maintain hemostasis during cardiac surgery and cardiac angioplasty procedures can pose a significant risk to the patient. Monitoring is required because of the varied heparin sensitivities demonstrated between patients. Overdosing heparin can result in dangerous bleeding and under dosing heparin can lead to thrombosis.

The ACT is performed by adding whole blood to a tube containing a clot activator and then measuring the length of time required for clot formation. The particular clotting activator used influences the time required for clot formation.

Specimen Requirements

1. Fresh whole blood collected in a plastic syringe.
2. Minimum volume is 0.4 mL for P214/ P215 tubes.
3. Do not collect blood from heparinized access line or indwelling heparin lock.
4. Do not collect fresh whole blood samples using glass blood collection tubes.
5. **Indwelling venous blood line.** Use a two-syringe technique.
 - a. Draw 2 mL of blood in a syringe and discard it.
 - b. For P214/ P215 tubes, draw 1.0 mL of blood in a second syringe for the test.
6. **Extracorporeal blood line port.** Use a two-syringe technique.
 - a. Flush the extracorporeal blood access line by withdrawing and discarding 5 mL of blood.
 - b. For P214/ P215 tubes, draw 1.0 mL of blood in a second syringe for the test.
7. Test specimen immediately.

Interfering Substances

1. Do not collect blood from a heparinized access line or indwelling heparin lock, as heparin contamination will prolong the ACT.
2. Protease inhibitors such as aprotinin, which may be administered to reduce post-operative bleeding, can prolong the Celite (diatomaceous earth) ACT. A Kaolin-activated ACT tube should be used with patients on a protease inhibitor such as aprotinin.
3. IV lines not adequately flushed before drawing test sample.
4. Improper storage of test kits such as prolonged exposure to heat.
5. Poor technique when collecting specimens and performing the test.
6. Glass blood collection tubes. Glass is a clot activator and can initiate clot formation before the specimen is delivered to the testing system.

Linearity

The P214/ P215 tube has a linear reportable range of 22-400 seconds.

Critical/Alert Values

Critical alert values are those results demonstrating such variance from normal as to represent a pathophysiological state with potential of being life threatening unless action is taken quickly. These results must be immediately reported to the care provider and be documented in the test record as to who was contacted, the time of contact, the person making contact, and if relevant, that the results were read back.

Report all ACT results outside of therapeutic range limits to the physician immediately.

Quality Control

Quality Control (QC) consists of Electronic Quality Control (EQC) and Liquid Quality Control.

Two levels of Electronic Quality Control are to be performed every eight hours of patient testing.

Two Levels of Liquid Quality Control are to be performed when opening a new box of test tubes and once each week during patient testing. If no patient testing is completed on the instrument, Liquid Quality control must be tested at least monthly.

Electronic System Verification (ESV) tubes are plastic tubes with battery-operated circuitry and are used to perform EQC. The tubes are placed in the test well of the analyzer and electronically simulate patient testing.

1. To perform Electronic System Verification Tube Quality Control:

Normal and Abnormal ESV tests are performed every eight hours of patient testing.

- a. Press START1 or START2 to begin a test on a well. A beep will signal the start of the test. At the same time the START button is pressed, press the 100 second button on the Electronic System Verification tube.
- b. Insert the ESV tube into the test well.
- c. Enter Operator ID (Employee Number).
- d. Press YES.
- e. A prompt to enter the serial number of the ESV tube is displayed.
- f. Enter the serial number.
- g. At completion of the test, the result is automatically printed. Compare the result to the ESV test selected. Results must be within 10 seconds of the selected time.
- h. Repeat the test, using the abnormal ESV QC for the first well.
- i. Repeat for the second well, using both normal and abnormal ESV tests.
- j. If the QC results are within the acceptable limits, patient testing may be performed:
- k. If QC results are not within acceptable limits, repeat the ESV test. If repeat test fails, do not perform patient testing. Call ITC for troubleshooting 1-800-631-5945.
- l. Document all action taken in QC Log Book.

2. To perform Liquid QC:

Normal and Abnormal Liquid QC is performed once a week and when a new box of tubes is opened.

P214/P215 tube liquid QC procedure

- a. Remove QC materials from refrigerator and allow vials to sit for 30 minutes to warm the samples to room temperature.

- b. Press MENU1 or MENU2 once.
- c. Press 2 QC Selections.
- d. Press 1 for normal control. The current lower limit for the normal control range is displayed.
- e. If needed enter the new lower limit.
- f. Press YES to save.
- g. Repeat for upper limit.
- h. Enter the lot number for the control.
- i. Visually inspect vial to ensure that the glass ampule is intact.
- j. Reconstitute the dropper vials as follows:

Reconstitution and mixing should be accomplished as quickly as possible. Upon reconstitution, the sample should be used immediately, as clotting will occur.

- i) Remove the label from the vial and **insert vial into protective sleeve**.
 - ii) Hold the vial upright and tap on table top to settle the glass ampule to the bottom of the vial.
 - iii) Crush the inner glass tube by either bending over the edge of a table or by crushing the vial between a finger and thumb.
 - iv) Immediately repeat the crushing action one or two more times to ensure complete breakage of glass ampule.
 - v) Quickly invert the dropper vial end to end 10 times.
- k. Remove and retain the vial cap.
 - l. Invert the vial (dropper tip down) and use a quick downward motion to ensure control material flows to the dropper tip.
 - m. Immediately dispense the entire vial content to fill the P214/215 tube to the fill line or until all contents of the vial have been dispensed.
 - n. At the same time as dispensing, depress the START button for the appropriate test well on the instrument.
 - o. Immediately ensure that the top of the ACT tube is sealed, and holding the tube

vertically, flick the bottom of the ACT tube 4 – 6 times to disperse activator.

- p. Insert the tube into the appropriate test well. Quickly rotate the tube clockwise.
- q. When a clot is formed, the analyzer will beep and display result. Record the QC result in QC Log Book.
- r. Repeat procedure using the abnormal control.
- s. Verify that the QC results are within the acceptable limits.
- t. If QC fails, repeat. If repeat QC fails, verify QC and test tube expiration dates and reconstitute a new vial. Repeat QC test using new QC vial. If repeat using new QC vial fails, do not perform patient testing and contact ITC Technical Support at 1-800-631-5945. Document all action taken in the QC Log Book.

Patient Test Procedure

An operator ID and a patient ID should be entered for each test.

1. To enter operator ID:
 - a. Press MENU1 or MENU2 (depending on the well used for the test) once.
 - b. Press 1. ID Selections will be displayed.
 - c. Press 2.
 - d. Enter your operator ID (Employee number).
 - e. *If necessary press BACKSPACE to undo an entry for retyping.*
 - f. Press Yes.
 - g. Press CANCEL to display the first page of the main menu.

A sample run immediately after entering control information as outlined above will be designated a control sample. If a control is the last sample run, you must designate when a patient sample is to be run.

2. To designate a patient sample.
 - a. Press MENU1 or MENU2 (depending on the well used for the test) once.
 - b. Press 2. QC Selections menu will be displayed.
 - c. Press 4. A prompt will confirm a patient test is being run.

3. To enter patient ID:
 - a. Press MENU 1 or MENU 2 (depending on the well used for the test) once.
 - b. Press 1. ID Selections will be displayed.
 - c. Press 2.
 - d. Enter patient medical record number.
 - e. Press YES to save the patient ID.
 - f. Press CANCEL to display the first page of the main menu.
4. To perform patient test.
 - a. Prepare or flush the collection sites according to the “specimen requirements” section. Collect at least the minimum amount of blood required for patient testing.
 - b. Immediately remove the needle from the syringe, flip open the cap of the HEMOCHRON test tube, and inject the blood sample into the tube. At the same time as blood is injected, press START1 or START2. A beep will signal the start of the test and timing of the test will begin.
 - c. Close the flip cap and agitate the test tube vigorously from end to end, ten times to disperse activator.
 - d. Insert test tube into the test well. The tube is rotated automatically in the well until clot formation is detected.

If the expiration date on a barcode label on the test tube label is exceeded the test will be aborted.

After START1 or START2 is pressed, the operator can only enter a patient ID or enter an Operator I. Other functions are inactive until test is completed. A test can be aborted once the timing has begun.

5. To abort a test:
 - a. Press CANCEL.
 - b. The instrument will display the message:
Press YES to abort
 - c. Press YES to stop the test.

6. Results Display

- a. While the test is running, the test name, temperature, patient ID #, and the elapsed time after starting the test are displayed.
- b. When clot formation is detected the instrument beeps three times the test name and clotting time is displayed. Under the results will be a note to remove tube.

If Test tubes do not have a readable barcode, the test to run must be specified.

7. To specify a test.

- a. Press MENU 1 or MENU 2 (depending on the well used for the test) once.
- b. Press 3. Test ID.
- c. Select ACT from list of tests. An arrow will be displayed after the number of the selected test.
- d. Press YES to save the selection

8. Instrument Shutdown.

- a. Press START1 or START2 and hold down.
- b. OR, the instrument will automatically shut down after it has remained inactive for 60 minutes.

Calculations

None

Results Reporting

1. All ACT results are reported to the staff surgeon and staff anesthesia tech.
2. Record results in the Patient's medical record.

Data Management

1. All Hemochron users are required to go through hands on training and competency both initially and annually. Upon completion of initial competency, POC staff or super user will enter testing personnel information and access to perform Hemochron testing will be granted. Users must complete annual competencies in order for access to be renewed every year.
2. QC data must be entered into the QC log book for both the EQC and LQC every time these checks are performed.

Reagents:

1. HepCheck Whole Blood Control for P214 tubes.
 - a. Vials are stable at 2-8°C until marked expiration date.
 - b. Vials are stable at room temperature for up to 4 weeks.
 - c. Dried, fixed bovine red blood cells.
 - d. Buffered sheep and horse plasma.
 - e. Diluent:
 - i. Sodium Chloride.
 - ii. Tween 20.
 - iii. Anticoagulant.
 - iv. Calcium Chloride

References

1. Brown MD, Elmer B. Progress in Hematology, Volume XII., 1981, pg 98 - 100
2. Beutler MD, Ernest; Marshall A. Lichtman, MD; Barry S. Coller, MD; Thomas J. Kipps, MD. Williams Hematology, fifth edition., 1995. pg L86 - L87.
3. Murano, Genesisio and Roger L. Bick. Basic Concepts of Hemostasis and Thrombosis. 1980, pg 249 -252
4. Hemochron Response Instruction Manual, International Technidyne Corporation. 2003.
5. HepCheck Whole Blood Control product insert, ITC, 2002.
6. Hemochron Whole Blood Coagulation Systems Activated Clotting Time (ACT) test tube package insert, ITC, 2003.