



Medical Center

Point of Care Testing

Clinical Laboratories

ACTIVATED CLOTTING TIME

Medtronic ACT Plus™ Automated Coagulation Timer

I PURPOSE:

Activated Clotting Time is a blood test for monitoring patients on heparin therapy at the point-of-care during cardiopulmonary bypass and other vascular surgical procedures.

II PRINCIPLE:

The ACT Plus™ is a microprocessor-controlled electromechanical coagulation instrument intended for determining coagulation endpoints in fresh whole blood and citrated whole blood samples. The endpoint of a test performed on the ACT Plus™ is formation of fibrin. Fibrin formation is detected by measuring the rate of fall of the plunger-flag mechanism in each cartridge channel. The plunger assembly falls rapidly at programmed intervals through an un-clotted sample. The fibrin web formed during clotting impedes the rate of fall of the plunger and is detected by a photo-optical system located in the actuator assembly of the instrument. The clotting times are performed in duplicate and the results for each channel, the average of the two channels and the difference are displayed.

Surgery monitors ACT using the ACT Plus™ from Medtronic Perfusion Systems. 7611 Northland Drive, Minneapolis, MN 55428-9947, 1 (800) 433-4311.

III SCOPE

This procedure is for the Clinical Laboratories, POCT, and ML Operating Room at UCSF.

IV PERSONNEL

The Anesthesiologists, Perfusion Services and all other personnel performing activated clotting times will use this procedure.

V EQUIPMENT AND MATERIALS

- A. High Range ACT (HR-ACT), catalogue # 402-03:

The HR-ACT is a kaolin activated clotting time test performed on fresh whole blood for use in the Cardiovascular Operating Room where the heparin concentration is 1.0 unit/ ml or higher. The reagent chamber contains kaolin, 0.05M CaCl₂, HEPES Buffer, and Sodium Azide. Each box contains 50 cartridges.

- B. Medtronic ACT Plus™ plus bar code scanners
C. Medtronic ACTtrac®

- D. Temperature Verification Cartridge, catalogue # 313-11
- E. Syringes, no larger than 10 ml
- F. 19 gauge blunt tip needle or other blood collection needles
- G. Liquid controls from Medtronics, CLOTtrac® normal and abnormal
- H. Instrument cleaning kit, catalogue #201673
- I. Sharps container
- J. Gloves
- K. QC log sheets
- L. Refrigerator, temperature range from 2^o and 10^oC
- M. Floppy diskettes

VI SPECIMEN REQUIREMENTS:

- A. Patient Preparation: All tests: Blood may be obtained either by venipuncture or from arterial or venous access lines. See instructions below.
 - 1. **Venipuncture Collection:** The venipuncture must be fast, non-traumatic, and the first 2 to 3 ml of blood collected and discarded in a separate syringe in order to prevent contamination of the test sample with tissue activator (thromboplastin) and the potential for erroneous results. Blood should flow quickly into the syringe.
 - 2. **Arterial or Venous Line Collection:** Flush the line with 5 ml saline, and using separate, single use syringes, collect at least 5 ml or 6 dead space volumes of blood and discard prior to collection of the test sample in order to eliminate the risk of excess dilution and contamination of the sample with heparin from the catheter or line.
- B. Specimen Type: High Range ACT (HR-ACT): Fresh Whole Blood, 0.40 ml per cartridge channel
- C. Handling Conditions: Fresh whole blood specimens should be tested as quickly as possible following sample collection. Test within 60 seconds when there is no anti-coagulant on board. Test within 2 minutes when the sample is heparinized.
- D. Cartridge Preparation:
 - 1. HR-ACT cartridges should be shaken or tapped to re-suspend the kaolin and pre-warmed for 3 to 5 minutes in the actuator heat block. HR-ACT cartridges may be pre-warmed for up to 12 hours and then discarded if not used.
- E. Performance Parameters:
 - 1. Duplicate clotting times for the HR-ACT should fall within 10% of each other for baseline or normal samples and 12% of each other for prolonged or heparinized samples.
- F. Storage Requirements for HR-ACT cartridges:
 - 1. All cartridges should be stored at 2 to 25^o C, in their original packaging for reference to the appropriate expiration date.
 - 2. Do not use cartridges that have exceeded their expiration date.
 - 3. Do not freeze the cartridges.
- G. Universal precautions must be observed for collection and testing of patient blood samples. Disposable gloves must be worn when collecting specimens, performing test procedures and cleaning test equipment. Hands must be thoroughly washed with soap and water after removing gloves. Dispose of all materials in a sharps container.

VII CALIBRATION / CALIBRATION VERIFICATION:

A. Not Applicable.

VIII QUALITY CONTROL:

- A. Quality Control testing for the ACT Plus™ is performed using a combination of liquid controls and electronic (ACTtrac®) controls. According to the CLIA guidelines two levels of control for coagulation procedures must be performed every eight hours of patient testing.
- B. **Electronic Control:** Two levels of electronic quality control are performed each 8 hours of patient testing using the ACTtrac®. The two levels are 100 and 500 seconds. The ACTtrac® is a battery powered software controlled electro-mechanical verification device that checks the following functions of the ACT Plus™ as they relate to proper test cartridge function: flag sensor function, reagent delivery pin height, lift wire height, and three levels of clotting times. The ACTtrac® is used to identify instruments that no longer fall within mechanical calibration specifications.
1. To perform the 100 second ACTtrac® test:
 - (a) From the Main Menu, select ACTtrac® as the cartridge type.
 - (b) Then press the Quality Control button to open the QC Menu
 - (c) Select [98-102], press Enter.
 - (d) On the ACTtrac® select 100 seconds as the desired timer setting.
 - (e) Insert the ACTtrac® into the heating block of the ACT Plus™.
 - (f) Close the actuator heat block to initiate the test.
 - (g) Results will be stored as a quality control test.
 2. To perform the 500 second ACTtrac® test.
 - (a) Follow the above procedure with the following changes.
 - (b) Select [490 – 510] on the Quality Control Menu of the ACT Plus™. Press Enter.
 - (c) On the ACTtrac® select 500 seconds as the desired timer setting.
- C. **Liquid Controls:** Two levels of liquid controls are performed each day of patient testing for all ACT analyzers in use. All CLOTtrac® controls for ACT testing are prepared from sheep whole blood and are packaged with vials of deionized water for reconstitution. Note: cartridge and control lot numbers must be entered prior to testing. Refer to section on Bar Code Entry.
1. HR-ACT: Two levels of liquid controls, the CLOTtrac® HR normal and abnormal are performed for the HR-ACT.
 2. Storage and stability: Store controls in the refrigerator, between 2° and 10°C. Controls are stable until the expiration date on the package when stored at refrigeration temperatures. After reconstitution, they are stable at room temperature for 60 minutes.
 3. Bar Code Entry of Cartridge Lot and expiration date.
 - (a) Select [Cartridge Lot] from the Main Menu. Page 1 of the Cartridge Lot/Expiration Date screen will appear.
 - (b) When there is one lot currently in the database, scan the bar code located on the side of the cartridge box. The lot number and expiration date will automatically populate their respective fields.
 - (c) Press Main Menu to return to the main menu.
 - (d) When there are two lot numbers in the database, Select [Remove Lot].
 - (e) To remove one of the lot numbers, toggle to the appropriate lot number.

- (f) To delete the selected cartridge lot number, select [Remove Selected Lot]
 - (g) Scan the bar code on the cartridge box. The lot number and expiration date will automatically populate their respective fields.
 - (h) Press Main Menu to return to the main menu.
 - (i) In the event the bar code reader is not working, all information must be entered manually. Refer to the Operator's Manual for direction.
4. Bar Code Entry of Control Lot Number, Expiration Date and Range
- (a) From the Quality Control Menu select [Control Lot]
 - (b) When there is one lot currently in the database for a control type, first scan the bar code on the control box. The lot number and expiration date will automatically populate their respective fields.
 - (c) The operator **must** enter the manufacturer's range by selecting [Set Range]. The format for entering the control range is 3 digits for both low and high values.
 - (d) To confirm the entry press [Enter].
 - (e) To return to the quality Control Menu, select [Exit to Quality Control Menu].
 - (f) When a control type has two lot numbers entered for a control type, delete the selected control lot number by toggling to the appropriate lot and select [Remove Selected Lot].
 - (g) To enter the new lot number, scan the bar code on the control box. The lot number and expiration date will automatically populate their respective fields.
 - (h) To enter the range for the control, select [Set Range]. The format for entering the control range is 3 digits for both low and high values.
 - (i) To confirm the entry, press [Enter].
 - (j) To return to the Quality Control Menu, select [Exit to Quality Control Menu].
- D. Preparation:
1. Remove controls and deionized water diluent from the refrigerator and bring to room temperature for approximately 10 minutes.
 2. Add 1.8 ml of deionized water to the lyophilized sheep blood.
 3. Allow at least 10 minutes for adequate rehydration. **DO NOT AGITATE OR MIX UNTIL COMPLETELY REHYDRATED.**
 4. Shake the control vigorously to mix until the red blood cells are uniformly dispersed and the control is completely reconstituted.
- E. Performance:
1. To run liquid quality control, select [HR-ACT] as the cartridge type from the Main Menu.
 2. Select the Quality Control menu to perform the control test.
 3. Enter the User ID.
 4. Select the Control Type, Normal or Abnormal and press enter to confirm.
 5. Tap or shake the HR-ACT cartridge to re-suspend the kaolin activator prior to inserting it in the actuator heat block. Pre-warm the cartridge for at least 3-5 minutes.

6. Using a syringe and blunt tip needle, fill each cartridge chamber with the appropriate control to the level between the fill lines. Sample size is 0.4 ml per channel.
 7. Immediately, insert the cartridge into the ACT Plus™, and close the actuator heat block to initiate the test.
 8. ACT Plus™ will incubate the control sample for 300 seconds, and then begin the clot detection cycle.
 9. Clot formation is signaled by an audible tone, the actuator heat block opens and the results are displayed.
 10. Record the results on the quality control log sheet.
- F. Pass Criteria
1. Control must be within the range programmed into the ACT Plus™.
 2. The difference between the two channels is less than 10% for normal control and 12% for abnormal control.
 3. ACT Plus™ will display “PASS” if QC result is within the acceptance limits. It will display “FAIL” if results fail.
- G. Corrective Action for Failed Controls
1. Review the Quality Control Menu page to assure the correct level was selected. The menu defaults to the last test.
 2. Review the acceptance range on the package insert. If it differs greatly from the programmed range, notify the clinical labs POCT coordinator.
 3. Repeat using the same control lot.
 4. If the repeat fails, test the instrument with 2 levels of ACTtrac® if you suspect that it has been dropped or mishandled.
 5. If liquid control fails again, test controls on another lot of cartridges and instrument. Controls or cartridges may have deteriorated during storage.
 6. Document the failure in the ACT logbook. Notify the Anesthesia Workroom supervisor. Take the ACT Plus™ out of service until the problem has been solved.

IX PATIENT TESTING PROCEDURE:

- A. To perform an HR-ACT patient test, select HR-ACT from the Main Menu as the cartridge type. Press Enter to confirm.
- B. Enter the Patient Medical Record Number. Note: the cartridge and control lot numbers must be entered prior to testing, and all required quality control tests must be performed before patient testing.
- C. Enter the User ID.
- D. Tap or shake the HR-ACT cartridge to re-suspend the kaolin activator prior to use. Pre-warm the cartridge for at least 3-5 minutes.
- E. Using a syringe and blunt tip needle, fill each cartridge chamber to the level between the fill lines. Sample size is 0.4 ml per channel.
- F. Insert the cartridge into the ACT Plus™ and close the actuator heat block to initiate the test.
- G. Upon completion, clot formation is signaled by an audible tone and then the actuator heat block will open. The results are displayed per channel as well as the average and difference in seconds between channels.

X QUALITY CONTROL AND PATIENT DATA DOWNLOAD:

- A. Transmission of quality control and patient testing data may be performed via the floppy drive. Transmissions of results should be performed at the beginning of each month.
- B. The output mode for tracking result transmission should be set in the Instrument Parameters prior to placing the ACT Plus™ in service.
- C. Transmit patient results:
 - 1. From the Main Menu, select Transmit Test Results
 - 2. Insert a 3.5 –inch IBM formatted floppy disk into the floppy drive.
 - 3. Select Transmit Unsent Patient Tests, to transmit patient tests performed since the last transmission.
- D. Transmit quality control results:
 - 1. From the Main Menu, select Transmit QC Results
 - 2. Insert a 3.5 –inch IBM formatted floppy disk into the floppy drive.
 - 3. Select Transmit Unsent QC Tests to transmit patient tests performed since the last transmission.

XI REPORTABLE RANGE:

- A. The analyzer timing range is 6-999 seconds.
- B. Acceptable variation between the 2 channels for normal ACT is 10% and 12% for an abnormal or extended clotting. If the test fails these limits, repeat with a new sample.
- C. The HR-ACT cartridge is designed to maintain an average population response of approximately 100 seconds per unit of heparin.
- D. Measure ACT on a patient baseline sample before giving a bolus of heparin. Many factors affect clotting and ACT is repetitively measured to monitor heparin therapy during surgery.
- E. Samples that give unexplained abnormal values should be redrawn and tested.
- F. Results are documented on the perfusion or anesthesia record.

XII REPORTING RESULTS:

- A. Normal ACT for the Medtronic ACT Plus™ is based upon the patient's baseline.
- B. Panic Value is >10% variation on baseline sample or 12% on abnormal or extended clotting time sample.

XIII MAINTENANCE:

- A. Routine Cleaning: Clean the exposed surfaces of the actuator and dispenser and the instrument case using a cloth dampened with 10% bleach, isopropyl alcohol, methanol, ethanol, Liqui-Nox®, hydrogen peroxide, or mild detergent.
- B. The ACT Plus™ cleaning kit is used to clean the sensors and lift-wire in the actuator.
- C. Cleaning should be performed at least monthly and more frequently as warranted by use.
- D. Temperature Verification. Verification of the ACT Plus™ heat block should be performed once a month and may be done with a Temperature Verification Cartridge (TVC) that is supplied with the instrument.
 - 1. To use the temperature verification cartridge select [Temperature Adjustment] from the Quality Control Menu, enter User ID.
 - 2. Insert the TVC into the actuator heat block.
 - 3. Press the button on the TVC for temperature reading.
 - 4. After 5 minutes check the TVC reading.

5. Enter the reading from the TVC using the numeric keypad. The entered value will appear highlighted in the Thermometer Reading on the display.
 6. Press Enter to confirm.
 7. Select [Repeat Adjustment] variable function key to repeat the temperature adjustment if necessary. Wait 10 minutes before repeat adjustments are performed.
 8. The Instrument displayed temperature should read between 36.5° to 37.5° C.
 9. The range of the TVC is between 35°C and 39°C.
 10. The time, date and temperatures of the thermometer and the display will be logged in the instruments temperature log.
 11. To transmit the temperature log to the output location selected in the instrument parameters, select [Transmit Temperature Lot].
- E. Trouble shooting:
1. The ACT Plus instrument self-diagnosis many error and precautionary conditions, which are displayed on the LCD screen. The ACT Plus provides three types of messages to indicate its operating conditions: Information / Status: Alerts; and Systems Alarms. These messages, with the exception of Systems Alarms, appear in the screen's Status Message area.
 2. Information / Status: Screen message with no audio tone.
 3. Alerts: Screen message with a three-beep audio tone.
 4. Systems Alarms: Screen message with a single, long audio tone. Systems Alarms are presented when the ACT Plus's self-testing mechanism detects a condition that may affect the ability of the instrument to function properly. These messages are displayed, if possible, and may be accompanied by a 3 digit Error Code.
 5. Displayed Messages. The following is a list of the more common messages that may be displayed. Refer to the Operator's Manual for a complete list.

System Message	Cause / Resolution
Both lot # or cartridges lots full	Remove one of the existing lot number
Bar Code is not valid	Rescan the bar code, reprogram the scanner
Expired cartridge or control lot	Make sure that the expiration date on the packaging matches the date in the entry screen
Invalid password	Enter the correct password
Run ACTtrac™ from QC Menu	User needs to be in the QC Menu
No cartridge lot number active	Enter the cartridge lot number for this test type
Preventive Maintenance due	Call POCT coordinator to schedule a PM
QC Due: HH/MM	QC for this cartridge will run out at HH:MM
No Control lot number active	Enter a valid lot number for the control

XIV PROCEDURE NOTES:

- A. The HR-ACT is intended for use with fresh whole blood in the CVOR and Cardiac Cath Lab where the heparin concentration is 1.0 units/ml or greater.
- B. During cardiopulmonary bypass the HR-ACT may be affected by the following: dilution of plasma coagulation factors, the use of citrated blood products, use of anti-platelet agents, hypothermia, change in platelet number or function.

XV LIMITATIONS OF THE PROCEDURE:

- C. Patient response to heparin varies with the individual. Those with low levels of antithrombin III or high levels of Factor 8 are more resistant to the anticoagulant effects of heparin therapy. The amount of heparin required to produce an arbitrary prolongation of blood coagulation can vary as much as threefold from patient to patient. The rate at which administered heparin disappears from the blood varies with each patient.
- D. Various conditions and drugs affect the clotting time especially drugs that inhibit platelet activation. The following factors should be taken into consideration when interpreting ACT results: antithrombin III levels, heparin potency, patient coagulation deficiencies, consumptive coagulopathies, use of citrated blood products, excessive sample dilution by the extracorporeal circuit and sample temperature. Samples that give unexplained abnormal values should be repeated with a freshly drawn sample.

XV REFERENCES:

- A. Medtronic ACT Plus™ Operator's Manual, 2004.
- B. Medtronic ACTtrac™ Electronic Quality Control Operator's Manual, 2001.
- C. Product Inserts for the following Medtronic ACT Plus™ Cartridges and Controls:
 - 1. Medtronic ACT Cartridges (HR-ACT, LR-ACT, RACT), June 2003.
 - 2. CLOTtra® Normal and Abnormal Controls for the High Range ACT
- D. NCCLS Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline, AST2-A, Volume 19, Number 9, June 1999.
- E. NCCLS Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline-Third Edition, H21-A3, Volume 18, Number 20, December 1998
- F. NCCLS Clinical Laboratory Technical Procedure Manuals; Approved Guideline-Third Edition, GP2-A3, Volume 16, Number 15, December 1996.