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Title: Point of Care - Medtronics ACT Plus Procedure		
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TITLE: Medtronics ACT Plus™

PRINCIPLE: The ACT Plus™ is a microprocessor-controlled electromechanical coagulation instrument intended for determining coagulation endpoints in fresh 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.

The ACT Plus™ may be used to perform the following tests:

High Range ACT (HR-ACT):

The HR-ACT is a kaolin activated clotting time test performed on fresh whole blood for use in the Cardiovascular Operating Room, Cath Lab, PCU/ICU(by PCU staff), Interventional Radiology (Specials) where the heparin concentration is 1.0 unit/ ml or higher.

SPECIMEN:

Patient Preparation:

All tests: Blood may be obtained either by venipuncture or from arterial or venous access lines.

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. Refer to Phlebotomy Manual for venipuncture collection procedure.

Arterial or Venous Line Collection: Using separate, single use syringes, collect at least 5 ml 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 the line.

Specimen Type:

High Range ACT (HR-ACT): Fresh Whole Blood, 400 ul per cartridge channel

Specimen Handling:

Fresh whole blood specimens should be tested as quickly as possible following sample collection. Test within 60 seconds when the patient has not been heparinized. Test within 2 minutes when the patient has been heparinized.

All body fluids should be handled as if capable of transmitting infectious diseases. Use universal precautions when in contact with such materials. Refer to Laboratory Infection Control

Policy.

EQUIPMENT AND MATERIALS:

Equipment:

Medtronic ACT Plus™
Medtronic ACTtrac®
Temperature Verification Cartridge

Materials:

Syringes, no larger than 10 ml
19 gauge blunt tip needle or other blood collection needle

Cartridge Preparation:

Cartridges for ACT testing should be shaken or tapped to re-suspend the kaolin and pre-warmed for 3 to 5 minutes in the heat block of the ACT PLUS. Cartridges for HR-ACT may be pre-warmed for up to 12 hours.

Performance Parameters:

Duplicate clotting times for the HR-ACT should fall within 10% spread of each other for baseline or normal samples and 12% spread of each other for prolonged or heparinized samples.

Storage Requirements:

All cartridges should be stored in their original packaging for reference to the appropriate expiration date. **Do not** use cartridges that have exceeded their expiration date.

HR-ACT:

HR-ACT cartridges are stable at either refrigeration or room temperature (2° to 25°C) until the expiration date. Do not use cartridges that have evidence of evaporation or contamination.
Do not freeze the cartridges.

CALIBRATION:

Not Applicable.

QUALITY CONTROL:

Quality Control testing for the ACT Plus™ is performed using liquid controls or a combination of liquid and electronic (ACTtrac®) controls.

Electronic Control: 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.

To perform an ACTtrac® test:

Two levels of ACTtrac®, electronic QC, need to be performed every eight hours of patient use.
ACTtrac® is selected as the cartridge type from the Main Menu.

The electronic control is performed from the Quality Control Menu by inserting the device into the actuator, selecting the desired timer setting on the ACTtrac® and the corresponding control type in the ACT Plus™ software on the instrument.
Close the actuator heat block to initiate the test.
Results will be displayed on the screen and stored as a quality control test in the software on the instrument.

Action: If the electronic quality control results are not within the acceptable range, repeat the test. Ensure that the same timer setting is selected on the instrument as on the ACTtrac®. If the results are still unacceptable, no patient testing may be performed. Contact the Point of Care Specialist at x4643.

Liquid Controls: Two levels of liquid control are performed for all ACT tests. All CLOTtrac® controls for ACT testing are prepared from sheep whole blood and are packaged with vials of deionized water for reconstitution. When used in conjunction with the ACTtrac® electronic control, liquid controls should be performed every seven days and with a change in cartridge lot number.

HR-ACT: Two levels of liquid control (the CLOTtrac® HR normal and abnormal controls) are performed for the HR-ACT. The following preparation and procedure need to be performed for both levels of liquid control.

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. CLOTtrac® controls are stable for 1 hour following reconstitution.

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 (20 minutes for the abnormal liquid control). DO NOT AGITATE OR MIX UNTIL COMPLETELY REHYDRATED.
4) After the 10 minute rehydration period, shake the control vigorously to mix until the red blood cells are uniformly dispersed and the control is completely reconstituted.

Performance:

1) To perform the HR-ACT control test select or confirm HR-ACT as the cartridge type in the Main Menu.
2) Select the Quality Control menu to perform the control test. (Note: cartridge and control lot numbers must be entered prior to testing.)
3) Enter the User ID.
4) Select the Control Type (Normal or Abnormal) and press enter to confirm.
5) Pre-warm the cartridge for at least 3-5 minutes.
6) Tap or shake the HR-ACT cartridge to re-suspend the kaolin activator.
7) Using a syringe and blunt tip needle, fill each cartridge chamber with the appropriate control to the level between the fill lines (400 ul per channel).
8) Insert the cartridge into the ACT Plus™, and close the actuator heat block to initiate the test.
9) The ACT Plus™ will incubate the control sample for 300 seconds, and then begin the clot detection cycle.

10) Clot formation is signaled by an audible tone, the actuator heat block opens and the results are displayed.
11) Results are stored as a quality control test in the software on the instrument.

Action: If liquid quality control results are not within the acceptable range, repeat with a new cartridge. Ensure that the corresponding level is being run that is selected on the instrument. If the results are still not acceptable, rehydrate new bottles of liquid control, and repeat test. If still unacceptable, use a cartridge from a different box to run the test. If results are still unacceptable, no patient testing may be performed. Contact the Point of Care Specialist at x4643.

Note: The electronic quality control has been validated by running in tandem with the liquid quality control for 20 days, therefore the liquid quality control is run once every 7 days. The electronic quality control must be run every 8 hours of instrument use.

PATIENT TEST PROCEDURE:

PCU / ICU: Obtain lab barcode label prior to starting each test

1) To perform an HR-ACT patient test select or confirm HR-ACT as the cartridge type in the Main Menu.
2) Cartridge and control lot numbers must be entered prior to testing, and all required quality control tests must be performed before patient testing.
3) Enter the Patient ID (Scan the lab barcode label or patient ID arm band. If bar code ID label and/or arm band is not available, manually enter the patient medical record number or scan the patient's arm band).
4) Enter your User ID.
5) Pre-warm the cartridge for at least 3-5 minutes. Cartridges may be pre-warmed for up to 12 hours without affecting performance.
6) Tap or shake the HR-ACT cartridge to re-suspend the kaolin activator.
7) Using a syringe and blunt tip needle, fill each cartridge chamber with the appropriate patient sample to the level between the fill lines (400 ul per channel).
8) Insert the cartridge into the ACT Plus™, and close the actuator heat block to initiate the test.
9) Clot formation is signaled by an audible tone, the actuator heat block opens.
10) Several results are displayed on the screen at the completion of the test. See Patient Result Interpretation below.
11) Using the patient ID bracelet or the patient bar code label, and all results meet the acceptable criteria, the results will automatically cross to the patient record when the results are manually transmitted.
    All results flagged by the ACTPlus will stop in the QML Exception Q for review by Point of Care.

PATIENT RESULT INTERPRETATION:

Results are displayed upon completion of the test and are stored in the software of the instrument. Results must be transmitted following each test or at the completion of a series of tests. The HR-ACTAV is to be reported as the patient result only if the results obtained for HR-ACT1 and HR-ACT2 fall within 10% spread of each other for baseline (unheparinized) samples and within 12%

spread of each other for extended or heparinized samples

Displayed results:

HR-ACT1: Results in seconds obtained from the first test channel
HR-ACT2: Results in seconds obtained from the second test channel
HR-ACTAV: The average in seconds between CH1 and CH2
HR-ACTDF: The difference in seconds between CH1 and CH2
HR-ACTSP: The percent spread of the results from CH1 and CH2
Block Temp: 37C +/- 0.5C

CALCULATIONS:

The ACT Plus™ calculates the mean or average clotting time for the duplicate channels and the difference in seconds between channels when a High Range ACT test is performed.

Sample Calculation:

Channel 1 clotting time:	210 seconds
Channel 2 clotting time:	200 seconds
Mean clotting time:	205 seconds
Difference:	10 seconds
12% spread:	25 seconds

The difference of 10 seconds is less than 12% spread (25 seconds). The mean clotting time of 205 seconds is acceptable and can be reported.

REPORTING RESULTS:

Reporting Format: Activated Clotting Time is reported in seconds.

Reference Ranges:
HR-ACT: 110 – 142 seconds.

Reportable Range:
HR-ACT: 85 - 856 seconds

Procedures for Questionable Results: If patient results are in question, sample collection and testing should be repeated.

EXPECTED VALUES:

Coronary Artery Bypass	>450 seconds
Cardiac Cath.	>=300 seconds (during angioplasty)
Radiology Special Procedures	<170 seconds (sheath removal)
Progressive Care Unit (PCU)	<170 seconds (sheath removal)

PROCEDURE NOTES:

HR-ACT: 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. 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.

LIMITATIONS OF THE PROCEDURE:

Interfering Substances:

Activated blood specimens, either in-vivo (patient's coagulation mechanism activated) or in-vitro, due to improper sample collection and handling may cause erroneous results.

QUALITY CONTROL AND PATIENT DATA DOWNLOAD:

Patient and quality control data is transmitted to the result repository in Telcor's Quick Multi Link (QML) in the laboratory after testing is completed. Upon review, patient test orders will be edited and allowed to cross to the patient'sEMR if all testing and QC criteria are met

Transmit Quality Control and Patient results:

- JaveLin/Lantronix Box is on and connected to the network
- A serial cable from the JaveLin/Lantronix Box is connected to the ACT Plus
    1. From the Main Menu, select **Transmit Test Results**
    2. Select **Transmit Unsent Patient Results.** Wait for the black title bar to appear at the top of the screen documenting that the patient results have been successfully sent.
    3. Select **Transmit Unsent QC Results** Wait for the black title bar to appear at the top of the screen documenting that the QC results have been successfully sent.

MAINTENANCE:

Instrument Case Cleaning: clean the case routinely by wiping off dust and dried blood with a cloth dampened with water or one of the following chemicals; Sani®- Cloth (Red or PurpleTop container) or Chlorox® Germicidal wipes.

Actuator Assembly Cleaning: the actuator assembly should be cleaned at least once a month and more frequently if required. If blood should get into the actuator assembly it is critical that the analyzer is cleaned as soon as possible.
Use the materials in the cleaning kit to perform eh following cleaning procedure:

1. Dip the swab provided in the bottle of Liqui-Nox® solution.

2. Swab the flag lift wire, removing all blood.

3. Swab the inside of the actuator assembly cover , especially the detector and emitter areas of the photo-optical sensor. Error code 4.

4. Remove any excess Liqui-Nox® solution with a dry swab.

Temperature Verification: Verification of the ACT Plus™ heat block should be performed once a month with a Temperature Verification Cartridge that is supplied with the instrument.

Using the Temperature Verification Cartridge:

From the Quality Control menu:

1. Enter User ID.
2. Select [**Temperature Adjustment**].
3. Insert the Temperature Verification Cartridge into the actuator heat block.
4. Press button on the Temperature Verification Cartridge for temperature reading.
5. After about 5 minutes check the Temperature Verification Cartridge reading.
6. Enter the reading from the Temperature Verification Cartridge using the numeric keypad. The entered value will appear highlighted in the Thermometer Reading on the display
7. Press **Enter** to confirm.
8. Select [**Repeat Adjustment**] variable function key to repeat the temperature adjustment if necessary.

Note:

- The instrument displayed temperature and thermometer measured temperature must read between 36.5° to 37.5° C.
- The thermometer temperature should be within ± 0.5° C of the instrument displayed temperature.
- The time, date and temperatures of the thermometer and the display will be logged in

the instruments temperature log.

- Wait a minimum of 10 minutes before repeat adjustments are performed.
- Values must be between 36.5°C and 37.5°C.

Battery Replacement for Thermometer:

Use single 1.55 VDC button-size battery (SR41, VCC392 or LR41).

Instrument Comparison: Twice annually the ACT instruments located in the CVOR, Main OR, Cardiac Catheterization Laboratories, and Interventional Radiology will be checked for comparability of results.

REFERENCES:

1. Medtronic ACT Plus™ Operator's Manual, 2003.
2. Medtronic ACTtrac™ Electronic Quality Control Operator's Manual, 2001.
3. Product Inserts for the following Medtronic ACT Plus™ Cartridges and Controls:
   Medtronic ACT Cartridges (HR-ACT), June 2003.
   CLOTtrac™ Normal and Abnormal Controls for the High Range ACT
4. NCCLS Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline, AST2-A, Volume 19, Number 9, June 1999.
5. 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
6. NCCLS Clinical Laboratory Technical Procedure Manuals; Approved Guideline-Third Edition, GP2-A3, Volume 16, Number 15, December 1996.
7. Concord Hospital Guideline: Care of the Cardiac Catheterization/Interventional Patient; July 2006
8. Anesthesiology: Evaluation of Tests Used to Monitor Heparin Therapy during Extracorporeal Circulation; v43 no3 Sept 1975.

DISTRIBUTION	CVOR, Cath Lab, PCU, Specials Radiology, SCU.	
RESPONSIBLE DEPARTMENT/UNIT	Laboratory.	
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