MEDTRONIC HEMOTEC ACTIVATED CLOTTING TIME (ACT)

OPERATING PROCEDURE

PRINCIPLE:
The ACT test is a definitive test used to monitor the anticoagulant effect of heparin. It measures the clotting time of fresh whole blood activated by surface contact. The test cartridges consist of reaction chamber, a reagent chamber containing Kaolin, and a plunger assembly. Dual channels are utilized as a means to monitor precision. Upon initiation of a test, the reagent is injected into the reaction chamber. The plunger assembly is lifted and allowed to fall through the unclotted sample and as a fibrin web is formed during clotting, the fall rate of the assembly is impeded. The instrument detects this decrease in the fall rate by a photo optical system located in its cover.

SPECIMEN:
0.8 CC OF BLOOD IN A SYRINGE.

EQUIPMENT:
Hemotec ACT machine
High Range HR-ACT cartridge
3 cc syringe with needle
Gloves

CALIBRATION:
The ACT calibration procedure includes:

1. Self test—when the instrument is turned on it will run through a series of self-tests to internally calibrate the instrument.

2. Temperature calibration.
QUALITY CONTROL:

(See Medtronic ACT quality control procedure)

PROCEDURE:

1. Gloves are to be worn following standard precautions.
2. Verify the ACT machine is plugged in.
3. If needed, turn the instrument “on” allowing the unit to complete the self-test and allowing the heat block to come to 37°C ± 0.5°C.
4. Verify the ACT machine is at the proper temperature (37°C ± 0.5°C).
5. Verify the expiration date on the cartridge box has not been exceeded and examine the cartridge to be sure it is not cracked, discolored, or disfigured.
6. Warm the cartridge in the heater block for a minimum of 3 minutes.
7. Draw at least 0.8 cc of fresh whole blood.
8. Tap the HR-ACT cartridge to mix reagents and disengage any reagent clinging to the chamber walls.
9. Inject the blood sample into each reaction chamber to the second line of the cartridge until the blood reaches at least the minimum fill line (0.4 ml) of each chamber. Avoid getting sample on the flag plunger assembly.
10. Place the cartridge in the ACT machine and pull the cover forward to initiate the test.
11. The instrument will test for the formation of a clot measuring elapsed time. An audible tone signals termination of the test.
12. Observe the clotting times of both channels.
13. Depress the display switch to the right. Record the average (mean) of the two results if the difference of the two channels is less and 12% of the mean. If the precision is not within range, the patient results cannot be accepted.

CALCULATIONS:

No calculations are required for this procedure.

REPORTING RESULTS:

The baseline clotting time for the HR-ACT cartridge is 100-140 seconds. Sheath removal is at the discretion of the physician. (A value of less than 150-160 seconds is recommended by the manufacturer).

The Linearity of the instrument is 0-999 sec.
The reportable range is 0-600 sec. Results that fall above the reportable range limit must be reported as greater than 600 (>600).

**INTERFERING SUBSTANCES:**

The response of the activated clotting time to heparin varies considerably from individual to individual. Various drugs affect the activated clotting time; in particular, drugs which inhibit platelet activation. A number of other factors can affect the response of an individual’s ACT to heparin (e.g. antithrombin III levels, heparin potency, coagulation factor deficiencies, sample activation consumptive coagulopathies, excessive sample dilution, and sample temperature) and should be taken into account when interpreting the results of activated clotting time tests.

**LIMITATIONS OF PROCEDURE:**

1. Both the instrument heat block and cartridge temperature should be at 37 +/- 0.5°C.
2. Activator must be thoroughly resuspended.
3. Blood must be free of tissue thromboplastin and run as soon as possible after drawing (fresh specimens).
4. Patient diagnosis and medications should be noted. Medications can alter clotting times.
5. To optimize precision, all technique variables should be held constant from test to test.

**REFERENCES:**


Np/poc/medtron
Temperature Calibration of the ACT II

1. Turn the automated coagulation timer on and allow the instrument to warm up for 5-10 minutes.

2. Insert the Temperature Verification Cartridge in the actuator. Wait for temperature equilibration to occur (about 15 min) and check the thermometer reading. The instrument temperature and actual measured temperature should both read within 36.5°C to 37.5°C. The measured temperature should be within +/-0.5°C of the instrument temperature.

3. If the temperature of the heat block lies outside of this range, the temperature can be adjusted with the screwdriver using the rear panel temperature adjustment labeled TEMP. **Clockwise** rotation increases the temperature of the heat block and **counterclockwise** rotation decreases the temperature of the heat block.

4. If the front panel display and the thermometer reading (+/-0.5°C) will not calibrate, contact the Medtronic Hemotec Technical Service (800-525-7007). **Do not use the instrument unless the Heat Block Temperature Verification is acceptable.**

5. Document the Heat Block Temperature Verification by recording the measured well temperature and display temperature on the Activated Clotting Time Quality Control and Maintenance Record.

**MONTHLY CLEANING PROCEDURE:***

It is important to clean the instrument at least once every 30 days or more as required. If blood should get into the actuator cover, it is critical that the instrument be cleaned as soon as possible dip the swab, provided in the Actuator Cleaning Kit, in the LiqiNox Solution. 

1. Swab flag-lifters, removing all blood.
2. Swab inside of actuator cover, especially the detector and lamp area (photo-optical system.)

If blood should get into the detector or lamp area and cannot be removed with a swab, error code 4, 5, 6 or 7 may be displayed. If this occurs, contact Medtronic Hemotec Technical Service (800-525-7007).

**REFERENCES:**

MEDTRONIC HEMOTEC ACTIVATED CLOTTING TIME (ACT)
QUALITY CONTROL PROCEDURE

PRINCIPLE:

The ACTtrac Electronic Control Device is a microprocessor-controlled instrument Verification cartridge for use with the ACT or ACTII coagulation instruments. The ACTtrac is used to maintain and demonstrate proper functioning of the ACT instrument.

EQUIPMENT AND MATERIALS:

HemoTec ACT instrument

ACTtrac timer

1.0 CALIBRATION:

The ACTtrac has been designed to identify instruments that are no longer in calibration due either to normal wear associated with portable instrumentation or inadvertent mistreatment. Instrument calibrations can also be adversely affected by failing to routinely clean the instrument. The ACTtrac is capable of detecting out-of-calibration instrument states which are not detected by the self-test parameters of the instruments’ software system.

1.1 The ACTtrac has been designed to detect the following out-of-calibration states:

1.1.1 Instrument push rod adjustment: At the beginning of a test, the instrument push rods force the bottomplug of the assay cartridge up, delivering the reagent to the reaction chamber. If this adjustment shifts out of calibration, not all of the reagent is injected into the sample and test variability (see attached). The sections of the ACTtrac housing that contact and interface with the instrument(s) have been designed to mimic the assay cartridge. The main part of this interface is the tube component. Located inside each tube is a mechanism that determines if the instrument push rods are in proper adjustment. Properly adjusted push rods will actuate this mechanism and cause the ACTtrac to power up and flash a top panel indicator three times. This indicates to the user that the ACTtrac has powered up and that the instrument push rods are in proper adjustment. If the instrument push rods are not properly adjusted, the mechanism will not be activated and the ACTtrac will not power up and flash the
indicator. This indicated to the user the instrument push rods are out of adjustment. The instrument should not be used to perform tests until this situation is corrected.

1.1.2 **Instrument assay cartridge plunger lift adjustment**: The plunger assembly is the cartridge component which both mixes the blood sample with the injected reagent and is the primary clot detection mechanism. The rise and fall of this plunger assembly (consisting of the flag, plunger, and daisy) is monitored by an optical system in each instrument which follows the motion of the flag portion of the plunger assembly. As a clot forms, the movement of the plunger assembly through the sample is impeded. The optical system detects this fall rate decrease and triggers an end of test. The accuracy of the clotting test is due in part of the daisy having been lifted to the proper sample. It is the instrument lifting mechanism for the plunger assembly that controls the maximum lift height for the plunger assembly during the performance of a test. The ACTtrac plunger component is designed to match the physical dimensions of the assay cartridge plunger. The ACTtrac has been designed to allow the ACTtrac plunger to be captured in the raised position. This allows the ACTtrac to emulate an assay cartridge in which a clot has formed. If the instrument plunger lifted assembly is out of adjustment, the plungers of the ACTtrac will not be lifted to their capture positions and the simulated clot will not occur at the user preselected time. This condition tells the user the instrument under test is out of adjustment and should not be used for clotting tests without first being serviced.

2.0 **QUALITY CONTROL**:

2.1 A normal and abnormal control must be performed every 8 hours the instrument in use. The ACTtrac can be used in place of liquid controls. However the lab has established liquid control (see liquid QC section 6.0) must be used at a minimum of once per week and with lot number changes. Proper documentation must be kept in the Quality Assurance record.

3.0 **PROCEDURE**:

3.1 Choose two ACTtrac time settings. One should be representative of a normal clotting time (98-102), the other an “abnormal or extended” clotting time (490-510).
### 3.2 Set the time selection for 98-102.

3.3 Place the ACTtrac into the actuator heat block and push the heat block back.

3.4 If the instrument is properly positioned, the status indicator will flash 3 times and the test will continue until it reaches the preselected clotting time.

3.5 Upon termination of the test, the instrument will sound an audible tone and the clotting time results will be displayed.

3.6 Verify the results obtained are within the range chosen and record results on the Quality Assurance record.

3.7 If the results are outside the preselected range, repeat the test. If the results are still outside the preselected range, contact Medtronic HemoTec technical service and fill out a “Quality Assurance Failure” report.

3.8 Repeat testing using the abnormal or extended time setting (490-510) and record results.

### 4.0 PROCEDURAL NOTES:

4.1 If the “stop” button is pressed on the Act instrument before the ACTtrac has finished its test cycle, the ACTtrac battery cover and battery must be removed and reinserted to reset the device.

4.2 The exterior surface of the ACTtrac should be cleaned with a mild detergent, as required. A swab moistened with detergent solution or hydrogen Peroxide can be used to clean the outside housing.

4.3 The top panel battery indicator illuminates when the battery voltage decreases and will remain on until the battery is replaced. The ACTtrac requires a single 1.5 volt AA battery.

### REFERENCE:

MEDTRONIC HEMOTEC ACTIVATED CLOTTING TIME (ACT)
QUALITY CONTROL PROCEDURE (Liquid Controls)

PURPOSE:

Quality control must be performed every 8 hours when the instrument is in use by a staff member proficient in ACT testing. Two levels of control will be performed. The liquid controls (CLOTtrac HR control and CLOTtrac HR Abnormal Controls) must be performed at a minimum of once per week and with each lot number change. The ACT trac electronic control device may be used for all other QC testing (see Medtronic Hemotec ACT procedure).

PRINCIPLE:

Citrated whole coagulation controls are utilized to verify the correct functioning of both The test cartridges and the instrument. Obtaining quality controls (QC) values within established ranges is also an indicator of operator proficiency.

1.0 EQUIPMENT AND MATERIALS:

1.1 Reagent composition:

1.1.1 CLOTtrac HR coagulation controls:
Lyophilized citrated whole blood (stabilized sheep red cells and plasma)

1.1.2 CLOTtrac Normal coagulation controls:
Lyophilized citrated whole blood (stabilized sheep red cells and plasma)

1.1.3 Non-sterile, deionized Type I reagent grade water.

1.1.4 HR-ACT cartridges:
Contains standardized kaolin as the activating agent.

1.2 Reagent storage requirements:

1.2.1 CLOTtrac HR coagulation controls and deionized water are stored at 2-10 degrees centigrade.
The expiration date of the controls and water is dictated on the vial label and refers to the end user date when stored under refrigerated conditions. Do not use vials beyond manufacturer’s expiration date.

Once reconstituted, the control is stable for 1 hour at room temperature (15-25 degrees centigrade).

Reagent precautions:

1. Intended for in vitro diagnostic use only.

2. Even though the control material is of non-human origin, all biological samples should be considered potentially hazardous and handled appropriately.

3. The deionized water is intended for single use only (to prevent contamination) and should not be used for any purpose other than reconstitution of controls with which they are shipped.

2.0 Procedure:

Reconstitute control.

1. Remove required number of CLOTtrac coagulation control and deionized water vials from refrigeration.

2. One control vial and one water vial will provide enough reconstituted sheep’s blood to test two ACT instruments with two dual chambered HR-ACT cartridges.

3. Using a 3 cc syringe, add 1.8 ml deionized water to each vial of lyophilized control.

4. Do not agitate the control until completely rehydrated.

5. Allow at least 2 minutes for adequate rehydration.

6. Inadequate hydration time may result in erratic QC results.
2.2 Once rehydrated, shake the control vigorously until the red blood cells are uniformly dispersed and the control is completely reconstituted.

2.3 Shake the cartridge to resuspend the cartridge reagents.

2.4 Do not use controls past the indicated expiration date. Once reconstituted, the controls is stable for 1 hour at room temperature.

3.0 Test Control

3.1 Using a syringe, transfer 0.4 ml of reconstituted control into each channel of the cartridge.

3.1.1 Fill to between the fill lines etched on each channel body.

3.2 Turn on the INCUBATE SWITCH which is located on the front panel of the instrument.

3.3 Place the filled cartridge into the instrument. Push the heat block back.

3.3.1 The test will automatically initiate after 300 seconds.

3.4 When the clot formation has been detected, an audible tone sound, indicating termination of the test.

3.5 Record the results displayed from both channels on the “HemoTec Quality Control Log.”

3.5.1 Channel #1 is the upper display.
3.5.2 Channel #2 is the lower display.

3.6 Depress the Display switch to the right. Record the mean (average) and the difference between the two results on the “HemoTec Quality Control Log.”

3.6.1 Mean (average) is the upper display.
3.6.2 Difference is the lower display.

4.0 Interpret of QC Values.

4.1 QC range check:
4.1.1 Verify that the results from both channels fall within the range established for the lot number of CLOTtrac control in use.

4.1.2 The established ranges are listed under the “Expected Results” section of the CLOTtrac product insert, which is included with every box of controls.

4.1.3 The ranges are documented on the “Hemo Tec ACT Quality Control Log” whenever a new lot is initiated.

4.1.4 Upon delivery of each new lot number of CLOTtrac control material, the manufacturer’s range will be validated.

4.1.5 Document QC range check on the “HemoTec ACT Quality control Log.”

4.2 QC precision check:

4.2.1 Calculate 12% of the mean.

4.2.2 Verify that the difference between the results obtained from both Channels does not exceed 12% of the mean.

4.2.3 Document QC precision check on the “HemoTec ACT Quality Control Log.”

5.0 Take corrective action for failed QC. If the results obtained fail the QC range check and/or the QC precision check, the following actions should take place:

5.1 Ensure that the instrument has successfully completed its start-up internal check.

5.1.1 If necessary, perform start-up internal check. Refer to the “Hemotec ACT Preventative Maintenance” procedure for detailed instructions.

5.2 Ensure that both the cartridge and the control solution are at 37+/ -0.5 degrees centigrade before initiating the test.

5.2.1 Use the INCUBATE option to ensure this.
5.3 Ensure that the cartridge and control in use have not exceeded their respective expiration date.

5.3.1 Report outdated controls/cartridges to the Supervisor.
5.3.2 Remove outdated stored controls/cartridges from service.
5.3.3 Obtain controls/cartridges which are within their expiration date for repeat testing.

5.4 Ensure that the control was properly reconstituted.

5.4.1 If necessary, reconstitute a fresh vial of control.

5.5 Inspect the control vials for visible clot formation.

5.5.1 Discard vial if clots are present.
5.5.2 If necessary, reconstitute a fresh vial.

5.6 Ensure that the control and cartridge have been properly stored.

5.6.1 Report improperly stored controls/cartridges to the Supervisor.
5.6.2 Remove improperly stored controls/cartridges from service.
5.6.3 Obtain properly stored controls/cartridges for repeat testing.

5.7 Ensure that the actuator is free of blood.

5.7.1 Clean if necessary. Refer to the “Hemotec ACT Preventive Maintenance” procedure for detailed instructions.

5.8 Repeat QC testing.

5.8.1 If the repeated QC results fails the QC range check and/or the QC precision check, immediately report the problem to the Department Supervisor.

5.8.2 The Department Supervisor will evaluate whether the failed QC is related to a specific lot of HR-ACT cartridges, a specific lot of control, or instrument function. The supervisor may contact the PLM Quality Assurance Coordinator for assistance.
5.8.3  Affected lots of cartridges/control will be removed from service and returned to the manufacturer for replacement.

5.8.4  HemoTec, Inc. will be notified of instrument failures. The instrument will be removed from service and a loaner instrument will be obtained from HemoTec, Inc.

5.8.5  Once the above steps have been performed, document the QC run information and all corrective action on the “HemoTec ACT Quality Control Failure Report.”

6.0  Frequency of QC Testing

6.1  On Monday or first case of the week, electronic and liquid QC testing will be done. Thereafter, electronic QC every 8 hour shift.

REFERENCES:

Medtronic HemoTec, Inc.: “CLOTtrac Coagulation Control” insert; Parker, Colorado:1996.