Dignity Health
Central Coast Service Area Procedure

Central Coast Service Area North:

☒ Santa Maria Campus, Marian Regional Medical Center ☐ Arroyo Grande Campus, Marian Regional Medical Center ☐ French Hospital Medical Center

Central Coast Service Area South:

☐ St. John's Pleasant Valley Hospital ☐ St. John's Regional Medical Center

SUBJECT: HR-ACT Testing using the Medtronic ACT Plus Instrument

I. PURPOSE:

To provide guidance on using the Medtronic ACT Plus instrument to test whole blood using the HR-ACT cartridge.

II. CLIA COMPLEXITY:

Moderately Complex

III. CLINICAL UTILITY:

The Medtronic ACT Plus® Automated Coagulation Timer is a microprocessor-controlled electromechanical coagulation instrument intended for in vitro determination of coagulation endpoints in fresh and citrated whole blood samples.

IV. PRINCIPLE:

Test reactions occur at 37°C ±0.5°C in single use cartridges placed in the Actuator Heat Block Assembly. Fibrin formation is the endpoint of tests performed on the ACT Plus® instrument. 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 timed intervals through an unclotted sample. The fibrin web formed during clotting impedes the fall rate of the plunger and is detected by a photo-optical system located in the ACT Plus® instrument's actuator assembly. Tests are performed in duplicate, and the clotting time results are displayed on the red Light Emitting Diode (LED) display and on the Liquid Crystal Display (LCD) screen of the ACT Plus® instrument.

V. TESTING LOCATIONS

Operating room

VI. OPERATORS

CVOR perfusionists certified by the Point of Care Coordinator

VII. SPECIMEN COLLECTION:

Sample Type	Container	Minimum Volume	Stability
Whole blood	Syringe	400 uL per channel	Baseline – test immediately Heparinzed samples – test within 2 minutes

VIII. MATERIALS:

Reagents / Media	**Supplies / Materials**	**Equipment**
• HR-ACT cartridges • CLOTtrac controls	• Syringe • 19 gauge blunt needle • Actuator Cleaning Kit • Temperature Verification Cartridge	• Medtronic ACT Plus

A. HR-ACT Cartridge Storage
   1. Store from 1-25°C
   2. Store in original tray to reference expiration date
   3. Do not use if cartridge appears damaged or contaminated or expired

B. CLOTtrac control Storage
   1. Store at 2-10°C
   2. Expiration date is on vial label
   3. Do not use past expiration date

IX. MAINTENANCE

A. Routine Cleaning

   Clean case after each use with hospital approved disinfecting wipes

B. Monthly
   1. Clean actuator assembly using Actuator Cleaning Kit
      a) Dip swab into the Liqui-Nox solution
      b) Swab the flag lift wire removing all blood
      c) Swab the inside of the actuator cover, especially the detector and emitter area of the photo-optical system
      d) Remove excess Liqui-Nox with a dry swab
   2. Heat Block Temperature Verification
      a) Turn the ACT Plus® instrument ON and allow the instrument to warm up for 15 minutes.
      b) Place the Temperature Verification Cartridge into the actuator heat block.
      c) Wait for temperature equilibration to occur (minimum 10 minutes) and check the Temperature Verification Cartridge reading.

1) The instrument-displayed temperature and the Temperature Verification Cartridge temperature should both be within 36.5°C to 37.5°C.

2) The Temperature Verification Cartridge temperature should be within ± 0.5°C of the instrument-displayed temperature

d) From the Quality Control Menu:

1) To change the temperature, if needed, or to record that the temperature has been verified, select [Temperature Adjustment].

2) Enter the temperature verification cartridge reading using the numeric keypad (values must be between 35°C and 39°C).

3) To accept the entry, press [Enter]. The time, date, and temperatures of the temperature verification cartridge and the display will be recorded in the temperature log.

e) **N**ote: If the temperature is still not within the specified range, adjustments can be repeated after a minimum of 10 minutes. To repeat adjustments, select [Repeat Adjustment].

f) If temperature calibration cannot be achieved, do NOT use instrument and request service

X. CALIBRATION

Instrument calibration performed by Medtronic Service technician annually

Temperature Verification Cartridge must be validated by the laboratory annually

XI. INDIVIDUALIZED QUALITY CONTROL PLAN

The original Risk Asessment and IQCP was performed and analyzed in March 2016. Please refer to IQCP binder in the Laboratory Managers office

A. Risk Assessment – **Low**

Scoring Based on Risk Identification and Mitigation in place.
Annual Review and reassessment is required.

B. Quality Control Plan

1. Self Test

a) Performed after instrument is started

b) IF self test fails, record error code and call for service

2. Liquid Quality Control

a) Quality Control Material

1) CLOTtrac Normal control

2) CLOTtrac Abnormal control

3) Store refrigerated 2-10°C

4) Expiration date is indicated on the vial label

5) Reconstituted controls are stable for 2 hours at room temperature

b) Frequency of performance

1) Each new box of cartridges

2) If 7 days has passed since the last successful liquid control run
3) After major maintenance or calibration
4) If instrument performance is suspect

c) Acceptable ranges are lot dependent (see sticker on controls)

d) Reconstitute prior to use
1) Remove vial of control and deionized water vial from refrigerator
2) Add 1.8 mL of deionized water using a syringe.

Do NOT agitate the control until completely rehydrated
3) Let sit a minimum of 10 minutes for rehydration
4) Once rehydrated, shake the control vigorously until the suspension is uniformly dispersed and the control is completely reconstituted
5) Repeat for other control

e) Procedure
1) From the Main Menu, select or confirm that the cartridge type is set to HR-ACT
2) From the QC menu, select HR Normal Control
3) Transfer 0.4 mL of reconstituted control into each channel of the cartridge
4) Fill to between the fill lines etched on each channel body
5) Place the filled cartridge into the instrument and close the actuator heat block to start the test
6) Clot formation is signaled by an audible tone, the opening of the actuator heat block and the displaying of results
7) Record results on quality control log

f) Acceptable results
1) Each channels results are within stated range
2) Mean of the two channels is within the stated range
3) Less than 10% variability between the individual channel results
4) Do NOT use if quality control results are unacceptable
a. Repeat using freshly reconstituted quality control material
b. If still unacceptable, do NOT use instrument and call for service

3. Electronic Quality Control

a) Perform every 8 hours of patient testing

b) Procedure
1) Set the Medtronic ACTtrac time selector to 98-102 seconds (normal) and place ACTtrac into the heat block wells
2) Push the block forward to activate the beginning of the timer
3) When complete, record results on quality control log
4) Repeat after setting time selector to 490-510 seconds (abnormal)

c) Acceptable Results

1) Normal – 98-102 seconds

2) Abnormal 490-510 seconds

3) Do NOT use instrument if results are unacceptable

Repeat once, if still unacceptable do NOT use instrument and call for service

C. Quality Assurance

1. Monthly review of Quality Controls and any corrective action documented
2. Monitoring of the environmental conditions per Policy and Procedure
3. Monitoring of physician/clinician complaints, iVOS (occurrence reports), and patient safety event forms. All reports are reviewed, thoroughly investigated, and addressed.
4. Review of any applicable Proficiency Testing result outliers.
5. Review of any ECRI Institute – Health Device Alerts (HDA), Manufacturer notifications/recalls, technical bulletins or memorandums.
6. The iQCP will be updated when applicable and presented to the Medical Director for review/approval.

XII. PROCEDURE

A. Select HR-ACT from the Main Menu. Press Enter to confirm

B. Enter the patient medical record number

Note: cartridge and control lot numbers must be entered prior to testing, and all quality control tests must be performed prior to patient testing

C. Gently tap or shake the HR-Act cartridge to resuspend the kaolin activator

D. Place cartridge into heat block and prewarm for at least 3 minutes

E. Cartridge can be warmed up to 12 hours without affecting performance

F. Collect sample using a syringe

G. Attach and prime the blunt tip needle

H. Fill each cartridge chamber to the level between the lines (approximately 400 uL)

I. Insert cartridge into the instrument

J. Rotate the actuator forward to the closed position to start the test

K. Clot formation is signaled by an audible tone and the actuator heat block will open

L. Results are displayed for each channel as well as the average and difference in seconds between the means

M. Discard cartridge

XIII. RESULT REPORTING

A. Acceptable Results

1. Difference between the two channels must be <12%; 10% for baseline sample
2. Unexplained values should be repeated

B. Reference Range

   Based on heparin dose

C. Assay Range

   25-999 seconds

D. Values are documented directly on the perfusionists record

E. Critical Value

   Not applicable

XIV. LIMITATIONS OF PROCEDURE

A. Both the instrument heat block and cartridge temperature should be at 37°C ± 0.5°C.

B. It is critical to clean the instrument as soon as possible if blood contaminates the light path.

C. The kaolin activator must be thoroughly resuspended prior to introduction of the test sample.

D. The test sample must be free of tissue thromboplastin and tested as soon as possible following collection.

E. Patient diagnosis and medications should be noted. Medications can alter clotting times.

F. To optimize precision, all technique variables should be held constant from test to test.

G. A prolonged activated clotting time is not specific for heparin. Prolonged ACTs may be due to heparin, other anticoagulant drugs (warfarin, direct thrombin inhibitors), hemodilution, administration of large volumes of citrated blood products, some antiplatelet drugs, hypothermia, severe thrombocytopenia, markedly abnormal platelet function,

H. Excessive blood dilution during bypass can lead to postsurgically hemodiluted patients. This dilution can be great enough to extend the activated clotting time.10 In severe instances, the dilution may lead to an unmeasurable clotting time.

XV. REFERENCES:

A. Medtronic ACT Plus Operators Manual

B. Medtronic Activated Clotting Time Cartridges Instructions for Use

C. Medtronic CLOTtrac High Range (HR) Normal Coagulation Control Instructions for Use

D. Medtronic CLOTtrac (HR) Abnormal Coagulation Control Instructions for Use

E. Medtronic ACTtrac Electronic Quality Control Instructions for Use