Wake Forest™
Baptist Medical Center

Point-of-Care Testing
Hemochron Response ACT
Education Module

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Disclaimer

- This presentation does not include all information regarding ACT testing. It only highlights information.

- For complete information, refer to the Hemochron Response ACT procedure,“Activated Clotting Time (ACT) Determination at Point-of-Care Testing Sites Using the Hemochron Response ACT Timer System”.

- The procedure can be found on the WFBMC Intranet—Departments—Point of Care Testing—Policies/Procedures/Guidelines

All ACT's are not created equal

- ACT values differ depending on the analyzer and clot activator used.
- Know your site's method and clot activator.
- Do not assume all other site's ACT results will match results you obtain on your tubes and equipment.

Hemochron Support

- Hemochron Technical Support 1-800-631-5945
- WFBH Clinical Engineering
- Clinical Laboratory Point-of-Care Testing Coordinator
- Refer to the Hemochron Response Operator’s Manual and WFBMC ACT procedure
- Contact the ECMO Coordinator

Hemochron Response Operator ID

- User specific
- Serves as identification of testing personnel
- **Do NOT share operator ID's**

Safety

- Always wear gloves when handling analyzer
  - Including patient testing and performing QC
  - Disinfect analyzer when contaminated with blood AND between EVERY patient
  - Routine external cleaning is recommended for infection control purposes
- DO NOT use a sharp needle when filling the ACT tube
- When performing p214/215 ACT liquid QC, use the plastic protective sleeve to cover the liquid QC vial when breaking it.

Basic Principle of ACT Testing

- Fresh whole blood is added to a test tube containing an activator and timed for the formation of a clot.
- The test tube is inserted into a Hemochron instrument and mechanical detection of a fibrin clot in the blood sample automatically terminates the test causing the instrument's digital timer to display the coagulation time in seconds.
- The mechanism consists of a precision aligned magnet within a test tube and a magnetic detector located within the test well.
- Following insertion of the test tube containing a whole blood sample into the well, the magnetic detector senses a magnet within the test tube as the tube slowly rotates.
- When the clot begins to form, it causes the magnet to lift within the tube.
- Since the magnet has been displaced, it is no longer sensed by the instrument’s magnetic detector. The instrument gives an audible beep and displays the coagulation time.

Hemochron Components

- Analyzer
- Tubes
- Electronic Quality Control Probe
- Liquid Quality Control Materials

Hemochron Response Analyzer

- Dual well
  - Multiple ACT's can be performed simultaneously

- Can operate via battery power for short period of time.
  - % battery charge will display on the screen

Hemochron Response Analyzer

- To Power ON the Analyzer:
  - (Should be done prior to QC/Patient Testing)
    - Press START 1 or 2 Keypad
- Check that Self-Tests are OK
- Troubleshoot if a Self-Test FAILS
  - Do NOT use the device for patient testing until failure is resolved

Required Information Entered into Hemochron Response

- User specific operator ID
- Patient medical record #
  - Do NOT enter a bogus patient ID
  - The Hemochron database serves as an audit resource

Tubes Used by ECMO

- P214/p215
  - Glass bead clot activator
  - **ONLY used by ECMO**
  - Sample volume=EXACTLY 0.4cc added to the ACT tube

Electronic Quality Control (EQC)

- ONLY verifies performance of ACT analyzer
- The QC probe should be handled carefully—DO NOT drop
- 2 Levels of EQC must be performed each 8 hours of patient use

To Perform Electronic QC

- Use the Multi-Level QC Probe
- **ON THE ANALYZER**: Press START 1 or 2 keypad, corresponding to the desired well for QC Performance.
- **ON THE QC PROBE**: Immediately press the keypad of the desired level of QC. (100, 300, 500)
- Insert the QC probe into the analyzer. The QC probe should begin to turn
- Enter your PIN # and press YES
- Enter the ESV serial # (located on the back of the QC probe) and press YES.
- When the QC probe has completed the test cycle, verify that the QC results are within acceptable limits.
- Document on the QC Log.
- Remove the QC probe from the analyzer.

Documentation

- Accurately document patient and quality control values.

Quality Control Troubleshooting

- If all **3 lights flash** at any time on the EQC probe, change the batteries.
  - If the batteries are low, then EQC failures will occur.

- If **EQC fails** try the following:
  - Repeat the same level in the same test well
  - Try changing the EQC batteries
  - Try a different EQC probe
- If **EQC continues to fail**:
  - Perform BOTH levels of liquid QC in BOTH test wells.
    - If liquid QC passes, consider the EQC probe is faulty.
    - Contact Clinical Engineering or ITC Tech Support for a replacement probe.
- **If liquid QC fails:**
  - Do NOT use the analyzer or tubes for patient testing.
  - Contact Clinical Engineering for troubleshooting assistance.

- **Document all actions on the problem log or on the back of the QC record. An accurate audit record should be maintained.**

Analyzer handling prior to sending to Clinical Engineering

- Clean the outside of the analyzer with Caviwipe or approved bleach wipe.
- Ensure there are NO blood/body fluids on the device.
- Download the analyzer and save data to shared file. Contact site manager for assistance.

Analyzer Re-Implementation Post Repair

- If an analyzer goes to Clinical Engineering or ITC Tech Support for check or repair, ALL of the following MUST be completed PRIOR to patient use:
  - Perform BOTH levels of EQC in BOTH test wells
  - Perform BOTH levels of liquid QC in BOTH test wells
  - ALL QC results must be within acceptable limits
  - Perform patient sample comparison with another Hemochron analyzer
  - Confirm correct analyzer programming:
    - Correct date and time
    - QC and operator lockouts
    - Operator ID’s programmed into the analyzer
    - Patient ID entry required
- An analyzer post-repair checklist MUST be completed and returned to the Clinical Laboratory Point-of-Care Testing Coordinator

Liquid Quality Control

- Used to validate performance of ACT tubes
- Also validates performance of analyzer and operator
- Consists of 2 levels—normal and abnormal
- Should be performed:
    - On each new box of ACT tubes PRIOR to patient use—by user site staff
    - Weekly—on one analyzer. All analyzers should have liquid QC performed each month—by user site staff
    - If ACT tube/analyzer performance is in question
- Follow instructions in the ACT procedure
- Confirm that EQC has not “timed out” before beginning liquid QC process.

Liquid Quality Control

- Acceptable ranges can be found on the lot specific insert that comes with each box of ACT liquid QC.

- Liquid QC results MUST be documented on the ACT liquid QC log for the permanent record.

Quality Control Documentation

- Document ALL QC values on the QC logs, including QC failures. This helps track on-going problems.

- The daily EQC log MUST have QC values or “Not in Use” (NIU) documented for each 8 hour QC slot.

- If you document NIU, you must sign/initial next to NIU.

Quality Control Responsibility

- If you perform patient ACT testing, you are responsible for ensuring the required QC has been performed on the analyzer and ACT tubes.

- The analyzer will display time left before next required EQC is due. Check before attempting to perform patient or liquid QC testing.

- Everyone who performs patient testing must also perform electronic and liquid QC sometime during the year.

- NEVER use an analyzer or tubes for patient testing if required QC checks are not within acceptable limits.

Hemochron Response Maintenance

- Check/clean fan filter each month, as applicable

Sample Requirements

- **<u>ONLY</u> <u>FRESH</u> <u>whole blood</u> should be tested on the Hemochron Response**

- Arterial or venous blood is acceptable

Sample Considerations

- Testing should be performed IMMEDIATELY after collection.
- Any delay in testing will alter ACT results
- NEVER use a sample collected in a heparinized syringe.
- Only a sample collected in a plain syringe with NO anti-coagulant is acceptable.

Sample Considerations—Samples Collected from In-Dwelling Lines

- Always adequately “clear” line prior to collecting a sample for ACT testing

- Inaccurate results will be given if samples are contaminated.

Factors affecting results

- Commons factors include:
  - Improper sample volume added to ACT tube
  - Improper mixing of blood with clot activator
    - P214/215 tubes should be flicked 5 times and not inverted
  - Delay in sample testing—run sample immediately after collection

Factors Affecting Results

- Improperly stored ACT tubes
  - Too cold or too warm
  - DO NOT refrigerate tubes
- Diluted samples
  - Improper collection
  - Contamination by IV fluids
- Certain medications
- Refer to the ACT procedure and ACT tube package insert for a complete list

Patient identity

- Follow WFBH policy for verification of patient identity—Use 2 patient identifiers at the patient bedside

- Ensure sample identity throughout entire testing and reporting process

- Verify medical record # again when entering ID into the Hemochron Response

Performing a Patient Sample—**p214/215 ACT Tubes—ECMO ONLY**

- **This information is for ECMO ONLY**
- Tap the p214/215 ACT tube so the glass beads are at the bottom of the ACT tube.
- Flip open tube. From the collection syringe, dispense exactly 0.4cc of blood into the ACT tube. At the same time, depress the “START” button of the HEMOCHRON test well as blood first appears in the tube.
- Close the flip top and flick the bottom of the tube 5 times to mix blood with the clot activator.
- Insert test tube into the Hemochron test well and rotate the tube clockwise until the green “Detector” light is illuminated.
- Turn at least one additional revolution to assure that the green light remains lit**.**
- Enter operator and patient ID information.

Magnet Detect/Stuck Magnet

- For the test to function properly, the Hemochron Response must detect the magnet in the tube when the tube is inserted into the test well
- Ensure that the analyzer displays the green detect light under the test well when the tube is inserted
- If the green detect light does not illuminate within approximately 75 seconds, a stuck magnet error will occur and testing will have to be redone
- It is NEVER acceptable to take a tube out of the analyzer, re-mix and reinsert into the test well and re-test
- A fresh sample MUST be collected and re-tested

Analyzer Error Codes

- If an analyzer error occurs, refer to the Hemochron Response Operator’s manual

Note Regarding Tube Rotation

- Only rotate ACT tubes and EQC in a clockwise rotation.

- Do NOT rotate counter-clockwise.

Result Considerations

- **Hemochron Response Reportable Range**
  - 80-600 seconds
- Any ACT value of less than (<) 80 seconds should be considered invalid and **NEVER** reported/acted on for patient treatment.
- Any ACT value greater than 600 seconds that is NOT expected should be repeated.
  - Consider sample contamination.
- Consider ACT tube and analyzer performance or operator error if these results persist. **Troubleshoot!**

Result considerations

- Unexpected and unexplained results should be verified by another test method.

- Problems should be reported to the Clinical Laboratory Point-of-Care Testing Coordinator

Troubleshooting

- Report problems to Clinical Engineering and the Clinical Laboratory Point-of-Care Testing Coordinator

- Document all actions on the ACT problem log and/or the QC logs

ACT Orders/Documentation

- All ACT testing should have a documented physician order or follow a documented protocol.
- All ACT results should be documented in the permanent patient record.
  - Results should include:
    - ACT result with units of measure(seconds)
    - Testing personnel
    - Date of testing
    - Time of testing
- A clear audit trail should be maintained correlating patient results with quality control results for the analyzer and tubes that were used for patient testing.

Result Recall

- QC and patient results are stored in the analyzer data base.

- To Recall Patient or QC Results
  - Press Menu 1 or 2—SELECT THE MENU BUTTON THAT CORRESPONDS TO THE TEST WELL IN WHICH TESTING WAS PERFORMED.
  - Press “4-Database”
  - Press “1-Query Pat Rec” or “3-Query QC Rec”
  - Press “Yes”.
  - Press 0 or 9 to view the records in sequence (forward or backward) or press “1-Search” to search by patient ID, operator ID, or date.

  - CANCEL will take you out of the Menu screens.

Quality Concerns

- Any concerns regarding reliability of ACT testing should be reported to the ECMO Coordinator and to the Clinical Lab Point of Care Testing Coordinator.

- If the employee feels that their concerns are not adequately addressed by WFBH management, the College of American Pathologists (CAP) can be contacted at 1-866-236-7212.

Notes

- If the START button is held for a few seconds, the analyzer will shut off.

- Take care not to do this when performing QC or patient testing.

Congratulations

- You have completed the Hemochron Response education module.
- Please note that this module does not replace the Hemochron ACT procedure
- The presentation only provides highlights of Hemochron ACT information
- New users: Please complete the on-line ACT exam within 1 week of training.

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