# aiACT Kit

**REF 800-0442 (℥100), REF 800-0441 (℥24)**

## INTENDED USE

The aiACT Kit is a celite/clay blend activated in vitro diagnostic test for use with Sonoclot® Analyzer Systems. It may be used with native whole blood and citrated whole blood. The aiACT Kit is intended for high dose heparin management. The aiACT test provides quantitative ACT and Clot Rate results that are substantially unaffected by aprotinin. It is not intended for platelet function monitoring.

## SUMMARY AND PRINCIPLES

The activated clotting time is the amount of time it takes to form a clot by contact activation of the coagulation cascade. A variety of materials are commonly used in ACT tests for contact activation, including glass beads (silica), celite (diatomacious earth), and clay (kaolin).

The aiACT is formulated from materials specifically selected to obtain a heparin dose response that is substantially unaffected by aprotinin. In comparison, a celite test can be significantly prolonged by aprotinin. For many people, a kaolin test shows less aprotinin effect than the celite test, but these results are highly variable from patient to patient.

ACT tests are useful in monitoring heparin anticoagulation effect by reporting longer ACT results at higher heparin dosages. The aiACT test is recommended for high dose heparin management only.

The aiACT test is less affected by aprotinin than any celite or kaolin activated test examined by the manufacturer. Every lot of aiACT activator is specifically tested to ensure consistent performance in the presence of aprotinin (Trasylol®).

## REAGENTS

Each aiACT Kit contains lidded yellow plastic activation cuvettes, probes, and these instructions for use. Cuvettes should contain a controlled amount of contact activator and a magnetic stir bar. If any components are missing or appear defective, discard the cuvette. Packaging sizes of 100 (800-0442) and 24 (800-0441) are available.

## STORAGE


## PROCEDURE

### A. Equipment Required:

1) Sonoclot Analyzer System: Model DP-2951, SC1, SCP1, SCP2, or SCP4

### B. Preparation

1) Make sure that the Sonoclot Analyzer is turned on and warmed up with the head assembly in the down position. Check that the analyzer is correctly connected to the desired output device (see operator's manual).
2) Sharply tap the cuvette against a hard surface, cap side up, to dislodge activation powder from the sides and lid.
3) Place the cuvette into a warming or convenience well. Model DP-2951: Allow the cuvette to warm in the well for at least 5 minutes before beginning a test. Model SC1, SCP1, SCP2, or SCP4: Allow the cuvette to warm in the cuvette holder for 30 seconds before beginning a test. Probes fit into the cuvette lids for convenient storage. Multiple cuvettes may be placed in the wells.

### C. Cuvette and Probe Set-up

1) Open the head by tilting it backwards.
2) With a slight twisting motion, seat the probe on the mount hub. This motion should result in the probe sliding straight over the probe mount hub. **The hub should not move sideways.** The probe must be fully seated for proper operation.
3) **While the cuvette is still in the well,** remove the cuvette lid by popping it off with your thumb and forefinger. Model DP-2951: **Do not remove the cuvette lid while the cuvette is in the cuvette holder; the cuvette holder may break.** Insert the opened cuvette into the cuvette holder with a slight twisting motion. Make sure that it is fully seated. Check that the cuvette contains a stir bar.

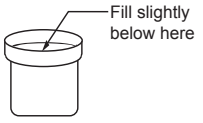
### D. Obtaining the Blood Sample

Native whole blood must be analyzed within 2 minutes or less from collection. When drawing blood, observe the following precautions:

- Carefully decide where to draw the sample. Contamination (from a heparinized line, a heparin-impregnated catheter, or a surgery prep line) will cause inaccurate results.
- Withdraw blood in a smooth, slow, and non-traumatic manner. Do not use force.
- When drawing from an anesthesia or pump port, use a 2-syringe technique. Use the first syringe to draw a sample sufficient to remove any blood that may be affected by the line. Use the second syringe for the sample.
- Human blood is a biohazardous material. The operator should wear appropriate protective gear when handling blood and/or test cuvettes containing blood samples. Biocontaminated materials should be handled and disposed of properly in accordance with hospital and governmental regulations.

Please contact Sienco, Inc. for specific sample handling and testing instructions for using citrated whole blood.

### E. Running the Sonoclot Analyzer




1) Transfer the whole blood sample from the syringe into the warmed cuvette. Use a blunt cannula tip for a clean and controlled fill. Fill the warmed cuvette with the blood sample until the fluid level is slightly below the inner rim of the cuvette. This volume is approximately 330 to 360 µl. Leaving the head open, immediately press the START/STOP switch. The magnetic stirrer will rotate and the display will read "Mixing." Watch the cuvette to make sure the sample is mixing properly.
2) When mixing is completed, the analyzer will beep and the display will read "CLOSE HEAD". Gently close the analyzer head.
3) The sample is initially a liquid. After several minutes, the sample begins to evolve into a clot. The analyzer detects this initial clot formation, beeps and displays the time that the sample remained a liquid (ACT).
4) During the next several minutes of analysis, the fibrinogen converts into a fibrin gel. The analyzer calculates the rate of change in the clot signal, beeps, and displays the Clot Rate value (CR).
5) When analysis is complete, press the START/STOP switch. Model DP-2951: The analyzer will automatically stop after 60 minutes (default value). Model SC1: The analyzer will automatically stop when all results have been calculated or after 30 minutes. Models SCP1, SCP2, SCP4: The analyzer will automatically stop when all results have been calculated or after 45 minutes. The automatic shut-off feature can be customized to your specific requirements. Please refer to the Signature Viewer operator's manual for complete instructions.
6) Open the analyzer head and remove the probe from

the hub with a probe extractor. **Avoid moving the hub sideways.** Properly discard the probe and cuvette. Gently close the head to maintain temperature control of the analyzer.

### F. Quality Control

Proper performance of the aiACT requires regular quality control (QC) tests. QC should be performed prior to the use of a new shipment and monthly throughout use of the stock. More frequent testing may be required to comply with local, state and national QC requirements. Sienco offers the Reference Plasma Quality Control Kit, part 900-1318 to verify activation cuvette performance. Sienco offers Reference Viscosity Oil Quality Control Kits, part 900-1302 (DP-2951), 900-1303 (SC1, SCP1), 900-1323 (SCP2), 900-1343 (SCP4) to verify Sonoclot Analyzer performance.

## EXPECTED VALUES

Reference values for healthy individuals are summarized by analyzer model in the table below.

| aiACT Test: 800-0441, 800-0442<br>Whole Blood - Healthy Population - No Heparin | | | |
|---|---|---|---|
| **Result** | **DP-2951 Reference Values - Native** | **SC1, SCP1, SCP2, SCP4 Reference Values - Native** | **SC1, SCP1, SCP2, SCP4 Reference Values - Citrated** |
| ACT/ Onset | 62 -93 seconds | 67 - 91 seconds | 71 - 114 seconds |
| Clot RATE | 22 - 41 Clot Signal Units / minute | 18 - 68 Clot Signal Units / minute | 36 - 72 Clot Signal Units / minute |

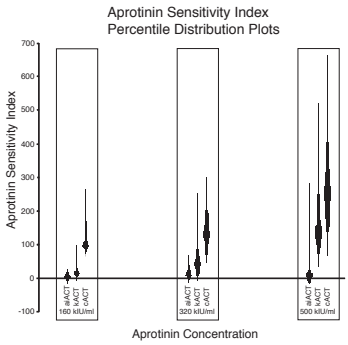
It is important to understand that reference values for healthy populations may be different than reference values for specific patient populations. Medication, variations in sampling, and operator technique can alter reference values at each institution. The hemostatic system responds to the stress of surgery in ways that affect Sonoclot results, typically by accelerating clot retraction. Even though there are multiple sources of variability, the following reference values provide a useful baseline. Each institution should establish reference values based upon their own patient populations.

## APROTININ SENSITIVITY

Aprotinin is known to prolong ACT results. The aiACT is formulated to reduce the effect of aprotinin on the ACT result. A convenient way to characterize the deleterious effect of aprotinin is to compare the ACT result both with and without aprotinin with the following expression:

$$\textit{Aprotinin Sensitivity Index} = \frac{ACT_{\textit{heparin and aprotinin}} - ACT_{\textit{heparin}}}{ACT_{\textit{heparin}} - ACT_{\textit{control}}}$$

The Aprotinin Sensitivity Index is useful because it is reasonably constant across a wide range of heparin levels. The following chart shows Aprotinin Sensitivity Index results for Sienco's aiACT, kACT, and SonACT (cACT) tests.




## PLATELET FUNCTION TESTING

The aiACT test is not intended for platelet function monitoring. The gbACT+ test is recommended for platelet function monitoring. Please refer to the gbACT+ test for further information regarding platelet function testing.

## OPERATIONAL PRECAUTIONS AND LIMITATIONS

Test result quality depends on proper technique. Carefully follow these precautions.

1) Only properly trained lab personnel and healthcare professionals should operate the analyzer.
2) Diagnosis should not be based solely on Sonoclot test results. The attending physician is responsible for interpreting the analyzer test results in conjunction with the patient's condition, other test results, and clinical observations.
3) Handle materials with care:
   - When taking a blood sample, avoid heparin contamination from catheters.
   - Never use the first sample from a new line to avoid sample contamination with tissue thromboplastin.
   - Keep blood, dirt, and other substances away from the probe mount hub to avoid contaminating the electromechanical transducer.
   - Never reuse a probe or cuvette to prevent thrombin contamination.
4) If the analyzer is not at the desired temperature (normally 37°C) then the analyzer will display an error message and not run the test.
5) For consistent results the cuvettes should be warmed prior to analysis. Do not store the cuvettes in the warming wells for extended periods of time (i.e. overnight) to avoid sample degradation from prolonged exposure to heat.
6) Always remove the cuvette cap before placing it into the cuvette holder. Failure to do so can damage the transducer. When placing the cuvette in the cuvette holder, verify that the cuvette contains a stir-bar.
7) The cuvette must be fully seated in the cuvette holder to avoid interference between the probe and stir-bar.
8) Do not overfill the cuvette. The proper fill level is 330 - 360µl, slightly below the inner rim of the cuvette.
9) Always insert and remove the probe by moving it vertically over the probe mount hub. Never move the hub horizontally. Make sure the probe is fully seated to avoid interference with the stir-bar.
10) Perform QC testing to verify proper operation of the analyzer and activation cuvettes.
11) Use proper biohazard handling techniques to dispose of probes and cuvettes.
12) On rare occasions, mechanical disturbances may cause incorrect results. Always inspect results to ensure that they are consistent.
13) Extremely high viscosity blood samples, (immersion response on analyzer > 25 clot signal units) can stratify. Use an external device to mix the blood sample before placing it in the cuvette.

## PERFORMANCE

Clinical precision testing for the aiACT is similar in performance to other activated tests run on the Sonoclot Analyzer. Typical CVs: ACT/Onset - 6%, Clot RATE - 5%. The Onset time CV should not exceed 10% for a test sample run side by side on multiple Sonoclot Analyzer Systems. The Clot Rate CV may be slightly greater since the Clot Rate parameter is more technique dependent. Due to sample aging effects, it is not practical to run a test sample multiple times on one Sonoclot Analyzer System to determine a CV.

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