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kACT Kit
#800-0400 (100s), #800-0401 (24s)
For In Vitro Diagnostic Use

INTENDED USE

The kACT Kit is an in vitro diagnostic test for use with the Sonoclot® Coagulation & Platelet Function Analyzer System. The kACT test is a kaolin activated whole blood clotting time test. It may also be used with citrated whole blood and plasma.

The kACT Kit is intended for high dose heparin management with or without aprotinin. The kACT test provides quantitative Onset/ACT and Clot Rate results with the Sonoclot Analyzer. The kACT test 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).

ACT tests are useful in monitoring heparin anticoagulation effect by reporting longer ACT results at higher heparin dosages. Some ACT test results are additionally prolonged if both aprotinin and heparin are present in the blood sample in comparison to the same sample without aprotinin. This prolonged ACT result in the presence of both heparin and aprotinin can potentially result in inadequate heparin administration. The kACT has been formulated to minimize the affect of aprotinin on the ACT result.

REAGENTS

Each kACT Kit contains lidded blue plastic activation cuvettes, probes and these instructions for use. The activation cuvettes contain a controlled amount of kaolin and a magnetic stir bar. Packaging sizes of 100 (800-0400) and 24 (800-0401) are available.

STORAGE

Store at room temperature. Protect from heat.

PROCEDURE

A. Equipment Required:

1. Sonoclot Analyzer System

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 Printer is ON and ON-LINE.
2. Sharply tap the cuvette against a hard surface, cap side up, to dislodge any activation powder from the sides and lid of the cuvette. It is normal for some of the powder to remain on the sides of the cuvette.
3. Place the cuvette into the instrument warming well so it will be warm and ready to go when the sample is ready for analysis. Allow the cuvette to warm for at least 5 minutes prior to testing. Probes fit into the cuvette lids for convenient storage. Several cuvettes may be prepared and placed in the warming wells prior to initial testing.

C. Cuvette and Probe Set-up

1. Proper mounting of the probe on to the probe mount hub is an essential step in ensuring the reliable performance of the Sonoclot Analyzer.
2. Open the head assembly by tilting it backwards on its hinge.
3. With a slight twisting motion, push a clean disposable tubular probe over the probe mount hub inside the head assembly. 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 on the probe mount hub for proper operation.
4. **While the cuvette is still in the warming well**, remove the cuvette lid by popping it off with your thumb and forefinger. **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. Ensure that the cuvette is fully seated in the cuvette holder. Check that the cuvette contains a stir bar.

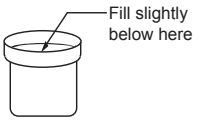
D. Obtaining the Blood Sample

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

- Sample withdrawal must be smooth, slow and atraumatic. Under no conditions should a sample be drawn with force. The sensitivity of platelets to disturbance makes good sampling technique especially important.
- Care should be exercised in deciding where the sample will be drawn to prevent possible heparin contamination.
- A two syringe technique is recommended for drawing the blood sample. The first syringe of 2 to 3 ml is discarded and the second syringe is used for the sample. Plastic syringes are mandatory to avoid uncontrolled glass activation.

Citrated whole blood or plasma samples can also be used with the kACT test. Please refer to the Operator's Manual for specific sample handling and testing instructions.

E. Running the Sonoclot Analyzer



1. For native whole blood testing, fill the warmed cuvette with the blood sample from the syringe so that the fluid level is slightly below the inner rim of the cuvette as shown below (≈360 µl). Transfer the sample from the syringe into the cuvette either with or without a blunt needle or cannula. Immediately press the START/STOP switch to the START position. The magnetic stirrer will automatically rotate and the Printer will begin to print.
2. After 10 seconds, the Sonoclot Analyzer will beep and the panel display will prompt you to CLOSE HEAD. Close the head assembly. At this time, if you wish to run an analysis for mare than twenty to thirty minutes, carefully place a drop of SonOil™ on the top of the sample. The SonOil will prevent the clot from drying out and forming a crust on the top of the sample.
3. The sample is initially a liquid. After several minutes, the sample begins to evolve into a clot. The instrument detects this initial clot formation, beeps and displays the time that the sample remained a liquid above the ACT/ONSET legend.
4. During the next several minutes of analysis, the fibrinogen converts into a fibrin gel. The Sonoclot Analyzer determines this rate of conversion by calculating the rate of change in the Clot Signal Value and reports this rate above the Clot RATE legend.
5. When your analysis is complete, momentarily press the START/STOP switch to the STOP position to stop the Printer. If you forget press the STOP switch, the Printer will automatically stop after 60 minutes (default value). The automatic shut-off feature can be customized to your specific

requirements. Please refer to the Operator's Manual for complete instructions.

6. Open the head assembly. Remove the tubular probe with a probe extractor or other tool. Use a straight motion that pulls the probe straight away from the probe mount hub. **Avoid moving the hub sideways.** Properly discard the probe and cuvette. Lower the head assembly to maintain temperature control of the instrument.

F. Quality Control

kACT test performance should be verified with reference plasma coagulation controls. If plasmas are being run to QC both the activation cuvettes and Sonoclot Analyzer, testing should be performed once each day prior to sample testing. If plasmas are being run to QC activation cuvettes only, testing should be performed prior to the use of a new shipment and monthly throughout use of the stock. In either case, more frequent testing may be required to comply with local, state and federal QC requirements. Sienco offers the Reference Plasma Quality Control Kit, part # 900-1318 to verify the performance of activation cuvettes and the Sonoclot Analyzer. Sienco offers the Reference Viscosity Oil Quality Control Kit, part # 900-1302 to verify performance of the Sonoclot Analyzer.

EXPECTED VALUES

Expected results for the kACT in unheparinized cardiopulmonary bypass patients are summarized in the following table. Medication and variations in sampling and operator technique can alter average results at each institution. Even though there may be sources of variability, the following ranges provide a useful base line.

kACT Test (#800-0400, 800-0401) Native Whole Blood	
Result	**Typical Unheparinized Range**
ACT/Onset	94 - 178 seconds
Clot RATE	15 - 33 Clot Signal Units / minute

PLATELET FUNCTION TESTING

The kACT 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 analysis.

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 filling the cuvette.

PERFORMANCE

Clinical precision testing for the kACT 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. Each trained user should establish a mean and standard deviation on a month to month basis as a quality control monitor.

BIBLIOGRAPHY

Sonoclot Coagulation & Platelet Function Analyzer Operator's Manual