SIENCO, Inc.

CE IVD

gbACT Kit

REF 800-0410 (100), REF 800-0416 (24)

INTENDED USE

The gbACT Kit is a glass bead activated in vitro diagnostic test for use with the Sonoclot® Analyzer Systems. It may be used with native whole blood and citrated whole blood. The gbACT Kit is intended for general purpose global hemostasis monitoring. The monitoring information is typically used for anticoagulant management at low to moderate heparin levels (0 to 2 units per ml), hypercoagulable and/or hypocoagulable screening, and hyperfibrinolysis screening. The gbACT test provides quantitative ACT and Clot Rate results as well as qualitative and quantitative information on the Sonoclot Signature including: fibrin formation and hyperfibrinolysis.

Warning: The gbACT test is not intended for high dose heparin management during cardiopulmonary bypass surgery. The gbACT test is not intended for platelet function assessment.

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 gbACT test is formulated to provide less activation than Sienco's celite activated SonACT test or kaolin activated kACT test. Glass beads are a weaker contact activator than celite or kaolin. Therefore, the ACT is slower with the gbACT test. This glass bead formulation provides greater ACT sensitivity to heparin compared to the SonACT or kACT test. Additionally, clot retraction captured on the Sonoclot Signature is typically stronger and faster with the gbACT test.

In the presence of heparin, the ACT result produced with the gbACT test is more prolonged than the ACT result produced with the SonACT or kACT test. This increased sensitivity makes the gbACT test better suited for anticoagulation management at low to moderate heparin levels (0 to 2 units per ml). The gbACT test is not appropriate for managing anticoagulation at heparin levels greater than 2 to 3 units/ml as would be encountered during cardiopulmonary bypass surgery. Instead, use the SonACT or kACT test for this application. In general, as heparin levels increase weaker clots are formed and platelet function becomes less observable on the Sonoclot Signature.

REAGENTS

Each gbACT Kit contains lidded yellow plastic activation cuvettes, probes, and these instructions for use. Cuvettes should contain a controlled amount of glass beads and a magnetic stir bar. If any components are missing or appear defective, discard the cuvette. Packaging sizes of 100 (800-0410) and 24 (800-0416) are available.

STORAGE

PROCEDURE

A. Equipment Required:

1) Sonoclot Analyzer System: 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. 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. 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.

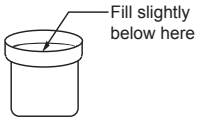
D. Obtaining the Blood Sample

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 SC1: The analyzer will automatically stop when all results have been calculated or after 30 minutes. Model 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 gbACT 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 hospital and governmental 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 900-1303 (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.

gbACT Test: 800-0410, 800-0416 Whole Blood - Healthy Population - No Heparin		
Result	**SC1, SCP1, SCP2, SCP4 Reference Values - Native**	**SC1, SCP1, SCP2, SCP4 Reference Values - Citrated**
ACT/Onset	100 - 155 seconds	100 - 240 seconds
Clot RATE	10-36 Clot Signal Units / minute	10-35 Clot Signal Units / minute

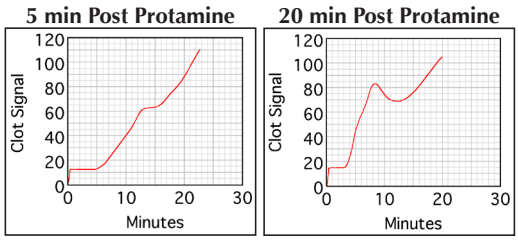
It is important to understand that reference values for healthy populations may be different than reference values for specific patient populations. Medication, variations in sampling, and operator technique can alter reference values at each institution. The hemostatic system responds to the stress 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.

PLATELET FUNCTION TESTING

The gbACT 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.

PROTAMINE EFFECT ON THE gbACT

Protamine has a strong effect on gbACT test results. Protamine prolongs the ACT result and reduces the Clot Rate result. This alteration of test results can occur if blood samples are collected from the patient too quickly after protamine administration. The two graphs below show test results taken a few minutes post protamine and then taken after protamine was cleared by the patient. The gbACT is much more affected by protamine than is a typical ACT formulated for high dose heparin management. For example, kaolin ACT results do not show a protamine effect. The half-life of protamine is short (typically less than a few minutes). gbACT samples should not be run until approximately 10 minutes post protamine administration. If protamine effects may have altered the test results, sequential testing is recommended.



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 gbACT 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.

BIBLIOGRAPHY

Sonoclot Analyzer operator's manuals

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