H-gbACT+ Kit

REF 800-0448 (⩛50), REF 800-0449 (⩛20)

INTENDED USE

The H-gbACT+ Kit is a glass bead activated in vitro diagnostic test with added heparinase for use with the Sonoclot® Analyzer System. It may be used with native whole blood and citrated whole blood. The H-gbACT+ Kit is intended for general purpose global hemostasis monitoring. The monitoring information is typically used for clot assessment, hypercoaguable and/or hypocoaguable screening, hyperfibrinolysis screening, and platelet function assessment. The H-gbACT+ test contains heparinase capable of neutralizing up to 5 units/ml of heparin. The H-gbACT+ test provides quantitative ACT, Clot Rate, and Platelet Function results as well as qualitative and quantitative information on the Sonoclot Signature including: fibrin formation, platelet function, and hyperfibrinolysis.

Warning: The H-gbACT+ test is not intended for high dose heparin management during cardiopulmonary bypass surgery.

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). Heparinase has been added to a glass bead formulation to allow platelet function information to be visualized on the Sonoclot Signature at up to 5 units/ml of heparin.

REAGENTS

Each H-gbACT+ Kit contains lidded plastic activation cuvettes, probes, distilled water for reconstituting the lyophilized pellet, and these instructions for use. The activation cuvettes contain controlled amounts of glass beads and heparinase, and a magnetic stir bar. Packaging sizes of 20 (800-0449) and 50 (800-0448) are available.

STORAGE

PROCEDURE

A. Equipment Required:

1) Sonoclot Analyzer System: Model DP-2951, 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 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.
4) Reconstitute the lyophilized pellet: open the 80-001 Distilled Water Pipette by carefully cutting off the end of the plastic tip on an angle. Add one drop (≈20µl) of distilled water to the cuvette by gently squeezing the pipette bulb. Press the Start button to begin mixing to ensure the whole pellet is reconstituted. After a couple of seconds, press the Start button again to stop mixing. Check that the cuvette contains a stir bar.
5) After reconstituting the pellet, place a red cap on the Distilled Water Pipette and return it to the kit case.

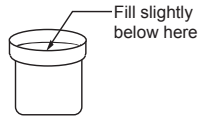
D. Obtaining the Blood Sample

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. 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." Close the analyzer head. **DO NOT drop the head closed. It may damage the analyzer.**
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.
5) The analyzer continues to monitor viscoelastic changes within the blood sample after initial clot formation to quantify platelet activation and clot retraction as a measurement of platelet function (PF).
6) When analysis is complete, press the START/STOP switch. Model DP-2951: The analyzer will automatically stop after 60 minutes (default value). 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 operator's manual for complete instructions.
7) 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. Lower the head assembly to maintain temperature control of the analyzer.

F. Quality Control

Proper performance of the H-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 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 (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.

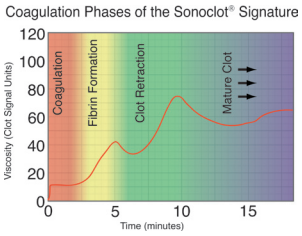
H-gbACT+ Test: 800-0448, 800-0449 Whole Blood - Healthy Population - No Heparin			
Result	**DP-2951 Reference Values * - Native**	**SCP1, SCP2, SCP4 Reference Values - Native**	**SCP1, SCP2, SCP4 Reference Values - Citrated**
ACT/ Onset	119 - 195 seconds	146 - 193 seconds	127 - 229 seconds
Clot RATE	7 - 23 Clot Signal Units / minute	14 - 33 Clot Signal Units / minute	18 - 38 Clot Signal Units / minute
Platelet Function	Time to peak < 17 minutes	Platelet Function Result 2.3 - 4.3	Platelet Function Result 1.8 - 4.5

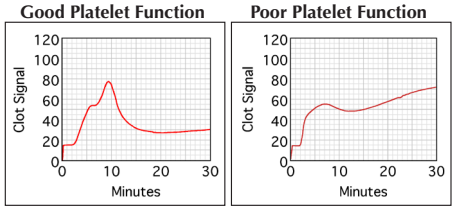
*Normal ranges based on comparison with the gbACT+ test.

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

Platelet function information is obtained during the clot retraction phase of the Sonoclot Signature. As platelets cause the clot to retract, the Sonoclot Analyzer observes changes in the viscoelastic measurement of the clot. Rapid or strong changes indicate greater platelet function.





The reference Signature on the left shows good platelet function because the Sonoclot Signature shows significant changes during the clot retraction phase.

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 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 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 H-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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