HEMONART **BlacT**
Activated Clotting Time Test Tube

Ref: ACT3017

CE IVD

INTENDED USE

The HEMONART BlacT ACT test tube is commonly used for heparin anticoagulation monitoring during cardiopulmonary bypass surgery, percutaneous transluminal coronary angioplasty (PTCA), interventional radiology, extracorporeal membrane oxygenation (ECMO), hemofiltration, hemodialysis and critical care. The tests are performed using fresh whole blood at the patient bedside.
FOR IN VITRO DIAGNOSTIC USE ONLY

SUMMARY

ACT test results reflect the ability of a blood sample to clot in this fashion, and they are prolonged in the presence of heparin. The more prolonged the ACT result is from baseline or normal values, the greater the degree of anticoagulation. ACT test is widely used to assess an individual patient's response to a given heparin dose. Especially when moderate to high levels of heparin are administered and during extra-corporeal circulation, the ACT is a practical and accurate method for controlling anticoagulation therapy.
BlacT ACT test tubes are sensitive to different levels of heparin anticoagulation, making them useful in a variety of clinical settings.

PRINCIPLES

The ACT was first introduced by Hattersley M.D. in 1966 and is still the most widely used monitor of heparin effect during cardiac surgery. While heparin therapy is essential in maintaining hemostasis during these procedures, its administration poses significant risk to the patient. Overdosing heparin can result in dangerous bleeding, whereas under dosing heparin can lead to thrombosis. Therefore, monitoring heparin therapy is vital in guarding against these undesirable side effects. The ACT is a test in which fresh whole blood is added to a test tube containing an activator (Celite®, glass particles or kaolin) and timed for the formation of a clot. The type of activator used may affect the degree of prolongation of the ACT. BlacT Test tube with filled whole blood must mix then inserted into the Compact One9 instrument where the tube is rotated and warmed to 37°C (± 0.5°C) until a fibrin clot is mechanically detected.

REAGENTS

BlacT ACT test tube, act3017; It is glass tube contains celite as an activator. It has black flip-top. 2 ml blood sample is required.
Each box contains 100 BlacT test tubes.
BlacT ACT test tubes can be use with Hemonart® Compact One9.

STORAGE AND STABILITY

BlacT ACT test tubes can be stored at room temperature (15-30°C).
They must not be used past the expiration date that appears on each test tube and its box.

SPECIMEN COLLECTION AND HANDLING

Materials Provided

• Activated Clotting Time test tubes:
- BlacT ACT test tube, black flip-top

Materials Required

• HEMONART CompactOne 9 ACT analyzer
• Appropriate syringe for sample collection
Use a 5cc syringe.

BLOOD COLLECTION;

Indwelling venous blood-line

(Do not obtain blood from a heparinized access line, or indwelling heparin lock):
Discontinue fluids drip, if required.
Use a two-syringe technique - discard the first 5 cc draw. Obtain a 3 cc sample with the second syringe for testing.

Extracorporeal blood line port

Flush the extracorporeal blood access line by withdrawing and discarding 5 cc of blood.
Draw 3 cc sample (1 cc for P214) with a second syringe for testing.

Venipuncture

Obtain a 3 cc sample with a syringe for testing
Warning: Do not collect fresh whole blood samples using glass blood collection tubes.

TEST PROCEDURE

Note: Refer to the appropriate Operator's Manual for detailed instrument instructions.
For Compact One9;
1. Press START key on Compact One9
2. From the collection syringe, dispense exactly 2.0 cc of blood into the ACT test tube.
3. Immediately close the flip-top and agitate the test tube vigorously from end-to-end ten times.
4. Insert the ACT test tube into the appropriate test well in 60 sec after pressing the START key. Quickly rotate the tube clockwise.
5. At the sound of the buzzer, record the test result.

IMPORTANT NOTES FOR PROCEDURE

1. Do not use BlacT test tubes after expire date.
2. Specimen contamination and inappropriate technique can affect ACT results.
3. The ACT results may be affected by hemodilution, hypothermia, pharmacologic compounds, and various coagulopathies. Test results should be interpreted with respect to the patient's condition and the clinical circumstances.
4. The transfer of the blood to the test tubes from a syringe should be performed using a needleless system. The flip top stopper should be opened completely to dispense the blood specimen and closed completely before shaking.

5. Always use a two-hand technique to transfer blood. One hand securely holds the tube while the second hand dispenses the blood specimen
6. Though not recommended, if a needle transfer procedure must be used, the needle must be placed in the tube parallel to the sides and centered within the tube during transfer.
7. The flip top stopper should never be pierced by a needle or sharp object, due to the danger of slipping off the flip top and piercing a finger.
8. All used test tubes containing human derived blood should be discarded in approved biohazard containers.

NORMAL RANGE

HEMONART BlacT ACT tests were evaluated on healthy volunteer donors and cardiopulmonary bypass patients before heparin dosing. The expected range is;

97-158 seconds for healthy donors
88-149 seconds for CPB patients.

PERFORMANCE CHARACTERISTICS

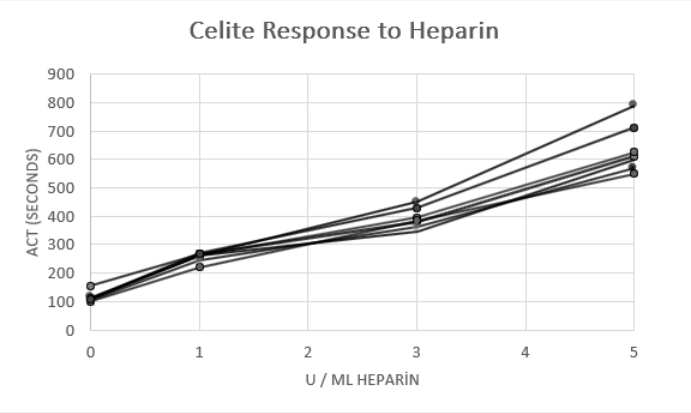
Precision

Reproducibility was determined using 2 level HEMONART control material for ACT test tubes.

	n	Mean	CV
Level 1	30	112	8,2%
Level 2	32	435	6,4%

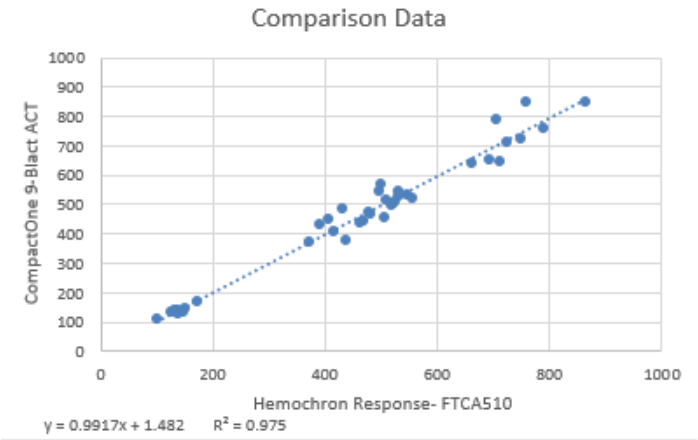
Heparin Sensitivity

Freshly obtained citrated blood was heparinized to create the below concentrations. Below graph show BlacT ACT response to different heparin concentration.



Method Comparison

Patient samples from all clinical sites were tested using Hemonart Blact ACT test tubes in CompactOne 9 ACT analyzer and Hemochron FTCA510 test tubes in Hemochron Response instrument. The datas and correlation value was shown in below graph



QUALITY CONTROL

Routine quality control (QC) testing and tracking should be a part of a comprehensive quality assurance program. HEMONART Liquid Quality Control products are available to make routine QC according to CLIA regulations in 2 levels. Hemonart QC materials should be ordered separately.

REFERENCES

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Manufacturer

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