Medtronic ACT Plus Low Range: Appendix B - Low Range Cartridge

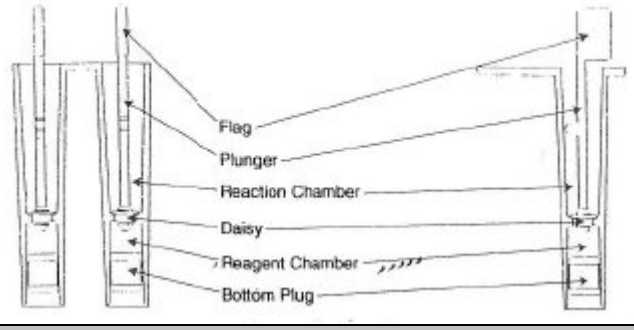
INTENDED USE:

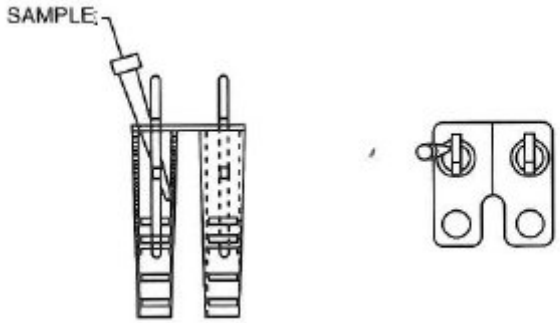
- For use in determining the activated clotting time of whole blood.
- LR-ACT cartridge has increased response to heparin.
- Increased sensitivity allows better control at therapeutic heparin levels.

PRINCIPLES OF THE PROCEDURE

- Measures the clotting time of fresh whole blood activated by surface contact.
- Activating agent is with specially prepared and standardized kaolin, which minimizes lot to lot variation in activation characteristics.
- Endpoint of the test is the detection of clot (fibrin) formation by measuring the rate of fall of the plunger-flag mechanism contained in each cartridge channel.
- Plunger assembly falls rapidly through an unclotted sample, but is impeded once the fibrin web is formed during clotting.
- Rate of impedence is measured by the photo optical system located in the cover assembly of the instrument.

Test Cartridge	• Includes reagent chamber, reaction chamber, and the plunger assembly.
Reagent Chamber	• located in the bottom section of the cartridge. • contains the activator and reagents - 0.1 mL per channel • 0.75% Kaolin; 0.0025MCaCl2; HEPES Buffer; Sodium Azide. • enclosed on the top by the “daisy”. • “daisy” is attached to the bottom of the plunger assembly and is seated in the diaphragm. • Bottom of the chamber is a flexible plug.
Reaction Chamber	• Located above the reagent chamber. • Test sample introduced into the reaction chamber. • When testing is initiated, the plunger assembly is lifted, releasing the “daisy” and the bottom plug of the reagent chamber is pushed up, delivering the contents of the reagent chamber into the reaction chamber.
Plunger Assembly	• Consists of the “daisy” and the flag assembly.
Daisy	• Provides the upper seal for the reagent chamber. • Mechanical sensing element for clot formation.
Flag	• Rate of impedence is detected by the movement of the flag.





STORAGE

- 2°C to 25°C for the expiration dating period indicated on the cartridge container.
- Do not use if cartridge appears discolored, cracked or disfigured, of if the reagent appears to have evaporated or be contaminated.

SAMPLE TESTING

- Fresh whole blood run as quickly as possible after being drawn.
- Baseline samples which contain no anticoagulant – run within one(1) minute.
- Heparinized samples – run within two(2) minutes.

RESULTS

- Response of the ACT to heparin varies considerably from individual to individual.
- Various drugs affect the Act, in particular, drugs which inhibit platelet activation. A number of other factors can affect the response. Eg. Antithrombin III levels, heparin potency coagulation factor deficiencies, sample activation, and consumptive coagulopathies.
- Samples which give unexplained abnormal values should be redrawn and retested.

LIMITATIONS OF THE PROCEDURE

- Both heat block and cartridge temperature should be at 37°C $\pm$ 0.5°C.
- Reagent must be thoroughly suspended.
- Blood must be free of tissue thromboplastin and run immediately after collection.

SPECIFIC PERFORMANCE CHARACTERISTICS

- ACT in the clotting time range of 0-600 seconds, typically do not exceed a variation of 12% between duplicate samples for any one individual.

REFERENCES

Medtronic Activated Clotting Time Cartridges Directional Insert. Medtronic, Inc.2004
Medtronic ACT Plus Automated Coagulation Timer Operator's Manual. Medtronic, Inc.2004

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document	30 Dec 2013	Elvira Kozak	Dr. Cathy Halstead
1.1	Minor	Document title and number change. Upload to QMS document control	22 Dec 2016		Dr. Benjamin Jung

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