

Medtronic ACT Plus Low Range: Patient Test Procedure

PURPOSE: This procedure provides instructions on performing Patient Testing for Activated Clotting Time using the Low Range Cartridge on the ACT Plus.

MATERIALS REQUIRED:

- 1 cc tuberculin syringes (non-additive)
- 18 gauge blunt end transfer needle (non-filter)
- ACT – LR Cartridge
- Gloves
- Tissue
- Timer

	Action	Related Documents Title Number
1.	<p>Instrument is ON. Display is in Main Menu.</p> <ul style="list-style-type: none"> • Instrument Self Test has passed. • Instrument Parameters are correct. • Temperature is within specification. • Cartridge type and lot # is correct. • Liquid Quality Control is within range. 	
2.	<p>Press [Enter ID].</p> <ul style="list-style-type: none"> • Enter User ID. Confirm entry. Press [Enter] to accept. • Enter Patient Medical Record Number. Confirm entry. Press [Enter] to accept. • Press [Exit to Main Menu]. <p><i>Note: Remove ID's post patient procedure. Operator ID and Patient ID's are retained as current in use, until manually removed.</i></p>	
3.	<p>Place LR ACT Cartridge in the actuator heating block.</p> <p>a) Hold Cartridge without touching the flag assembly.</p> <ul style="list-style-type: none"> • Visually inspect cartridge integrity. • Cartridge is intact, no cracks. <p>b) Shake up and down 10 times.</p> <ul style="list-style-type: none"> • Reagent is homogeneous, cloudy and white. <p>c) Place the cartridge into the actuator heating block. 37 +/-0.5 °C</p> <ul style="list-style-type: none"> • Prewarm the cartridge for a minimum of 3 minutes. Set timer. <p><i>Note: Cartridge maximum time in heater block is 12 hours.</i></p>	
4.	Wear gloves for sample handling	
5.	<p>Collect sample in 1mL syringe.</p> <ul style="list-style-type: none"> • Remove any bubbles. 	
6.	<p>Add 0.2 mL sample into each cartridge well.</p> <ul style="list-style-type: none"> • Dispense down inside wall of the cartridge. • Measure with the syringe, using the etched lines as a visual guide. • The sample level should be between the upper and lower fill lines in each reaction chamber. • Take care to avoid getting the sample on the flag, the plunger assembly or to touch the “daisy” separating the reaction and reagent chambers. 	

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	Action	Related Documents Title Number
7.	<p>Gently place the cartridge into the actuator heat block. Push block in to the closed position.</p> <ul style="list-style-type: none"> • Flags face the instrument. • Reagent is delivered into the reaction chamber, and the time to clot formation is measured. • An audible tone sounds, and the actuator heat block automatically rotates to the open position when clot formation is detected. 	
8.	<p>Document results onto the Patient Record Sheet and review the results obtained.</p> <ul style="list-style-type: none"> • Results in duplicate – Channel 1 & 2. • Report the “Average” value. • There is less than 12% variation between channel clotting times. <p><i>Note: Instrument operable range is 25 to 999 seconds.</i></p>	
9.	Discard Cartridge in appropriate biohazard waste.	

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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