Medtronic ACT Plus Low Range: Appendix C - Quality Control

When is Quality control Testing Performed

- QC is performed daily prior to patient testing
- Normal and Abnormal Levels at the onset of an ECLS patient.
- Alternate Levels either (Normal or Abnormal Level) during an ECLS patient
- When troubleshooting the "ACT Plus system"
- When starting a new box or new lot number of Medtronic LR-ACT Cartridges.
- When starting a new box or new lot number of Medtronic Coagulation control.

Intended Use

- To check the "ACT Plus system" – instrument, reagents, operator performance
- To check reproducibility of testing, any pre-analytical factors in testing, reagent integrity, operator performance and result reporting
- To comply with national regulatory guidelines for Point of Care Testing

Reagent

- CLOTtrac CWB Control – normal level (Cat# H-550-01).
- CLOTtrac LR Abnormal Control – abnormal level (Cat# H-550-09).
- Corresponding vial non-sterile, deionized Type 1 reagent grade water.
- Control consists of lyophilized citrated sheep plasma and erythrocytes.
- Calcium Chloride (Cat# H-550-11).

Storage and Stability

- Transported at room temperature. Refrigerated immediately upon arrival.
- 2^{o}C to 10^{o}C storage to expiry date on the box.
- Once vials are removed from expiry date storage DO NOT RETURN. DISCARD if not used.
- Once reconstituted, Quality Control is stable at room temperature (15^{o}C to 25^{o}C):
  CLOTtrac CWB Control – normal level – up to 2 hours
  CLOTtrac LR Abnormal Control – abnormal level – up to 1 hour.
- Calcium Chloride, once open for use, is stable at room temperature for 10 days.

Limitations of the Procedure

- Intended for in vitro diagnostic use only.
- Results are dependent on good technique and adherence to protocol.
- Strict adherence to rehydration requirements is recommended (10 minutes at room temperature prior to rehydration. Hydrate for 10 minutes prior to mixing reconstituted vial).
- Clotting time QC range is dependent on proper storage, reconstitution and handling prior to testing.
- Must obtain QC results within the posted QC range prior to patient testing.
- Controls are considered a biological sample. Handle with appropriate infection control guidelines.

REFERENCES

Medtronic Activated Clotting Time Quality Control 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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