Title: Procedure to Prepare ACE Control Material

Purpose: To assist the laboratorian in preparing control material for assay use.

Procedure:
Control material, derived in part from human serum components, is to be handled observing all Universal Precautions.

To prepare Chemistry Control 1 and 2 material:
1. Remove the current lot of controls from the Kelvinator at CLASS. If unsure which lot is appropriate, consult with the senior technologists or Lab Manager.
2. Remove the plastic screw cap and rubber stopper from each vial to be used.
3. Using a Class A volumetric pipet, add exactly 5.0 mL of ddI water (Type 1) to each vial.
4. Replace the stopper and screw cap on each vial, invert gently, and allow it to sit 20 minutes at room temperature, swirling occasionally.
5. Swirl the content until homogeneous.
6. Record the date of preparation on the vial label using a sharpie or indelible pen.
7. Determine the expiration date of the vials prepared and record the date on the vials using a sharpie or indelible pen. Refer to the product insert for specific lot stability period. Unreconstituted chemistry control is stable until the expiration date shown on the box and vial labels when stored at 2-8°C. Reconstituted material in past has been stable for 7 days when stored at 2-8 °C except for ALT/GPT and AST/GOT (currently not assayed at CLASS).

To prepare LDL-C control material:
1. Remove the current lot of controls from the Kelvinator at CLASS. If unsure which lot is appropriate, consult with the senior technologists or Lab Manager.
2. These controls are liquid and ready to use. Thoroughly mix the contents of the vial by gently inverting for several minutes prior to each use.
3. Determine the expiration date of the vials prepared and record the date on the vials using a sharpie. Refer to the product insert for specific lot stability period. Unopened LDL-C Controls are stable until the expiration date printed on the box and vial labels when stored refrigerated at 2-8°C. In past, once opened the controls are stable for 30 days when stored tightly capped and refrigerated. Do not freeze. Do not use the control if it is turbid or displays other evidence of contamination.