

# HITACHI

 **Hitachi Chemical Diagnostics, Inc.**

## CLA<sup>®</sup> NEGATIVE CONTROL SERUM

Doc. No. 0475  
Rev.: 06  
Lot No.: 1273-79  
Control Kit Part Number: 94173  
Bottle Part Number: 80620  
Control Kit Contents: 3 x 3 mL

### **1** *Intended Use*

CLA Negative Control Serum is intended for use in quality control procedures which evaluate performance of the CLA Allergen Specific IgE Assay.

### **2** *Summary and Principle*

The use of quality control materials is indicated as an objective assessment of assay performance.

### **3** *Reagent*

CLA Negative Control Serum is prepared from human serum. The control is provided in liquid form.

### **4** *Storage and Stability*

When stored at  $-20 \pm 10^{\circ}$  C, the CLA Negative Control Serum is stable until the expiration date indicated on the vial label. The serum is supplied in volumes of 3 mL. When ready to use, thaw, remove the volume needed and re-freeze the unused material immediately. Do not store in the refrigerator. Unused portions of control reagents may be frozen at  $-20 \pm 10^{\circ}$ C or refrigerated at 2 - 8°C if used within 5 – 7 days. Only one freeze-thaw cycle is recommended. Thus aliquoting the control reagents into smaller volumes before refreezing may be helpful.

### **5** *Expected Values*

Each laboratory should establish its own mean values and acceptable ranges. Acceptable performance may be defined as a percentage of the results falling within the nondetectable range. For example:

Negative Control Reagent: 80% of the allergens have readings of 0-11 Lus.

### **6** *Procedure*

The CLA Negative Control Serum should be tested using the same procedure as, and in parallel with, patient specimens. Frequency of use may be determined by each laboratory's Quality Control policies. Allow control serum to equilibrate to room temperature. Invert gently several times and centrifuge for 10-20 minutes at 2000-3000xg or 2500-3600 rpm immediately prior to use. The reference serum should be run using the test procedure indicated for patient specimens.

### **7** *Limitations*

The CLA Negative Control Serum should not be used past the expiration date. If there is evidence of microbial contamination or excessive turbidity, discard the vial.

### **WARNING**

**This product contains human source material. Treat as potentially infectious.**

Each donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg) and antibody to HIV-1. No test method can offer complete assurance that products containing human source materials will be absent of these and other infectious agents. Handle this product with the same precautions used with patient specimens.

### **FOR IN VITRO DIAGNOSTIC USE ONLY**



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