

HITACHI

 **Hitachi Chemical Diagnostics, Inc.**

AP 1800™ NEGATIVE CONTROL REAGENT



Doc. No. 0658 - ENG
Rev.: 05
Lot No.: 1273-45
Control Kit Part Number: 93529
Bottle Part Number: 82064
Control Kit Contents: 3 x 3 mL

1 Intended Use

AP 1800 Negative Control Reagent is intended for use in quality control procedures, which evaluate performance of the AP 1800 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

AP 1800 Negative Control Reagent contains human and horse serums. The control is provided in liquid form.

4 Storage and Stability

When stored at $-20 \pm 10^{\circ}\text{C}$, the AP 1800 Negative Control Reagent is stable until the expiration date indicated on the vial label. The reagent 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 $-20 \pm 10^{\circ}\text{C}$. 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. Hitachi Chemical Diagnostics, Inc. defines acceptable performance criteria for this control as 85% of the allergens falling within the nondetectable class range.

6 Procedure

The AP 1800 Negative Control Reagent should be tested using the same procedure as patient specimens. Frequency of use may be determined by each Laboratory's Quality Control policies. Allow control reagent 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.

7 Limitations

The AP 1800 Negative Control Reagent should not be used past the expiration date. If there is evidence of microbial contamination or excessive turbidity, discard the vial.

WARNING

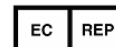
This product contains human source material. Treat as potentially infectious.

Each donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Antigen, 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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