

HITACHI

 Hitachi Chemical Diagnostics, Inc.

AP 1800™ POSITIVE CONTROL REAGENT



Doc. No. 0657 - ENG
Rev.: 05
Lot No.: 38198652
Control Kit Part Number: 93528
Bottle Part Number: 82063
Control Kit Contents: 3 x 3 mL

1 Intended Use

AP 1800 Positive 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. This positive control has been assayed for various specific allergens and their expected values are provided. Allergens that are not listed here may test positive with this lot of control reagent.

3 Reagent

AP 1800 Positive 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 Positive 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

The expected ranges printed in this insert were established by Hitachi Chemical Diagnostics, Inc. and are specific to this lot of AP 1800 Positive Control Reagent. Individual laboratory means should fall within the expected range for each allergen. Procedural or reagent modifications may alter the mean values. Each laboratory should establish its own mean values and acceptable ranges and use those provided only as guides.

Hitachi Chemical Diagnostics, Inc. defines acceptable performance criteria for this control as 85% of the assayed target allergens falling within the expected class range.

6 Procedure

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

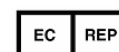
WARNING

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

Allergens	Expected Values	
	Class Range	NCCLS Code
Alternaria	1-3	m6
Apple	2-4	f49
Aspergillus	2-4	m3
Bermuda Grass	2-4	g2
Black Alder	2-4	t2
Candida	1-3	m5
Casein	1-3	f78
Cat	1-3	e1
Cladosporium	1-3	m2
Corn Pollen	2-4	g202
Cultivated Rye	2-4	g12
Dog	1-3	e5
English Plantain	1-3	w9
Four Grass Mix	2-4	g3/g5/g6/g8
Hazelnut Pollen	1-3	t4
Lamb's Quarters	1-3	w10
Latex	1-3	k82
Milk	1-3	f2
Mite, farinae	1-3	d2
Mite, pteronyssinus	1-3	d1
Oat Pollen	2-4	g14
Orchard Grass	2-4	g3
Pea	1-3	f12
Peanut	1-3	f13
Penicillium	1-3	m1
Potato	1-3	f35
Sesame Seed	1-3	f10
Short Ragweed	1-3	w1
Soybean	1-3	f14
Timothy Grass	2-4	g6
Tomato	1-3	f25
Velvet Grass	2-4	g13
Wheat	1-3	f4
Wheat Pollen	2-4	g15
White Birch	2-4	t3



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