HITACHI

Hitachi Chemical Diagnostics, Inc.

CLA® POSITIVE CONTROL SERUM

Doc. No. 0474
Rev.: 18
Lot No.: 41B20964
Control Kit Part Number: 93026
Bottle Part Number: 80621
Control Kit Contents: 3 x 3 mL

1 Intended Use

CLA Positive Control Serum is intended for 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. 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 serum.

3 Reagent

CLA Positive Control Serum is prepared from human serum with the addition of a preservative. The control is provided in liquid form.

4 Storage and Stability

When stored at -20±10°C, the CLA Positive 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 ± 10°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 CLA Positive Control Serum. 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 80% of the assayed target allergens falling within the expected class range.

6 Procedure

The CLA Positive 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 Positive 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), 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
Aspergillus	2-4	m3
Baker's Yeast	1-3	f45
Beef	1/0-2	f27
Cat	2-4	e1
Cocklebur	2-4	w13
Dog	1-3	e5
Elm Mix	2-4	t8/t38/t44/t45
English Plantain	3-4	w9
Garlic	2-4	f47
Housedust	1-3	h2
Lamb's Quarters	2-4	w10
Maple Box Elder	3-4	t1
Mite, farinae	2-4	d2
Mountain Cedar	1-3	t6
Mugwort	2-4	w6
Oat	2-4	f7
Orange	3-4	f33
Penicillium	2-4	m1
Pork	1-3	f26
Rough Marshelder	3-4	w16
Short Ragweed	3-4	w1
Sagebrush Mix	2-4	w6/w24
Sheep Sorrel	3-4	w18
Shellfish Mix	2-4	f23/f24/f207
Soybean	3-4	f14
Timothy Grass	3-4	g6
Tomato	3-4	f25
Walnut/Hickory/ Pecan Mix	1-3	t10/t22/t41/t91
Wheat	2-4	f4
White Ash	1-3	t25
White Oak	2-4	t7

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