HITACHI

Hitachi Chemical Diagnostics, Inc.

OPTIGEN® UNIVERSAL PANEL 20 POSITIVE CONTROL

Doc. No. 0920
Rev.: 00
Lot No.: 1244-120
Control Kit Part Number: 80107
Bottle Part Number: 90107
Control Kit Contents: 3 x 3mL

1 Intended Use

OPTIGEN Positive Control is intended for use in quality control procedures, which evaluate the performance of the OPTIGEN Universal Panel 20.

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.

3 Reagent

OPTIGEN Positive Control is prepared from human serum with the addition of a preservative. The control is provided in frozen form.

4 Storage and Stability

When stored at -20 ± 10° C, the OPTIGEN Positive Control is stable until the expiration date indicated on the vial label. Once the reagent is defrosted, store the control at 2-8 ° C for no longer than 8 weeks. Avoid freeze-thaw cycles.

5 Control Ranges

The control ranges printed in this insert were established by Hitachi Chemical Diagnostics, Inc. and are specific to this lot of OPTIGEN Positive Control. Control ranges have been assigned with reagents available at the time of assay and may vary with different reagent lots. Individual laboratory means should fall within the expected range for each allergen, however each laboratory should establish its own mean values and acceptable ranges using the ranges provided as guides. Procedural or reagent modifications may alter the mean values.

6 Procedure

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

8 Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

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	Control Class Range	CLSI Code
Alternaria	1-3	m6
Aspergillus	2-4	m3
Birch, White	1-3	t3
Cat	2-4	e1
Cladosporium	1-3	m2
Cockroach Mix	1-3	i6/i206
Codfish	0	f3
Dog	1-3	e5
Egg White	2-4	f1
Latex	1-3	k82
Milk	2-4	f2
Mite Farinae	3-4	d2
Mite Pteronyssinus	3-4	d1
Mugwort	2-4	w6
Peanut	2-4	f13
Ragweed Mix I	1-3	Rw209
Rice	2-4	f9
Soybean	3-4	f14
Timothy Grass	2-4	g6
Wheat	2-4	f4

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