

OPTIGEN NEGATIVE CONTROL REAGENT

Bulk lot No: 1273-21



INTENDED USE

OPTIGEN Negative Control Reagent is intended for use as an assayed quality control serum to monitor the performance of the OPTIGEN Assay.

SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of assay performance. This negative control has been assayed for various specific allergens and their expected values are provided.

REAGENT

OPTIGEN Negative Control Reagent is prepared from human serum. The control is provided in liquid form.

STORAGE AND STABILITY

When stored at $-20 \pm 10^{\circ}\text{C}$, the OPTIGEN Negative Control Reagent is stable until the expiration date indicated on the vial label. Avoid freeze-thaw cycles.

ASSIGNMENT OF VALUES

The mean values and acceptable ranges printed in this insert were established by Hitachi Chemical Diagnostics, Inc. and are specific to this lot of OPTIGEN Negative 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 range.

PROCEDURE

OPTIGEN Negative Control Reagent should be run with each new kit lot. Allow control reagent to equilibrate to room temperature. Invert gently several times before use. The reference reagent should be run using the test procedure indicated for patient specimens.

LIMITATIONS

The OPTIGEN 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) 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

<u>EXPECTED VALUES</u>	<u>Class</u>
Alternaria	0
Aspergillus	0
Birch, White	0
Cat	0
Cladosporium	0
Cockroach Mix	0
Codfish	0
Dog	0
Egg White	0
Latex	0
Milk	0
Mite, farinae	0
Mite, pteronyssinus	0
Mugwort	0
Peanut	0
Ragweed Mix I	0
Rice	0
Soybean	0
Timothy	0
Wheat	0

Control Kit Part number:
Bottle Part Number
Control Kit Contents:

82062
93527
3 x 3 mL