HITACHI

Hitachi Chemical Diagnostics, Inc.

OPTIGEN® UNIVERSAL PANEL 20 NEGATIVE CONTROL

Doc. No. 0921
Rev.: 00
Lot No.: 1273-125
Control Kit Part Number: 80108
Bottle Part Number: 90108
Control Kit Contents: 3 x 3mL

1 *Intended Use*

OPTIGEN Negative Control is intended for use in quality control procedures, which evaluate 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.

3 *Reagent*

OPTIGEN Negative 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 Negative Control is stable until the expiration date indicated on the vial label. Once the reagent is defrosted, store the reagent at 2-8ºC for no longer than 8 weeks. Avoid freeze-thaw cycles.

5 *Control Ranges*

Each laboratory should establish its own mean values and acceptable ranges. Procedural or reagent modifications may alter the mean values.

6 *Procedure*

OPTIGEN Negative 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. The control reagent should be run using the test procedure indicated for patient specimens.

7 *Limitations*

The OPTIGEN Negative 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

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