



**CLARITY**  
**Liquid Covid-19 Human IgG Antibody Control**  
**(Unassayed)**

**CATALOG NUMBER: CD-COV-IgGCTL**

**KIT CONTENT:** Covid-19 Liquid IgG Antibody Control.

**1 x 2 ml of Level - 1 (Negative) Lot Number 1650698N    Bi-Level Kit: 1650690**  
**1 x 2 ml of Level - 2 (Positive) Lot Number 1650699P    Exp. Date: Jan 2021**

**INTENDED USE:**

The Clarity Liquid Covid-19 IgG antibody serum controls are intended for use as unassayed precision control reagents. These controls are to be used with in vitro immunoassay procedures for the qualitative determination of Covid-19 IgG antibody in human serum assays. The controls are designed for routine use to provide a means of estimating precision and monitoring system performance. For use only with Clarity COVIBLOCK™ COVID19 IgG/IgM Antibody Test Cassette.

**SUMMARY AND EXPLANATION:**

The usefulness of Quality Control materials for monitoring the accuracy and precision of clinical testing is well documented. The Clarity Liquid Covid - 19 Serum Control is designed specifically to be used in qualitative analysis of Covid - 19 IgG antibody assay in serum. The control should be used like a patient sample to assist in the assessment of the analytical procedures and routinely used for the day to day quality control of the assay system. **Clarity Liquid Covid - 19 IgG serum for antibody assay is liquid, stable for Six Months at a refrigerated temperature of 2-8° C.**

**REAGENTS:**

The Clarity Covid - 19 IgG antibody negative control serum is prepared by mixing appropriate amount of Covid - 19 negative human serum with other serum until desired concentration of Covid - 19 IgG antibodies are obtained. The Clarity Covid-19 IgG antibody positive control serum is prepared by mixing appropriate amount of Covid-19 IgG with other serum until desired concentration of Covid - 19 IgG antibodies are obtained. All sera were preserved with a mixture of 0.1% Sodium azide as preservative. The volume of Covid - 19 negative and Covid - 19 positive human sera to be used in the preparation was determined by analysis of Covid - 19 IgG antibodies in these sera by chromatographic immunoassay with available commercial kits: For use only with Clarity COVIBLOCK™ COVID19 IgG/IgM Antibody Test Cassette.

Follow the manufacturer's recommended protocol in assaying Clarity Liquid Covid-19 IgG antibody control.

## WARNINGS AND PRECAUTIONS:

- \* FOR IN VITRO DIAGNOSTIC USE ONLY
- \* **BIOHAZARD Caution:** Human source material used in the preparation has been found non-reactive for HBsAg when tested by RIA, and also negative for HIV-1 antibody when tested by ELISA. However, no known test method can assure that a product derived from human source does not contain hepatitis or HIV-1 viruses.
- \* **Please Note:** There is no Biohazard related to COVID19 with these controls.
- \* If particulate matter is observed in the product, discard the product.
- \* **WASTE DISPOSAL METHOD:** The above product contains 0.1% **sodium azide** as preservative. Best disposal method for biological material containing sodium azide is to wash it down the sewer with large excess of water. Disposal should be made in accordance with existing disposal practices. Observe all Federal, State and Local laws.
- \* HANDLE AS IF CAPABLE OF TRANSMITTING HEPATITIS
- \* NOT FOR INTERNAL USE BY HUMANS OR ANIMALS.

## STORAGE AND STABILITY

### STORE AT 2<sup>o</sup>-8<sup>o</sup> C.

The product is stable up to the expiration date printed on the label if kept at 2-8°C. Once opened it is stable for 7 days at Room Temperature and till labelled date of expiration if stored between use at 2-8°C.

This product is warranted to perform as described in its labeling and in the product literature. Clarity Diagnostics disclaims any implied warranty, merchantability, or fitness for any other purpose, and in no event shall be liable for any consequential damages arising out of the aforesaid expressed warranty.

### PROCEDURE:

The Clarity Liquid Covid - 19 IgG antibody Serum Control should be used like a patient sample to assist in the assessment of the analytical procedures and routinely used for the day to day quality control of the assay system.

### Using Controls with Micropipette:

Open the Negative Control vial and Pipette 10µl of Negative control, add 10µl of Negative control to the specimen well (S) of the test cassette, then add 2 drops of buffer to the buffer well (B) and start the timer. Wait for colored line to appear. Read Results at 10 minutes. Do not interpret results after 20 minutes.

Open the Positive Control vial and Pipette 10µl of Positive control, add 10µl of Negative control to the specimen well (S) of the test cassette, then add 2 drops of buffer to the buffer well (B) and start the timer. Wait for colored line (s) to appear. Read Results at 10 minutes. Do not interpret results after 20 minutes.

Negative Controls should only produce 1 band, Control Band and Positive Controls should only produce 2 bands, Control Band, and the IgG Band. If In-valid results are obtained, please perform the QC test again.

**Using Controls with vial dropper tip:**

Squeeze 1 drop of Negative Control to the specimen well (S) of the test cassette, then add 2 drops of buffer to the buffer well (B) and start the timer. Wait for colored line to appear. Read Results at 10 minutes. Do not interpret results after 20 minutes.

Squeeze 1 drop of Positive Control to the specimen well (S) of the test cassette, then add 2 drops of buffer to the buffer well (B) and start the timer. Wait for colored line to appear. Read Results at 10 minutes. Do not interpret results after 20 minutes.

Negative Controls should only produce 1 band, Control Band and Positive Controls should only produce 2 bands, Control Band, and the IgG Band. If In-valid results are obtained, please perform the QC test again.

Carefully follow the test procedures of the manufacturer of the test kit including bringing the controls to room temperature if so indicated, for the analysis of the Clarity Liquid Covid - 19 IgG antibody serum controls. The LIQUID CONTROL is specially designed and packaged to be stable in liquid state for 6 months. Once opened it is stable for 7 days at Room Temperature and till labelled date of expiration if stored between use at 2-8°C. The stable LIQUID CONTROL eliminates errors arising from lyophilization, pipeting errors and discrepancies due to uneven lyophilization or improper mixing.

**QUALITY CONTROL**

**SPECIFIC PERFORMANCE CHARACTERISTICS:**

Clarity Liquid COVID-19 IgG ANTIBODY SERUM CONTROL is formulated to give consistent result for use in clinical quality control. It is recommended that each laboratory validate the use of each lot of reagents with each specific assay system prior to its routine use in the laboratory.

**INTERPRETATION OF THE RESULTS:**

Once a laboratory has established the range of values for the Liquid Covid - 19 IgG antibody controls it can use those values for routine day to day quality control of clinical test. However, the values are method dependent and different laboratories may observe variations because of differences in techniques, or reagent variation, method modifications and other systemic and random errors.

**LIMITATION OF THE PROCEDURE:**

The Clarity Covid-19 human IgG antibody Serum Controls are not intended to be used as calibrators and should not be used for calibration of the assays. The controls should be used only when testing serum specimens following protocol of the test kit manufacturer. Performance characteristic of the controls were determined for Covid - 19 human IgG antibody only. Control should be used only in test involving serum; it is not intended for use in test of plasma or other body fluid.



**Manufactured for:**



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