CLARITY
Liquid COVID-19 Human IgM+IgG Antibody Control
(Unassayed)

CATALOG NUMBER: CD-COV19-GMCTL

KIT CONTENT: COVID-19 Liquid IgM+IgG Antibody Control.

1 x 1 ml of Negative Lot Number 274098N Bi-Level Kit: 274010
1 x 1 ml of Positive Lot Number 274099P Exp. Date: March 2021

INTENDED USE:
The Clarity Liquid COVID-19 IgM+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 IgM and 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 with Sienna^{TM} COVID-19 IgG/IgM Rapid Test Cassette and 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 IgM and 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 IgM+IgG serum for antibody assay is liquid, stable for Six Months at a refrigerated temperature of 2-8º C.**

REAGENTS:
The Clarity COVID-19 antibody negative control serum is prepared negative human serum.. The Clarity COVID-19 IgG and IgM antibody positive control serum is prepared by mixing appropriate amount of COVID-19 IgM and IgG with other serum until desired concentration of COVID-19 IgG and IgM 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 with Sienna^{TM} COVID-19 IgG/IgM Rapid Test Cassette and Clarity COVIBLOCK™ COVID19 IgG/IgM Antibody Test Cassettes.***

Follow the manufacturer's recommended protocol in assaying Clarity Liquid COVID-19 Ig M+IgG antibody control.

WARNINGS AND PRECAUTIONS:

* FOR IN VITRO DIAGNOSTIC USE ONLY

* FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY

* This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests.

* This product has been authorized only for detecting the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

* The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

* **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^{o}C – 8^{o}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 till labelled date of expiration if stored between use at 2-8°C. Do NOT use beyond the expiration date.

This product is warranted to perform as described in its labeling and in the product literature.

PROCEDURE:

The Clarity Liquid COVID-19 IgM+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.

For use with Sienna™ COVID-19 IgG/IgM Rapid Test Cassette and Clarity COVIBLOCK™ COVID19 IgG/IgM Antibody Test Cassettes:
Using Controls with Micropipette:

Allow the test cassette(s) to equilibrate to room temperature.

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 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 (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 3 bands, Control Band, IgM and IgG Band. If In-valid results are obtained, please perform the QC test again.

QUALITY CONTROL

SPECIFIC PERFORMANCE CHARACTERISTICS:

Clarity Liquid COVID-19 IgM+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 IgM+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. If control testing did not yield the expected results, review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the test and control immediately and contact the test distributor.

LIMITATION OF THE PROCEDURE:

The Clarity COVID-19 human IgM/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 venous/fingerstick whole blood, serum, or plasma specimens following protocol of the test kit manufacturer. Performance characteristic of the controls were determined for COVID-19 human IgM and IgG antibody. 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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REV_03:12232020 **150303-061025**