

INTENDED USE:

The CoronaChek COVID-19 IgG controls are an In Vitro Diagnostic (IVD) device, for professional use only that is intended for use as quality control solution to monitor the functionality of the COVID-19 Rapid Test Cassette (whole blood/plasma serum).

SUMMARY AND EXPLANATION:

The IgG control is manufactured using a biological buffer matrix that has been stabilized to insure that the solution will be viable for 7 days after opening. The non-IgG containing control is manufactured using a biological buffer matrix that has been stabilized to insure that the solution will be viable for 30 days after opening.

STORAGE & STABILITY -**Unopened:**

- A. The IgG control is stable for 30 days after the bottling date when stored at 2° to 8°C.
- B. The non-IgG control is stable for 90 days after the bottling date when stored at 2° to 8°C.

After Opening:

- A. The IgG control is stable for 7 days after opening, when stored at 2° to 8°C prior to use.
(Controls can be refrigerated and brought back to room temperature up to 7 times)
- B. The non-IgG control is stable for 30 days after opening, when stored tightly capped at 2° to 8°C.
- C. Controls should be allowed to come to room temperature followed by gentle inversion before use.

PROCEDURE:

Allow controls to come to room temperature followed by gentle inversion before use. DO NOT SHAKE. Pipette one drop into the sample well (labeled with an S). No buffer is needed.

LIMITATIONS:

This control is meant to be used to validate the performance of the CoronaChek COVID-19 IgG Rapid Test Cassette only. It has not been validated for use with COVID serology tests from any other provider. The CoronaChek controls are unassayed; each laboratory or test site should run these controls as unknowns in order to establish "in-house" expected results. ***This product is not meant to be used as a standard or calibrator.***

ORDERING INFORMATION

Catalog # : COVID-19-IgG Size 0.5 mL, each

Description: CoronaChek IgG control and CoronaCheck non-IgG

Manufacturer:
CLIAwaived, Inc
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San Diego, CA 92121

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For additional information on our other products
please contact us or refer to our website.

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SYMBOL LEGEND	
	Consult Instructions for Use
	Temperature Limits
	<i>In Vitro</i> Diagnostic Medical Device
	Batch Code
	Product Catalog Number
	Manufacturers Identification
	Use by Date