

COVID-19 Antibody Tests (CA)

Product Specification Sheet



INSTI® COVID-19 Antibody Tests (50 individual tests with support materials)

Product Code

90-1092

List Price

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Sample Type

Human venipuncture whole blood, serum and plasma

Kit Contents

50 individual tests per box

1 Single Test with Support Materials

• 1 Membrane Unit

• 1 Bottle 1, Sample Diluent (1.5 mL)

• 1 Bottle 2, Colour Developer (1.5 mL)

• 1 Bottle 3, Clarifying Solution (1.5 mL)

• 1 Single-Use Safety Sterile Lancet

• 1 Capillary Test Pipette

• 1 Alcohol Swab

• 1 Instructions for Use

Test Run Time

1 minute

Shelf Life¹

6 months

QC

Requirements

 \bullet For new $\mathsf{INSTI}^{\circledR}$ operator verification prior to performing testing on patient specimens

· When switching to a new lot number of INSTI test kits • Whenever a new shipment of kits is received

• When temperature during storage of the kit falls outside of 2 - 30°C (35.6 - 86°F)

• When the temperature of the test area falls outside of

15 - 30°C (59 - 86°F)

· Approved for lab use only

Storage **Conditions**

2 - 30°C (35.6 - 86°F) until expiration date

Performance²

Sample Type

PPA

NPA

Plasma/Serum

98.2% (163/166) 99.6% (259/260)

¹From date of manufacture. Shelf life will be updated/extended as further stability data becomes available.

Performance estimated using SARS-CoV-2 PCR positive plasma/serum samples and negative plasma/serum samples, with negative samples collected October 2019 or prior.

Additional Accessories (Sold Separately) Code

Product

Manufactured by:



bioLytical Laboratories Inc.

406-13251 Delf Place Richmond, BC Canada V6V 2A2 1-866-674-6784 I info@biolytical.com

