1.3. *Venous Whole Blood Samples*. Thirty-seven (37) SARS-CoV-2 negative whole blood samples (collected in K_2EDTA tubes) were assessed with REVEALCOVID-19™ Total Antibody Test prior to studies. Blood specimens were then fractionated and ~300µL of plasma from each was exchanged for the RT-PCR confirmed SARS-CoV-2 positive plasma samples.

		Clinical Truth	
		Positive	Negative
REVEALCOVID-19™ Total Antibody Test	Positive	36	1
	Negative	0	37

PPA = 97.1%
NPA = 100.0%

2. Cross-Reactivity. A total of 91 serum or plasma specimens were tested to assess the cross-reactivity. Three (3) independent replicates of each were assayed. Two (2) specimens (present among sample types marked by an asterisk (*) below) were found to be of a viscous consistency, were unable to successfully penetrate the test membrane, and repeatedly produced Invalid results. These samples were excluded as outliers. One (1) specimen (present among sample types marked by a double asterisk (**) below) produced consistent false positive results.

Sample Type	Number of Samples
Multiparous female	(n=2)
*Pregnant female	(n=4)
Influenza Vaccine recipient	(n=1)
Hepatitis A Vaccine recipient	(n=1)
Hepatitis B Vaccine recipient	(n=1)
Self-reported drug user	(n=1)
Non-viral liver disease	(n=1)
HAV IgG Positive	(n=2)
Nuclear Antibody (ANA)	(n=2)
VZV IgG Positive	(n=2)
HSV-1 IgG Positive	(n=2)
Chlamydia IgG Positive	(n=2)
Leptospira IgG Positive	(n=2)
Mumps IgG Positive	(n=2)
Malaria IgG Positive	(n=2)
Lyme IgG Positive	(n=2)
SLE, Diagnosed	(n=2)
HTLV I/II Antibody	(n=2)
Hepatitis Delta	(n=2)
HIV-1	(n=3)
HIV-2	(n=2)
HBV	(n=3)
HCV	(n=3)
*Treponema pallidum IgG positive	(n=3)
Elevated C-reactive protein	(n=2)
Elevated Gamma Glutamyl transferase (GGT)	(n=2)
Elevated Aspartate Transaminase (AST)	(n=1)
Elevated Aspartate Transaminase (AST), HIV positive	(n=1)
Elevated IgG, HIV positive	(n=1)
Elevated IgG	(n=1)
Elevated IgM	(n=2)
**E. coli culture	(n=2)
Elevated Alkaline Phosphatase (ALP)	(n=2)
Elevated Bilirubin	(n=2)
Elevated Rheumatoid factors	(n=2)
Elevated Alanine Aminotransferase (ALT)	(n=2)
Parvovirus B19 IgG	(n=2)
Rubella IgG	(n=5)
Cytomegalovirus IgG	(n=5)
Toxoplasmosis IgG	(n=5)
EBV IgG	(n=5)

PRODUCT WARRANTY: MedMira Inc. guarantees the quality of this product if stored and used as instructed. Any component of the test found to be defective shall be replaced free of charge upon return of the defective product. MedMira Inc. disclaims any implied warranty of merchantability or fitness for a particular purpose, and in no event shall MedMira Inc. be liable for consequent damage.

Explanation of Symbols

- Temperature Limit
- Do not reuse
- Manufacturer
- Date of Manufacture
- Use by date
- REF Catalogue number
- IVD *In vitro* Medical Device
- LOT Lot number
- Consult Instructions for use

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REVEALCOVID-19™
Total Antibody Test

REF 815311006623

INTENDED USE: REVEALCOVID-19™ Total Antibody Test is an *in vitro* diagnostic test for the qualitative detection of total antibodies to the specific SARS-CoV-2 epitopes in human serum, plasma and whole blood samples collected in CLIA certified laboratories and/or by the healthcare workers at the point-of-care.

THIS PACKAGE INSERT MUST BE READ COMPLETELY BEFORE PERFORMING THE TEST. FAILURE TO FOLLOW INTRUSIONS MAY YIELD INACCURATE RESULTS.

DEVICE DESCRIPTION: REVEALCOVID-19™ Total Antibody Test is a manually performed, visually interpreted Rapid Vertical Flow® (RVF) immunoassay that detects total antibodies to SARS-CoV-2, the causative agent of COVID-19 disease, in human serum, plasma and whole blood. REVEALCOVID-19™ Total Antibody Test consists of a Test Cartridge, an InstantGold Cap, and two (2) vials of pre-aliquoted multifunctional Universal Buffer solution. Test Cartridge consists of two plastic casings (top and bottom) that snap together to securely hold the immunoreactive membrane overlaid on top of the absorbent pad. The membrane is coated with a combination of synthetic proteins that correspond to the conserved regions of the SARS-CoV-2 nucleocapsid protein (T zone), thus, allowing the capture of SARS-CoV-2 antibodies present in a drop of human serum, plasma or whole blood. Following the application of InstantGold cap, which contains proprietary Protein A/L colloidal gold conjugates, antigen – antibody immunocomplexes are visualized. As a procedural/reagent control, Protein A is immunoprinted in a designated area (C zone) on the immunoreactive membrane to allow a non-specific capture of IgG antibodies. Universal Buffer solution is a proprietary formulation of ionic and non-ionic detergents in Tris-buffered saline solution with four main functions: a) lysis of blood cells in whole blood specimens; b) optimization of the interactions between capture antigens on the test membrane and antibodies present in the specimen; c) reduction of non-specific binding to the membrane; d) reconstitution of the colorimetric detection agent contained in the InstantGold Cap.

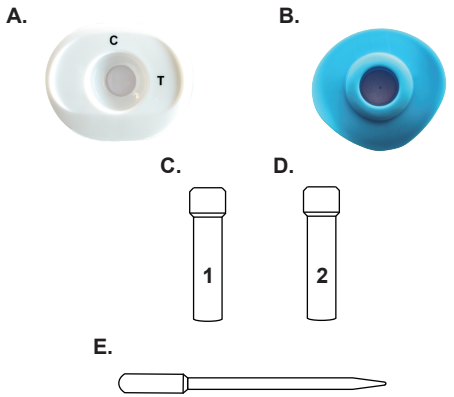
LIMITATIONS:

- This test has not been reviewed by FDA
- This test is for use with serum, plasma, or whole blood specimens only. Use of other types of specimens may yield inaccurate results.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with molecular diagnostics should be considered to rule out infection in these individuals
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E
- This test is not intended for the screening of donated blood

REAGENTS AND MATERIALS PROVIDED: This test is supplied in Point-of-Use (POU) format.

50 Pouches each containing:

(A) - 1 Test Cartridge
(B) - 1 InstantGold Cap
(C) - 1 Universal Buffer Vial 1
(D) - 1 Uvinersal Buffer Vial 2
(E) - 1 disposable pipette
1 silica gel packet



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WARNINGS AND SAFETY PRECAUTIONS:

1. The test is intended for *in vitro* diagnostic use by healthcare professionals. This product is not for self-testing.
2. Handle specimens, and all materials contacting specimens as if capable of transmitting infectious agents. It is recommended that all specimens and test reagents are handled according to Universal Precautions.
3. Do not open the sealed pouch until you are ready to perform the test.
4. Do not use expired devices.
5. Equilibrate all components to room temperature (15-27°C) for 30-60 minutes before use.
6. Do not touch the immunoreactive test membrane. Touching the membrane may compromise test results.
7. Do not pipette by mouth.
8. Exercise care in handling test components to prevent contamination.
9. Wear disposable gloves, laboratory coat and eye protection throughout the test procedure.
10. Do not smoke, eat, or drink in areas where specimens or test reagents are handled.
11. Dispose of all test specimens and materials used in the test as directed by governing infectious waste guidelines.
12. Store in a dry place at 2 - 30°C.
13. Do not interchange reagents or devices from different lots.

SPECIMEN COLLECTION AND HANDLING:

1. Serum and Plasma samples

- Plasma obtained using EDTA, heparin, or sodium citrate as anticoagulants is suitable for testing
- Use of fresh specimens is recommended. If not tested immediately, store at 2-8 °C for up to 5 days, and at ≥ -20 °C for more than 5 days.
- Particulate matter can block the test membrane. Cloudy or viscous specimens should not be used for testing.
- If previously frozen, thaw completely at room temperature (15-27°C) and mix by gently tapping the capped tube. Centrifuge the specimen in a small, capped tube at room temperature at 3,361 X g for ≥ 5 minutes and use only the clear supernatant for testing.
- Avoid multiple freeze-thaw cycles. A specimen should not be frozen and thawed more than twice prior to use.

2. Venipuncture Whole Blood Samples

- Use standard venous phlebotomy procedures to collect a whole blood sample in a tube containing K_2EDTA anticoagulant. If not tested immediately, store at 2-8 °C for up to 5 days. Prior to testing, mix blood by gentle inversion.

3. Fingerstick Whole Blood Samples

- This test has not been tested with fingerstick whole blood samples. Use of fingerstick whole blood is not recommended

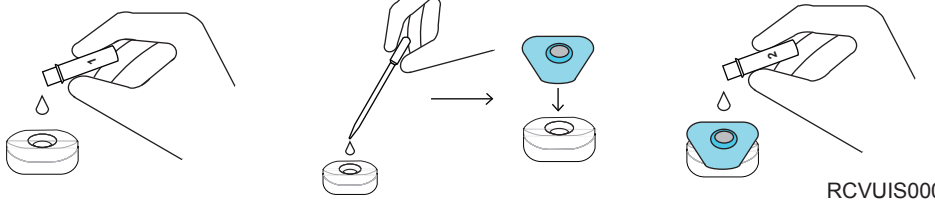
TEST PROCEDURE:

A. Serum or Plasma Samples:

STEP 1: Pour the entire contents of the Universal Buffer Vial 1 into the center of the Test Cartridge. Allow to absorb COMPLETELY.

STEP 2: Add one (1) drop of sample directly onto the test membrane. Allow to absorb. Place the InstantGold cap on the test cartridge

STEP 3: Pour the entire contents of Universal Buffer Vial 2 onto the InstantGold cap and allow to absorb completely. Remove the InstantGold cap, allow the remaining solution to completely flow through. Read test results immediately.

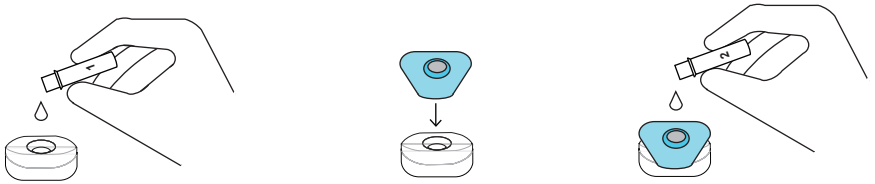


A. Venipuncture Whole Blood Samples:

STEP 1: Add one (1) drop of blood sample to the Universal Buffer Vial 1, mix and pour the entire contents of the vial into the center of the Test Cartridge. Allow to absorb COMPLETELY.

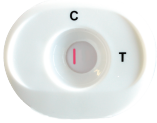
STEP 2: Place the InstantGold cap on the test cartridge

STEP 3: Pour the entire contents of Universal Buffer Vial 2 onto the InstantGold cap and allow to absorb completely. Remove the InstantGold cap, allow the remaining solution to completely flow through. Read test results immediately.



INTERPRETATION OF RESULTS:

REACTIVE TEST RESULTS (Total antibodies to SARS-CoV-2 are probably present)
The presence of both a vertical red Control Line (C) and a red dot (T) on the test, regardless of intensity, means the individual might have antibodies to SARS-CoV-2 in the blood. Any visible dot beside T on the test must be considered to be a Reactive result. The intensity of the red dot does not necessarily correlate with the antibody titre of the specimen. All Reactive test results should be confirmed and evaluated with respect to overall clinical evaluation before a diagnosis is made.



NON-REACTIVE TEST RESULTS (Total antibodies to SARS-CoV-2 are probably absent)
The presence of a vertical red Control Line (C) means the individual might not have antibodies to SARS-CoV-2 in the blood, or the antibody concentration is below the detection level. Following the exposure to SARS-CoV-2 it may take several days for the antibody response to reach detectable levels. If there is a reason for concern, the test should be repeated within 3 to 6 days.

INVALID TEST RESULTS
The result is Invalid if red line under the C is broken or absent, even if a dot appears beside T. Invalid result means there has been a problem, either with the test or the specimen. The test should be performed again, using a new device. If the problem persists, contact MedMira Customer Support.

ASSAY PERFORMANCE SUMMARY:

1. Percent Positive and Negative Agreement Studies.

1.1. *Plasma Samples*. Thirty-seven (37) RT-PCR confirmed SARS-CoV-2 positive and 124 negative (collected between 2013 and 2015) plasma samples were tested.

		Clinical Truth	
		Positive	Negative
REVEALCOVID-19™ Total Antibody Test	Positive	36	2
	Negative	1	122

PPA = 97.1%
NPA = 98.1%

1.2. *Serum Samples*. Thirty-one (31) RT-PCR confirmed SARS-CoV-2 positive and 110 negative (collected between 2013 and 2015) serum samples were tested.

		Clinical Truth	
		Positive	Negative
REVEALCOVID-19™ Total Antibody Test	Positive	31	1
	Negative	0	109

PPA = 100.0%
NPA = 99.0%