Camp Medica Distribution - No. 29 Stanei Street, S4, Bucharest, Romania
phone: +4021-450 58 90
e-mail: export@campmedica.ro
http : //www.campmedica.ro

"See Now" Rubella IgG/IgM Test
Whole Blood/Serum/ Plasma
For in vitro Diagnosis Use
Product Code: SN 10.1

INTENDED USE
"See Now" Rubella IgG/IgM Test is a rapid and convenient immunochromatographic *in vitro* assay. It is for detection of IgG and IgM antibodies of Rubella Virus in human serum, plasma or whole blood. The test provides a visual, qualitative result, and all positive specimens must be confirmed with other qualified assays. The test is intended for healthcare professional use only.

SUMMARY OF TEST
Rubella virus is a member of the *Togaviridae* family, found mainly in human populations. Although rubella can strike people of all ages, it poses the greatest danger to unborn babies. Congenital rubella syndrome (CRS) occurs when the rubella virus attacks a developing fetus. Up to 85% of infants infected during the first trimester will be born with birth defects, including deafness, blindness, heart defects, and mental retardation. Miscarriages are also common. Growth retardation and diabetes mellitus have also been associated with late complications of congenital rubella.
In an adult, IgG antibodies usually persist throughout life, while IgM appear after the rash fade but don't persisit after serveral weeks. So, the determination of rubella IgM antibody is particularly useful for the effective distinction between recent infection or vaccination, and acquired immunity. Screening for IgG antibodies to rubella virus is also a useful tool for diagnosis of the rubella disease and for determination of the immune status.
"*See Now*" RV IgG/ IgM test is based on the principle of Gold immunochromatography Assay. Specific RV recombinant antigens and anti-human monoclonal antibodies are used to detect RV IgM and IgG antibodies respectively in the human serum samples with high sensitivity and specificity.
If there is RV IgM/IgG antibody in the specimen, these antibodies will react with the anti-human RV IgM/IgG monoclonal antibody in the membrane strip, chemical complexes will form. These complexes move along the strip chromatographically to the test region (T), where these complexes will be captured by the pre-coated recombinant RV antigen. Then a red or pink line will appear, indicating a positive result. The unbounded complex moves on to the control region (C), where they are captured by the anti-mouse antibody, and a red or pink line will appear, indicating the assay is a valid one. So the control line provides an internal quality control mechanism.

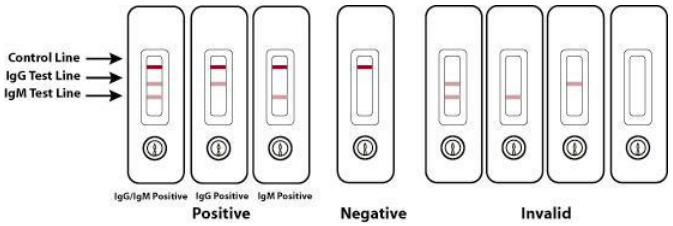
Materials Provided
Pouch Contents: Cassette, Sample Dropper, Desiccant, Test instruction, buffer bottle.

Materials needed but not provided
- Clean, specimen collection container.
- Clock or timer.

SPECIMEN COLLECTION & PREPARATION
- Collect blood in a tube without anticoagulant for serum samples and allow to clot.
- For whole blood / plasma samples, collect the blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

TEST PROCEDURE
1. Remove the testing device from the sealed pouch by tearing at the notch. Then place the testing device on a leveled surface.
2. Holding the sample dropper vertically add one drop **10µL** of specimen into the sample well, then using buffer bottle add 2 drops, around **80µL** of buffer.
3. Read the result at 15 minutes. Ensure that the background of the test area is white before interpreting the result. Do not read after 30 minutes.

INTERPRETATION OF RESULTS
Negative: Only one pink colour band appears on the control region. There is no apparent colour band on the test region.
Positive: Distinct pink colour bands appear at the control and either/both IgG and IgM test line regions.
Invalid: A total absence of color in both regions and no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. If the problem persists,



LIMITATIONS
- This product is designed for in vitro diagnostic use only.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics

IgG Results

Method		*Rub.* EIA (IgG)		Total Results
Rubella IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	83	2	85
	Negative	4	298	302
Total Results		87	300	387

Relative Sensitivity: >97.6%
Relative Specificity: >98.6%
Accuracy: 97.90%

IgM Results

Method		*Rub.* EIA (IgM)		Total Results
Rubella IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	66	1	67
	Negative	1	356	357
Total Results		67	357	424

Relative Sensitivity: 98.5%
Relative Specificity: > 99.7%
Accuracy: 98.35%