Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) Package Insert

REF ORF-302	English

A rapid test for the qualitative detection of rheumatoid factor in human serum or plasma. For professional in vitro diagnostic use only.

【INTENDED USE】

The Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of rheumatoid factor in human serum or plasma as an aid in the diagnosis of rheumatoid arthritis.

【SUMMARY】

Rheumatoid factor (RF) is an autoantibody most relevant in rheumatoid arthritis. It is an antibody against the Fc portion of IgG, which is itself an antibody. RF is often evaluated in patients suspected of having any form of arthritis even though positive results can be due to other causes. It is part of the usual disease criteria of rheumatoid arthritis, and RF may serve as one of several serological markers for autoimmunity unrelated to rheumatoid arthritis[1]. High levels of rheumatoid factor (generally above 20 IU/ml) occur in rheumatoid arthritis (present in 80%) and Sjögren's syndrome (present in 70%)[2,3]. Rheumatoid Factor (RF) Rapid Test Cassette utilizes RF antibodies to specifically detect the presence of RF in human serum/plasma without the use of an instrument.

The Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) is a rapid test that utilizes a combination of rheumatoid factor antibodies coated colored particles for the detection of Rheumatoid Factor in human serum or plasma.

【PRINCIPLE】

Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) is a qualitative membrane based immunoassay for the detection of RF in serum or plasma. During testing, RF in the specimen reacts with the particle coated with human denatured IgG. The mixture migrates upward on the membrane chromatographically by capillary action to react with human denatured IgG on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains human denatured IgG coupled colloidal gold particles; human denatured IgG coated in the test region of the membrane; polyclonal anti-mouse IgG antibodies coated in the control region of the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma.
- 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 specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

【MATERIALS】

Materials provided

- Test cassettes
- Buffer
- Droppers
- Package insert

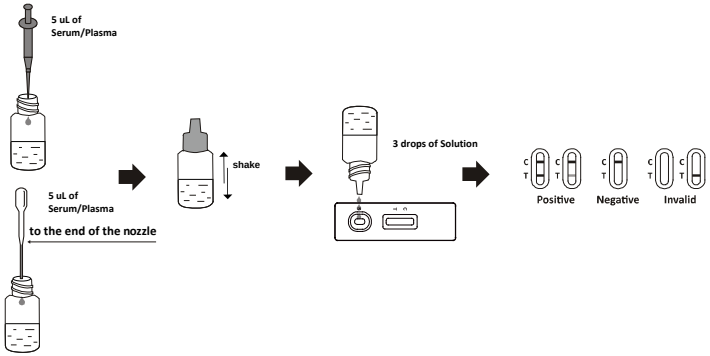
Materials required but not provided

- Specimen collection containers
- Micropipette
- Centrifuge
- Timer

【DIRECTIONS FOR USE】

Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
   - To use a dropper: Hold the dropper vertically, draw the specimen up to the upper end of the nozzle (approximately 5µl), and transfer the specimen into prepared vial containing 5ml of diluents, shake the vial to mix the specimen and the diluents.
   - To use a micropipette: Pipette and dispense 5µl of specimen into prepared vial containing 5ml of diluents, shake the vial to mix the specimen and the diluents.
3. Unscrew the cap on the vial and dispense 3 drops of specimen solution into the sample well of the test cassette.
4. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of RF present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test cassette immediately and contact your local distributor.

【QUALITY CONTROL】

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, confirming sufficient buffer volume and adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of rheumatoid factor in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in rheumatoid factor concentration can be determined by this qualitative test.
2. The Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) will only indicate the presence of rheumatoid factor in the specimen and should not be used as the sole criteria for the diagnosis of rheumatoid arthritis.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. The use of a rapid test alone is not sufficient to diagnose rheumatoid arthritis. Also, a negative result does not preclude the possibility of rheumatoid arthritis.
5. Grossly hemolyzed, icteric or lipemic specimens should be avoided.

【EXPECTED VALUES】

The Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial Rheumatoid Factor test. The correlation between these two systems is 97.8%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Analytical sensitivity of Rheumatoid Factor (RF) Rapid Test Cassette is 25IU/ml. Three lots of Rheumatoid Factor (RF) Rapid Test Cassette were tested with different concentrations of RF reference (0IU/ml,12.5IU/ml, 25IU/ml and 50IU/ml). The total number of determinations per level was 10. The diagnostic sensitivity was determined when all 10 replicates showed positive results.

RF Concentration (IU/ml)	Lot 1 (+/-)	Lot 2 (+/-)	Lot 3 (+/-)
0	0/10	0/10	0/10
12.5	5/5	6/4	6/4
25	10/0	10/0	10/0
50	10/0	10/0	10/0

The Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) has correctly identified a panel of specimens. Besides, a side by side comparison study was conducted using the test with a leading commercially available predicate Rheumatoid Factor test. Testing was performed with total of clinical samples.

The results show that the overall relative sensitivity of the Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) is 98.0%, and the relative specificity is 97.7%, and the relative accuracy is 97.8%.

Method		Reference Method		Total Result
Rheumatoid Factor Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	98	3	101
	Negative	2	127	129
Total Result		100	130	230

Relative sensitivity: 98.0% (95%CI*: 93.0%~99.8%)
Relative specificity: 97.7% (95%CI*: 93.4%~99.5%)
Accuracy: 97.8% (95%CI*: 95.0%~99.3%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: 0IU/ml, 25IU/ml and 50IU/ml. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: 0IU/ml, 25IU/ml and 50IU/ml. Three different lots of the Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Rheumatoid Factor Rapid Test Cassette (Serum/Plasma) has been tested by HAV, HBsAg, Syphilis, HIV, HCV, HEV, Systemic lupus erythematosus, Triglyceride and Total bilirubin positive specimens. The results showed no cross-reactivity.

【BIBLIOGRAPHY】

1. Rostaing L, Modesto A, Cisterne JM, Izopet J, Oksman F, Duffaut M, Abbal M, Durand D. "Serological markers of autoimmunity in renal transplant patients with chronic hepatitis C". American journal of nephrology 18 (1): 50 – 56, 1998.
2. Goodyear CS, et al. Rheumatoid factors and other autoantibodies in rheumatoid arthritis. In: Firestein GS, et al. Kelley's Textbook of Rheumatology. 8th ed. Philadelphia, Pa.: W.B. Saunders Elsevier; 2008.
3. Shmerling RH. Origin and utility of measurement of rheumatoidfactors.http://www.uptodate.com/home/index.html. Accessed Aug. 19, 2010.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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