RA Kit Update/Correlation

A new RA/RT test from Fisher Healthcare is replacing the older, outdated test from Siemens. Effective July 6th, 2023 the new test will become active. A validation/correlation study was performed to ensure the results from the Siemens RT test are in alignment with the new Fisher Healthcare test. 10 negative patient samples were tested using both tests, with an agreement between them of 100%. Positive quality control was used to correlate positive results between the two kits, 6 tests were performed with 100% agreement.

The procedure has been updated and signed off by the CLIA Medical Director.

The new RT Sure Vue test is approved for patient testing.

(See attached documents)

Review/Approval:_____ Date: 6-28-23

CLIA Lab Director

FHN Lab Procedure

SUBJECT Rheumatoid Factor (RF or RA test)			
FORMER SUBJECT SAME	DATE REVISED 06/28/2023	DATE EFFECTIVE 07/06/2023	PAGE 1 OF 1
OWNER: Laboratory Services	Medical Director INIT/DATE 6-28-23	APPROVED BY:	
DATE ORIG. WRITTEN 03/1994	DATE REVIEWED:		
SPECIAL APPROVAL DEPT. OR COMMITTEE APPROVING		DATE OF MEETING:	
APPLIES TO: Laboratory			

PURPOSE: To provide guidelines for the use of the slide agglutination assay for the qualitative and semiquantitative determination of rheumatoid factor (RF) in human serum.

POLICY STATEMENTS:

A. Polystyrene particles coated with human gammaglobulin are agglutinated when mixed with samples containing rheumatoid factor.
B. The approximate screening sensitivity of the test is 8.0 IU/ml.

METHOD OF IMPLEMENTATION:

A. SPECIMEN

1. Serum can be tested. Other body fluids may not be used for this test. The serum can be stored refrigerated for no more than 48 hours or frozen if not assayed immediately. Markedly lipemic sera or microbial contamination may cause false positive agglutination.

B. REAGENT/SUPPLIES/EQUIPMENT

2. In kit
   a. RF Latex Reagent
   b. Glycine-saline solution
   c. RF positive control serum
   d. RF negative control serum
   e. Test card

3. Not in kit
   a. Mixing sticks
   b. Test tubes
   c. 40 ul. pipette
   d. Light source
   e. Laboratory timer
   f. Gloves

C. QUALITY CONTROL

1. Each new lot number kit will be tested with known controls before put into use.
2. Positive and negative controls shall be used in each patient testing series.
3. If positive and or negative controls don't react correctly, check expiration dates and examine reagents. If okay, repeat testing carefully following printed procedure.

4. If controls are okay, report result.
5. If controls still don't react properly, try a new kit if available. Save patient serum to send out test if no new kit available.
6. Notify Microbiology department of problem.
7. Document all steps taken to resolve problem on the corrective action log.

D. PROCEDURE

1. Bring all reagents and serum samples to room temperature.
2. Gently mix reagents prior to use.
3. Using the test card in the kit, place:
   a. 1 drop of RF positive control serum on field 1
   b. 1 drop of RF negative control serum on field 2
   c. 0.05 ml (50 ul) of patient's serum on field 3
4. Gently mix the RF Latex reagent to obtain a uniform suspension.
   a. Expel the contents of the dropper, refill and add 1 drop to each field containing a sample or control.
   b. Mix each field with a separate mixing stick, spreading the mixture over most of the field.
   c. Rotate the slide by hand for 2 minutes.
5. Examine for agglutination. Checking for agglutination under a light source can be facilitating.

E. LIMITATIONS

1. Reaction times longer than 2 minutes may produce false positive reactions.
2. Markedly lipemic or contaminated sera may also cause false positive reaction.
3. Care should be taken to keep the RF latex reagent dropper vial tightly closed to prevent flocculation due to evaporation of the suspension.
4. Approximately 2% of sera of healthy individuals give a positive RF reaction. Also 6% of people with other disease states may show reactivity (i.e. liver disease, a-globulinemia, hepatitis, endocarditis and parasitic and viral infections.)

F. INTERPRETATION

1. Positive Test
   a. Any agglutination of patient field, may be weaker than positive control.

2. Negative Test
   b. No agglutination in patient field as compared to negative control.

G. REFERENCES

1. Fisher Healthcare Sure Vue RF Slide Test package insert 10/2021