REAGENT STORAGE AND STABILITY

1. Reagents are stable until stated expiration date on bottle label when stored refrigerated (2 - 8°C).
2. DO NOT FREEZE.
3. The CRP latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, slight sedimentation may occur and should be considered normal.
4. Do not use the latex reagent or controls if they become contaminated.

SPECIMEN COLLECTION AND STORAGE

1. Use fresh serum collected by centrifuging clotted blood.
2. If the test cannot be carried out on the same day, the serum may be stored between 2 - 8°C for no longer than 72 hours after collection.
3. For longer periods, the sample must be frozen.
4. As in all serological tests, hemolytic or contaminated serum must not be used.
5. Do not use plasma.

MATERIALS AND REAGENTS PROVIDED

1. CRP Latex Reagent
2. CRP Positive Control
3. CRP Negative Control
4. Glycine-Saline Buffer
5. Reaction Slide
6. Pipette/Stir Sticks

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer
2. Test tubes
3. Test tube rack

PROCEDURE

QUALITATIVE TEST:

1. Bring reagents and specimens to room temperature before use.
2. Place one drop (50 µl) of the CRP Positive Control on field #1 of the reaction slide. Place one drop (50 µl) of the CRP Negative Control on field #2. The remaining fields are used for test specimens. Using pipettes provided, place one drop of the undiluted specimens on successive fields. Retain pipette/stir sticks for mixing step.
3. Gently resuspend the CRP Latex Reagent and add one drop to each test field. Use pipette/stir stick to spread reaction mixture over the entire test field.
4. Rotate the slide for three (3) minutes and read immediately under direct light.

SEMI-QUANTITATIVE TEST:

1. Set up at least five test tubes: 1:2, 1:4, 1:8, 1:16, etc.
2. Dilute sample according to dilution factor on each test tube with diluted saline solution.
3. Place one drop of each of positive and negative controls onto separate slide fields. Place one drop of each dilution on successive fields of the reaction slides.
4. Gently resuspend the CRP Latex Reagent and add one drop to each test field.
5. Mix well with the flat end of the pipette. Gently rock the slide for three (3) minutes and read immediately under direct light.
6. The titer of the serum is the reciprocal of the highest dilution:
exhibiting a positive reaction multiplied by the concentration of
the positive control.

\[
\text{mg/dL of serum} = \frac{\text{concentration of assay cutoff}}{\text{reciprocal of last dilution showing a positive result}}
\]

<table>
<thead>
<tr>
<th>Dilution</th>
<th>Reciprocal</th>
<th>Conc. of serum (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:2</td>
<td>2</td>
<td>1.6</td>
</tr>
<tr>
<td>1:4</td>
<td>4</td>
<td>3.2</td>
</tr>
<tr>
<td>1:8</td>
<td>8</td>
<td>6.4</td>
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<tr>
<td>etc.</td>
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</tbody>
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QUALITY CONTROL
1. CRP Positive and Negative Control should be included in each test batch.
2. Acceptable performance is indicated when a uniform milky suspension
with no agglutination is observed with the CRP Negative Control and agglutination
with large aggregates is observed with the CRP Positive Control.

INTERPRETATION
Negative Result: A negative reaction is indicated by a uniform milky
suspension with no agglutination as observed with the CRP Negative Control.

Positive Result: A positive reaction is indicated by any observable
agglutination in the reaction mixture. The specimen reaction should
be compared to the CRP Negative Control (Figure 1).

![Positive and Negative Reaction](Image)

Figure 1.

EXPECTED VALUES
1. CRP in healthy individuals is approximately 0.02-1.35 mg/dL.
   The mean value in adults is 0.047 mg/dL.
2. A weak positive correlation was found between CRP and age.
3. It is important to determine the level of CRP for monitoring
   patient progress. This is due to (1) the concentration of CRP is
   an index of tissue damage incurred and (2) increasing or
decreasing levels of CRP (e.g. daily) indicate the progress of
   inflammatory process.7

LIMITATIONS
1. Reaction time is critical. If reaction time exceeds three (3)
   minutes, drying of the reaction mixture may cause false positive
   results.
2. Freezing the CRP Latex Reagent will result in spontaneous
   agglutination.
3. Intensity of agglutination is not necessarily indicative of relative
   CRP concentration; therefore, screening reactions should not be
   graded.
4. A false negative can be attributed to a prozone phenomena
   (antigen excess). It is recommended, therefore, to check all
   negative sera by retesting at a 1:10 dilution with glycine buffer.

PERFORMANCE
1. Sensitivity: greater than 0.8 mg/dL
2. Linearity: 25 mg/dL.
3. Comparison:
   A. Qualitative Results: A study performed using CRP Latex
      Reagent and a commercially available product yielded
      100% accuracy.
   B. Semi-quantitative Results: A panel of 32 CRP positive
      serum samples was assayed (semi-quantitated) on same
day. The results of the study indicated that CRP Latex
      Reagent has 92.9% precision.

REFERENCES

CRP: 04/12

Manufactured by:

TECO DIAGNOSTICS
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