LIMITATIONS OF THE PROCEDURE

1. CRP levels in the range of 15 mg/L or above can cause false negative results due to the phenomenon known as prozone.
2. Serum CRP levels increase in the first trimester of pregnancy. Women on oral contraceptives and utilizing intrauterine devices may also have elevated serum CRP levels[3].
3. CRP levels are higher among men who suffer MI or ischemic stroke later in life[4].
4. Contaminated, lipemic, or grossly hemolyzed sera should not be used because of the possibility of nonspecific results.
5. Plasma samples should not be used because of the possibility of nonspecific results.
6. Temperature of the reagents and samples is crucial to test outcome. It should be between 20- 30°C.
7. Reaction times longer than specified might cause false positive results due to a drying effect.
8. In accord with all diagnostic methods, a final diagnosis should not be made on the result of a single test, but should be based on a correlation of test results with other clinical findings.

EXPECTED VALUES

CRP has been detected in serum obtained from apparently healthy adults[5] and normal children[6]. The reported mean value [5,6,7] ranged from 0.1 mg/L in newborns to 0.5 mg/L in male adults. The CRP level can increase significantly (>10-fold) above the normal values with the onset of a substantial inflammatory stimulus.

WARRANTY

This product is warranted to perform as described in its labeling and ARLINGTON SCIENTIFIC, INC. literature. ARLINGTON SCIENTIFIC, INC. disclaims any implied warranty of merchantability or fitness for a particular purpose and in no event shall ARLINGTON SCIENTIFIC, INC. be liable for consequential damages.

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6004-500 02/11

ASI
CRP SLIDE TEST

For in vitro diagnostic use

Catalog Number	Kit Size
500025	25 Tests
500050	50 Tests
500100	100 Tests
5001000	1000 Tests

CPT Code: 86140

INTENDED USE

The **ASI CRP Slide Test** is a slide agglutination assay for the qualitative and semi- quantitative detection of C-reactive protein (CRP) in human serum. No initial dilution of patient samples is required for this test. These materials are intended to be acquired, possessed and used only by health professionals.

SUMMARY AND EXPLANATION

Elevated levels of CRP are known to be sensitive indicators of inflammation associated with the acute phases of such diseases as rheumatic fever, rheumatoid arthritis and most bacterial and some viral infections. The serum CRP level tends to appear sooner and also subside faster than an elevated Erythrocyte Sedimentation Rate (ESR)[1]. Monitoring the CRP level may provide valuable information on the progress of a disorder and its treatment.

PRINCIPLE OF THE PROCEDURE

Since the discovery that rabbits form precipitating antibodies against CRP[2], many immunoprecipitating techniques have been developed. The **ASI CRP Slide Test** is based on the immunologic agglutination reaction between CRP as antigen and the corresponding antibody coated on the surface of biologically inert latex particles. The CRP latex reagent is prepared to provide a sensitivity (detectable limit) of 6 mg/L and a specificity of >95%.

REAGENTS

LATEX REAGENT - Suspended inert latex particles coated with anti-CRP, with 0.1% sodium azide as preservative.

GLYCINE-SALINE SOLUTION - Glycine buffer in saline, with 0.1% sodium azide as preservative.

CONTROLS (REACTIVE, NONREACTIVE) - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use

1. ASI CRP LATEX REAGENT, GLYCINE-SALINE SOLUTION and CONTROLS contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large quantities of water to prevent azide buildup.
2. ASI CRP CONTROLS contain human serum or plasma which has been tested at the donor level for HBsAg and for HIV-1, HIV-2 and HCV antibodies and found to be nonreactive. As no known test offers complete assurance that infectious agents are absent, the CONTROLS should be considered potentially infectious and universal precautions should be used. The CDC/NIH Health Manual "Biosafety in Microbiological and Biomedical Laboratories" describes how these materials should be handled in accordance with Good Laboratory Practice.
3. Do not pipet by mouth.
4. Do not smoke, eat, drink or apply cosmetics in areas where plasma/serum samples are handled.
5. Any cuts, abrasions or other skin lesions should be suitably protected.
6. This product contains synthetic latex.

Handling and Procedural Notes

1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples.
2. Do not use past the expiration date indicated on the kit.
3. Do not interchange components of one kit with those of another kit.

Storage Instructions

Store all reagents at 2-8°C in an upright position when not in use. Do not freeze reagents. Pipets and cards do not require refrigeration.

Indications of Deterioration

1. Turbidity or precipitation in controls is indicative of deterioration and the component should not be used
2. Bacterial contamination of reagents or specimens may cause false positive results.

SPECIMEN COLLECTION AND STORAGE

1. Use only serum that is free from contamination. Test samples should not be heat-inactivated.
2. It is preferable to test samples on the day of their collection. If samples cannot be tested immediately, maintain them in their original tubes at 2-8°C and test within 48 hours.
3. Serum samples stored longer than 48 hours should be stored at -20°C or below until testing. Avoid repeated freezing and thawing of specimens.
4. If necessary before testing, centrifuge the specimens at a force sufficient to sediment cellular components
5. Samples to be sent out for testing should be placed on ice packs and packaged like any other biohazardous material that could potentially transmit infection.

PERFORMANCE OF THE TEST

Materials Provided:

	25 Tests	50 Tests	100 Tests	1000 Tests
CRP LATEX REAGENT	1.0 ml	2.0 ml	2 x 2.0 ml	20 x 2.0 ml
REACTIVE CONTROL	0.5 ml	1.0 ml	1.0 ml	10 x 1.0 ml
NONREACTIVE CONTROL	0.5 ml	1.0 ml	1.0 ml	10 x 1.0 ml
GLYCINE-SALINE SOLUTION	50 ml	100 ml	100 ml	10 x 100 ml
0.05 ml Disposable Stirrer Pipets	25	50	100	1000
Disposable Test Cards (6-Well)	5	9	17	170

Additional Materials Required

- Timing device
- 13 x 75 mm test tubes
- Volumetric pipet to deliver 0.25 ml
- Mechanical rotator (optional)

TEST PROCEDURE

PREPARATION FOR THE ASSAY

1. Allow all reagents and samples to warm to room temperature (20-30°C) before use. Remove reagents from foam holders. Do not heat reagents in a water bath.
2. All reagents are ready for use as supplied. Gently mix the reagents before use; avoid foaming.
3. Gently mix the LATEX REAGENT before each use to ensure homogeneity.

ASSAY PROTOCOL - QUALITATIVE

1. Using the stirrer pipets, dispense one free-falling drop (0.05 ml) of each serum sample onto a separate circle on the test card. Use a fresh stirrer pipet for each sample. When using the stirrer pipet, keep it in a vertical position to ensure accurate delivery. Repeat by adding one free-falling drop of REACTIVE or NONREACTIVE CONTROL from the dropper vials supplied. Note the location of each sample by using the numbers located below and to the right of each circle.
2. Expel the contents of the LATEX REAGENT dropper and refill. Add one drop of the reagent to each serum specimen and to each control.
3. Using the flat end of the stirrer pipets, mix each specimen and control serum with the LATEX REAGENT, in a circular manner, over the entire area in the circles of the card.
4. Gently tilt and rotate the card for two (2) minutes and observe for agglutination. All test results should be compared to both REACTIVE and NONREACTIVE CONTROLS.

ASSAY PROTOCOL - SEMIQUANTITATIVE

1. Prepare serial dilutions of patient serum, in GLYCINE-SALINE SOLUTION, in test tubes as follows:

Tube	Dilution	Composition
1	1:2	0.25 ml of serum + 0.25 ml GLYCINE-SALINE SOLUTION. Mix.
2	1:4	0.25 ml from tube 1 + 0.25 ml GLYCINE-SALINE SOLUTION. Mix.
3	1:8	0.25 ml from tube 2 + 0.25 ml GLYCINE-SALINE SOLUTION. Mix.
4	1:16	0.25 ml from tube 3 + 0.25 ml GLYCINE-SALINE SOLUTION. Mix.
5	1:32	0.25 ml from tube 4 + 0.25 ml GLYCINE-SALINE SOLUTION. Mix.

Testing on additional dilutions should be performed as needed.

2. Using each dilution as a separate test specimen, apply the samples to the card as described in step 1 of the "Qualitative Assay Protocol" and proceed with steps 2 through 4 of the "Qualitative Assay Protocol". Include undiluted sample if not tested previously on that day with the same lot of LATEX REAGENT.

QUALITY CONTROL

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact ASI Technical Support at 800.654.0146.

INTERPRETATION OF RESULTS- QUALITATIVE

Agglutination indicates a CRP concentration of greater than or equal to 6 mg/L in the serum sample. Sera that elicit a positive result should be retested and titered using the "Semiquantitative Assay Protocol".

INTERPRETATION OF RESULTS- SEMIQUANTITATIVE

The highest dilution in which visible agglutination occurs is considered the endpoint titer. The corresponding CRP concentration (in mg/L) is calculated as the product of the endpoint dilution factor and the assay cut-off value as shown in the following table.

Dilution	CRP mg/L
NEAT*	6
1:2	12
1:4	24
1:8	48
1:16	96
1:32	192

NEAT = undiluted

For example, if the endpoint dilution is 1:8, the corresponding CRP serum concentration would be 8 x 6, or 48 mg/L.