SERUM AMYLOID A (SAA) ASSAY

The Diazyme SAA Assay is an intended use for quantitatively determining SAA levels in human serum. SAA proteins are released into the bloodstream during inflammation and bind to HDL particles. Increased SAA levels are associated with acute phase responses and can indicate inflammation in autoimmune disorders and chronic inflammatory diseases. SAA is considered a sensitive marker for conditions like rheumatoid arthritis, atherosclerosis, amyloidosis, vasculitis, viral infections, and rejection reactions to kidney transplants[1-2]. However, it is not meant for diagnostic procedures and is only approved for research use in the USA.

DIAZYME SAA ASSAY ADVANTAGES

- Fast test results (<10 minutes) for a rapid turnaround time
- Low sample volume required
- Wide range of instrument parameters available for simplifying implementation
- Liquid stable reagent kit; lyopholized calibrator and control sets offered separately

REGULATORY STATUS

USA: For Research Use Only.

Not For Use In Diagnostic Procedures.

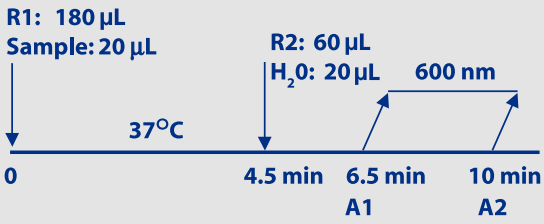
SERUM AMYLOID A (SAA) ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Serum • Plasma - EDTA - Li-heparin Sample Volume 20 µL
Method Comparison	Slope = 0.9933 y-intercept = 1.2494 R^2 = 0.9545
Linearity	Up to 150 mg/L
LOQ	4.43 mg/L
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	Stable until the expiration date on label (when stored at 2-8C)

SAA Assay Procedure**



***Analyzer Dependent**

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

1. Jovanovic DB, Clinical importance of determination of serum amyloid A, Srp Arh Celok Lek.132(7-8):267-71, 2004.

2. O'Hara R, Murphy EP, Whitehead AS, FitzGerald O, Bresnihan B. Local expression of the serum amyloid A and formyl peptide receptor-like 1 genes in synovial tis-sue is associated with matrix metalloproteinase produc-tion in patients with inflammatory arthritis, Arthritis Rheum.50(6):1788-99, 2004.

ASSAY PRINCIPLE

The Diazyme SAA Assay is based on a latex enhanced immunoturbidimetric assay. When an antigen-antibody reaction occurs between SAA in a sample and anti-SAA antibodies which have been sensitized to latex particles, agglutination occurs. This agglutination is detected as an absorbance change (660 nm), with the magnitude of the change being proportional to the quantity of SAA in the sample. The actual concentration is then determined from a 6-point calibration curve prepared from calibrators of known concentrations.

ASSAY PRECISION

A high and low level control were tested in duplicate two runs a day for 5 days. The high with a concentration mean of 100.33 mg/L and the low a concentration mean of 17.69 mg/L. The CV were 3% and 6% respectively.

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