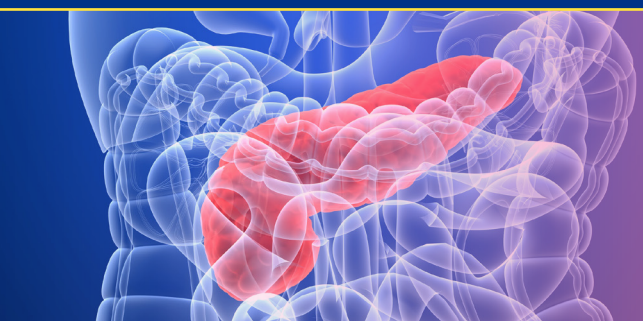
ADIPONECTIN ASSAY

Diabetic Marker



Adiponectin is an abundant circulating protein hormone that is predominantly expressed by adipose tissue.[1] Published study shows that decreased expression of Adiponectin correlates with insulin resistance. Hypoadiponectinemia, caused by interactions of genetic factors such as SNPs in the Adiponectin gene and environmental factors causing obesity, appears to play an important causal role in insulin resistance, type 2 diabetes, and the metabolic syndrome, which are linked to obesity.[2]

Diazyme's Adiponectin Assay is a cost effective latex enhanced immunoturbidimetric methodology utilized for the determination of total Adiponectin concentration in serum.

DIAZYME ADIPONECTIN ASSAY ADVANTAGES

- Available for chemistry analyzers
- Latex enhanced immunoturbidimetric method
- Measuring Range: Up to 40 µg/mL
- Improves laboratory efficiency and workflow
- Fast test results (10 minutes) for facilitating faster patient diagnosis and treatment plan implementation compared to traditional ELISA based testing
- Liquid stable format requires no reagent preparation

REGULATORY STATUS

USA: For Research Use Only

DIAZYME
Innovations in Clinical Diagnostics

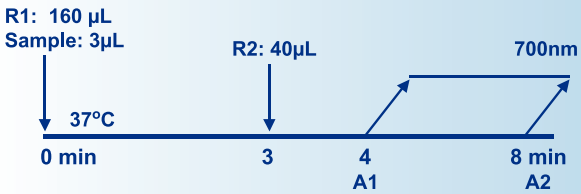
ADIPONECTIN ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Serum Sample Volume 3 µL
Method Comparison	Passing and Bablok Regression: N = 40 y-Intercept = -0.4449 Slope = 0.9902 R = 0.9593 Sample Range: 3.01 - 39.24 µg/mL
Linearity	1.12 - 40 µg/mL
LOB **LOD** **LOQ**	0.02 µg/mL 0.27 µg/mL 1.12 µg/mL
Calibration Levels	6-Point Calibration A saline solution is required to generate a 6-point calibration

Adiponectin 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. Wang, Y. et al., Adiponectin Inhibits Cell ProliferationbyInteracting with Several Growth Factors in anOligomerization Dependent Manner. Journal of BiologicalChemistry, 2005, 280(18): 18341-18347.

2.Takashi K. et al. Adiponectin and adiponectin receptorsin insulin resistance, diabetes, and the metabolicsyndrome J Clin Invest. 2006 Jul 3; 116(7): 1784–1792.

ASSAY PRECISION

The precision of the Diazyme Adiponectin Assay was evaluated according to CLSI EP5-A2 guideline. In the study, 2 levels of serum based controls containing 4.67 and 13.21 µg/mL of Adiponectin, and three serum samples containing approximately 5.81, 22.71, and 38.88 µg/mL of Adiponectin, respectively, were tested with 2 runs per day in duplicates over 5 working days. Results were calculated using the EP Evaluator software precision statistic template and summarized in the following table:

Sample	Mean (µg/mL)	Within-Run %CV	Between-Run %CV	Between-Day %CV	Total %CV
Control 1	4.67	2.8	4.9	1.5	5.8
Control 2	13.21	4.3	3.8	6.3	8.5
Sample 1	5.81	2.6	1.2	2.6	3.9
Sample 2	22.71	1.9	4.5	2.8	5.6
Sample 3	38.88	2.4	0.0	2.7	3.6

ASSAY INTERFERENCE

To determine the level of interference from the substances present in serum, the Diazyme Adiponectin Assay was used to test two Adiponectin controls, which contain "low" and "high" adiponectin concentrations spiked with various concentrations of substances following Clinical and Laboratory Standards Institute EP7-A2. The following substances do not interfere with this assay at the levels tested (less than 10% bias):

Interferent	Concentration
Absorbic Acid	176 mg/dL
Bilirubin	40 mg/dL
Bilirubin Conjugated	40 mg/dL
Hemoglobin	1000 mg/dL
Triglycerides	1000 mg/dL
Rheumatoid Factor	200 IU/ml

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