

# Ready-to-use ITA Reagents

Our immunoturbidimetric assays are dual vial liquid reagent systems for the quantitative determination of target protein in serum, plasma or urine.

## Advantages:

**Ready-to-use:** Providing all required reagent including assay kit, calibrator and control sets, and all in liquid stable format requires no additional reagent or reagent preparation

**Rapid:** Fast sample test under 10 min

**Robust:** Particle enhanced R2 improves the assay sensitivity and analytical range

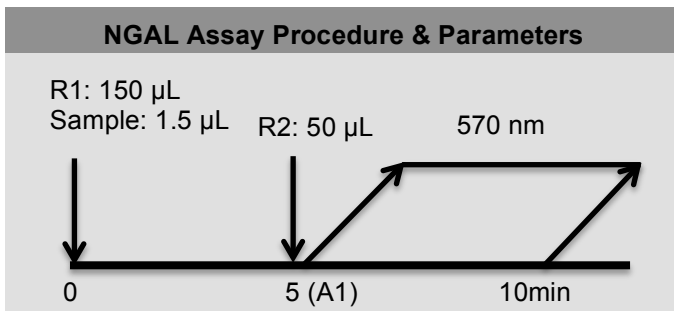
**Reliable:** comprehensive clinical validation guarantee the precision, accuracy and analytical specificity



## Neutrophil gelatinase-associated lipocalin (NGAL) Assay

Renal health is most frequently assessed by measuring serum creatinine level, as serum creatinine is a marker of impaired renal function; whereas NGAL is a marker of kidney injury. NGAL levels are a more precise and sensitive marker for diagnosing AKI than serum creatinine levels.

Quality Characteristic	Target/specification	Actual data		
Low end measuring range	≤100 ng/mL	50 ng/mL		
High end measuring range	≥5000 ng/mL	6000 ng/mL		
Lower Detection Limit	≤100 ng/mL	2 ng/mL		
Within-run Imprecision	≤200 ng/mL: SD ≤ 10 ng/ml >200 ng/ml: CV≤6%	<b>Mean</b>	<b>SD</b>	<b>CV%</b>
		172	4.8	2.78
		516	9	1.75
		141	7.4	5.25
Between-day Imprecision	≤200 ng/mL: SD ≤ 10 ng/ml >200 ng/ml: CV≤6%	<b>Mean</b>	<b>SD</b>	<b>CV%</b>
		81	5.5	6.73
		243	5.6	2.3
		230	8	3.47
Reagent Stability On Board Storage	Unopened: 12 months Opened: 4 weeks	Unopened: 12 months Opened: 4 weeks		



Reagent 1: 150 µL  
Reagent 2: 50 µL  
Sample Size: 1.5 µL  
Main Wavelength: 570 nm  
Reaction type: Endpoint  
Direction: increase

**Assay Reference range :** Plasma sample: 0 – 180 ng/ml

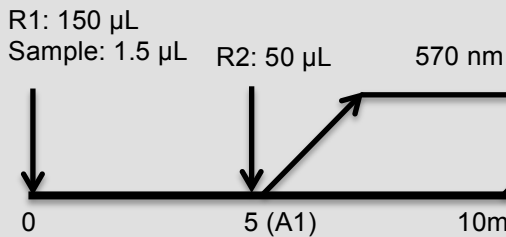
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## Adiponectin (ADPN) Assay

Many clinical studies demonstrated that circulating adiponectin levels are decreased significantly in type 2 diabetes, coronary heart diseases and stroke. Decreased circulating adiponectin levels indicate the increased risk for the development of aforementioned diseases.

Quality Characteristic	Target/specification	Actual data		
Low end measuring range	≤1 mg/L	0.5 mg/L		
High end measuring range	≥40 mg/L	80 mg/L		
Lower Detection Limit	≤1 mg/L	0.3 mg/L		
Within-run Imprecision	≤5mg/L: SD ≤ 0.2 mg/L	Mean	SD	CV%
	>5 mg/L: CV≤6%	3.7	0.08	2.18
		10.7	0.16	1.52
Between-day Imprecision	≤2mg/L: SD ≤ 0.1 mg/L	27	0.313	1.16
	>2 mg/L: CV≤6%	Mean	SD	CV%
		2.7	0.107	3.96
		10.3	0.175	1.7
		19.7	0.217	1.1
Reagent Stability	Unopened:12 months Opened: 4 weeks	Unopened:12 months Opened: 4 weeks		
On Board Storage				

### ADPN Assay Procedure



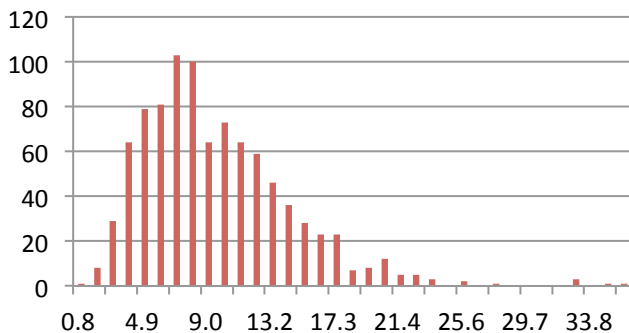
Reagent 1: 150 µL  
Reagent 2: 50 µL  
Sample Size: 1.5 µL  
Main Wavelength: 570 nm  
Reaction type: Endpoint  
Direction: increase

### Assay Reference range

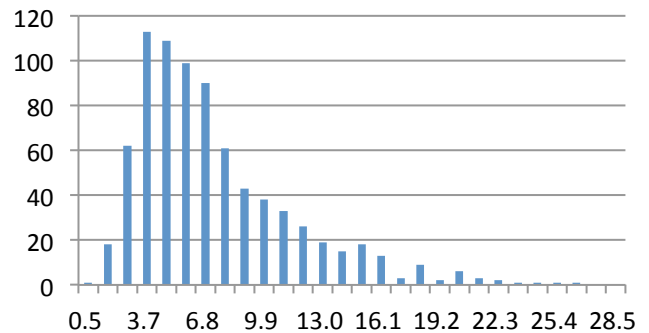
Female serum sample ≥ 4 mg/L

Male Serum Sample ≥ 3.5mg/L

### Serum Adiponectin concentration:



Female Serum Adiponectin Concentration (mg/L) N=929



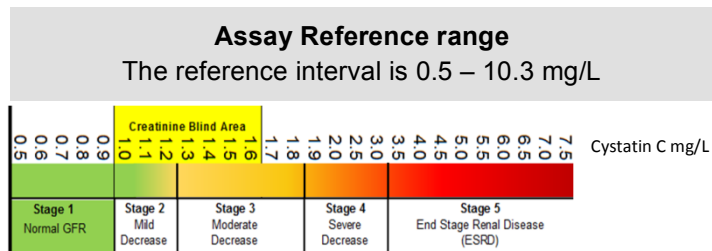
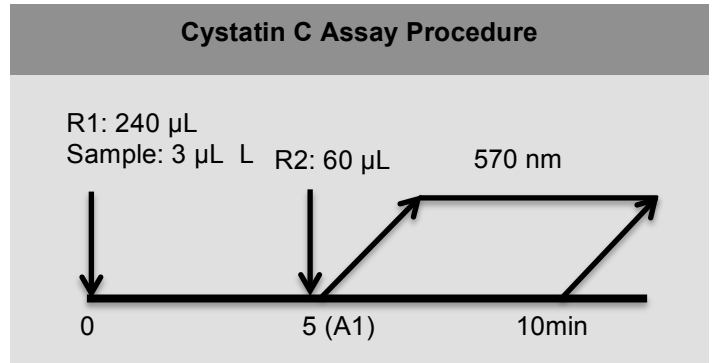
Male Serum Adiponectin Concentration (mg/L) N=787

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## Cystatin C Assay

Cystatin C is an emerging renal biomarker for the estimation of glomerular filtration rate (eGFR) and for the early conformation and diagnosis of Chronic Kidney Diseases (CKD). A meta-analysis study, which includes data from 40 countries and more than 90,000 participants indicates that the kidney function stages categorized by cystatin C were much better at reflecting future risk than were the stages based on creatinine-based estimates of kidney function. Furthermore, Cystatin C serum levels are not strongly affected by age, sex, or race compared with creatinine.

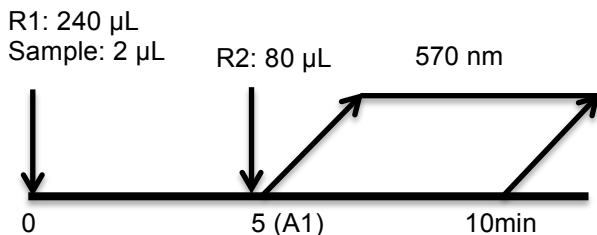
<b>Assay specifications</b>	
<b>Sample type</b>	Serum Plasma -Heparin -EDTA
<b>Sample volume</b>	3µL
<b>Low end measuring range</b>	≤0.5 mg/L
<b>High end measuring range</b>	≥8 mg/L
<b>Lower Detection Limit</b>	≤0.5 mg/L
<b>Within-run Imprecision</b>	CV≤ 5%
<b>Between-day Imprecision</b>	CV≤ 8%
<b>Traceability</b>	ERM-DA471/IFCC Standardized
<b>Reagent Stability</b>	Unopened: 12 months On Board Storage Opened: 4 weeks



## Retinol binding protein (RBP) Assay

RBP is a sensitive biomarker for the early diagnostics and observation of curative effect of the liver diseases and malnutrition. Because it is mainly synthesized by hepatic cells, and its serum levels decreased significantly under the condition of liver injury or malnutrition.

RBP is also a renal function biomarker. It is mainly absorbed and degraded by the proximal renal tubular epithelial cells, its serum and urine levels increased significantly in several renal disorders.



<b>Assay specifications</b>	
<b>Sample type</b>	Serum Plasma -Heparin -EDTA Urine
<b>Sample volume</b>	2µL
<b>Low end measuring range</b>	≤ 2mg/L
<b>High end measuring range</b>	≥ 150 mg/L
<b>Lower Detection Limit</b>	≤ 2 mg/L
<b>Within-run Imprecision</b>	CV≤ 5%
<b>Between-day Imprecision</b>	CV≤ 8%
<b>Reagent Stability</b>	Unopened: 12 months On Board Storage Opened: 4 weeks

### Assay Reference range

The reference interval of serum RBP is 25 - 70 mg/L