

Triplex CRP LIT Assay on Hitachi 7170

Performance on Hitachi 917(7170) chemistry analyzer

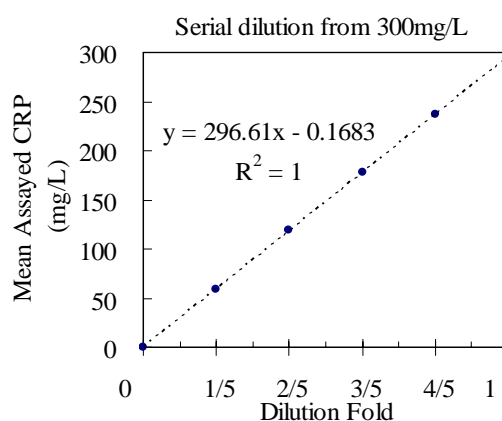
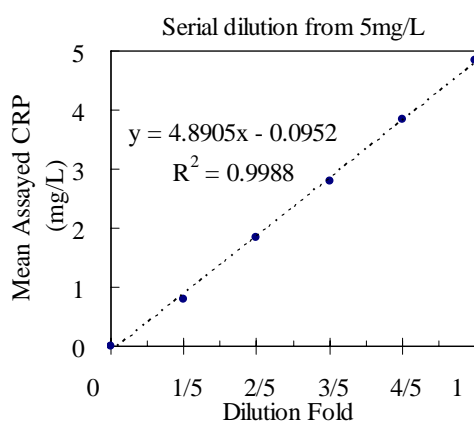
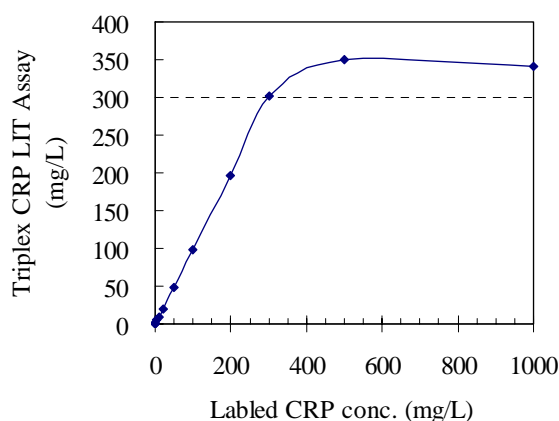
Universal Mode : For serum/plasma specimen

Specimen pretreatment:

One volume of serum/plasma was diluted with 9 volumes of dd-H₂O prior to analysis.

The following performance data were obtained using Hitachi 917 (7170) analyzer and the suggested parameter setting (sample/R1/R2= 2/240/60, assay range 1-300 mg/L).

Antigen Excess: CRP concentration up to 1000 mg/L did not produce a false negative value.



Precision:

Control-L (n=20)			Control-M (n=20)			Control-H (n=20)		
Mean	SD	CV%	Mean	SD	CV%	Mean	SD	CV%
1.600	0.141	8.84%	5.620	0.209	3.72%	56.125	0.575	1.02%

Detection limit: ~ 0.34 mg/L

The lower detection limit represents the lowest measurable CRP concentration that can be distinguished from zero. It is calculated as the mean plus two standard deviation of 20 replicates of the lowest standard (0 mg/L CRP).

Interference:

Criterion: Recovery within ± 5% of initial value.

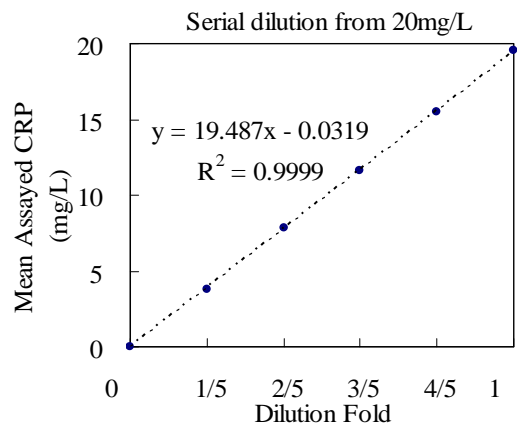
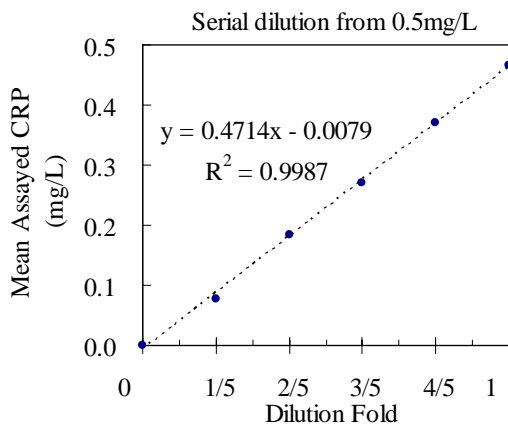
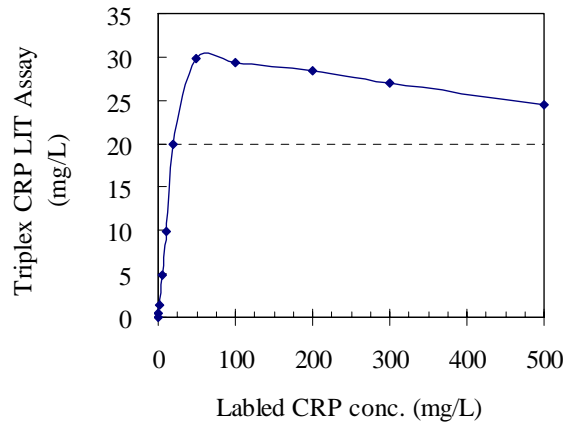
No significant interference from bilirubin up to 60 mg/dl; no significant interference from hemoglobin up to 500 mg/dl; no significant interference from lipemia up to 10 g/L of Liposyn, (at which concentration the triglyceride readout is 1376 mg/dl).

Triplex CRP LIT Assay on Hitachi 7170

High Sensitivity Mode : For serum/plasma specimen

The following performance data were obtained using Hitachi 917 (7170) analyzer and the suggested parameter setting (sample/R1/R2= 2/240/60, assay range 0.1-20 mg/L).

Antigen Excess: CRP concentration up to 500 mg/L did not produce a false negative value.



Precision:

Control-L (n=20)			Control-M (n=20)		
Mean	SD	CV%	Mean	SD	CV%
1.645	0.045	2.72%	5.628	0.064	1.14%

Detection limit: ~ 0.04 mg/L

The lower detection limit represents the lowest measurable CRP concentration that can be distinguished from zero. It is calculated as the mean plus two standard deviation of 20 replicates of the lowest standard (0 mg/L CRP).

Interference:

Criterion: Recovery within ± 5% of initial value.

No significant interference from bilirubin up to 60 mg/dl; no significant interference from hemoglobin up to 500 mg/dl; no significant interference from lipemia up to 10 g/L of Liposyn, (at which concentration the triglyceride readout is 1376 mg/dl).

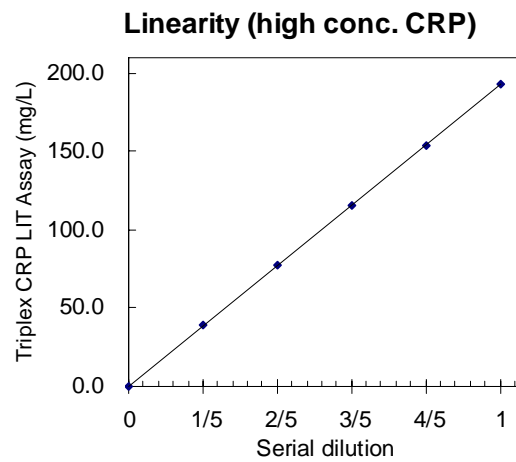
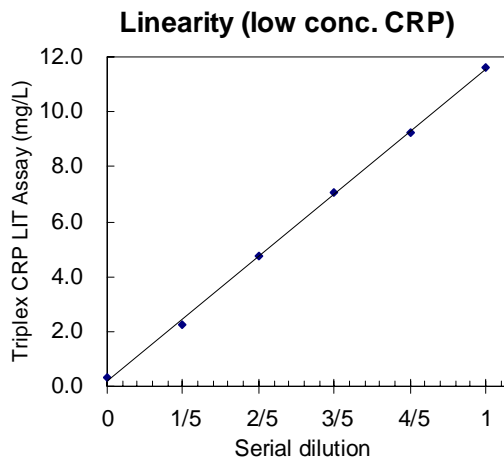
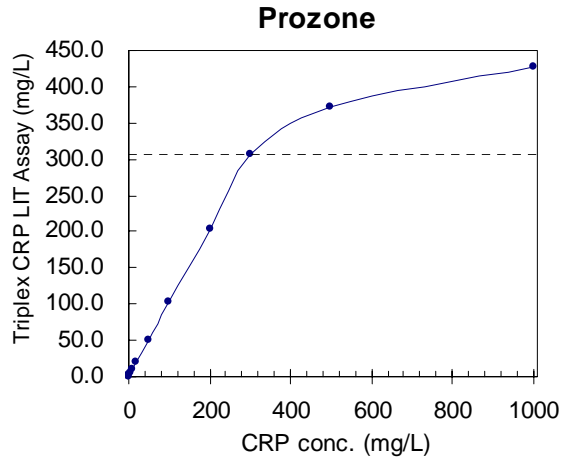
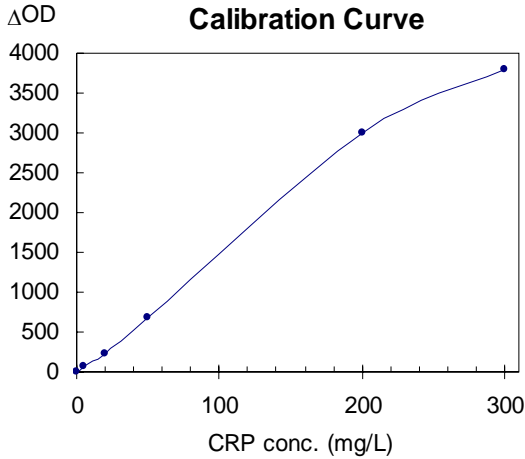
Triplex CRP LIT Assay on Hitachi 7170

Universal Mode : For whole Blood specimen

Specimen pretreatment:

One volume of whole blood was diluted with 9 volumes of dd-H₂O prior to analysis.

The following performance data were obtained using Hitachi 917 (7170) analyzer and the suggested parameter setting (sample/R1/R2= 2/240/60, assay range 2-300 mg/L).



Precision:

Low concentration (n=10)			High concentration (n=10)		
Mean	SD	CV%	Mean	SD	CV%
13.6	0.2751	2.1%	156.9	0.9866	0.6%

Detection limit: ~ 1.4 mg/L

The lower detection limit represents the lowest measurable CRP concentration that can be distinguished from zero. It is calculated as the mean plus two standard deviation of 20 replicates of the lowest whole blood specimen (CRP concentration: 0 mg/L).

Interference:

Criterion: Recovery within ± 5% of initial value.

No significant interference from bilirubin up to 60 mg/dl; no significant interference from lipemia up to 10 g/L of Liposyn, (at which concentration the triglyceride readout is 1376 mg/dl).