

Triplex CRP LIT Assay on VITROS 5,1FS

Performance on VITROS 5,1FS chemistry system

Universal Mode :

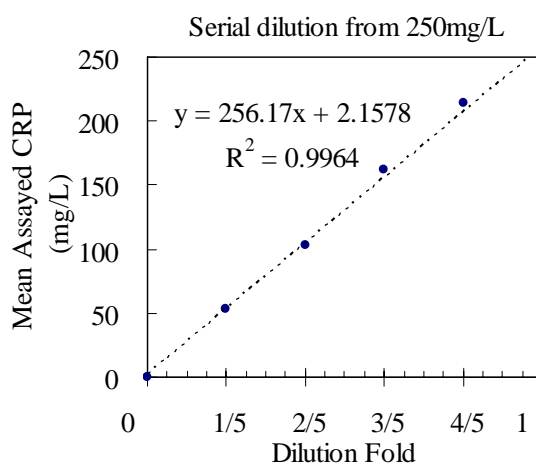
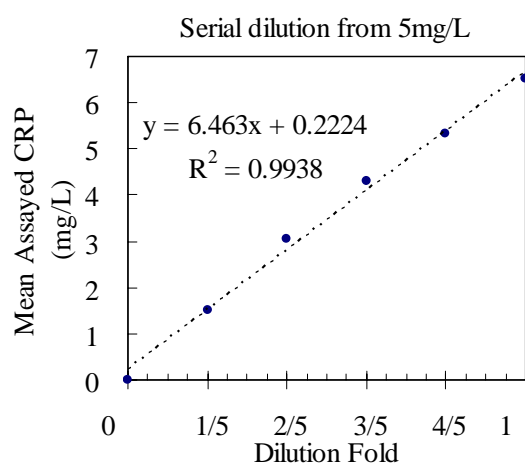
Specimen pretreatment:

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

The following performance data were obtained using VITROS 5,1FS chemistry system and the suggested parameter setting (R1/R2/sample = 60/90/3, assay range 2-250 mg/L).

Antigen Excess:

CRP concentration up to 1000 mg/L did not produce a false negative value on condition that the appropriate "Antigen Excess Factor" is set on VITROS 5,1FS chemistry system.



Precision:

Control-L (n=20)			Control-M (n=20)			Control-H (n=20)		
Mean	SD	CV%	Mean	SD	CV%	Mean	SD	CV%
2.125	0.089	4.19%	6.528	0.145	2.22%	54.855	1.413	2.58%

Detection limit: ~ 0.68 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 $\pm 5\%$ of initial value.

No significant interference from bilirubin up to 60 mg/dl; no significant interference from hemoglobin up to 300 mg/dl; no significant interference from lipemia up to 10 g/L of Liposyn, (at which concentration the triglyceride readout is 1376 mg/dl).

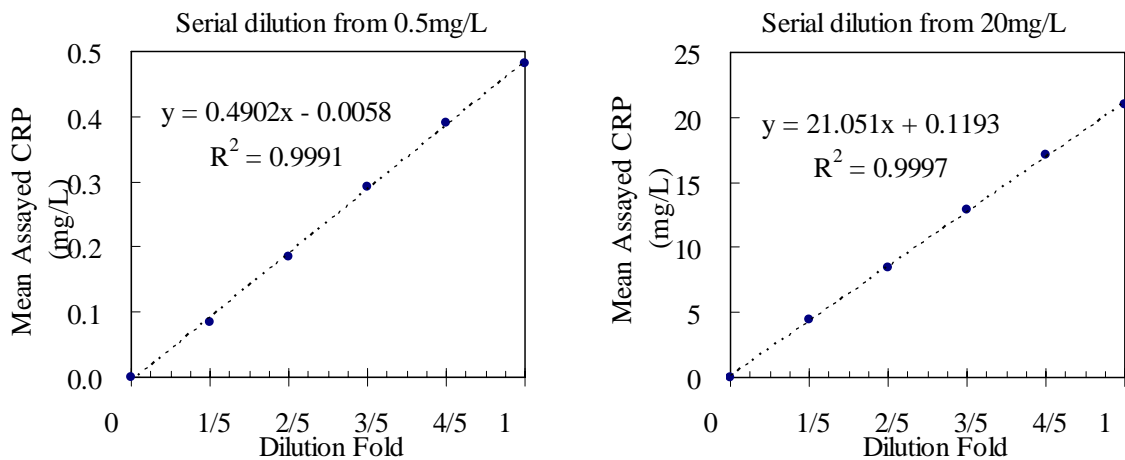
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High Sensitivity Mode :

The following performance data were obtained using VITROS 5,1FS chemistry system and the suggested parameter setting (R1/R2/sample= 60/90/2.5, assay range 0.2-20 mg/L).

Antigen Excess:

CRP concentration up to 500 mg/L did not produce a false negative value on condition that the appropriate "Antigen Excess Factor" is set on VITROS 5,1FS chemistry system.



Precision:

Control-M (n=20)			Control-H (n=20)		
Mean	SD	CV%	Mean	SD	CV%
1.807	0.074	4.10%	5.799	0.150	2.59%

Detection limit: ~ 0.013 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 $\pm 5\%$ of initial value.

No significant interference from bilirubin up to 60 mg/dl; no significant interference from hemoglobin up to 300 mg/dl; no significant interference from lipemia up to 10 g/L of Liposyn, (at which concentration the triglyceride readout is 1376 mg/dl).