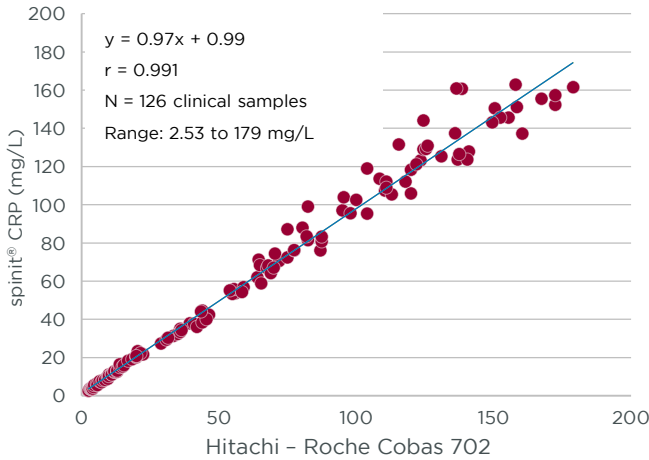


Key Features

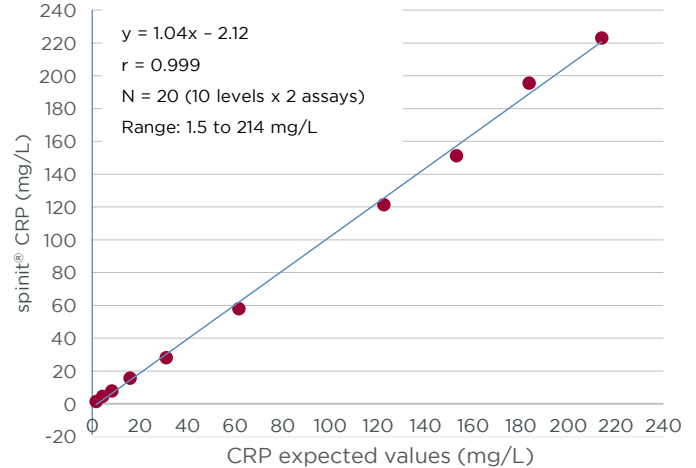
- One small drop of blood - 5µL
- Sample volume check
- Short assay time
- Measuring range: 2-180 mg/L
- No interference from haematocrit
- Advanced fail-safe mechanisms
- Simultaneous reading of 4 reactions
- No user calibration necessary

Method Comparison



Studies performed according to CLSI guideline EP9-A3 [Approved Guideline - third edition, Vol33 No.11 (2013) CLSI/NCCLS]

Linearity



Linearity studies performed using two different spinit[®] instruments, one CRP cartridge lot. Samples tested ranged from 1.5 to 214 mg/L. N=20

Accuracy

Sample Type	N	Mean [CRP] (mg/L)	CV %	Bias %
ERM-DA474*	20	41.0	5.7	-0.5

* Reference material specification 41.2 ± 2.5

Precision

Sample	Sample 1	Sample 2	Sample 3
CRP (mg/L)	6.0	10.7	71.2
Total CV (%)	8.1	6.5	8.8
Repeatability (%)	8.1	5.5	8.2

Using four different spinit[®] instruments, four CRP cartridge lots over a period of 15 days. Control solutions distributed throughout the analytical range. N=60 measured in duplicate.

Interference Studies

Patient samples at various CRP concentrations and containing various levels of the interfering substances were used. No significant interference of the following substances.

INTERFERENT	NO INTERFERENCE WAS OBSERVED UP TO THE FOLLOWING CONCENTRATIONS
Bilirubin	5.9 mg/dL
Cholesterol	355 mg/dL
Triglycerides	355 mg/dL
Rheumatoid factor	618 IU/mL
High CRP concentration	No "Hook effect" up to 2000 mg/L

Contacts

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