EN

spinit® CRP tests | Product Ref. No 240300 (C- Reactive Protein)

INSTRUCTIONS FOR USE

INTENDED USE

The spinit® CRP disc is an in vitro diagnostic test, used with the spinit® instrument to perform a quantitative determination of C-reactive protein in whole blood samples. Alternatively, serum and plasma samples of human origin may also be used.

PRINCIPLE OF THE ASSAY

The spinit® CRP test is used to determine the C-reactive protein concentration from a small blood sample collected using the spinit® sample collection strip and analysed in 4 minutes. The sample is diluted, mixed and processed within the disc through automated sample processing allowing for an antibody-antigen conjugate reaction. The reaction is measured in real time by the spinit® instrument using an optical-based detection system (photometry based) that measures light absorbance and determines the CRP concentration in the sample.

CALIBRATION

The spinit® instrument is pre-loaded with standard calibration data. All spinit® CRP test disc lots have unique identification numbers which are coded together with lot-specific calibration data in the product label barcode. A plug-and-play barcode reader is provided for this purpose.

COMPOSITION

Each package contains:

- 20 spinit® CRP discs;
- 20 spinit® sample collection strips;
- 1 IFU (instructions for use)

Each disc contains the following reagents: Latex beads coated with anti-CRP recombinant antibody and water. Necessary materials required but not supplied: sterile standard lancets appropriate for capillary sample collection.

WARNINGS AND PRECAUTIONS

When using capillary blood, the analysis of the disc must start immediately. If the test does not begin within one minute, the sample material may dry or coagulate. An information code may be displayed.

- Do not use the disc if the pouch has been opened for more than 10 minutes.
- Do not use the disc if the pouch or the disc have been damaged.
- Do not use the disc after the expiry date or if the discs have not been stored in accordance to recommendations.
- Do not re-use the disc.
- Not following the above recommendations may result in test failure and an information code is displayed to the user.
- All discs should be disposed of immediately after use. Proper handling and disposal methods should be followed in accordance with the applicable country laws.

STORAGE AND HANDLING

The spinit® CRP test shelf-life is indicated on the foil pouch printed label. The discs are stable when stored in vacuum sealed pouches at temperatures between +2°C and +8°C. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

Alternatively, to capillary samples, venous whole blood (K_2EDTA) may be used. The spinit® CRP test is ready-to-use and does not require any reagent or sample preparation steps.

PROCEDURE

Please read spinit® user manual for proper use of the system.
Please read spinit® CRP quick guide for detailed information on how to perform a test.

1. Remove test from refrigerated box and wait at least 5 minutes before opening pouch **2.** Scan barcode from pouch label and follow on-screen instructions **3.** Remove disc from pouch and place it on a flat surface with label facing up **4.** Press the blister using the thumb **5.** Collect the blood sample with the collection strip by bringing the tip of the strip against the surface of the patient sample; wipe off the strip paying special attention not to squeeze as this will remove the sample.
Important! Capillary blood samples must be collected from one finger prick (do not squeeze finger for multiple collections from same finger prick) **6.** Immediately insert the strip all the way into the disc and fold it back until it breaks, leaving the loaded part of the strip inside the disc **7.** Once the disc is ready, click Next on-screen and place the disc on the tray **8.** Follow on-screen instructions.

LIMITATIONS OF THE METHOD

spinit® CRP test is not intended to measure CRP as a risk marker for coronary heart disease.

PERFORMANCE CHARACTERISTICS

ANALYTICAL RANGE

The spinit® CRP test reportable analytical range is from 2 to 250 mg/L when used as per recommended procedure. If the analyte concentration is outside the analytical range, the instrument will indicate a less than 2 mg/L or more than 250 mg/L.

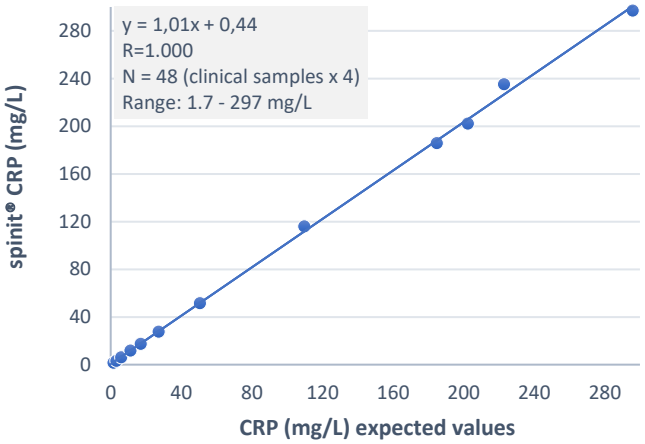


Fig 1. spinit® CRP test Linearity.

STANDARDIZATION | ACCURACY

The spinit® CRP test is traceable to ERM® -DA474 from IFCC.

PRECISION

Between-day precision

Between-day, within-run and total precision studies were conducted as per CLSI EP5-A3 guidelines. Results from duplicate measurements of control solutions distributed throughout the analytical range, performed twice a day using 2 different instruments and disposable discs from 4 production lots over a period of 20 days (N=80), are presented in Table 2.

Sample	Sample 1	Sample 2	Sample 3
CRP (mg/L)	7.9	44.9	83.7
Total CV (%)	6.1	6.9	6.5
Repeatability (%)	4.9	6.5	5.0

Table 2. Between-day precision for the spinit® CRP test assay performed with 2 instruments and 4 manufactured lots

METHOD COMPARISON

Method comparison studies were conducted using the CLSI EP9-A3 guideline. The equivalency between the spinit® system and a reference method for the quantification of C-reactive protein was assessed using regression analysis based on recovered CRP concentrations of clinical samples. A total of 6 different spinit® instruments and 4 different test lots were used for the study.

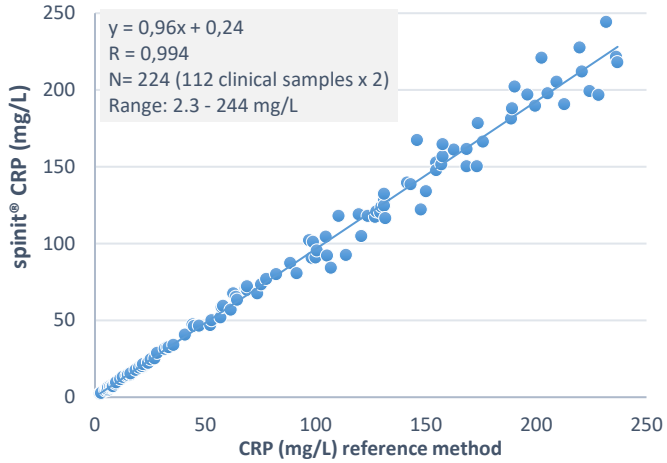


Fig 2. Regression plot for CRP results using spinit® system and Hitachi - Roche Cobas 702

IMPRECISION

Total imprecision calculated for the full analytical range in low, medium and high CRP concentrations using clinical samples.

CRP (mg/L)	2.0 – 20.0	20.0 – 80.0	80.0 – 250.0	2.0 – 250.0
Total imprecision (%)	3.6	4.1	4.5	4.2
95% CI – LL	2.8	3.3	3.8	3.7
95% CI – UL	5.0	5.5	5.5	4.8
Bias (%)	-3.9	-1.2	-4.1	-3.7
95% CI – LL	-6.4	-3.1	-6.1	-5.4
95% CI – UL	-1.3	0.7	-2.2	-1.9
N	25	31	56	112

Table 3. Total imprecision calculated in low, medium and high concentration ranges and for the full range. 95% confidence intervals are reported for both imprecision and bias. LL – Lower Limit and UL – Upper Limit. Assays were performed with 6 instruments and 4 manufactured lots.

INTERFERENCE

Patient samples with varying CRP concentrations and containing different levels of the interfering substance were tested and no interference was detected for bilirubin, cholesterol, triglycerides, rheumatoid factor, haemolysis index and samples with high CRP concentrations. For additional information on test performance, please contact your local supplier.

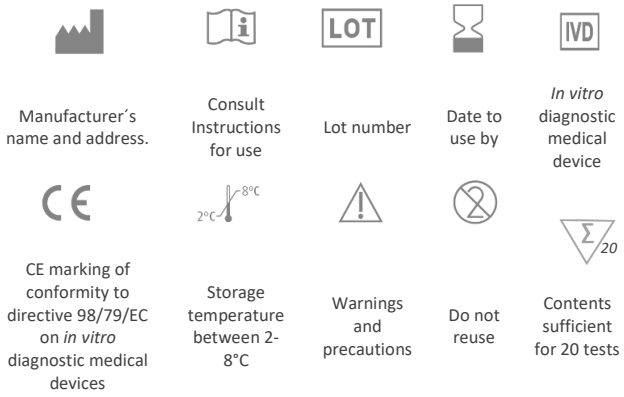
Interferent	No interference was observed up to the following concentrations
Bilirubin	15.2 mg/dL
Cholesterol	450 mg/dL
Triglycerides	1702 mg/dL
Rheumatoid Factor	412.1 IU/mL
Haemolysis Index	76
High CRP concentration	No “Hook effect” up to 2000 mg/L

CONTROL MATERIAL

Each spinit® CRP disc contains multiple integrated quality control verification steps to ensure reliability of the tests. If the user chooses to perform additional Quality Control checks, biosurfit recommends testing commercially available quality control reagents with the acceptable ranges previously established for the spinit® system. Use Quality Control mode for control testing. See spinit® user manual for further details.

ISO13485 certified company.

SYMBOLS USED:



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