EN

spinit® CRP tests | Product Ref. No 240101 (C- Reactive Protein)

INSTRUCTIONS FOR USE

INTENDED USE

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

PRINCIPLES OF THE METHOD/PROCEDURE

The spinit® CRP test cartridge is used to determine the C-reactive protein concentration from a small blood sample (5 µL) in less than 4 minutes. The microfluidic disc allows for automated sample processing and conducting the assay based on antibody-antigen reaction. The reaction is followed in real time by the spinit® instrument using an optical-based detection system (photometry based) and CRP concentration determined from reaction data.

CALIBRATION

The spinit® instrument is pre-loaded with standard calibration data. All spinit® CRP test cartridge 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 to this effect.

COMPOSITION

Each package contains spinit® CRP test cartridges, instructions for use and 5 µL capillary tubes. Each disc contains the following reagents: Latex beads coated with Anti-CRP recombinant antibody, water and anti-coagulant reagent (K_2EDTA). Necessary materials required but not supplied: sterile lancets appropriate for capillary sample collection.

WARNINGS AND PRECAUTIONS

Using capillary blood, the sample should immediately be introduced into the test cartridge after collection.

Once the pouch has been opened, the disc must be loaded and inserted in the spinit® instrument within 10 minutes.

Do not use the test cartridge if the pouch or the disc have been damaged.

Do not use the test cartridge after the expiry date or if the test cartridges have not been stored in accordance to recommendations.

Do not re-use the test cartridge.

Not following the above recommendations may result in test failure and an information code is displayed to the user.

All test cartridges 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 cartridge shelf-life is indicated on the pouch printed label, requiring the discs to be stored in vacuum sealed pouches at temperatures between +2°C and +8°C. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

Freshly drawn fingertip blood (capillary sample) is preferred. Alternatively, venous whole blood (K_2EDTA) can be used. A positive bias (within the possible bias ranging around 5 to around 15%) may be observed when testing serum or plasma compared to whole blood. The spinit® CRP test cartridge is ready-to-use and does not require any reagent preparation step.

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.** Lift the adhesive flap and press the blister using the thumb **5.** Collect the blood sample with a 5µL capillary tube and insert it into sample well by gently squeezing the pressing area of the capillary tube available from the holder. In replacement of the capillary tube, a micropipette can be used (biosurfit recommends pipetting 6 µL) **6.** Remove adhesive flap protection and firmly seal the sample well **7.** Once you have the disc 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 or coronary heart disease.

PERFORMANCE CHARACTERISTICS

ANALYTICAL RANGE

The spinit® CRP test reportable analytical range is from 2 to 180 mg/L when used 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 180 mg/L.

The calibrators used to to calibrate the CRP assay of the spinit® CRP test are traceable to the ERM®-DA474 reference material.

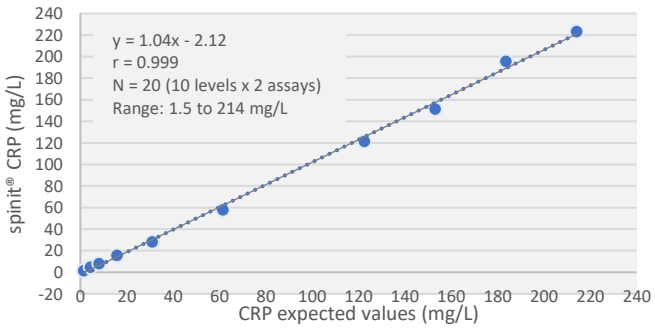


Fig 1. spinit® CRP test Linearity.

PRECISION

Within-day precision

Within-day precision was performed with six whole blood samples, 20 replicas of each sample in one day as shown below in table 1.

WB Sample	CRP (mg/L)	Total CV (%)	N (replicas)
Sample 1	5.3	7.2	20
Sample 2	7.1	8.2	20
Sample 3	42.9	4.7	20
Sample 4	44.9	3.4	20
Sample 5	89.1	2.9	20
Sample 6	148.3	5.5	20

Table 1. Within-day precision for the spinit® CRP assay performed with 4 instruments and 2 manufactured lots

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, using 4 different instruments and disposable discs from 4 production lots obtained over a period of 15 days (N=60) are presented in Table 2.

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

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

METHOD COMPARISON

Method comparison studies were conducted using the CLSI EP9-A3 guideline. The equivalence 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 4 different spinit® instruments and 5 different test lots were used for the study.

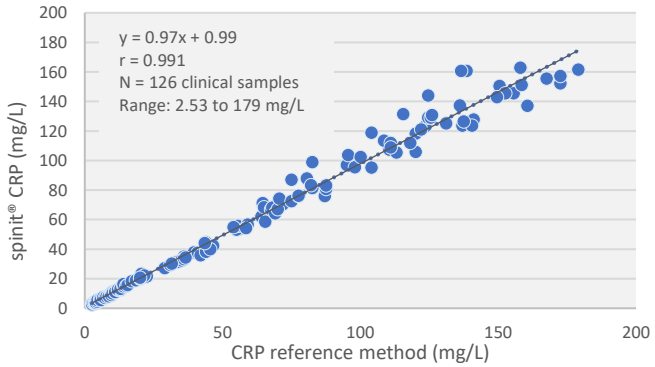


Fig 2. Regression plot for CRP results using spinit® system and Hitachi - Roche Cobas 702

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 – 60.0	60,0 – 180.0	2.0 – 180.0
Total imprecision (%)	6.1	6	8.3	7
95% CI – LL	4.9	4.9	6.9	6.2
95% CI – UL	7.9	7.7	10.5	8
Bias (%)	2.3	-3.4	-1.2	-1.6
95% CI – LL	0.2	-5.4	-3.8	-3.5
95% CI – UL	4.4	-1.4	1.5	0.3
N	37	42	47	126

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 4 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 and samples with high CRP concentrations. For additional information on test performance please, contact your local supplier.

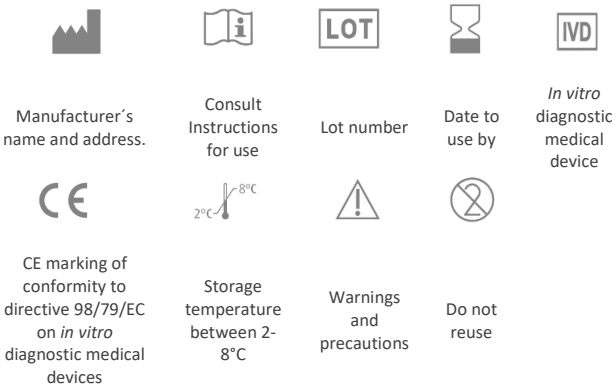
Interferent	No interference was observed up to the following concentrations
Bilirubin	5.9 mg/dL
Cholesterol	355 mg/dL
Triglycerides	379 mg/dL
Rheumatoid Factor	618 IU/mL
High CRP concentration	No “Hook effect” up to 2000 mg/L

CONTROL MATERIAL

Each spinit® CRP test cartridge 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 previously tested and commercially available quality control reagents with the respective ranges of acceptability for the spinit® system. Use Quality Control mode for control testing. See spinit® user manual for further details.

ISO13485 certified company.

SYMBOLS USED:



Manufacturer´s name and address. | Consult Instructions for use | Lot number | Date to use by | *In vitro* diagnostic medical device

CE marking of conformity to directive 98/79/EC on *in vitro* diagnostic medical devices | Storage temperature between 2-8°C | Warnings and precautions | Do not reuse

Developed and Manufactured by biosurfit SA
Rua 25 de Abril nº66,
2050-317 Azambuja, PORTUGAL
info@biosurfit.com | www.biosurfit.com

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