Quality approved by SD BIOSENSOR / For *In vitro* use only

REF C-CRP-1, C-CRP-2

# SDB CRP Control

PLEASE READ THE INSTRUCTION CAREFULLY BEFORE YOU PERFORM THE TEST

## EXPLANATION AND SUMMARY

### [Intended use]

It is important to perform control tests with more than one level of control materials to assure your system is working properly. SDB CRP Control is intended for use as a quality control material to check the performance of MultiCare™ or STANDARD F System for CRP testing.

### [Test principle]

The use of CRP quality control materials is indicated as an objective assessment of the precision of methods and techniques in use. Two levels of control are available to allow performance monitoring within the clinical range.

## ACTIVE INGREDIENTS OF MAIN COMPONENT

### [Contents]

① SDB CRP Control - Level 1: 10 tablets in each tube (white colored tube)
② SDB CRP Control - Level 2: 10 tablets in each tube (red colored tube)
③ Instructions for use

### [Reagents composition]

This product is prepared from human hemoglobin protein and contains preservatives and stabilizers.

| Components | Composition (per 1 ea) |
|---|---|
| Level 1 | Human CRP protein 1.5μg |
| Level 2 | Human CRP protein 5μg |

* The amount of human hemoglobin protein is indicated on the label of each control bottle.

### [Materials required but not provided]

- MultiCare Analyzer
- MultiCare CRP Test kit
- STANDARD F Analyzer
- STANDARD F CRP

## STORAGE AND STABILITY

Store the SDB CRP Control at 2-30°C/36-86°F. Kit materials are stable until expiration date printed on the outer box. Do not freeze.

## WARNINGS AND PRECAUTIONS

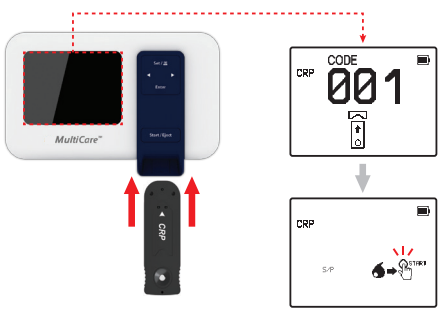
1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the reconstituted control, discard the bottle.
3. This product is not intended for use as CRP standard.
4. The control reagent tablet should be stored in tightly capped bottle.

## CONTROL TEST PROCEDURE

## 1. MultiCare System

### [Preparation]

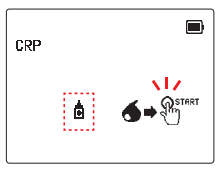
1. Prepare the MultiCare CRP Test Kit and MultiCare Analyzer and place a MultiCare Analyzer on a level surface.
2. Insert a code chip into the analyzer and then insert a test panel too with the 'CRP' inscription facing upwards. When the test panel reaches the correct position, the test panel is automatically inserted deeper into the analyzer. If the test panel does not have any problem (damaged or defective), the Blood and START button icons are displayed.




CAUTION

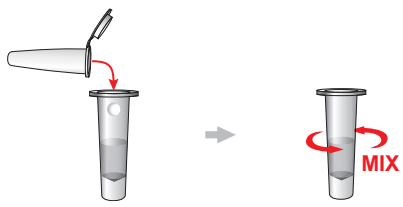
- Before testing, analyzer must be Serum/Plasma sample mode, not Whole blood sample mode. If WB on LCD, please press right button for 3seconds to change S/P.

3. Press the left button for 3 seconds to check the testing system using a control.

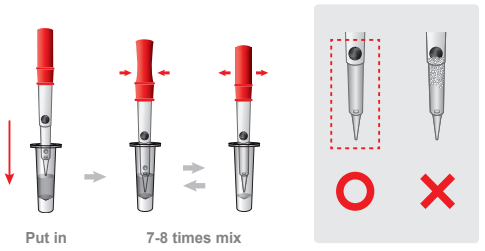



4. Open the bottle of the SDB CRP Control and take a tube out of the bottle.


5. Pour the control tablet in the tube into an extraction buffer tube in the MultiCare CRP Test Kit.
6. Slightly shake the buffer tube to dissolve the tablet well.

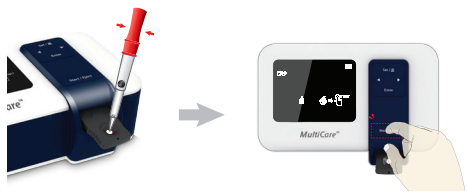



7. Insert the edge of the spoit in the MultiCare CRP Test Kit into the extraction buffer tube to mix control mixture with latex tablet in the spoit.
8. Carefully press and release the rubber at the top of the spoit for 7-8 times to dissolve the latex tablet in the spoit. Take care to avoid bubble forming.
9. Collect all the mixture with the spoit from the extraction buffer tube.

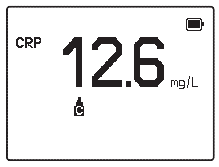



### [Analysis of control]

1. Collect the whole control solution mixture from the buffer tube by releasing the rubber of the spoit.
2. Apply the whole control solution mixture to the test panel by pressing the rubber of the spoit. Then, press the 'START' button.




3. The result will appear on the screen after 3 minutes. Compare this result with the assignment of value on the label of the control bottle.



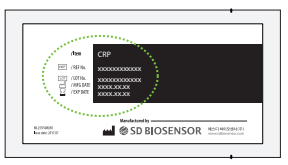

NOTE

- If this result is out of the range for the control level you applied, repeat the control test. If the unacceptable value appears again, stop using the MultiCare CRP Test Kit and please contact the customer service center.

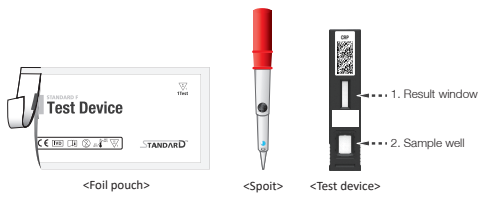
## 2. STANDARD F System

### [Preparation]

1. Prepare the STANDARD F CRP and STANDARD F Analyzer and place a STANDARD F Analyzer on a level surface.
2. Check the expiry date at the label of a SDB CRP Control bottle and back of the foil pouch of a STANDARD F CRP. Use another lot if expiry date has passed.


3. Open the foil pouch of the STANDARD F CRP, and check the test device and Spoit (Red) with anti-CRP latex tablet in the foil pouch.



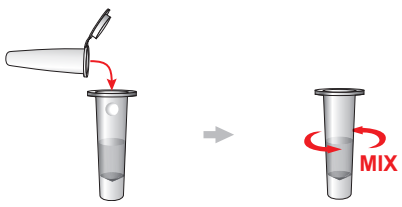

<Foil pouch> <Spoit> <Test device>

CAUTION

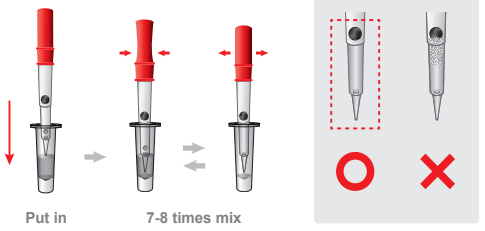
- Do not write on the bar code or damage the bar code of the test device.

4. Open the bottle of the SDB CRP Control and take a tube out of the bottle.


5. Pour the control tablet in the tube into an extraction buffer tube in the STANDARD F CRP test kit.
6. Slightly shake the buffer tube to dissolve the tablet well.



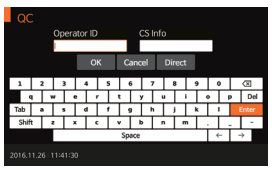

7. Insert the edge of the spoit in the STANDARD F CRP into the extraction buffer tube to mix control mixture with latex tablet in the spoit.
8. Carefully press and release the rubber at the top of the spoit for 7-8 times to dissolve the latex tablet in the spoit. Take care to avoid bubble forming.
9. **Collect all the mixture** with the spoit from the extraction buffer tube.




### [Analysis of control]

- **Applying QC sample to STANDARD F100, F200 and F2400 analyzers**

1. Prepare a STANDARD F Analyzer and select the "QC" mode according to the analyzer's manual. In case of STANDARD F100 Analyzer, select the 'STANDARD TEST' mode, and then press the right (►) button to conduct the QC test.
2. In case of STANDARD F200 and F2400 analyzers, select "Control ID" column, and then scan the barcode on the control bottle or manually enter the barcode number on the control bottle.




<F200>


<F2400>

3. Take the test device out of the foil pouch.

4. Insert the test device into the Test Slot of the analyzer.


5. Apply the control sample mixture into the sample well of the test device.

6. Immediately press the **'TEST START'** button.


<F100>




<F200>


<F2400>

7. The analyzer will automatically display the test result after 3 minutes.


8. **[STANDARD F100 analyzer]**
   Compare the result of the control test with the range printed on the label of each SDB CRP Control bottle. If the result is out of the range for the control level you applied, repeat the control test.

   **[STANDARD F200 and F2400 analyzers]**
   The test result will be concluded "Passed" or "Failed" with a quantitative value. If the result is out of range(Failed), repeat the test.

   If the unacceptable value appears again, stop using the STANDARD F CRP test set and please contact the customer service center.

**Product Disclaimer**
Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

**Warning**
The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

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**Manufactured by SD Biosensor, Inc.**
**Head office :** C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
**Manufacturing site :** 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

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