Infection

ichroma™ CRP

INTENDED USE

ichroma™ CRP is a fluorescence Immunoassay (FIA) for the quantitative determination of CRP in human whole blood / serum / plasma. It is useful as an aid in management and monitoring of autoimmune diseases and infectious processes, such as rheumatoid arthritis.[1,2]

For *in vitro* diagnostic use only.

INTRODUCTION

The C-Reactive Protein (CRP) is synthesized by the liver in response to interleukin-6 and well known as one of the classical acute-phase reactants and as a marker of inflammation. CRP is the first acute-phase protein to be described and is an exquisitely sensitive systemic marker of inflammation and tissue damage. The acute-phase response comprises the nonspecific physiological and biochemical responses of endothermic animals to most forms of tissue damage, infection, inflammation, and malignant neoplasia. The serum CRP level may rise from a normal level of <5 mg/L to 500 mg/L during the body's general, non-specific response to infectious and other acute inflammatory events. For some time, the measurement of CRP concentration has been used as a clinical tool for monitoring autoimmune diseases and infectious processes, such as rheumatoid arthritis.[1,2]

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by instrument for ichroma™ tests to show CRP concentration in sample.

COMPONENTS

ichroma™ CRP consists of 'Cartridges', 'Detection Buffer Tubes', 'Sample Collectors' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human CRP at the test line, while rabbit IgG at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains anti human CRP-fluorescence conjugate, anti rabbit IgG-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packaged in a box and further packed in a Styrofoam box with ice-pack for the shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instructions for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, ID chip and detection buffer) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test result(s).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- Do not keep the sample in a freezer, which could affect the test value of CRP. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- **ichroma™ CRP** as well as the instrument for ichroma™ tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that instrument for ichroma™ tests may produce minor vibration.
- Used detection buffer tubes, pipette tips and cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **ichroma™ CRP** will provide accurate and reliable results subject to the following conditions.
  - Use **ichroma™ CRP** should be used only in conjunction with instrument for ichroma™ tests.
  - Any anticoagulants other than **EDTA, heparin sodium, sodium citrate** should be avoided.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4 - 30℃.
- The detection buffer pre-dispensed in a tube is stable for 20 months if stored at 2 - 8℃.
- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF i-CHROMA CRP-25

Components of **ichroma™ CRP**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction For Use 1
  - Sample Collectors 25
- Box containing Detection Buffer tubes
  - Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ CRP**. Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ D** REF 13303
- **ichroma™ Printer** REF FPRR007
- **ichroma™ CRP Control** REF CFPO-2

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ CRP** is human whole blood / serum / plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20 °C. The freezing storage of sample up to 3 months does not affect the quality of results.
- The whole blood sample should not be kept in a freezer in any case.
- Once the sample was frozen, it should be thawed one time and only for test, because repeated freezing and thawing can result in the change of test values.
- Fingertip blood sample should be collected as follows:
  - Position the hand with the palm facing upwards. Blood should be normally drawn from the middle or ring finger of the non-dominant hand. Apply intermittent pressure towards its tip.
  - Wipe the fingertip clean with an alcohol pad.
  - Allow the finger to dry completely because blood will not form a drop if the puncture site is moist and because the residual alcohol at the fingertip may dilute the blood sample and affect the test result.
  - Hold the finger and puncture the fingertip by firmly pressing a new sterile lancet against it at an off-center position.
  - Wipe away the first drop of blood with a sterile gauze pad or cotton ball.
  - Massage the finger towards its tip to form a new drop of blood. Blood will flow easily if the finger is held lower than the elbow.
  - Hold the handle of a capillary tube and touch the mouth of the capillary to the drop of blood.
  - Let the blood fill the capillary tube completely.
  - It may be sometimes necessary to massage the finger again for an additional drop of blood for filling the capillary tube.

TEST SETUP

- Check the contents of **ichroma™ CRP**: Sealed Cartridge, Detection Buffer Tubes, Sample Collector and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.
- Keep the sealed cartridge (if stored in refrigerator) and the detection buffer tube at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for ichroma™ tests.
- Insert the ID Chip into the ID chip port of the instrument for ichroma™ tests**.**
- Press the 'Select' button on the instrument for ichroma™ tests. (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

1) Make a puncture on the top of the detection buffer tube by inserting an empty sample collector.
2) Draw 10 µL (Human whole blood / serum / plasma / control) of sample with a sample collector.
3) Assemble the sample collector and the tube into one.
4) Shake the 10 times or more until the sample out of the sample collector by inversion. The mixture of buffer and the sample has to be used within 30 seconds.
5) Remove the cap off the top of assembled tube. Discard two drops of reagent onto the paper towel before applying to the cartridge
6) Load only two drops of the mixture onto the sample well of the cartridge.
7) Leave the Cartridge at room temperature for 3 min before inserting the device into the holder.
8) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
9) Press 'Select' button on the instrument for ichroma™ tests to start the scanning process.
10) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
11) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays CRP concentration of the test sample in terms of mg/L.
- The cut-off (reference value) : 10 mg/L
- Working range : 2.5~300 mg/L.
- Effect of Hematocrit
  The CRP Whole Blood of ichroma™ Reader is calibrated to read the CRP serum concentration of a blood sample with a hematocrit of 40%. If the actual hematocrit value deviates from 40%, the result should be corrected by multiplying with the respective factor in the table: deviates from 40%, the result should be corrected by multiplying with the respective factor in the table:

Hct %	Factor	Hct %	Factor
20-29	0.8	56-58	1.4
30-36	0.9	59-61	1.5
37-42	1.0	62-63	1.6
43-47	1.1	64-65	1.7
48-51	1.2	66-67	1.8
52-55	1.3	68-69	1.9

Reference range, HCT:

- Woman: 35 – 44 %
- Men: 39 – 48 %

QUALITY CONTROL

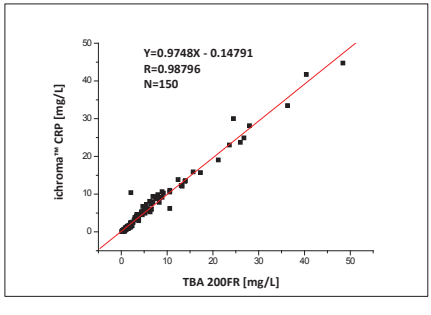
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **ichroma™ CRP**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Specificity**: There, in test samples, are biomolecules such as hemoglobin, CEA, AFP, ALT, Troponin I, CK-MB, Albumin, and serum amyloid P component in higher concentration than their normal physiological levels. But this doesn't interfere with the **ichroma™ CRP** test measurements, nor occurs any significant cross-reactivity.
- **Precision**: The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard twenty times each with three different lots of **ichroma™ CRP.** The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing ten times each different concentration.

CRP Concentration (mg/L)	Intra assay		Inter assay	
	Mean value (mg/L)	CV (%)	Mean value (mg/L)	CV (%)
5	4.9	4.2	4.6	7.2
100	100	2.3	101.6	5.9
250	251.3	3.9	251.2	4.6

- **Comparability:** CRP concentrations of 150 serum samples were quantified independently with ichroma™ CRP and TBA 200FR as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y=0.9748X - 0.14791 and R = 0.98796 respectively.



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Note: Please refer to the table below to identify various symbols

	Read instructions for use
	Use by
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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