Diagnostic Kit for C-reactive protein

(fluorescence immunochromatographic assay)

Instructions for Use

INTENDED USE

This kit is applicable to vitro quantitative detection of C-reactive protein (CRP) in human serum/plasma/whole blood/fresh finger terminal blood samples, for auxiliary diagnosis of acute and chronic inflammation or infection. This kit only provides the test result of C-reactive protein, and the obtained result shall be analyzed in combination with other clinical information. It must only be used by healthcare professionals.

SUMMARY

C-reactive protein (CRP) is a sensitive inflammatory marker and acute-phase reactive protein, with molecular weight as 115KD and circular half-life as 19 hours. CRP is composed of five identical non-glycosylated polypeptide chain subunits, each of which contains 206 amino acids. These subunits are combined through noncovalent bond to form an annular pentamer. CRP has many biological functions. It plays a regulating role through activating complement and strengthening phagocytosis of phagocyte, thus, to eliminate pathogenic microorganisms invading the body and damaged, necrotic, and apoptotic tissue cells as well as exert an important protective action during body immunization process. Serum CRP is synthesized by the liver. The most significant regulatory factors for its synthesis include interleukin 6, interleukin 1b and tumor necrosis factor. In normal human serum, only minimal CRP exists. Generally, serum CRP is less than 2mg/L for newborn and less than 10mg/L for children and adults. In nonspecific response process of many diseases, especially bacterial infection, inflammation or tissue damage, CRP increases sharply within 4-6 hours, reaches the peak at the 48th hour, decreases immediately after disease regression and then restores to normal level. However, in case of viral infection, there is no significant increase of CRP. This provides a basis for identifying early infection type of disease. It is also a tool for distinguishing viral or bacterial infection. Thus, C-reactive protein has very extensive application value in infectious diseases, especially for evaluation of inflammation or bacterial infection.

PRINCIPLE OF DETECTION

This kit uses the double-antibody sandwich reaction principle with high specificity and fluorescence immunochromatography to quantitatively test the C-reactive protein (CRP) in the serum/plasma/whole blood/fresh finger terminal blood samples. Test strip contains anti-CRP antibody pre-immobilized on the test area (T) of the membrane and goat anti-rabbit IgG antibody in the control area (C). The labeling pad contains pre-coated fluorescently labeled anti-CRP antibody and rabbit IgG antibody. In the detection of samples, CRP antigen in the samples firstly binds to fluorescently labeled anti-CRP antibody to form an immune complex. Under the immunochromatographic effect, the complex and the sample flow in the inside nitrocellulose membrane towards the absorbent paper. The complex binds with the coated anti CRP antibody while it passes through test area (T), to form "anti CRP antibody-CRP antigen-fluorescence-labeled anti CRP antibody" complex and thus aggregate. When passing through the control area (C), the fluorescently labeled rabbit IgG antibody binds to the coated goat anti-rabbit IgG antibody to form a "goat anti-rabbit IgG antibody-fluorescently labeled rabbit IgG antibody" complex and agglutinates. The CRP concentration in the sample is positively correlated with

the fluorescence intensity, and the concentration of CRP in the sample can be detected by the fluorescence immune analyzer.

MAIN KIT COMPONENTS

Catalogue number	52320801	52320805	52320820	52320825
specification / Components	1 Test/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit
Test Device(s)	1	5	20	25
Sample Diluents	1	5	20	25
Instructions for Use	1	1	1	1

MAIN ACTIVE INGREDIENTS

1 Test line (T line): T line area of nitrocellulose membrane is coated with anti-CRP antibody

2 Control line (C line): C line area of nitrocellulose membrane is coated with Goat anti-rabbit IgG antibody.

3 Labeling pad: It is coated with fluorescent-microsphere-labeled anti CRP antibody and rabbit IgG antibody.

4. Main component of sample diluent is 20mM, pH7.4 PBS solution.

Warning: The diluent includes 0.1% Proclin300

H317: May cause an allergic skin reaction.

H412: Harmful to aquatic life with long lasting effects.

P280: Wear protective gloves/protective clothing/face protection.

P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

STORAGE CONDITION

1. The kit should be stored at 2°C~30°C. The shell life of the kit is 24 months.
2. Do not use the kit after the expiration date

APPLICABLE INSTRUMENT

The test must be quantified with Igloo Reader Pro, available from goodscare GmbH, Germany.

SAMPLE COLLECTION AND STORAGE

1. This kit is indicated for testing of venous whole blood, serum, plasma, and fresh finger terminal blood. For whole blood and plasma samples, can use anticoagulant such as EDTA-K2, heparin, and sodium citrate.
2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedure.
3. To avoid interference with the test result, do not use hyperlipidemic, hemolytic or turbid sample.
4. Whole blood collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Whole blood shall be tested as soon as possible after collected. If test cannot be performed in time, the sample shall be stored at 2°C~8°C for up to 2 days
5. Serum/plasma collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Serum and plasma shall be separated as soon as possible after blood sampling to avoid hemolysis. The separated serum and plasma shall be

tested immediately. If test cannot be performed in time, the separated samples can be stored at 2℃~8℃ for 7 days. If frozen below -15℃, samples can be stored 6 months.

6. Fresh terminal blood of fingertips should be used immediately after collection.

7. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifugation or filtered to clarity.

8. Before test, sample should be in room temperature and mixed thoroughly.

REAGENT PREPARATION

1. Use immediately after open the aluminum foil bag.

2. Before test, restore the reagent to room temperature.

TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

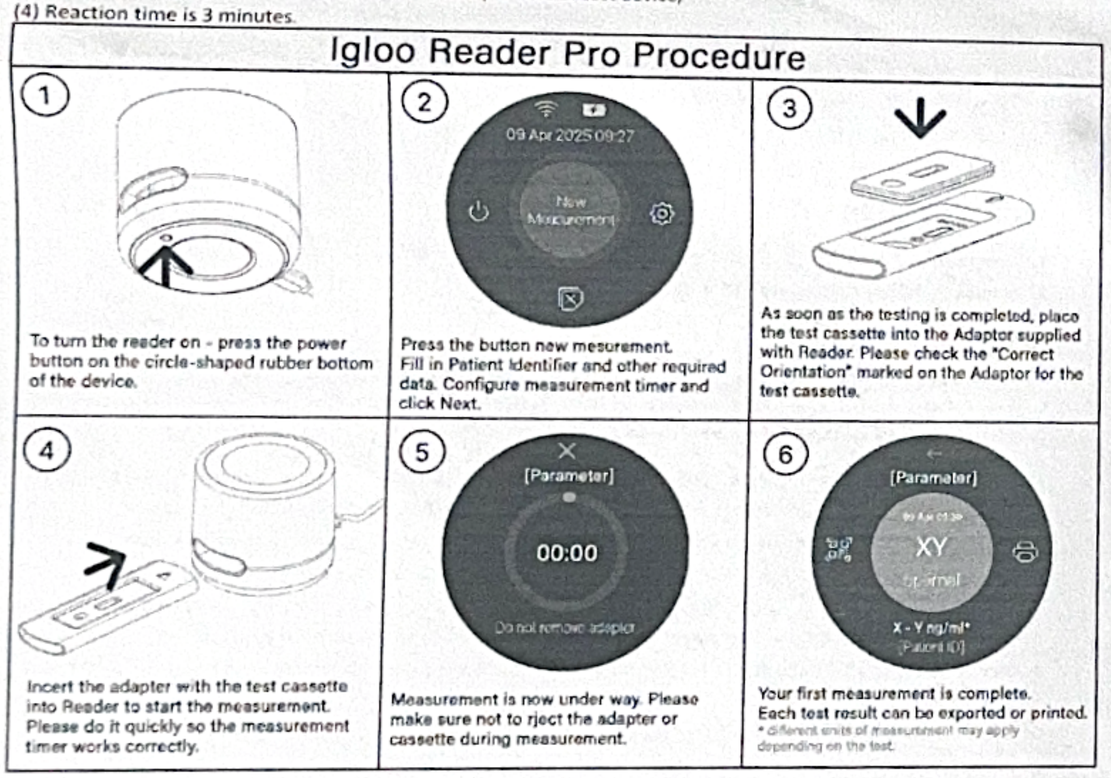
Drip the sample into the test device

(1) Open the aluminum foil bag package, take out the test device, and horizontally place it on examination table;

(2) Add 5μL serum/plasma (or 10μL whole blood/fresh finger terminal blood) into sample diluent, and mix well;

(3) Add 80μL of above mixed solution into the sample hole of test device;

(4) Reaction time is 3 minutes.



REFERENCE INTERVAL

1. Study of CRP reference interval is conducted through referring to C28-A2 document published by US Clinical and Laboratory Standards Institute (CLSI)- How to Define and Determine Reference Intervals in the Clinical Laboratory-Second Edition and WST 402-2012 Define and Determine the Reference Intervals of Test Items in Clinical Laboratory. The obtained reference interval of CRP is: <10mg/L.

2. Due to difference in geography, race, age etc., each laboratory is suggested to establish reference interval of CRP that is suitable for local populations and has clinical significance.

INTERPRETATION OF THE RESULT

1. If the measured CRP concentration of the sample is higher than the range of reference value, state such as physiological change or stress reaction should be excluded. It is indeed abnormal and should be diagnosed in combination with clinical symptoms. Above result is only for reference.

2. Test result of this method is only applicable to evaluation using the reference value established in this method and cannot be directly compared with result of other method.

3. Other factors that may cause wrong test result include technical reason, operation error and other sample factors.

*Invalid result: If the assay result is invalid, the Igloo Reader Pro will display an "invalid" result. The test personnel should read the kit instructions and portable immunoassay analyzer instructions carefully and repeat the test. If the "invalid" result is obtained If it reappears, please contact the device manufacturer.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.

2. This kit is for healthcare professionals only.

3. Before test, restore reagent and sample to room temperature.

4. This kit is disposable.

5. Do not use expired reagent.

6. Sample collection and storage must be performed in strict accordance with this instruction.

7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.

8. Do not open the aluminum foil bags before test and protect the products from moisture; do not use if the aluminum foil bags are damaged or if the test reagents are wet.

9. For all components of the kit, it is recommended not to mix or interchange different batches.

10. Excessive or insufficient sample may lead to deviation of result.

11. Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.

12. Test method should strictly follow the instruction for use.

13. For specific explanation of test result, analysis shall be performed in combination with clinical information.

14. The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.

15. Desiccant in aluminum foil bag is inedible.

16. Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.

17. During test, test procedure, precautions and result explanation of the reagent must be followed to avoid wrong result.

PRODUCT PERFORMANCE INDEX

Evaluation performed using internal reference material of the enterprise demonstrates that all performance indexes of this kit conform to standard. Specific performance indexes are as below:

1. Reportable range of the reagent (kit) is 0.5mg/L~2000mg/L.
2. Linear range: Within the linear range of 0.5~200 mg/L in the reagent (kit), the analytical performance should meet the following requirements:

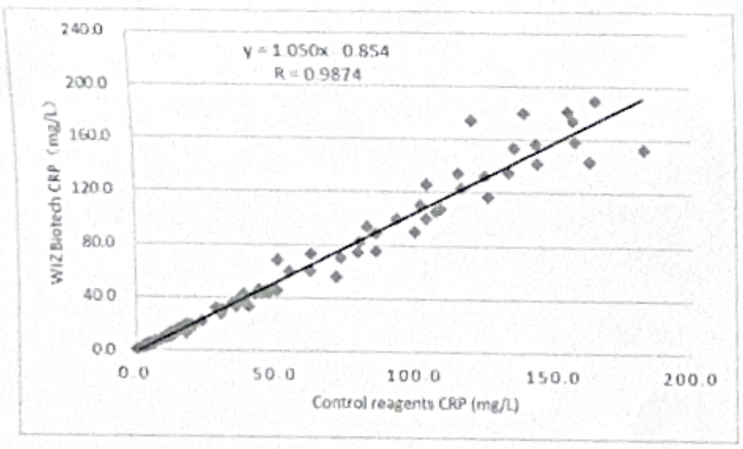
a) The correlation coefficient (r) of linearity should be ≥0.9900.

3. Accuracy: Relative deviation is within ±15%.
4. Limit of detection: ≤0.10mg/L.
5. Repeatability: CV≤15%.
6. HOOK effect: In case of CRP concentration is 1000mg/L, there is no HOOK effect.
7. Interfering substance: Following substances are found to cause no interference when they are tested at the given concentration.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	2 mg/mL	Triglyceride	40.0 mg/mL
Hemoglobin	10.0 mg/mL	Rheumatoid factor	1500IU/mL

8. Clinical performance

Clinical evaluation performance of the product is assessed through collecting 178 clinical samples. Use a corresponding marketed immunoturbidimetry kit as the control reagent and compare the test results. Use linear regress to investigate their comparability. The correlation coefficients of the two tests are Y=1.050X-0.854 and R=0.9874, respectively.



LIMITATION

1. This reagent is only used for testing human whole blood, serum, plasma, and fresh finger terminal blood.
2. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
3. Test shall be carried out at normal room temperature (18℃~25℃).
4. Linearity range of this kit is 0.5~200 mg/L. To measure accurate concentration of high-concentration sample that exceeds measurement linearity range of the kit, measurement and calculation should be performed after dilution to within the linearity range of the kit. Under the conditions of normal saline or sample diluents, the

maximum dilution multiple of this kit is 10 times and the reportable range is 0.5 mg/L ~2000 mg/L.

5. Due to low concentration of the analyte, this method cannot detect analyte, this will lead to result deviation.
6. Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
7. This test has a low probability of false positive results. Therefore, all positive results must be verified by other method.
8. If the obtained result is questionable, immediately re-test or use other method to test the sample.
9. Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.

LITERATURE REFERENCES

[1] Sproston NR, Ashworth JJ. Role of C-Reactive Protein at Sites of Inflammation and Infection. Front Immunol. 2018; 9:754. Published 2018 Apr 13.

[2] Ansar W, Ghosh S. Inflammation and Inflammatory Diseases, Markers, and Mediators: Role of CRP in Some Inflammatory Diseases. Biology of C Reactive Protein in Health and Disease. 2016;67-107. Published 2016 Mar 24.

[3] Mölkänen T, Ruotsalainen E, Rintala EM, Järvinen A. Predictive Value of C-Reactive Protein (CRP) in Identifying Fatal Outcome and Deep Infections in Staphylococcus aureus Bacteremia. PLoS One. 2016;11(5):e0155644. Published 2016 May 16.

SYMBOLS

Symbol	interpretation	Symbol	interpretation	Symbol	interpretation
	Consult instructions for use		Tests per kit		Manufacturer
IVD	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
2°C 30°C	Store at 2°C~30°C	REF	Catalogue number	LOT	Batch code
EC REP	Authorized Representative in the European Community		Caution		

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