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Read these instructions for use well before using.

IVD

Revised in June, 2023 (Second edition)

C-reactive Protein Test Kit

Banalyst CRP

■Intended use■

Measurement of C-reactive protein in human blood

■Clinical importance■[1)]

C-reactive protein (CRP) was found in 1930 as a substance that exhibits precipitation reaction with C-polysaccharide of pneumococcus. By subsequent researches, CRP was clarified to exist in very small amount in normal blood, but is produced during inflammation mainly in liver derived from IL-6 or TNFα raising its concentration in blood, and is classified as acute reactive protein.

A CRP test value (concentration in blood) is recognized as an index for judging existence and degree of inflammation. Further, as an inflammatory marker, although there is erythrocyte sedimentation rate, CRP is recognized as the subtlest index for judging intensity and length of inflammation in the case of acute inflammation because it reacts faster and disappears more slowly than erythrocyte sedimentation rate. Therefore, it is utilized in the tests for grasping heavy infections such as bacterial infection and sepsis, rheumatic diseases such as arthrorheumatism, inflammatory conditions such as autoimmune disease and historrhexis such as cardiac infarct.

■Measurement principle■

1. Measurement principle

Latex agglutination immuno-turbidimetric method

2. Reaction flow in the reagent chip - outline -

The reaction of a sample and reagent is completed in a reagent chip. The outline of reaction flow in the reagent chip is shown below.

[1] Blood cells in whole blood are separated in the reagent chip, and a certain quantity of plasma components move in the reagent chip.

[2] The C-reactive protein (CRP) contained in the plasma components reacts with anti-human CRP mouse monoclonal antibody sensitized latex to form latex aggregates corresponding to the CRP concentrations.

[3] The latex aggregates move in the reagent chip to reach the photometry portion.

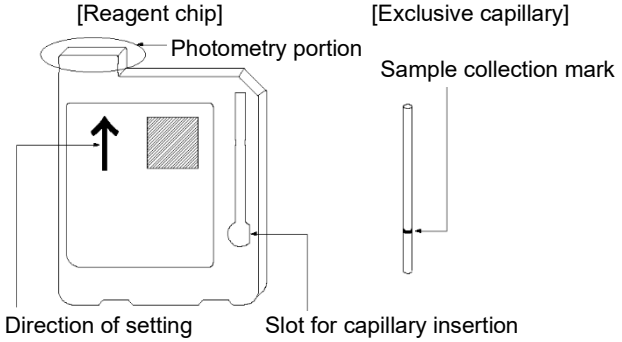
[4] The CRP concentrations are measured at 635 nm wavelength in the photometry portion, and displayed on the instrument.

■Reference substance for calibration■

Institute for Reference Materials and Measurements (IRMM)
ERM-DA 470

■Shape, structure, etc. (Kit constitution)■

1. Shape, structure



- Reagent chip (50 mm (H) × 40 mm (W) × 4.5 mm (D))
- Exclusive capillary (33 mm (L) × 1.8 mm (OD))

2. Kit constitution

Name	Component involved in reaction system	Quantity
Reagent chip	Anti-human C-reactive protein mouse monoclonal antibody sensitized latex	50 pieces
Exclusive capillary (accessory)	-	52 pieces

■Method of storage, expiration date■

1. Method of storage

To be refrigerated (2 °C to 8 °C, 36 °F to 46 °F)

2. Effective period

12 months after production

3. Expiration date (Exp.)

Written on the outer case, the aluminum bag, and the reagent chip

■General precautions■

- The reagent chips are in-vitro diagnostics. Do not use them for other purposes.
- Use the exclusive instrument (Banalyst) to measure reagent chips. Measurement is not possible with other instruments.
- For the use of reagent chips, follow the instructions on this paper and on the manuals provided with the instrument. Performance and measurement results cannot be guaranteed for use other than what is described.

■Precautions in use or handling■

1. Pay special attention to avoid infection from a sample. Wear protective gloves during sample handling, for example.
2. Store the reagent chips with the top of the outer case facing up. Do not turn the case upside down nor sideways.
3. Store the reagent chips in the method of storage described above. And do not use an expired reagent chip.
4. Repetition of refrigeration and leaving at ambient temperature shortens the shelf life of reagent chips. Avoid handling them in that way.
5. Do not freeze the reagent chips. And do not use a reagent chip once frozen.
6. Pay attention not to touch the photometry portion of a reagent chip.
7. Pay full attention in handling of reagent chips not to give strong impact such as dropping and shaking. Do not use any reagent chips damaged due to strong impact.
8. Make sure that the sample drawn into an exclusive capillary exceeds the sample collection mark. If the sample falls short of the mark, the measurement cannot be correct.
9. Pay attention not to soil the two-dimensional code of a reagent chip.
10. If an error occurs in reading a two-dimensional code, follow the instructions on the manuals provided with the instrument.
11. Immediately after the sample draw, insert the exclusive capillary into the reagent chip and start measurement quickly.
12. Do not turn the label side of a reagent chip down with an exclusive capillary inserted. The exclusive capillary may come off.
13. If an error occurs during measurement, measure the sample again.
14. Dispose of the reagent chips after use following the national and regional regulations relating to wastes.
15. Reagent chips are for one use only.

■Precautions in operation■

1. Sample properties and sample collecting

- Use whole blood or plasma as a measurement sample.
- Both capillary blood and venous blood can be used as a measurement sample.
- A minimum of 4.4 μL sample is required for the test.
- Draw the sample into the exclusive capillary through the end closest to the sample collection mark until the sample exceeds the mark. Even if the sample drawn through the opposite end, the measurement value is not influenced.
- Measure the sample immediately after the sample draw.
- When collecting the measurement sample from the fingertip or earlobe, avoid direct contact of the exclusive capillary with the sampling site. And do not squeeze or milk the blood from the sampling site in capillary blood sampling.

- When whole blood is measured, a hematocrit exceeding 60 % may influence the measurement values.
- The presence of other substances in the test sample may infrequently cause to give values higher (nonspecific reaction) or lower (interfering reaction) than the correct value.

2. Interfering substances
- The measurement values are not influenced by the presence of up to 1590 FTU (formazin turbidity) of chyle, up to 494 mg/dL of hemoglobin, up to 19.1 mg/dL of free bilirubin, up to 21.6 mg/dL of conjugated bilirubin, up to 55 IU/mL of rheumatoid factor, and up to 100 mg/dL of ascorbic acid.
- The measurement values are not influenced by the normal usage of anticoagulants (heparin, EDTA, or citric acid) and glycolytic inhibitor (NaF).

■Direction for use and dosage (operation method)■

1. Take a reagent chip out of the refrigerator and leave it in the aluminum bag for about 10 minutes until it warms up to ambient temperature. Use the reagent chip immediately after opening the aluminum bag.
2. Bring an end of the accompanying exclusive capillary with the sample to draw the sample until it exceeds the sample collection mark.
3. Immediately after the sample draw, insert the exclusive capillary into the reagent chip.
4. Put the reagent chip with the capillary inserted in place of the instrument quickly.
5. Press the “START” button of the instrument to start measurement.
6. The measurement results are displayed on the instrument after the measurement is completed.
7. Remove the used reagent chip from the instrument and dispose of it as a medical waste following the relevant national and regional regulations.

[Note] For more information on the instrument operations, refer to the manuals provided with the instrument.

■Judgment of measurement results■

Have a physician-in-charge execute comprehensive clinical diagnosis based on the measurement results together with clinical conditions and other test results.

■Performance■

1. Performance

(1) Sensitivity

[1] When normal saline is measured, “Low” is displayed.

[2] When an administrative test substance of 0.5 mg/dL is measured, the measurement results are in the range from 0.1 mg/dL to 0.9 mg/dL.

(2) Accuracy

[1] When administrative test substances of less than 1.5 mg/dL are measured, the displayed values are within ±0.4 mg/dL.

[2] When administrative test substances of 1.5 mg/dL or more and above are measured, the displayed values are within ±25 %.

(3) Within-run reproducibility

[1] When administrative test substances of less than 1.5 mg/dL are measured repeatedly 7 times, the standard deviation is 0.15 mg/dL or less.

[2] When administrative test substances of 1.5 mg/dL or more are measured repeatedly 7 times, the coefficient of variation is 10 % or less.

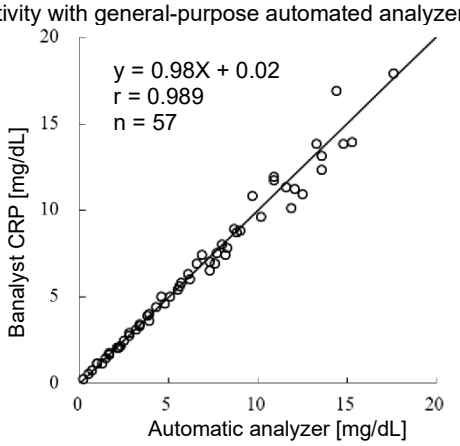
(4) Measurement range

0.1 mg/dL to 20 mg/dL

2. Correlativity test result

Correlativity between this product and existing product was studied and good correlativity was obtained.

Correlativity with general-purpose automated analyzer



■Reference value■

1. Reference value [2)]

Less than 0.5 mg/dL

2. Others

When the measurement value is lower than the measurement limit (0.1 mg/dL), “Low” is displayed.

When the measurement value is higher than the upper limit of measurement (20 mg/dL), “High” is displayed.

■Main literature■

1.Thompson D, Milford-Ward A, Whicher JT. The value of acute phase protein measurements in clinical practice. Ann Clin Biochem 1992; 29: 123-131.

2.Kindmark C-O. The concentration of C-reactive protein in sera from healthy individuals. Scand J Clin Lab Invest 1972; 29: 407-411.

■Symbols■

	This way up		Temperature limitation
	Handle with care		Do not freeze
	Manufacturer		Consult instructions for use
	Use by		*In vitro* diagnostic medical device
	Batch code		Product code
	Do not reuse		Contents

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