COVID-19 IgG/IgM Microfluidic Chip

For the qualitative detection of IgG/IgM antibodies in serum/ plasma and whole blood

(Single use test cartridge)

The instructions must be read carefully and completely prior to the use of the COVID-19 IgG/IgM Microfluidic Chip. Instructions must be followed carefully. If directions are not followed exactly, inaccurate test results may occur. Before performing the test, all operators must read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and Other Blood-Borne Pathogens in Health-Care Settings.

INTENDED USE

COVID-19 IgG/IgM Microfluidic Chip is for the detection of IgG/IgM in human serum, plasma or whole blood. It cannot be used as the basis for the diagnosis and exclusion of COVID-19. The kit is used in combination with the F10 FREND System produced by NanoEnTeK Inc. or the F10 Pro NewScen Fluorimetric Immunoassay Analyzer produced by our company.

PRINCIPLE

This kit uses microfluidic technology, fluorescence technology, and indirect immune capture principle of comprehensive detection technology to detect IgG/IgM of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum, plasma and whole blood. Microfluidic technology is a detection technology that uses the microchannel inside the reagent cartridge to realize liquid quantification and uniform flow. During the detection, SARS-CoV-2 antibodies in the sample first react with the fluorescently labeled gene recombinant antigens to form the antibodies ~ fluorescently labeled antigens immune complexes, the immune complexes depend on siphon action to flow forward automatically in the microchannel. When the complexes flow to the detection area, IgG in the immune complexes meet the pre-coated anti-human IgG and absorbes into the detection area, and forms the T1. Thereafter, IgM in the immune complexes meet the pre-coated anti-human IgM and absorbes into the detection area, forming T2. The unbound fluorescent labeled antigens continue to flow forward to the quality control area, and the antibodies encounter the recombinant antigens and absorbes into the quality control area, the residuum eventually flows to the waste area.

On the FREND System or NewScen Fluorimetric Immunoassay Analyzer, it collects the fluorescence signal that was excited by the excitation light in the detection area and the quality control area. The intensity of the fluorescence signal is positively correlated with the antibody content in the sample.

REAGENTS AND MATERIALS PROVIDED

1. Test cartridge (individually pouched)
2. Each pouch contains one cartridge with one desiccant bag
3. Diluent buffer
4. Instruction for use
5. Code chip
6. Pipette Tip (optional)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch
2. Pipette
3. Blood collection devices, for the testing of venipuncture whole blood, serum or plasma
4. Biohazard disposal container
5. Disposable gloves

For fingerstick samples, the following materials are required:

Alcohol pad

Sterile lancet

Sterile gauze or cotton

WARNING

For Medical Professional and In Vitro Diagnostic use ONLY

Read the package insert completely before use. It is very important that the correct procedure is followed. Fail to add the patient sample may lead to a false negative result (i.e. a missed positive).

PRECAUTIONS

1. This product is an in vitro diagnostic reagent to qualitatively detect the IgG/IgM of SARS-CoV-2 in human serum, plasma and whole blood.

2. Unqualified samples will lead to wrong results, such as the hemoglobin in the hemolysis sample > 10g/L, triglycerides in hyperlipidemia samples > 20g/L, bilirubin in jaundice samples > 0.6g/L, RF > 1200IU/mL in rheumatoid samples.

3. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.

4. Make sure the test is not expired (EXP Date is indicated on the kit box).

5. Do not use the test if the pouch has been perforated.

6. Calibrate pipette frequently to assure the accuracy of dispensing. Use a different disposal pipette tip for each specimen in order to avoid cross-contaminations.

7. Do not modify the test procedure.

8. Each test is for single use only.

9. Blood that has been chemically treated, heated, diluted, or otherwise modified may result in inaccurate results.

10. Different batch of product components cannot be mixed.

11. If desiccant bag is not present in the pouch, DO NOT USE the test.

12. Always add accurate volume of specimen by following the instruction.

13. The test cartridge must be used directly after unsealing. It is not allowed to divide it for use.

14. After the kit is stored in refrigerator, it should be placed at room temperature for 15 to 30 minutes, and then open the package for testing after returning to room temperature.

15. Read the result in 4~20 minutes. Interpret the test result after 20 minutes may cause false result.

STORAGE

COVID-19 IgG/IgM Microfluidic Chip should be stored in a dark place at 2~8°C for 12 months from the date of manufacture. Keep the test cartridge in sealed pouch until use. Before test, it should be restore to room temperature, once you have taken the test cartridge out of the pouch, use it immediately. Do not use the test beyond the indicated expiration date.

The kit can be transported at room temperature for no more than 15 days.

SAMPLE COLLECTION AND TEST PREPARATION

Fingerstick Specimens (Whole Blood)

1. Clean the area to be lanced with an alcohol pad.

2. Squeeze the end of the fingertip and pierce it with a sterile lancet.

3. Wipe away the first drop of blood with sterile gauze or cotton; collect the sample from the

second drop.

4. Use dropper to draw the fresh blood to 1/2 of the tube wall and dispense into the sample well.

Fingerstick whole blood should be used immediately after collection.

Serum/ Plasma specimens: fresh serum or plasma specimen can be used.

Plasma

1. Collect whole blood into a collection tube (containing EDTA, Na-citrate or heparin) by venipuncture.

2. Separate the plasma by centrifugation.

Serum

1. Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture.

2. Allow the blood to clot.

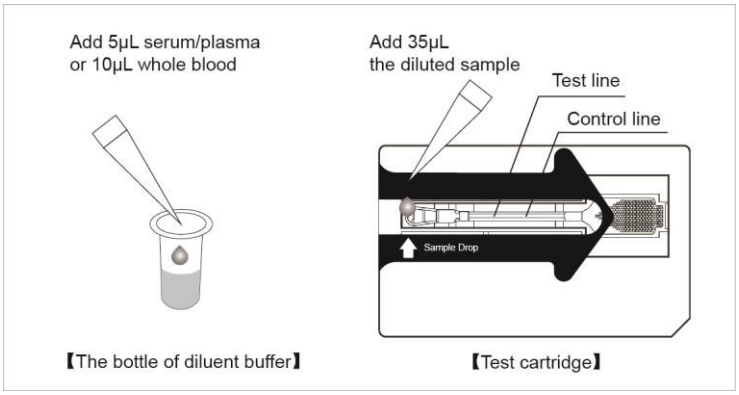
3. Separate the serum by centrifugation.

Avoid the use of hemolytic, turbid, microorganism contaminated specimens. Specimen should be stored at 2~8°C for up to 3 days or frozen at -20°C for up to 9 days. Avoid specimen deterioration by multiple freeze-thaw cycles.

Venipuncture Whole Blood

Venipuncture whole blood can be used immediately after collection or stored up to 3 days at 2~8°C.

ASSAY PROCEDURE



1. Sample preparation: Fresh serum, plasma or whole blood samples, no pretreatment is required. If the samples are stored in 2~8**℃** , the samples should be restored at room temperature for 15~30 minutes, returned to room temperature and thoroughly mixed before

testing.

2. Instrument preparation: follow the instruction and installation guide of FREND System or NewScen Fluorimetric Immunoassay Analyser. Import the code chip of the kit into the instrument.

3. Reagent preparation: Open the package. The pouch should be sealed well, If the test reagent is stored in the refrigerator, it should be restored at room temperature for 15~30 minutes. Then open the pouch and take out the test cartridge, place it on the platform.

4. Dilution of test sample: Add 5μL serum/plasma or 10μL whole blood samples to the diluent buffer and shaken well.

5. Detection and interpretation: Add 35μL the diluted sample to the sample drop, start timing. In 4-20 minutes, insert test cartridge in the direction of the black arrow to the instrument. The result is invalid after more than 20 minutes.

6. Calibration procedure: Before reading the reagent, confirm the instrument is in normal operation state, and be calibrated by the instrument calibration card.

INTERPRETATION OF RESULTS

The test result is represented by S/CO value, S represents the signal value of the test sample, and CO1 represents the Cut-off value of IgG, CO2 represents the Cut-off value of IgM.

1. **Positive of IgG:** In area T1, the test result S/CO1≥1.1, indicates that the IgG antibody test result is positive.

2. **Negative of IgG:** In area T1, the test result S/CO1≤0.9, indicates that the IgG antibody test result is negative.

3. **Uncertain of IgG:** In area T1, the test result 0.9 < S/CO1 < 1.1, indicates that the IgG antibody test result is uncertain.

4. **Positive of IgM:** In area T2, the test result S/CO2≥1.1, indicates that the IgM antibody test result is positive.

5. **Negative of IgM:** In area T2, the test result S/CO2≤0.9, indicates that the IgM antibody test result is negative.

6. **Uncertain of IgM:** In area T2, the test result 0.9 < S/CO2 < 1.1, indicates that the IgM antibody test result is uncertain.

LIMITATION

1. The kit is only used to detect human serum, plasma and whole blood sample.

2. The accuracy of the test depends on the process of sample collection. Improper sample collection, improper sample storage or repeated freezing and thawing of samples will affect the test results.

3. The test results of this reagent are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of the patient should be considered in combination with other laboratory tests of the patient's symptoms/signs history and treatment response.

4. Due to the limitation of antibody detection reagent methodology, nucleic acid detection or virus culture identification method is recommended to confirm the negative test results.

5. Too low levels of the antibodies in the sample can lead to false negative results.

6. The mutation of virus gene may change the epitopes of antibody and result in false negative results.

PERFORMANCE CHARACTERISTICS

1. **Negative reference sample coincidence rate:** 10 negative enterprise reference samples were tested and the results were all negative.

2. **Positive reference sample coincidence rate:** 5 IgG positive enterprise reference samples were tested and the results were all positive. 5 IgM positive reference samples were tested and the results were all positive.

3. **Minimum detectability:** 3 IgG limited detection of enterprise reference samples were used for testing, L1 should be negative, L2 was an uncertain result, and L3 should be positive. 3 IgM limited detection of enterprise reference samples were used for testing, L4 should be negative, L5 was an uncertain result, and L6 should be positive.

4. **Intra-lot repeatability:** Parallel test IgG enterprise repeatability reference sample 10 times, the coefficient of variation (CV) should not be higher than 10%.

Parallel test IgM enterprise repeatability reference sample 10 times, the coefficient of variation (CV) should not be higher than 10%.

5. **Inter-lot repeatability:** Parallel determination of IgG enterprise repeatability reference sample with 3 batches of reagents, each batch repeated 10 times, the 3 batches coefficient of variation (CV) should not be higher than 15%.

Parallel determination of IgM enterprise repeatability reference sample with 3 batches of reagents, each batch repeated 10 times, the 3 batches coefficient of variation (CV) should not be higher than 15%.

6. **Interfering substance:** Unqualified samples will lead to wrong results, such as the hemoglobin in the hemolysis sample > 10g/L, triglycerides in hyperlipidemia samples > 20g/L, bilirubin in jaundice samples > 0.6g/L, RF > 1200IU/mL in rheumatoid samples.

7. **Cross reaction:** This kit has no cross reaction against human immunodeficiency virus antibody, hepatitis B surface antibody, hepatitis C virus antibody, treponema pallidum antibody, mycoplasma pneumoniae antibody, helicobacter pylori antibody positive samples.

8. **Clinical sample compliance:** A total of 794 clinical samples were verified, of which 161 were positive and 633 were negative. The test results are as follows:

NewScen	Clinical samples information				Total	
	+		-			
+	A	147	B	0	A+B	147
-	C	14	D	633	C+D	647
Total	A+C	161	B+D	633	A+B+C+D	794

Sensitivity:

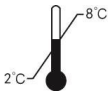
A/(A+C)% = 91.30% (95% credibility interval: 85.84% ~ 95.16%)

Specificity:

D/(B+D)% = 100.00% (95%credibility interval: 99.42% ~ 100.00%)

Total Accuracy:

(A+D)/(A+B+C+D)% = 98.24% (95%credibility interval: 97.06% ~ 99.03%)

	Do not re-use
	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
	Temperature limitation
	Consult instructions for use
	Batch code
	Manufacturer

Product disclaimer: This product has been manufactured under strict GMP regulations to ensure the diagnostic accuracy of the test. It is out of control of the manufacture when the test is performed in diverse environment and by diverse group of individuals that may affect the results to a certain degree.

Note: The manufacturer, the distributor, or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.

IVD

Human serum amyloid A (SAA)/C-reactive protein (CRP) Microfluidic Chip

For the quantitative detection of SAA/CRP in serum/heparin plasma/EDTA plasma or whole blood

(Single use test cartridge)

The instructions must be read carefully and completely prior to the use of Human serum amyloid A (SAA)/ C-reactive protein (CRP) Microfluidic Chip. Instruction must be followed carefully. If directions are not followed exactly, inaccurate test results may occur. Before performing the test, all operators must read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and Other Blood-Borne Pathogens in Health-Care Settings.

INTENDED USE

Human serum amyloid A (SAA)/C-reactive protein (CRP) Microfluidic Chip is for the detection of the quantitative detection of SAA/CRP in serum/heparin plasma/EDTA plasma or whole blood.

The kit is used in combination with F10 FREND System produced by NanoEnTeK Inc. or F10Pro NewScen Fluorimetric Immunoassay Analyser produced by our company.

PRINCIPLE

This kit uses microfluidic technology, fluorescence technology, and double-antibody sandwich immune principle of comprehensive detection technology to detect SAA/CRP in serum, heparin plasma, EDTA plasma or whole blood. Microfluidic technology is a detection technology that uses the microchannel inside the reagent cartridge to realize liquid quantification and uniform flow. During the detection, SAA/CRP in the sample first react with the fluorescently labeled antibodies to form the antigens ~ fluorescently labeled antibodies immune complexes, the immune complexes depend on siphon action to flow forward automatically in the microchannel. When flow to the detection area, meet coated paired antibodies and absorbed in the detection area, the unbound fluorescent labeled antibodies

continue to flow forward, and when they flow to the quality control area, encounter the SAA/CRP recombinant antigens and absorbed in the quality control area, the residuum eventually flows to the waste area. On the FREND System or NewScen Fluorimetric Immunoassay Analyser, it collects the fluorescence signal that excited by the excitationlight in detection area and the quality control area, the intensity of the fluorescence signal is positively correlated with the SAA/CRP content in the sample.

REAGENTS AND MATERIALS PROVIDED

1. Test cartridge (individually pouched)
2. Each pouch contains one cartridge with one desiccant bag
3. Diluent buffer
4. Instruction for use
5. Code chip
6. Pipette Tip (optional)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch
2. Pipette
3. Blood collection devices, for the testing of venipuncture whole blood, serum or plasma
4. Biohazard disposal container
5. Disposable gloves

For fingerstick samples, the following materials are required:

Alcohol pad

Sterile lancet

Sterile gauze or cotton

WARNING

For Medical Professional and In Vitro Diagnostic use ONLY

Read the package insert completely before use. It is very important that the correct procedure is followed. Fail to add the patient sample may lead to a false negative result (i.e. a missed positive).

PRECAUTIONS

1. This product is an in vitro diagnostic reagent to quantitatively detect SAA/CRP in serum, heparin plasma, EDTA plasma or whole blood. The test results alone cannot be used as the basis for a definitive diagnosis.

2. Unqualified samples will lead to wrong results, such as the hemoglobin in the hemolysis sample > 10g/L, triglycerides in hyperlipidemia samples > 20g/L, bilirubin in jaundice samples > 0.6g/L, RF > 1200IU/mL in rheumatoid samples.

3. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.

4. Make sure the test is not expired (EXP Date is indicated on the kit box).

5. Do not use the test if the pouch has been perforated.

6. Calibrate pipette frequently to assure the accuracy of dispensing. Use a different disposal pipette tip for each specimen in order to avoid cross-contaminations.

7. Do not modify the test procedure.

8. Each test is for single use only.

9. Blood that has been chemically treated, heated, diluted, or otherwise modified may result in inaccurate results.

10. Different batch of product components cannot be mixed.

11. If desiccant bag is not present in the pouch, DO NOT USE the test.

12. Always add accurate volume of specimen by following the instruction.

13. The test cartridge must be used directly after unsealing. It is not allowed to divide it for use.

14. After the kit is stored in refrigerator, it should be placed at room temperature for 15 to 30 minutes, and then open the package for testing after returning to room temperature.

15. Read the result in 4~20 minutes. Interpret the test result after 20 minutes may cause false result.

STORAGE

Human serum amyloid A (SAA)/ C-reactive protein (CRP) Microfluidic Chip should be stored in dark place at 2~8°C for 12 months from the date of manufacture. Keep the test cartridge in sealed pouch until use. Before test, it should be restore to room temperature, once you have taken the test cartridge out of the pouch, use it immediately. Do not use the test beyond the indicated expiration date.

The kit can be transported at room temperature for no more than 15 days.

SAMPLE COLLECTION AND TEST PREPARATION

Fingerstick/earlobe endings Specimens (Whole Blood)

1. Clean the area to be lanced with an alcohol pad.

2. Squeeze the end of the fingertip/earlobe endings and pierce it with a sterile lancet.

3. Wipe away the first drop of blood with sterile gauze or cotton; collect the sample from the second drop.

4. Use dropper to draw the fresh blood to 1/2 of the tube wall and dispense into the sample well.

Fingerstick/earlobe endings whole blood should be used immediately after collection.

Serum/ Plasma specimens: fresh serum or plasma specimen can be used.

Plasma

1. Collect whole blood into a collection tube (containing EDTA or heparin) by venipuncture.

2. Separate the plasma by centrifugation.

Serum

1. Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture.

2. Allow the blood to clot.

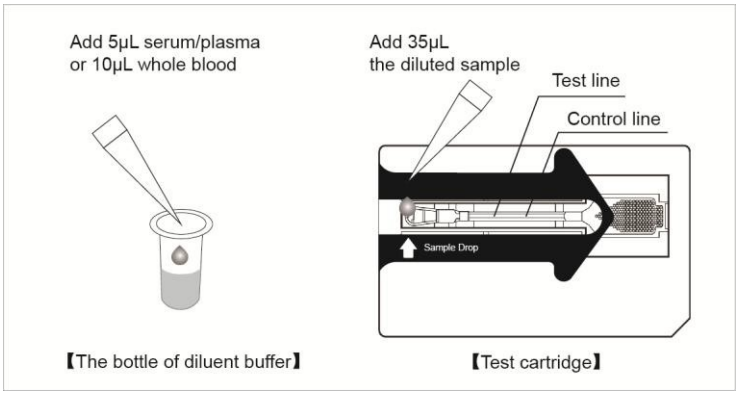
3. Separate the serum by centrifugation.

Avoid the use of hemolytic, turbid, microorganism contaminated specimens. Plasma and serum specimen should be stored at 4°C for up to 5 days or frozen at -20°C for up to 3 months. Avoid specimen deterioration by multiple freeze-thaw cycles. The diluted samples should be used immediately and cannot be stored for a long time.

Venipuncture Whole Blood

Venipuncture whole blood can be used immediately after collection.

ASSAY PROCEDURE



1. Sample preparation: Fresh serum, plasma or whole blood samples, no pretreatment is required. If the samples are stored in 4**℃** or -20°C, the samples should be restored to room

temperature and thoroughly mixed before testing.

2. Instrument preparation: follow the instruction and installation guide of FREND System or NewScen Fluorimetric Immunoassay Analyser. Import the code chip of the kit into the instrument.

3. Reagent preparation: Open the package, the pouch should be sealed well, If the test reagent store in the refrigerator, it should be restored at room temperature for 15~30 minutes. Then open the pouch and take out the test cartridge, place it on the platform.

4. Dilution of test sample: Add 5μL serum/heparin plasma/EDTA plasma or 10μL whole blood samples to the diluent buffer and shaken well.

5. Detection and interpretation: Add 35μL the diluted sample to the sample drop, start timing. In 4-20 minutes, insert test cartridge in the direction of the black arrow to the instrument. The result is invalid after more than 20 minutes.

6. Calibration procedure: Before reading the reagent, confirm the instrument is in normal operation state, and be calibrated by the instrument calibration card.

7. Quality control procedure: LiquichekTM Elevated CRP Control&WHO International Standard SERUM AMYLOID A (SAA) 1st International Standard produced by Bio-Rad can be used for quality control.

INTERPRETATION OF RESULTS

1. In the early diagnosis of infectious diseases, the combination of SAA and CRP test can be used for early recognition of viral and bacterial infections. When both SAA and CRP are elevated, the possibility of bacterial infection is suggested. If the SAA is elevated and the CRP is not, it is suggests the possibility of viral infection. Dynamic monitoring is required for clinical efficacy evaluation.

SAA concentration	CRP concentration	Clinical indication
<10mg/L	<10mg/L	No acute inflammation
10mg/L~100mg/L	10mg/L~50mg/L	Viral infection (mild)
100mg/L~500mg/L	>50mg/L	Bacterial infection, SAA and CRP are observed dynamically to evaluate the therapeutic effect.
>500mg/L	10mg/L~50mg/L	Virus infection (severe), bacterial infection, reexamination in 12-24h.

2. SAA>500 mg/L: This indicates that the concentration of SAA in the sample is higher than the upper limit of the test range. There is no Hook effect in the range of 1~1000mg/L. CRP>150mg/L: This indicates that the content of CRP in the sample is higher than the upper limit of the test range. There is no Hook effect in the range of 0.5~1000mg/L.

If accurate quantification is needed again, it is recommended to repeat the test after dilution, and the optimal dilution ratio is 10 times. The specific method is to take 35μL the diluted sample and add them to 315μL diluent buffer. After dilution mixing, detection conducted, and the detection result is multiplied by the dilution factor (×10) to obtain the true concentration of the sample.

LIMITATION

1. The kit is only used to detect human serum, heparin plasma, EDTA plasma or whole blood.

2. The accuracy of the test depends on the process of sample collection. Improper sample collection, improper sample storage or repeated freezing and thawing of samples will affect the test results.

3. The test results of this reagent are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of the patient should be considered in combination with other laboratory tests of the patient's symptoms/signs history and treatment response.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** SAA≤1mg/L, CRP≤0.5mg/L.

2. **Specificity:** Test the specific enterprise internal control samples of 50g/L human serum albumin, 5000pg/mL IL6, and 50ng/mL PCT. In the negative specific test results, the SAA should not be higher than 0.5mg/L, the CRP should not be higher than 0.1mg/L, and the relative deviation of the specific test results should not exceed ±10%.

3. **Accuracy:** The concentration was determined by series of enterprise internal control samples, the relative deviation between the detection result and the calibration value shall not exceed ±10%.

4. The linearity of the dose-response curve:

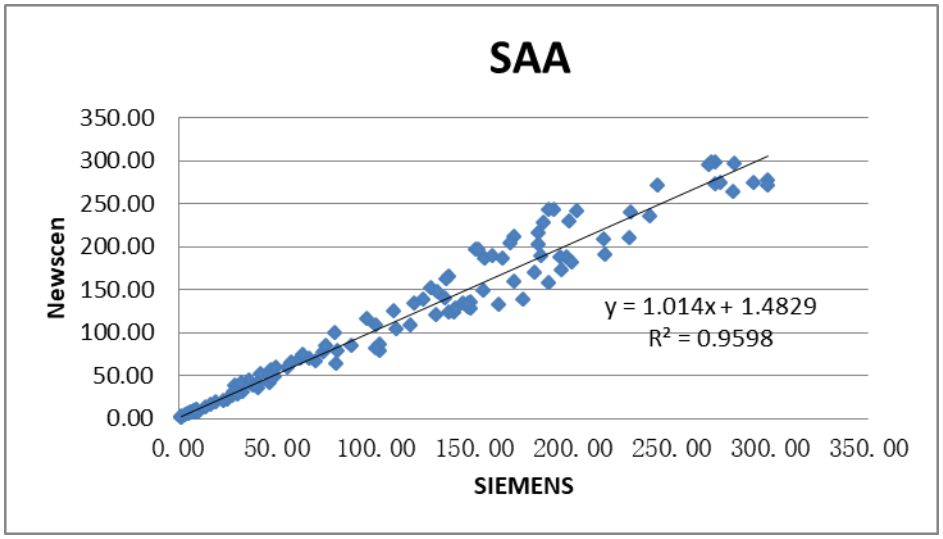
4.1 The range of SAA in the detection is 1~500mg/mL, the correlation coefficient r should be no less than 0.9900 and the absolute deviation of each concentration should be no more than 0.5mg/L, and the relative deviation should be no more than ±10%.

4.2 The range of CRP in the detection is 0.5~150mg/L, the correlation coefficient of rshould be no less than 0.9900 and the absolute deviation of each concentration should be no more than 0.3mg/L, and the relative deviation should be no more than ±10%.

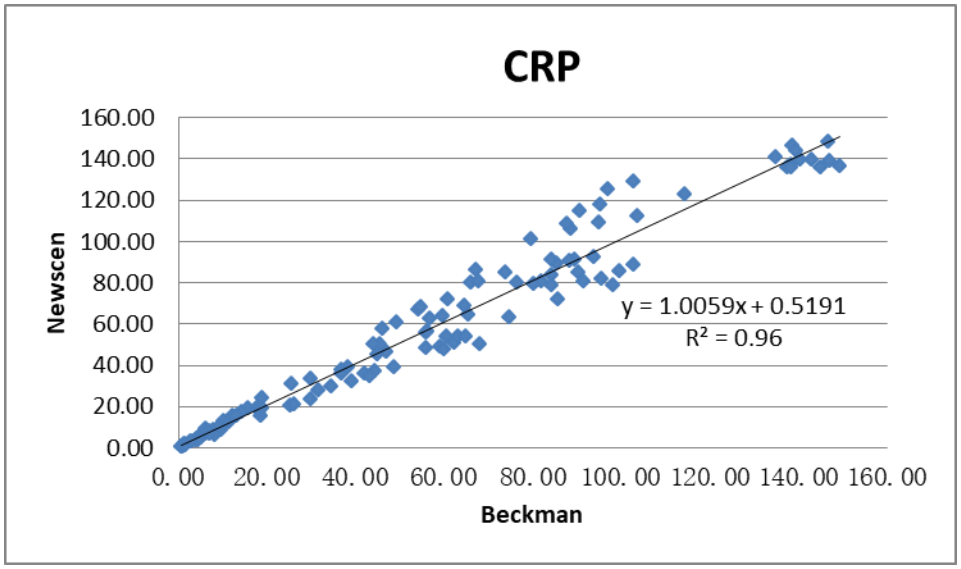
5. **Intra-lot repeatability:** Parallel test enterprise internal control samples 10 times, coefficient of variation (CV) should not be higher than 10%.

6. **Inter-lot repeatability:** Parallel determination enterprise internal control samples with 3 batches of reagents, each batch repeated 10 times. With 3 batches of reagents coefficient of variation (CV) should not be higher than 15%.

7. **Clinical performance:** The test results of SAA of 120 clinical samples were statistically analyzed. The test results of reference reagent product by Siemens were taken as the independent variable (X) and the test reagent product by our company as the dependent variable (Y), and the linear fitting was conducted, in which the coefficient of consistency R^2=0.9598 and the value of R >0.975. The test results of the two reagents showed a high consistency.



The test results of CRP in 120 clinical samples were calculated. The test results of the reference reagent product by Beckman were the independent variable (X) and the test reagent product by our company were the dependent variable (Y), and the linear fitting was carried out. The consistency coefficient R^2=0.960, and the R >0.975.



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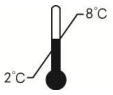
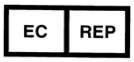
INDEX OF SYMBOLS

	Do not re-use
	For In Vitro Diagnostic medical device

	Use by date
	Date of manufacture

	Temperature limitation
	Consult instructions for use
	Authorized Representative in the European Community
	Batch code
	Manufacturer

Product disclaimer: This product has been manufactured under strict GMP regulation to ensure the diagnostic accuracy of the test. It is out of control of the manufacture when the test is performed in diverse environment and by diverse group of individuals that may affect the results to a certain degree.

Note: The manufacturer, the distributor, or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.