

BIOEAST

Biochemistry Solution and Catalog

Serve Science
See the Future



COMPANY PROFILE

HANGZHOU BIOEAST BIOTECH Co., Ltd. is a leading high-tech enterprise dedicated to pioneering research and development in the field of key raw materials for In-Vitro Diagnostic, Life Science, and Biomedical reagent solutions. Established in 2018, BIOEAST BIOTECH has emerged as a trusted provider of innovative solutions in the industry.

We specialize in developing advanced technologies and cutting-edge solutions to meet the evolving needs of the diagnostic, life science, and biomedical sectors. Our product portfolio encompasses a wide range of offerings, including microspheres, antigens, antibodies, enzymes, active proteins, chromatographic products, and integrated solutions for various diagnostic platforms such as Biochemistry, CLIA, ELISA, FIA, Rapid Test and Immunoturbidimetric assay.

With our leading R&D and manufacturing facilities, ISO13485 certified quality system, and round-the-clock technical support with assay development experience;

BIOEAST has proudly served hundreds of manufacturers with customized solutions and also has 2 wholly-owned companies to serve manufacturers for different needs. AICHEK - POCT integrated solutions BiogenMicro - Biomedicine raw material solutions

As your trusted partner along the way of life science, we are committed to creating a glorious future together. Let's collaborate to achieve breakthroughs and drive innovation in the industry.

Technical parameters can be adjusted and customized services can be provided according to customer requirements

1. Overview

Clinical significance

- Used for screening of organic diseases such as acute and chronic inflammation caused by bacterial infections, autoimmune diseases, or immune complex diseases; tissue necrosis and malignant tumors.
- Differentiation of concurrent infections: CRP > 100mg/L indicates bacterial infection, <50mg/L indicates viral infection, Gram-negative bacterial infection can be as high as 500mg/L.
- Evaluation of disease activity and monitoring of therapeutic efficacy.

2. Reagent composition

The reagent is divided into three components.

- Reagent 1 (R1) Description: Reaction buffer, characterized by a colorless or pale yellow transparent liquid.
- Reagent 2 (R2) Description: Latex solution for antibody coating, characterized by a milky white liquid.
- Calibrator Description: Calibrator with different concentrations, characterized by a liquid form.

Methodology: Transmittance/scattering customizable.

Reagent ratio: The ratio of R1 to R2 can be customized between 1:1 and 10:1; sample detection volume generally ranges from 1-15µL.

Calibrator: The values of calibrators can be customized according to requirements.

3. Test scheme

Sample Requirements

- Fresh whole blood, serum, or plasma.
- When testing serum, avoid hemolyzed or lipemic samples.

Protocol

- **Sample volume:** 1-15µL, customizable according to different manufacturer parameters.
- **Calibration method:** Spline or other multipoint nonlinear calibration.
- **Endpoint reading method:** Two-point endpoint method.
- **R1:R2 ratio:** 1:1 to 10:1, customizable according to different manufacturer parameters.
- **Reaction direction:** Upward.
- **Testing procedure:** As shown in the figure below.

STEP 1

Mix R1 with the sample, incubate.

STEP 2

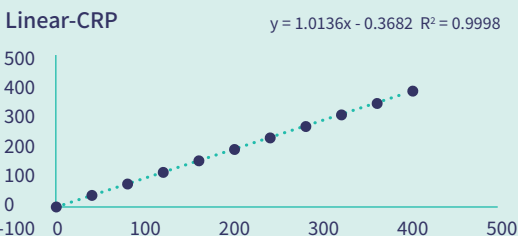
Add R2, mix, incubate, and test absorbance at point A1.

STEP 3

Incubate further and test absorbance at point A2.

4. Performance profile

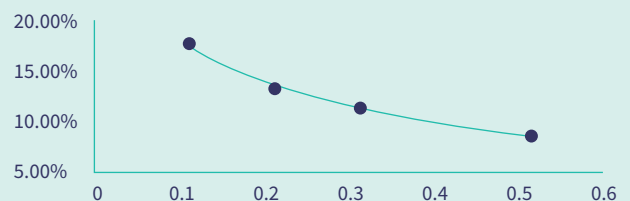
- **Linear range:** 0.1-400 mg/L (linear range varies depending on different sample volumes, ranging from 0.1-320/400/500)



- **Precision:** For samples around 0.5mg/L, CV ≤ 10%.
- **Interference resistance:** RF ≤ 500 IU/mL, Hemoglobin ≤ 5 g/L, Chyle ≤ 185 mg/L, Free bilirubin ≤ 185 mg/L, Conjugated bilirubin ≤ 210 mg/L. Under the aforementioned interference concentrations, the deviation of the result is <10%.

- **Detection limit:** The CV for this reagent is shown in the figure below for values below 0.5mg/L.

Functional sensitivity - CRP



- **Value tracing:** Calibration is performed using ERM-DA474.
- **Accuracy:** Use ERM-DA474 for accuracy control or compare with mature products already on the market for methodological comparison.

Technical parameters can be adjusted and customized services can be provided according to customer requirements

1. Overview

Test scheme

- RBP has a short physiological half-life and high biological specificity. Many clinical diseases can affect the microcirculation of RBP. Therefore, RBP is often used as an indicator for evaluating clinical nutritional status and diagnosing early malnutrition. It is also used for screening organic diseases, such as liver and biliary system diseases, and hyperparathyroidism, which can cause a decrease in RBP in the blood. Conversely, it increases in chronic kidney diseases.
- Normal reference range: Male: 27-60 mg/L; Female: 19-46 mg/L.
- It is used for evaluating disease activity and monitoring therapeutic efficacy

2. Reagent composition

The reagent is divided into three components

- Reagent 1 (R1) Description: Reaction buffer, characterized by a colorless or pale yellow transparent liquid.
- Reagent 2 (R2) Description: Latex solution for antibody coating, characterized by a milky white liquid.
- Calibrator Description: Calibrator with different concentrations, characterized by a liquid form.

Methodology: Transmittance/scattering customizable.

Reagent ratio: The ratio of R1 to R2 can be customized between 1:1 and 4:1; the sample detection volume generally ranges from 1.5-8μL.

Calibrator: The values of calibrators can be customized according to requirements.

3. Test scheme

Sample requirements

- Fresh serum.
- Avoid hemolyzed or lipemic samples when testing serum.

Protocol

- Sample volume:** 1.5-8μL, customizable according to different manufacturer parameters.
- Calibration method:** Spline or other multipoint nonlinear calibration.
- Endpoint reading method:** Two-point endpoint method.
- R1:R2 ratio:** 1:1 to 4:1, customizable according to different manufacturer parameters.
- Reaction direction:** Upward.
- Testing procedure:** As shown in the figure below.

STEP 1

Mix R1 with the sample, incubate for 180-300 seconds.

STEP 2

Add R2, mix, incubate for 20 seconds, and test absorbance at point A1.

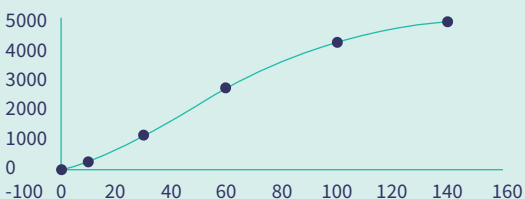
STEP 3

Incubate for 270-300 seconds and test absorbance at point A2.

4. Performance profile

Calibration Curve

Calibration curve - RBP

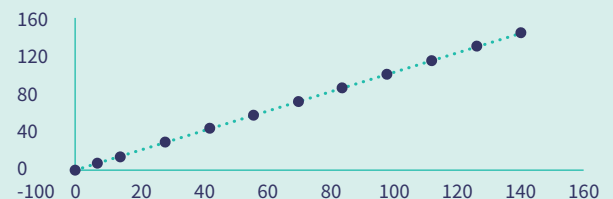


- Precision:** For samples around 2mg/L, CV ≤ 10%
- Interference Resistance:** RF ≤ 500IU/mL, Hemoglobin ≤ 5g/L, Chyle ≤ 185mg/L, Free Bilirubin ≤ 185mg/L, Conjugated Bilirubin ≤ 210mg/L. Under the aforementioned interference concentrations, the deviation of the result is <10%.

Linear Range: 2-140mg/L

Linear - RBP

$$y = 1.0243x - 0.2474 \quad R^2 = 0.9993$$



- Value tracing:** Calibration is performed using KQST-008.
- Accuracy:** Use KQST-008 for accuracy control or compare with mature products already on the market for methodological comparison.

Technical parameters can be adjusted and customized services can be provided according to customer requirements

1. Overview

Clinical significance

- dimer is a good indicator for diagnosing the activity of fibrinolysis. It has important diagnostic value for thrombotic diseases such as disseminated intravascular coagulation (DIC), deep vein thrombosis, cerebrovascular diseases, pulmonary embolism, liver diseases, malignant tumors, postoperative conditions, acute myocardial infarction, and other diseases.

2. Reagent composition

Reagents consisting of three components

- Reagent 1 (R1) Description: Reaction buffer, characterized by a colorless or pale yellow transparent liquid.
- Reagent 2 (R2) Description: Latex solution for antibody coating, characterized by a milky white liquid.
- Calibrator Description: Calibrator with different concentrations, characterized by a liquid form.

Methodology: Transmittance/scattering customizable.

Reagent ratio: The ratio of R1 to R2 can be customized between 1:1 and 5:1; the sample detection volume generally ranges from 3-6 μ L.

Calibrator: The values of calibrators can be customized according to requirements.

3. Test scheme

Sample requirements

- Fresh plasma or whole blood.

Protocol

- Sample volume:** 3-6 μ L, customizable according to different manufacturer parameters.
- Calibration method:** Spline or other multipoint nonlinear calibration.
- Endpoint reading method:** Two-point endpoint method.
- R1:R2:** 1:1 to 5:1, customizable according to different manufacturer parameters.
- Reaction direction:** Upward.
- Testing procedure:** As shown in the figure below.

STEP 1

Mix R1 with the sample, incubate.

STEP 2

Add R2, mix, incubate, and test absorbance at point A1.

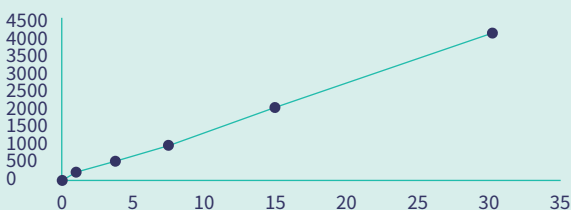
STEP 3

Incubate further and test absorbance at point A2.

4. Performance profile

Standard Curve

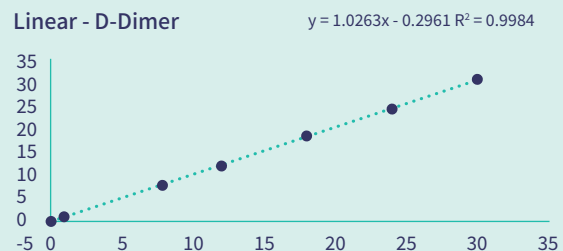
Calibration Curve - D-Dimer



- Precision:** For samples around 0.5mg/L, CV < 8%
- Interference Resistance:** RF \leq 500IU/mL, Hemoglobin \leq 5g/L, Chyle \leq 185mg/L, Free Bilirubin \leq 185mg/L, Conjugated Bilirubin \leq 210mg/L. Under the aforementioned interference concentrations, the deviation of the result is <10%.

- Linear Range:** Upper limit (linear upper limit can reach 20-50mg/L depending on different sample volumes), Lower limit (linear lower limit is approximately 0.1-0.5mg/L).

Linear - D-Dimer



- Value tracing:** Calibration is performed using GBW(E)090732.
- Accuracy:** Use GBW(E)090732 for accuracy control.

Technical parameters can be adjusted and customized services can be provided according to customer requirements

1. Overview

Clinical significance

- SAA is widely used in the auxiliary diagnosis of infectious diseases, risk prediction of coronary heart disease, efficacy and prognosis monitoring of tumor patients, observation of transplant rejection reactions, and improvement observation of rheumatoid arthritis.
- Used for early diagnosis of bacterial infections: Compared to CRP, SAA has the advantages of early rise, large increase, and high sensitivity in the early stage of infection. Moreover, it decreases faster and to a greater extent during recovery. In the early stage of infection, under weak inflammatory stimuli, SAA is more sensitive than CRP, thus providing better discrimination.
- Used for early diagnosis of viral infections: SAA rapidly increases in both bacterial and viral infections, while CRP increases only in bacterial infections. Therefore, combined detection of SAA and CRP can be used to differentiate between bacterial and viral infections. Combined detection of SAA with CRP and PCT is beneficial for the early diagnosis of infectious diseases in children (such as neonatal sepsis, septicemia, etc.).

2. Reagent composition

Reagents consisting of three components

- Reagent 1 (R1) Description: Reaction buffer, characterized by a colorless or pale yellow transparent liquid.
- Reagent 2 (R2) Description: Latex solution for antibody coating, characterized by a milky white liquid.
- Calibrator Description: Calibrator with different concentrations, characterized by a liquid form.

3. Test scheme

Sample requirements

- Fresh serum or whole blood.
- Avoid hemolyzed or lipemic samples when testing serum.

Protocol

- Sample volume:** 1-15 μ L, customizable according to different manufacturer parameters.
- Calibration method:** Spline or other multipoint nonlinear calibration.
- Endpoint reading method:** Two-point endpoint method.
- R1:R2 ratio:** 1:1 to 5:1, customizable according to different manufacturer parameters.
- Reaction direction:** Upward.
- Testing procedure:** As shown in the figure below.

STEP 1

Mix R1 with the sample, incubate.

STEP 2

Add R2, mix, incubate, and test absorbance at point A1.

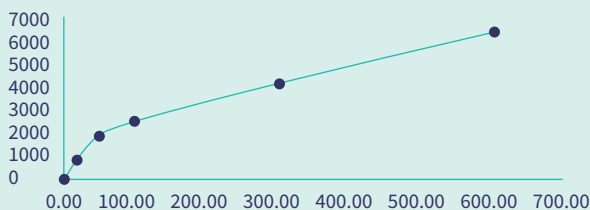
STEP 3

Incubate further and test absorbance at point A2.

4. Performance profile

Standard Curve

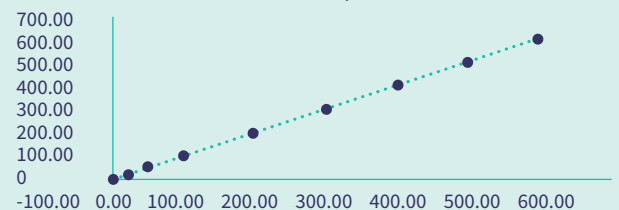
Calibration Curve-SAA



- Precision:** For samples around 5mg/L, CV < 8%
- Interference Resistance:** RF \leq 500IU/mL, Hemoglobin \leq 5g/L, Chyle \leq 185mg/L, Free Bilirubin \leq 185mg/L, Conjugated Bilirubin \leq 210mg/L. Under the aforementioned interference concentrations, the deviation of the result is <10%.

- Linear Range:** Upper limit (depending on different sample volumes, linear upper limit can reach 300-1000mg/L), Lower limit (linear lower limit is approximately 1-3mg/L).

Linear -SAA



- Value tracing:** Calibration is performed by comparing with Siemens products or traced back to NIBSC 92/680.
- Accuracy:** Methodological comparison with Siemens reagents, correlation coefficient $r > 0.975$.

Technical parameters can be adjusted and customized services can be provided according to customer requirements

1. Overview

Clinical Significance:

- Glycated hemoglobin (GHb) is a product of the combination of hemoglobin in red blood cells with sugars in the serum. It is formed through slow, continuous, and irreversible glycation reactions. Its concentration depends on the blood glucose concentration and the duration of contact between glucose and hemoglobin, and is not affected by factors such as the time of blood collection, whether the patient is fasting, or insulin use. Therefore, GHb can effectively reflect the average blood glucose level of diabetic patients over the past 8-12 weeks.
- GHb consists of HbA1a, HbA1b, and HbA1c, among which HbA1c accounts for about 70% and has a stable structure. Therefore, it is used as a monitoring indicator for diabetes control. HbA1c is the gold standard for glycemic control in diabetes. International authorities have clear control targets for HbA1c. The ADA (American Diabetes Association) recommends controlling HbA1c to less than 7%, and the IDF (International Diabetes Federation) recommends controlling HbA1c to less than 6.5%. Currently, the standard for controlling HbA1c in diabetic patients in China is below 6.5%.

2. Reagent composition

Reagents consisting of three components

- Reagent 1 (R1) Description: Reaction buffer, characterized by a colorless or pale yellow transparent liquid.
- Reagent 2 (R2) Description: Latex solution for antibody coating, characterized by a milky white liquid.
- Calibrator Description: Calibrator with different concentrations, characterized by a liquid form.

Calibrator: The values of the calibrator can be customized according to requirements.

3. principle

This kit employs a latex-enhanced immunoturbidimetric assay. By utilizing the immunological principle of specific binding between antigens and antibodies, it directly measures the percentage content of HbA1c in total Hb in the sample. Total Hb and HbA1c in the sample are immobilized by nonspecific adsorption onto latex, forming a solid phase. Upon addition of the HbA1c antibody, complexes of latex-HbA1c-HbA1c antibodies are formed, leading to aggregation. The degree of aggregation varies depending on the amount of HbA1c immobilized on the latex surface, and exhibits linear correlation within a certain range.

4. Test scheme

Sample Requirements

- Sample Collection: This method uses whole blood for testing. Samples should be collected in EDTA/heparin/citrate anticoagulant tubes. Patient samples should be tested within 4 hours and remain stable at 2-8°C for 48 hours.
- Sample Handling: After gently shaking to mix the whole blood sample, dilute it 50 times.

Protocol

- Sample Volume: 5-15μL, customizable according to different manufacturer parameters.
- Calibration Method: Spline or other multipoint nonlinear calibration.
- Endpoint Reading Method: Two-point endpoint method.
- R1:R2 Ratio: 1:1 to 5:1, customizable according to different manufacturer parameters.
- Reaction Direction: Upward.

STEP 1

Mix R1 with the sample, react for 20-300 seconds.

STEP 2

Add R2, mix, react for 100-300 seconds, and test absorbance at point A1.

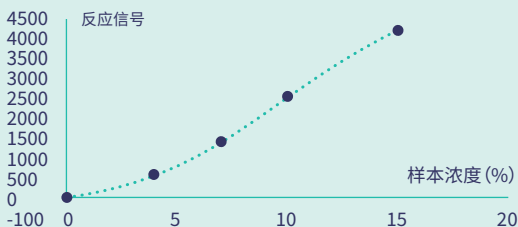
STEP 3

React for 20-300 seconds, and test absorbance at point A2.

5. Performance profile

Standard Curve

Calibration Curve - HbA1c



- Linear Range: 2%-15%
- Precision: Repeatability, CV < 3%
- Accuracy: Methodological comparison with Tosho-G8 HPLC; at 4%-15%, $r \geq 0.990$
- On-machine Stability: >30days

Technical parameters can be adjusted and customized services can be provided according to customer requirements

1. Overview

Clinical Significance

- Bile acids are important components of bile and play a crucial role in fat metabolism. They are the final products of cholesterol metabolism in liver tissue. When liver cells are damaged, they cannot effectively uptake bile acids that are reabsorbed from the intestines, resulting in an increase in blood bile acid concentration. In cases of bile stasis, liver cell secretion of bile is impaired, leading to poor bile acid excretion, which also results in elevated blood bile acid levels. Measurement of serum total bile acids is primarily used for the diagnosis of liver diseases and is one of the most sensitive liver function tests.

2. Reagent composition

Reagents consisting of three components

- Reagent 1 (R1) Description: Thio-NAD (thio-Nicotinamide adenine dinucleotide) Characteristics by Milky white suspension.
- Reagent 2 (R2) Description: NADH (Nicotinamide adenine dinucleotide) 6.0g/L 3 α -hydroxysteroid dehydrogenase (3 α -HSD) Characteristics by Colorless or pale yellow liquid.
- Calibrator Description: Lane multi-calibration / BIOEAST provides calibration sodium cholate Characteristics by Colorless transparent liquid.

Calibrator: Calibrators can be provided, or third-party calibrators can be used for calibration.

BIOEAST can provide bulk reagents, calibrators, and quality control materials, as well as TBA stabilizers

3. Test scheme

- Sample Volume: 3 μ L
- Calibration Method: Spline or other multipoint nonlinear calibration
- R1:R2 Ratio: Two-point endpoint method
- Reaction Direction: 3:1
- Reaction Direction: Upward
- Testing Procedure: As shown in the figure below

STEP 1

Mix R1 with the sample, incubate.

STEP 2

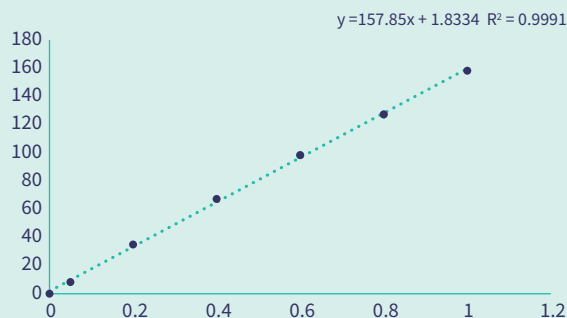
Add R2, mix, incubate, and test absorbance at point A1.

STEP 3

Incubate further and test absorbance at point A2.

5. Performance profile

Dilution Linearity



- On-machine Stability: 30 days
- Accelerated Stability: 37°C for 14 days, deviation < 10%
- Quality Control Testing: Compared with Lane, relative deviation < 10%

Technical parameters can be adjusted and customized services can be provided according to customer requirements

1. Overview

Clinical Significance

- Homocysteine (HCY) is closely associated with cardiovascular diseases and is an important risk factor for the onset of cardiovascular diseases. Elevated levels of HCY stimulate vascular walls, causing arterial damage, inflammation, and plaque formation on the vessel walls, ultimately leading to obstruction of blood flow to the heart.
- High levels of HCY can also lead to birth defects such as neural tube defects and congenital malformations.

2. Reagent composition

Reagents consisting of three components

- Reagent 1 (R1) Description: Enzyme reaction buffer solution Characteristics: Colorless transparent liquid
- Reagent 2 (R2) Description: Enzyme reaction buffer solution Characteristics: Light yellow transparent liquid
- Calibrator Description: Calibrator with different concentrations Characteristics: Liquid

3. Test scheme

Sample Requirements

- Fresh serum samples should be used. Serum samples should be tested within 24 hours after centrifugation, and repeated freeze-thaw cycles should be avoided.
- Avoid hemolyzed or lipemic samples when testing serum.

On-machine Plan

- **Sample Volume:** 1.5-3 μ L, customizable according to different manufacturer parameters
- **Calibration Method:** Linear calibration
- **Reading Method:** Rate method
- **R1:R2 Ratio:** 1:1 to 4:1, customizable according to different manufacturer parameters
- **Reaction Direction:** Downward reaction
- **Testing Procedure:** As shown in the figure below

STEP 1

Mix R1 with the sample, incubate for 180-300 seconds.

STEP 2

mix, incubate for 90 seconds, and test absorbance at point A1.

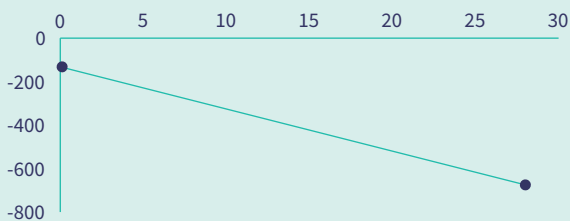
STEP 3

Incubate for 270-300 seconds and test absorbance at point A2.

4. Performance profile

Standard Curve

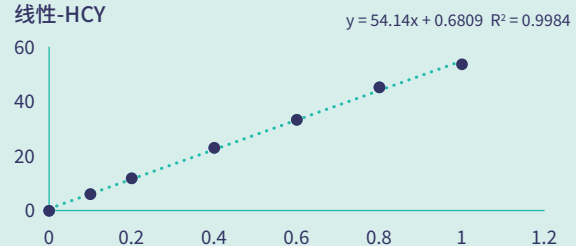
校准曲线-HCY



- **Precision:** For samples around 2 μ mol/L, the coefficient of variation (CV) is \leq 10%.
- **Accuracy:** Accuracy control comparison is conducted using GBW(E)091012.

- **Linearity:** The entire reaction shows linearity within the range of 0-50 μ mol/L, with an r-value greater than 0.990.

线性-HCY



- **Interference:** At interference concentrations such as RF \leq 500 IU/mL, hemoglobin \leq 5 g/L, chyle \leq 185 mg/L, free bilirubin \leq 185 mg/L, and conjugated bilirubin \leq 210 mg/L, the deviation of result values is $<$ 10%.
- **Traceability:** Calibration is performed using GBW(E)091012 for value assignment.

CARBOXYL LATEX MICROSPHERES

Product Series	Product Name Cat No.	Surface Group Size	Concentration	Application Platform
Lipids Series				
P0080CA	Carboxyl Group(COOH)	80nm	10%	PETIA
P0100C	Carboxyl Group(COOH)	100nm	10%	PETIA
P0120C	Carboxyl Group(COOH)	120nm	10%	PETIA
P0140C	Carboxyl Group(COOH)	140nm	10%	PETIA
P0160C	Carboxyl Group(COOH)	160nm	10%	PETIA
P0180C	Carboxyl Group(COOH)	180nm	10%	PETIA
P0200C	Carboxyl Group(COOH)	200nm	10%	PETIA
P0250C	Carboxyl Group(COOH)	250nm	10%	PETIA
P0300C	Carboxyl Group(COOH)	300nm	10%	PETIA
P0350C	Carboxyl Group(COOH)	350nm	10%	PETIA

BULK REAGENTS

Latex-enhanced immunoturbidimetric assay

Product Name	Cat.No	Sample Type	Sensitivity/Range	Recommended Wavelength
Coagulation Series				
D-dimer	D-D601	Plasma	0.1-12FEU/mL 0.2-20mg/L	578nm or customisable 570nm or customisable
FDP	FDP601	Serum	2-100mg/L	570nm or customisable
Glucose Metabolism Series				
HbA1c	HbA1c601	Whole blood	3.8%-14%	660nm or customisable
Inflammation Series				
CRP	CRP601	Whole blood	0.1-500mg/L	570nm or customisable
SAA	SAA601	Serum/Plasma/Whole blood	2-1000mg/L	570nm or customisable
Kidney Function Series				
Cys-C	Cys-C601	Serum/Plasma	0.2-8mg/L	570nm or customisable
β2-MG	B2-MG601	Serum	0.4-18mg/L	570nm or customisable
RBP	RBP601	Serum	2-140mg/L	570nm or customisable

Clinic Biochemistry assay

Product Name	Cat.No	R1/R2	Sample Type	Recommended Wavelength (nm)
Cardiovascular Series				
CK	CK601	4/1	Serum	340
LDH	LDH601	4/1	Serum	340
α-HBDH	A-HBDH601	4/1	Serum	340
HCY	HCY601	Customisable		340 / 405
Glucose Metabolism Series				
GLU	GLU601	4/1	Serum	500
Kidney Function Series				
BUN	BUN601	4/1	Serum	340
UA	UA601	4/1	Serum	546
CO2	CO2601	Customisable	Serum	405 / 660
Lung Function Series				
ACE	ACE601	Customisable	Serum	340

Clinic Biochemistry assay

Product Name	Cat.No	R1/R2	Sample Type	Recommended Wavelength (nm)
Liver Function Series				
ALT	ALT601	4/1	Serum	340
ALB	ALB601	/	Serum	630
IMA	IMA601	Customisable	Serum	600 / 800
AST	AST601	4/1	Serum	340
mAST	mAST601	Customisable	Serum	340 / 405
ALP	ALP601	4/1	Serum	405
TB	TB611	4/1	Serum	450
DB	DB611	4/1	Serum	450
TB	TB601	Customisable	Serum	450
DB	DB601	Customisable	Serum	450
TBA	TBA611	3/1	Serum	405
TBA	TBA601	Customisable	Serum	405 / 660
5'-NT	5-NT601	Customisable	Serum	546
GGT	GGT601	Customisable	Serum	405
TP	TP601	/	Serum	546
AMM	AMM601	Customisable	Serum	340 / 405
MAO	MAO601	Customisable	Serum	340 / 405
Lipids Series				
CHOL	CHOL601	4/1	Serum	500
NEFA	NEFA601	Customisable	Serum	505 / 700
TG	TG611	4/1	Serum	546
TG	TG601	Customisable	Serum	600 / 700
HDL-C	HDL-C601	3/1	Serum	546
LDL-C	LDL-C601	3/1	Serum	546
Others				
K	K601	Customisable	Serum	340 / 405
SA	SA601	Customisable	Serum	340 / 405

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