FLUORESCENCE IMMUNOASSAY SOLUTIONS

Uncut sheets, OEM Test kits, Proteins

SHENZHEN AIVD BIOTECH

Company Profile

Shenzhen AIVD Biotechnology, ISO 13485 and ISO 9001 certified, is a national high-tech enterprise specialized in supplying complete solution for IVD industry globally, our core team members have rich experience in products R&D, production and registration.

AIVD Biotech, offers professional, high-quality service for our clients by providing complete solutions from raw materials to finished products, products and services applicable to diverse application scenarios and platforms!

Ever since the foundation, AIVD has successfully delivered a number of first-of-its-kind diagnostic reagent products in China, solved numerous product process and production problems for our clients, furthermore, AIVD has partially realized the localization substitution of imported raw materials.

AIVD has working area of 5000 square meters, of which 3000 square meters of R&D and 2000 square meters of production. More than 100 employees of which 70% are R&D members composed of doctors, masters and bachelors. AIVD has 2 technology centers: diagnostic raw material technical center and diagnostic reagents technical center. The raw material technology center includes the R&D and production of recombinant antigens, antibodies (including nanoantibodies), enzyme and molecular diagnostics. The diagnostic reagent technology center includes ELISA, Colloidal gold and Fluorescence based Lateral Flow, Chemiluminescence, Immunoturbidimetric and molecular diagnostic platform.

For various R&D and production pain points faced by IVD industry, such as high cost of raw materials, long production development cycle, low product clinical data coincidence, unstable production, etc, AIVD provides complete technical solutions including custom development, mass production and OEM service from raw materials to finished products, optimization from products to manufacturing technique, etc.

Service Features

- OEM service for diverse parameters and performance requirements.

- Raw materials and semi-finished products: <u>proteins, uncut sheets, OEM test kits</u>

- Custom services for different platform applications and performance requirements.

- Personalized product and collaborative development, strategic cooperation among enterprises, technology sharing model.

Service Contents

- Raw materials development and production

- Optimization of raw material coupling process system

- Optimization of production process

- Guidance for production platform and personnel training

- Production of bulk reagents and uncut sheets

- Development for new products

- Technical transfer
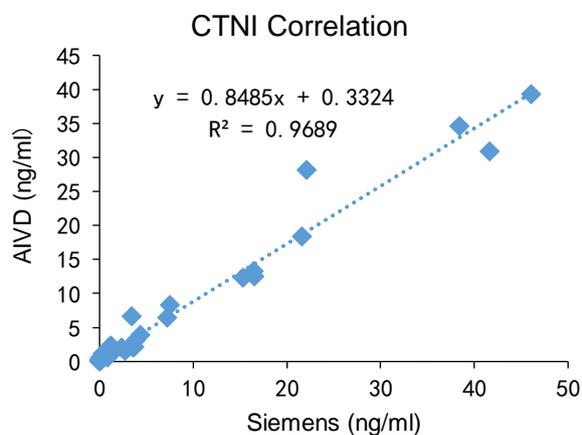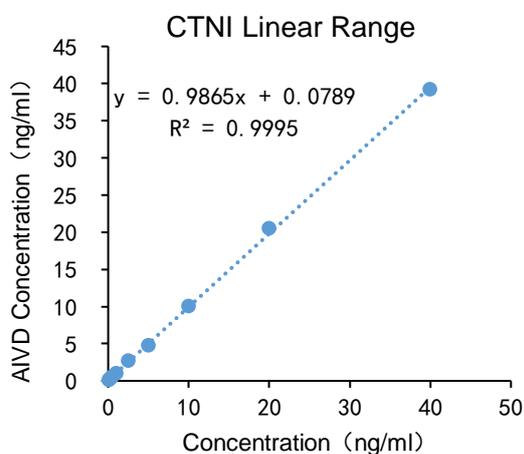
Product List

FIA Parameters

Cardiac markers

Cardiac Troponin-I
cTnI

Cardiac troponin I (cTnI) is specific and sensitive for cardiac tissue and is detected in the serum only if myocardial injury has occurred. cTnI increases 4-8h after chest pain, peaks at 12-24h, and lasts for 14 days. It's considered to be the top marker in diagnosis of the myocardial infarction now. Other causes of raised Cardiac Troponin I include unstable angina, congestive heart failure, perioperative myocardial injury and so on.

Performance Data

Catalog #	Linear Range	Linearity	CorrelationR^2	Detection limit
IFCNI001/ IFCNI100	0.1~40ng/ml	0.9995	0.969	0.0045ng/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

CTNI Linear Range

$y = 0.9865x + 0.0789$
$R^2 = 0.9995$

CTNI Correlation

$y = 0.8485x + 0.3324$
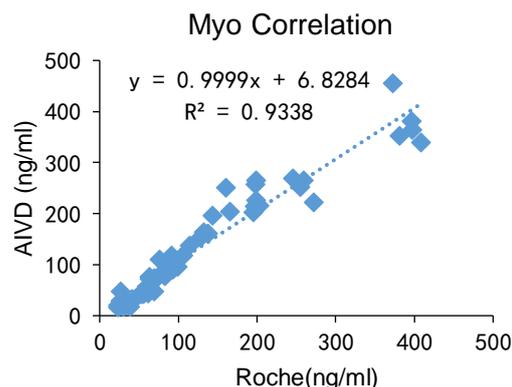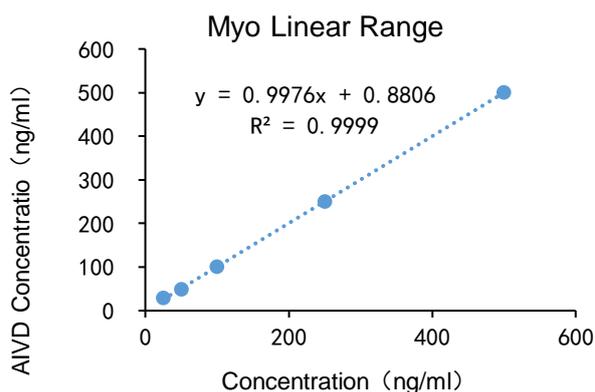$R^2 = 0.9689$

Cardiac markers

Myoglobin
Myo

Myoglobin (Myo) is the most sensitive marker in the early AMI diagnosis. Myo normal range for men is 2-80ng/ml, for women is 10-70ng/ml. It increases 2~4h after chest pain, peaks at 5~12h, back to normal at 18~30h. It will also increase when diseases like skeletal muscle damage and trauma, renal failure occur. A positive Myo can't make a definite diagnosis of myocardial infarction, while a negative Myo basically excludes the AMI.

Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFMYO001/IFMYO100	25-500ng/ml	0.9999	0.9338	15ng/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type</u>: whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

Myo Linear Range

$y = 0.9976x + 0.8806$
$R^2 = 0.9999$

AIVD Concentratio (ng/ml) vs Concentration (ng/ml)

Myo Correlation

$y = 0.9999x + 6.8284$
$R^2 = 0.9338$

AIVD (ng/ml) vs Roche(ng/ml)
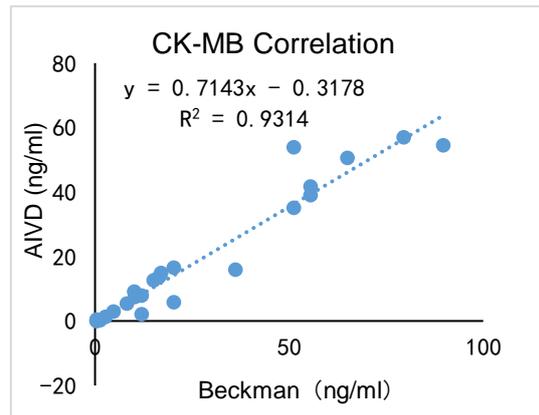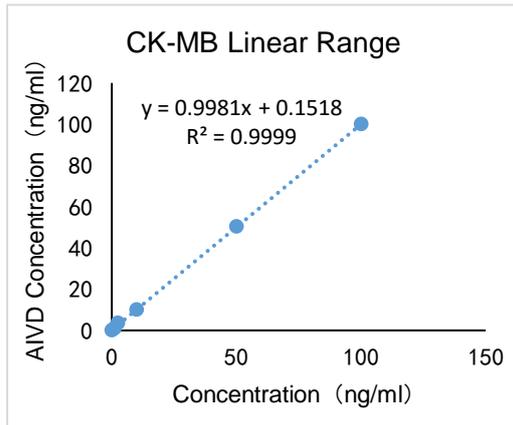
Cardiac markers

Creatine Kinase MB
CK-MB

Human body makes 3 forms of CK, including CK-BB, CK-MB and CK-BB. CK-MB mainly exists in myocardium, 15-25% of CK in myocardium is CK-MB. Normal cut off point for serum CK-MB is 5ng/ml, it increases more than 2 times 4~6h after myocardial infarction. Other than severe myocarditis and ischemic cardiomyopathy, CK-MB will also increase when myopathy diseases like progressive muscular dystrophy and exercise rhabdomyolysis occur.

Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFCKB001/IFCKB100	1-100ng/ml	0.9999	0.93	0.4ng/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type</u>: whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

CK-MB Linear Range

$y = 0.9981x + 0.1518$
$R^2 = 0.9999$

CK-MB Correlation

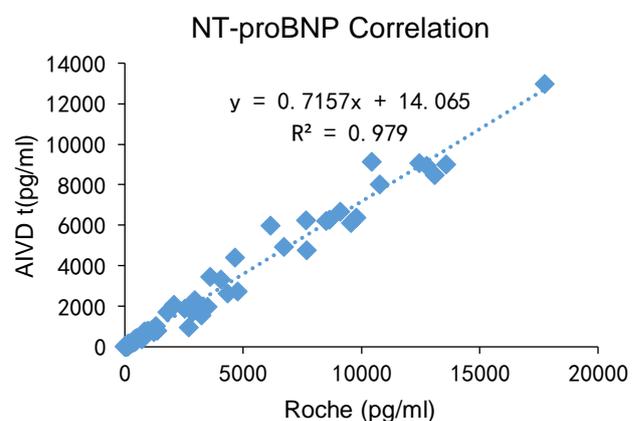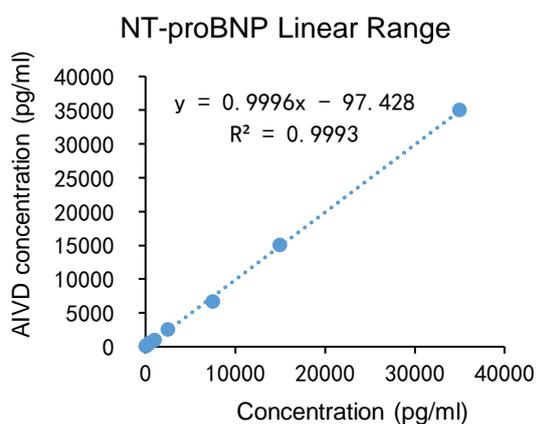$y = 0.7143x - 0.3178$
$R^2 = 0.9314$

N-terminal - pro hormone BNP
NT-pro BNP

N-terminal - pro hormone BNP (NT-pro BNP) is an inactive N-terminal fragment of brain natriuretic peptide (BNP). Compared with BNP, it has a longer half-life and is more stable. Its concentration can reflect the release of newly synthesized rather than stored BNP within a short period of time, so it can better reflect the activation of the BNP pathway. The level of NT-pro BNP in plasma increases in the event of the heart failure. An optimal strategy to identify acute HF is to use age-related cut-points of NT-pro BNP concentration: for adults under the age of 50 the cut-point is 450 pg/ml, the sensitivity and specificity for the diagnosis of acute heart failure are 93% and 95%, respectively; for adults of age > 50 the cut-point is 900 pg/ml, the sensitivity and specificity for the diagnosis of acute heart failure are 91% and 80%.

Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFNTP001/ IFNTP100	25-35000pg/ml	0.9993	0.979	25pg/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

NT-proBNP Linear Range

$y = 0.9996x - 97.428$
$R^2 = 0.9993$

NT-proBNP Correlation

$y = 0.7157x + 14.065$
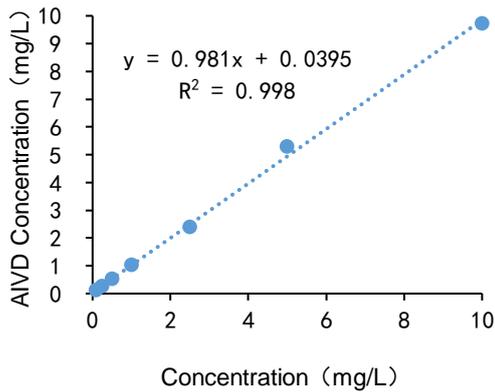$R^2 = 0.979$

Cardiac markers

D Dimer

D-dimer is a specific fibrin degradation product, a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. It is so named because it contains two D fragments of the fibrin protein joined by a cross-link. It has significance in thrombosis diagnosis. The specificity for the diagnosis of thrombosis is 93 to 95%, the normal range for D-dimer is <0.5mg/L. While a negative result practically rules out thrombosis, a positive result can indicate thrombosis, but does not exclude other potential causes. Its main use, therefore, is to exclude thrombosis disease where the probability is low.
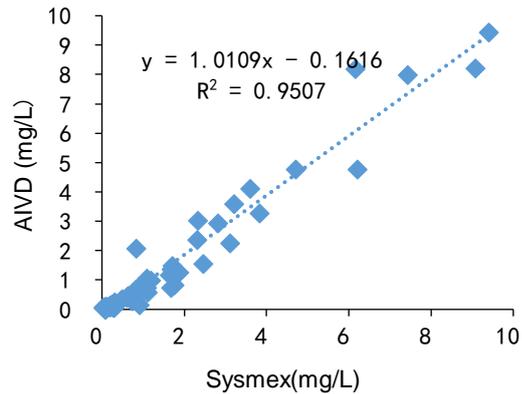
Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFDDT001/IFDDT100	0.1-10mg/L	0.9998	0.95	0.05mg/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type:</u> plasma				
<u>Sample volume:</u> 80 ul				

D-Dimer Linear Range

$y = 0.981x + 0.0395$
$R^2 = 0.998$

AIVD Concentration（mg/L）
Concentration（mg/L）

D-Dimer Correlation

$y = 1.0109x - 0.1616$
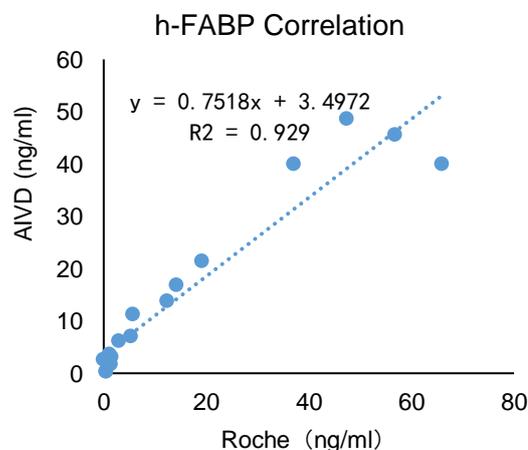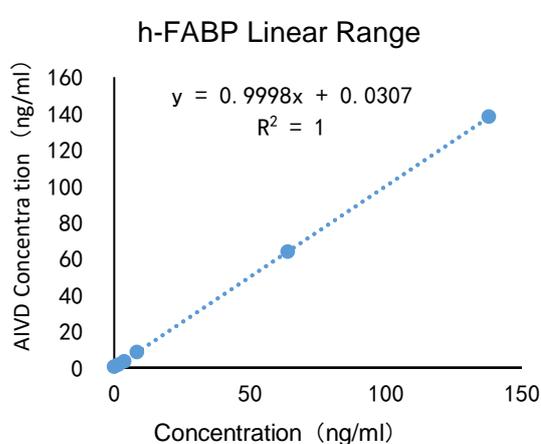$R^2 = 0.9507$

AIVD (mg/L)
Sysmex(mg/L)

Heart-Type Fatty Acid-Binding Proteins
h-FABP

Heart-Type Fatty Acid-Binding Proteins(h-FABP) is a new small cytoplasmic protein released from cardiac myocytes following an ischemic episode. It has high specificity, high sensitivity and high compliance rate towards myocardial infarction so it has been investigated as an early marker of acute myocardial infarction. The normal range for plasma h-FABP is <5μg. When myocardial ischemic injury appears, h-FABP will be detected 1~3h after chest pain, peaks at 6~8h and back to normal at 24~30h. Two continuous samples of h-FABP monitoring can identify almost all patients with persistent AMI in 1 hour and exclude non-AMI patients 100% without false-negative result. Combined detection of h-FABP and troponin can improve the diagnostic sensitivity, and is more valuable for the diagnosis of ACS.

Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFABP001/ IFABP100	2.5-160ng/ml	0.9996	0.93	1ng/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

h-FABP Linear Range

$y = 0.9998x + 0.0307$
$R^2 = 1$

AIVD Concentration (ng/ml) vs Concentration (ng/ml)

h-FABP Correlation

$y = 0.7518x + 3.4972$
$R2 = 0.929$

AIVD (ng/ml) vs Roche (ng/ml)

C-reactive protein
CRP

C-reactive protein (CRP) is a plasma protein generated by the liver, C-reactive protein is so-named because it can react with capsular polysaccharide in streptococcus pneumoniae, it is mainly seemed as the marker of inflammation. Normal range of C-reactive protein in plasma is 800-8000μg/L. It will increase rapidly and multiply in the hours after the onset of various acute inflammation, tissue injury, myocardial infarction, surgical wound, radiation damage and other diseases; and when the diseases improve, it quickly drops to normal, the magnitude of its elevation is positively related to the degree of infection. While C-creative isn't suitable for single disease diagnosis, it's clinical value mainly presents in the screening and monitoring of the tissue damage.

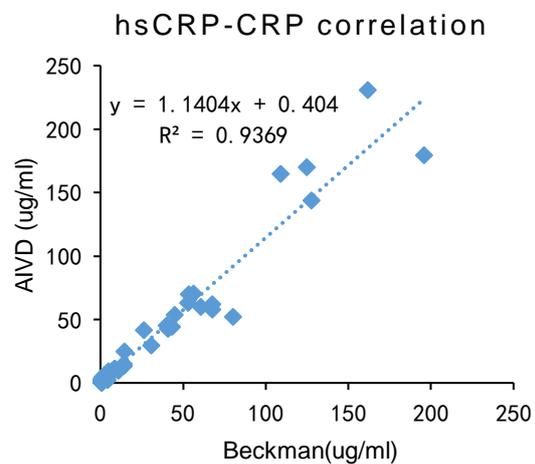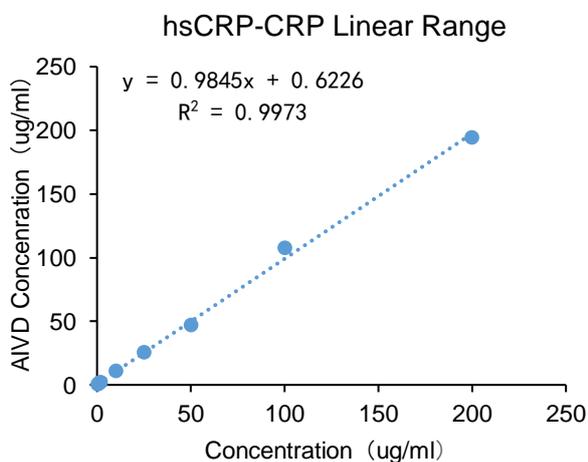1.When CRP's concentration is 0.1-10mg/L, it can be used as the hazard assessment factor of cardiovascular disease：

Detection Result	Clinical Prompts
<1.0mg/L	cardiovascular disease：Low-Risk
1.0-3.0mg/L	cardiovascular disease：Medium-Risk
>3.0mg/L	cardiovascular disease：High-Risk

2.When CRP's concentration is ＞10.0mg/L, it can be used as screening, monitoring, assessment of bacterial infection, various inflammation conditions, tissue necrosis, tissue injury and efficacy judgement ：

Detection Result	Clinical Prompts
10-25mg/L	Possible viral infections, if the course is short, can't exclude the bacterial infection, should detect again after a few hours
25-50mg/L	Exist general bacterial infection, viral infection can be basically ruled out
50-100mg/L	Exist more severe bacterial infections
>100mg/L	Serious infections such as septicemia or invasive infections or major illnesses

Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFCRP001/IFCRP100	0.5-200ug/ml	0.997	0.937	0.3ug/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

hsCRP-CRP Linear Range

$y = 0.9845x + 0.6226$
$R^2 = 0.9973$

hsCRP-CRP correlation
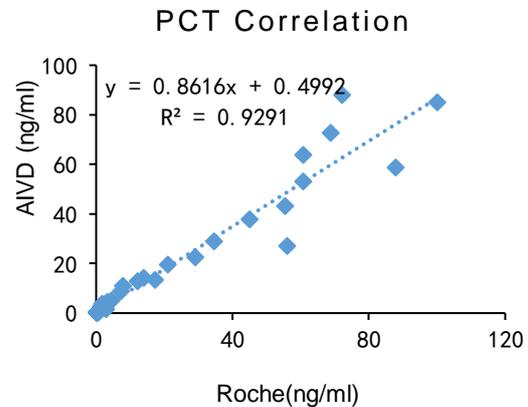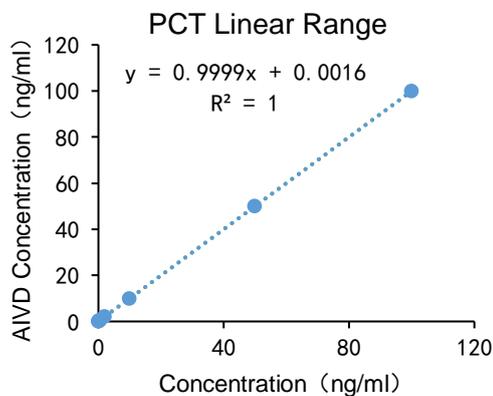
$y = 1.1404x + 0.404$
$R^2 = 0.9369$

Procalcitonin
PCT

Procalcitonin (PCT) is a protein, will increase in plasma when there are severe bacterial infection, fungal infection, parasitic infection, sepsis and MODS, whereas won't increase when autoimmune infection, allergic infection and viral infection appear, so PCT is a specific marker for severe bacterial inflammation and fungal infection. PCT ≥0.5 ug/ml suggests the presence of bacterial infection or sepsis. When infected with the bacteria, PCT will increase 2~4h after a systemic inflammatory response, peak at 24~48h, the half-life is 12~24h after peaking. PCT is very stable in serum, won't be affected by the hormones in the body. The half-life of PCT is very short, so it's more suitable for prognosis and efficacy observation, which can better help doctor to determine whether to use antibiotics.

Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFPCT001/IFPCT100	0.1-100ng/ml	1	0.929	0.075ng/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type:</u> whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

PCT Linear Range

$y = 0.9999x + 0.0016$
$R^2 = 1$

AIVD Concentration（ng/ml）vs Concentration（ng/ml）

PCT Correlation

$y = 0.8616x + 0.4992$
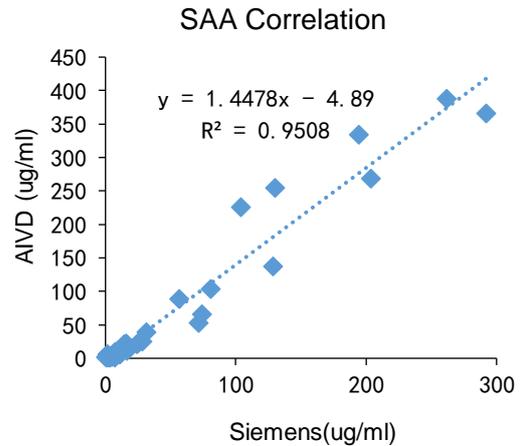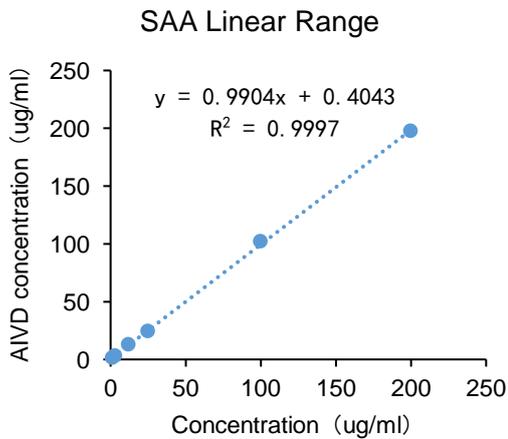$R^2 = 0.9291$

AIVD (ng/ml) vs Roche(ng/ml)

Serum amyloid A
SAA

Serum amyloid A(SAA) is an acute phase protein that binds to plasma high density lipoprotein, normal range is ＜10mg/L; After organism infected, SAA will increase rapidly by about 1000 times in 4~6h, and drop to normal range rapidly after clearing the pathogen, so it is a sensitive marker for body infection condition and inflammation recovery. Comparing with CRP, the most difference is the increase of SAA presents in viral infection, mycoplasma infection, bacterial infection, and the sensitivity of SAA is higher than combo detection of CRP and SAA shows more complementary advantages, offer more foundation for the diagnosis and identification of bacterial infection and viral infection, the ratio of SAA/CRP has more clinical significance which single marker can't reflect.

Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFSAA001/IFSAA100	2-200ug/ml	0.9997	0.95	0.02ug/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

SAA Linear Range

$y = 0.9904x + 0.4043$
$R^2 = 0.9997$

AIVD concentration（ug/ml） vs Concentration（ug/ml）

SAA Correlation

$y = 1.4478x - 4.89$
$R^2 = 0.9508$

AIVD (ug/ml) vs Siemens(ug/ml)
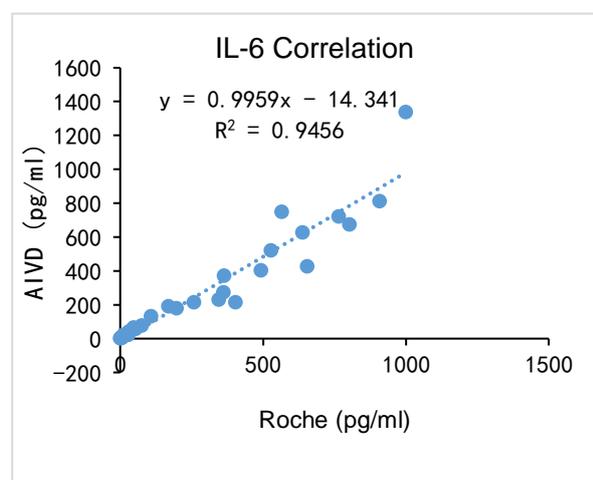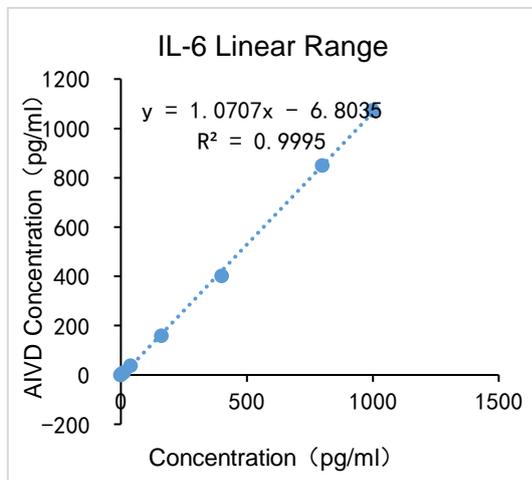
Inflammatory markers

Interleukin 6
IL-6

Interleukin-6(IL-6) is a cell factor generated by and acting on a variety of cells, it can regulate the growth and differentiation of a variety of cells, as well as the immune response, acute phase response and hematopoiesis, it plays an important role in anti-infective immune reaction in organism. IL-6 is involved in many diseases' occurrence and development, IL-6 level in blood is closely related to inflammation, viral infection and autoimmune diseases. The relatively advantage of IL-6 detection presents in the early detection of acute inflammation. In the inflammatory reaction, the rise of IL-6 is earlier than other cell factors, and lasts for a long time, so it can be used to aid in the early diagnosis of acute infection. IL-6 increases rapidly after bacterial infection, peaks in 2 hours, its increase level is consistent with the severity of the infection, so it can also be used to evaluate the infection severity and determine prognosis, undesirable prognosis is indicated when its concentration is >1000 ug/L, the observation of IL-6 trend can also help to know the progression of infectious diseases and the response to the treatment.

Performance Data

Catalog #	Linear range	Linearity	Correlation R2	Detection limit
IFPI6001/IFPI6100	5-1000pg/ml	1	0.945	3pg/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

IL-6 Linear Range

$$y = 1.0707x - 6.8035$$
$$R^2 = 0.9995$$

AIVD Concentration (pg/ml) vs Concentration (pg/ml)

IL-6 Correlation

$$y = 0.9959x - 14.341$$
$$R^2 = 0.9456$$

AIVD (pg/ml) vs Roche (pg/ml)
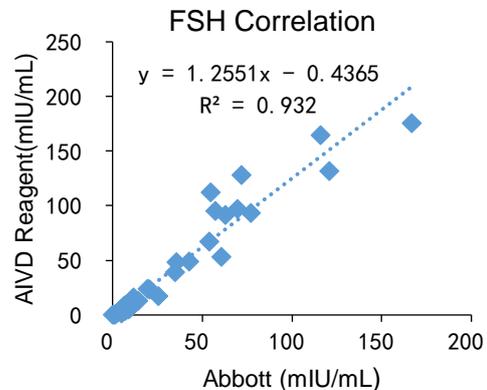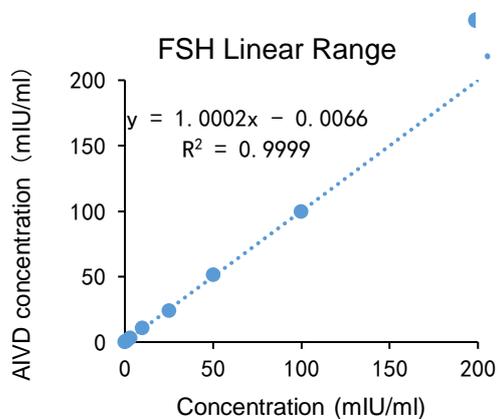
Hormone markers

Follicle-Stimulating Hormone
FSH

Follicle-stimulating hormone (FSH) is a substance secreted by pituitary gland, which determines the growth and maturity of human sperm and ovum, and plays a really important role in reproductive function. For male, FSH helps to promote the maturation of testes seminiferous tubules and the generation of sperm. For female, it helps to promote the growth and maturation of follicular, aid LH to promote mature follicular to secrete estrogen and ovulation, and participate in the formation of normal menstruation. For men, the normal concentration is 0.9～9.8mu/ml, for women, FSH concentration is 1.5-10mg/ml in the preovulatory phase, 8-20mg/ml in the ovulation, and 2-10mg/m in the post-ovulation phase. And no matter for women or men after the age of 50, FSH level will all increase with the decline of sexual gland function. FSH has an important clinical significance for the treatment of infertility. FSH detection can help doctor to know whether the secretory function of pituitary gland in infertile patients is normal, and to indirectly grasp whether the hypothalamus and ovary is abnormal, so to make accurate judgments about the cause of infertility.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFFSH001/IFFSH100	0.5-200mIU/ml	0.9999	0.932	0.3mIU/ml
Available for order: uncut sheets, assembled tests, strip				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

FSH Linear Range

$y = 1.0002x - 0.0066$
$R^2 = 0.9999$

FSH Correlation

$y = 1.2551x - 0.4365$
$R^2 = 0.932$

Luteinizing Hormone
LH

Luteinizing Hormone (LH) is a glycoprotein hormone secreted by the anterior lobe of the pituitary gland, which exits in human blood and urine, it can stimulate the release of mature ovum in ovary. LH is secreted sharply in the mid-menstruation from baseline level 5~20mIU/ml to 25～200mIU/ml at the peak. LH concentration in urine usually increases suddenly and substantially 36~48 hours before ovulation, peaks at round 14~28h, the theca folliculi ruptures 14~28h after the peak, and discharge mature ovum, LH level will back to normal range 2 days after ovulation and enter luteal phase which usually lasts 14 days. For male, LH normal concentration is 1.24～8.63mIU/ml; For female, LH level is 2.12～10.89mIU/ml in follicular phase, 19.18～103.03mIU/ml in ovulation, 1.20～12.86mIU/ml in luteal phase, 10.87～58.64mIU/ml in menopause. LH is used to predict the timing of ovulation, and help female to seize the fertilization timing, or to contracept in safe period. LH increase in blood usually is seen in PCOS, Turner syndrome, primary hypogonadism, premature ovarian failure, post-ovarian resection, and women with menopausal syndrome or menopause.

Performance Data

Catalog #	Linear range	Linearity	CorrelationR^2	Detection limit
IFLH001/ IFLH100	1-200mIU/ml	0.994	0.968	0.5mIU/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type</u>: whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

LH Linear Range

$y = 1.0304x - 0.8924$
$R^2 = 0.994$

LH Correlation

$y = 0.7782x - 0.8152$
$R^2 = 0.9683$
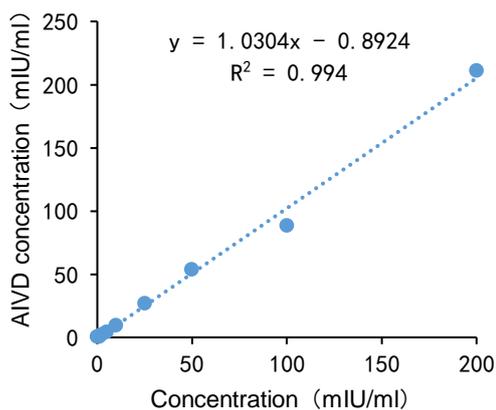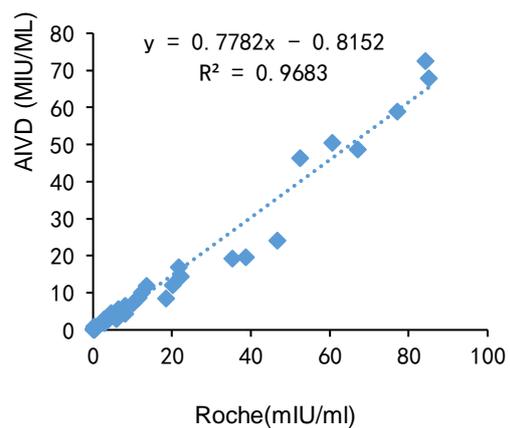
Progesterone
prog
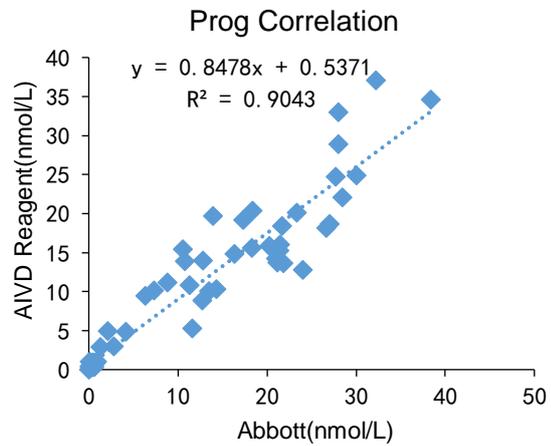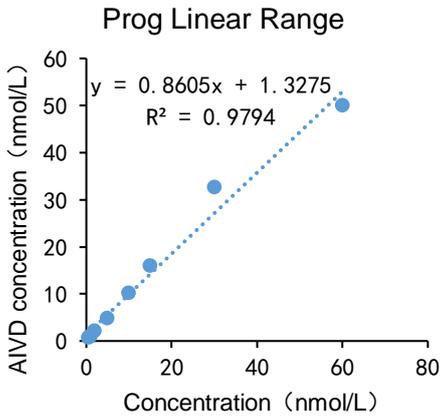
Progesterone(prog) are intermediates synthesized by the steroid hormone, it's secreted mainly by the ovary during non-pregnant, by the placenta during gestation. Prog Concentration is a significant clinical indicator to determine the ovulation insufficiency, Luteal Phase Defect(LPD), in vitro fertilization-embryo transfer(IVF-ET) prognosis and ectopic pregnancy. For male adult, normal concentration is <3.2nmol/L, for female, normal concentration is 0.6～1.0nmol/L in follicular phase, 1.0～11.2nmol/L in ovulation, 20.8～103.0nmol/L after ovulation. The increase of prog level mainly appears in hydatidiform mole, Pregnancy-induced hypertension syndrome (PIH), essential hypertension (EH), Ovarian tumor, multiple fetuses, Congenital Adrenal Hyperplasia (CAH). Decrease of prog level mainly appears in Luteal Phase Defect (LPD), polycystic ovary syndrome (PCOS), intrauterine growth retardation (IUGR), primary and secondary amenorrhea, anovulatory uterus, functional bleeding.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFPRO001/ IFPRO100	0.5-60nmol/L	0.979	0.904	0.3nmol/L
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type</u>: whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

Prog Linear Range

$y = 0.8605x + 1.3275$
$R^2 = 0.9794$

AIVD concentration（nmol/L）
Concentration（nmol/L）

Prog Correlation

$y = 0.8478x + 0.5371$
$R^2 = 0.9043$
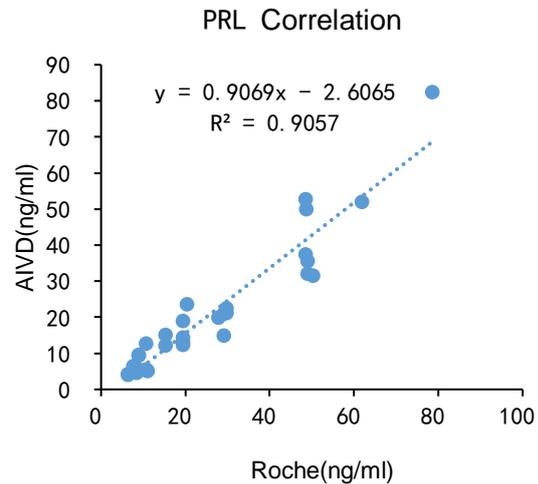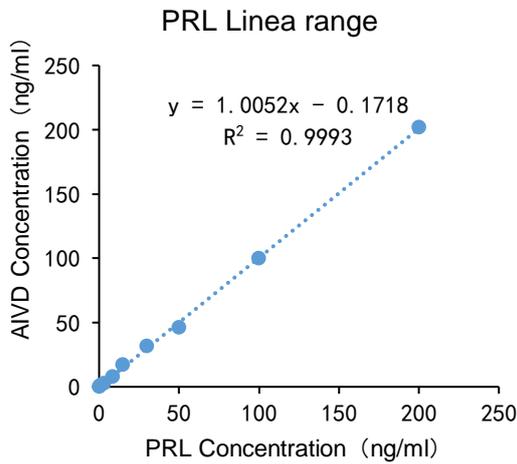
AIVD Reagent(nmol/L)
Abbott(nmol/L)

Hormone markers

Prolactin
PRL

Prolactin (PRL, also known as lactogen or prolactin) is a protein hormone secreted by the eosinophil of the anterior pituitary gland, the main role is to promote the growth of the mammary gland, stimulate and maintain the lactation, and to stimulate the generation of follicular LH receptor. Detection of PRL is a significant indicator of hypothalamus pituitary function, especially for the diagnosis of pituitary prolactinomas, Hyperprolactinemia (HPRL) caused by various factors. Normal PRL concentration in adult plasma is <20μg/L, 5.0～40.0μg/L in luteal phase, <80μg/L in the first trimester of pregnancy, <160μg/L in the second trimester, <400μg/L in the last trimester of pregnancy. Increase of PRL can be seen in pituitary tumor, breast tumor, non-functional tumors, Cushing's syndrome, acromegalia, pituitary stalk tumor; PRL decreases after removal of the pituitary gland because of breast cancer. While PRL increases in serum when the pituitary gland is not completely removed, decease after treatment with L-Dopa.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFPRL001/ IFPRL100	1-200ng/ml	0.999	0.906	0.03ng/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type</u>: whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

PRL Linea range

$y = 1.0052x - 0.1718$
$R^2 = 0.9993$

AIVD Concentration（ng/ml）
PRL Concentration（ng/ml）

PRL Correlation

$y = 0.9069x - 2.6065$
$R^2 = 0.9057$

AIVD(ng/ml)
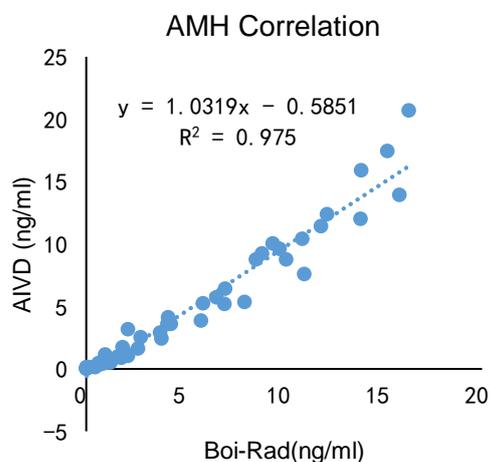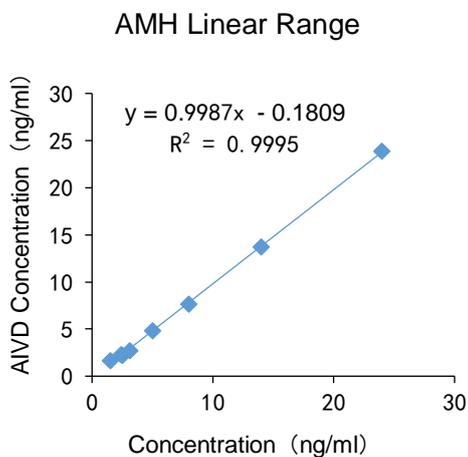Roche(ng/ml)

Hormone markers

anti-Müllerian hormone
AMH

anti-Müllerian hormone(AMH) is a glycoprotein that has many obvious advantages in assessing ovarian reserve, and is the most accurate biomarker of ovarian senescence. In terms of evaluating ovarian reserve function, AMH detection can remedy the shortcomings of traditional hormone detection and rapidly efficiently know the level of ovarian reservation capacity. Normal range of AMH is 2-6.8ng/ml, the higher the AMH value, the more egg stock in the ovary, the lower the value, the worse the ovarian function. In stage of embryonic development, AMH regulates the differentiation and growth of the reproductive ducts, which is essential for gender differentiation; After birth, AMH regulates the function of male testicular stromal cells; In adult female, AMH inhibits the raise of primordial follicle and growth of antral follicle, to prevent premature depletion of follicles.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFAMH001/IFAMH100	0.1-25ng/ml	0.999	0.975	0.1ng/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

AMH Linear Range

$y = 0.9987x - 0.1809$
$R^2 = 0.9995$

AIVD Concentration（ng/ml） vs Concentration（ng/ml）

AMH Correlation

$y = 1.0319x - 0.5851$
$R^2 = 0.975$

AIVD (ng/ml) vs Boi-Rad(ng/ml)
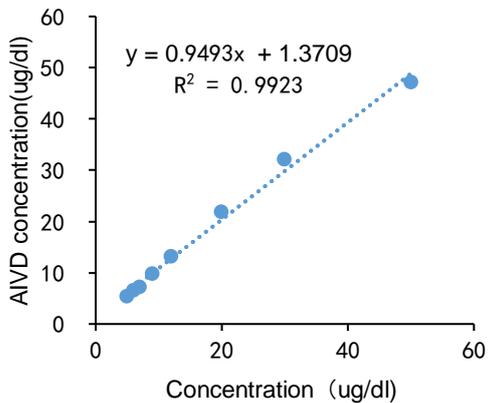
Hormone markers

Corticosterone
COR

Corticosterone (COR) is a kind of hormone generated by adrenal that has moderate but notable activity as a mineralocorticoid and glucocorticoid. Normal range in human body measured by the RIA method is 3.75~66.4 nmol/l COR is used to be the alternative treatment of adrenal cortical hypofunction, but has greater side effects. COR participates in the degradation of proteins, sugars and lipids, maintains blood pressure and regulates the immune system. COR concentration is affected by temperature(cold or hot）, infection, trauma, spirit, exercise, obesity and diabetes. The secretion of COR is cyclical, which increases in the morning, peaks at 8 a.m., and decreases at nightfall.   Insufficient COR would cause nonspecific symptoms including weight loss, muscle weakness, fatigue, hypotension and abdominal pain. Sometimes a decrease in COR may lead to an adrenal crisis which requires immediate medical attention. High COR would cause hypertension, hyperglycemia, obesity, fragile skin, purple streaks on the abdomen, muscle weakness and osteoporosis. Women may experience symptoms like abnormal menstrual cycles and increased body surface hair. Child may experience stunted growth and short stature.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFCOR001/IFCOR100	1-60ug/dL	0.9923	0.970	1ug/dL
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type:</u> whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

COR Linear Range

$y = 0.9493x + 1.3709$
$R^2 = 0.9923$

AIVD concentration(ug/dl) vs Concentration（ug/dl)

COR Correlation

$y = 1.0267x + 0.2055$
$R^2 = 0.970$

AIVD (ug/dl) vs Roche（ug/dl)

Hormone markers
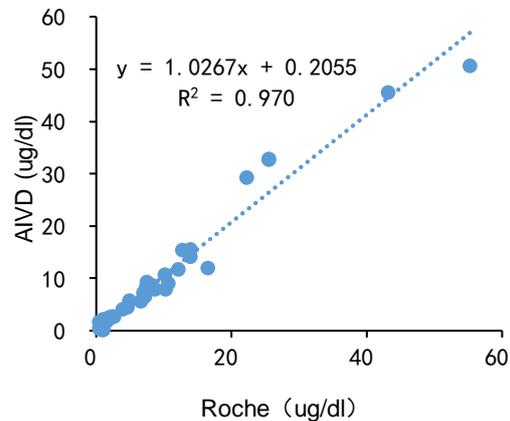
Human Chorionic Gonadotrophin
HCG
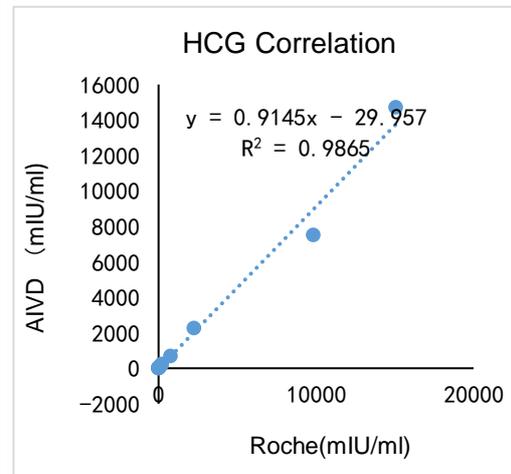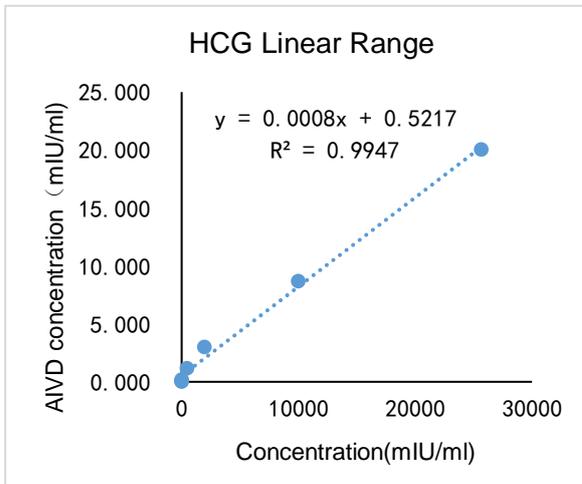
Human chorionic gonadotropin (HCG) is a hormone for the maternal recognition of pregnancy produced by trophoblast cells that are surrounding a growing embryo (syncytiotrophoblast initially), which eventually forms the placenta after implantation. In the first 1-2.5 weeks of pregnancy, HCG in serum and urine will increase rapidly, peak in the 8th week of pregnancy, decrease to medium level in the 4th month and maintain this level until late pregnancy. The normal level of HCG is 5mIU/ml, an hCG level of less than 5 mIU/mL is considered negative for pregnancy, and anything above 25 mIU/mL is considered positive for pregnancy. An HCG level between 6 and 24 mIU/mL is considered a grey area, and you'll likely need to be retested to see if your levels rise to confirm a pregnancy. The check for HCG has significant meaning in the diagnosis of early pregnancy, also has certain meaning in the diagnosis, identify and course observation of diseases like pregnancy-related illness and trophoblastic tumors.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFHCG001/IFHCG100	5-50000mIU/ml	0.99	0.99	5mIU/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

HCG Linear Range

$y = 0.0008x + 0.5217$
$R^2 = 0.9947$

AIVD concentration（mIU/ml）
Concentration(mIU/ml)

HCG Correlation

$y = 0.9145x - 29.957$
$R^2 = 0.9865$

AIVD（mIU/ml）
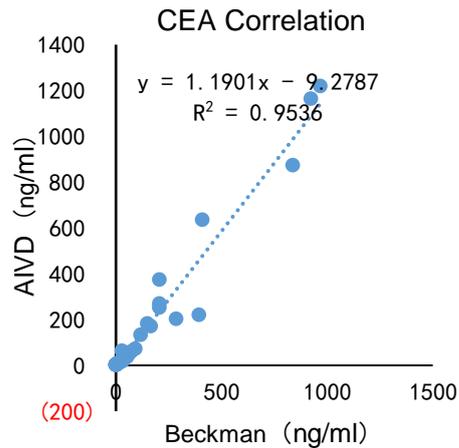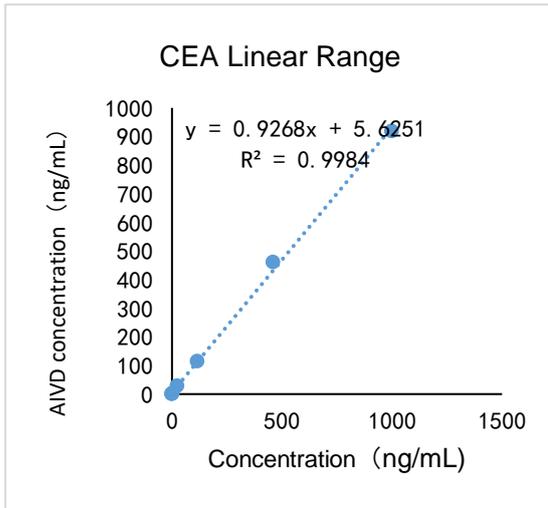Roche(mIU/ml)

Tumor markers

Carcinoembryonic Antigen
CEA

Carcinoembryonic antigen（CEA）is an acidic glycoprotein with the characteristics of human embryonic antigen, it is so called because it was first found in colon cancer and fetal intestinal tissue. CEA was used as a specific marker for the early diagnosis of color cancer and rectum cancer, after numerous clinical trials, it was found that the increasement of CEA not only seemed in gastrointestinal malignant tumors, but also in the serum of breast cancer, lung cancer and other cancer, so CEA is a broad-spectrum tumor marker. Continuous monitoring of CEA level can be used for efficacy observation and prognosis judgement of tumor therapy. Normal level of CEA is <5.0ng/ml, generally the CEA level increases when disease develops, decreases when disease improves.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFCEA001/IFCEA100	1-1000ng/ml	0.9984	0.95	1ng/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type</u>: whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

CEA Linear Range

$y = 0.9268x + 5.6251$
$R^2 = 0.9984$

AIVD concentration （ng/mL）
Concentration （ng/mL）

CEA Correlation

$y = 1.1901x - 9.2787$
$R^2 = 0.9536$
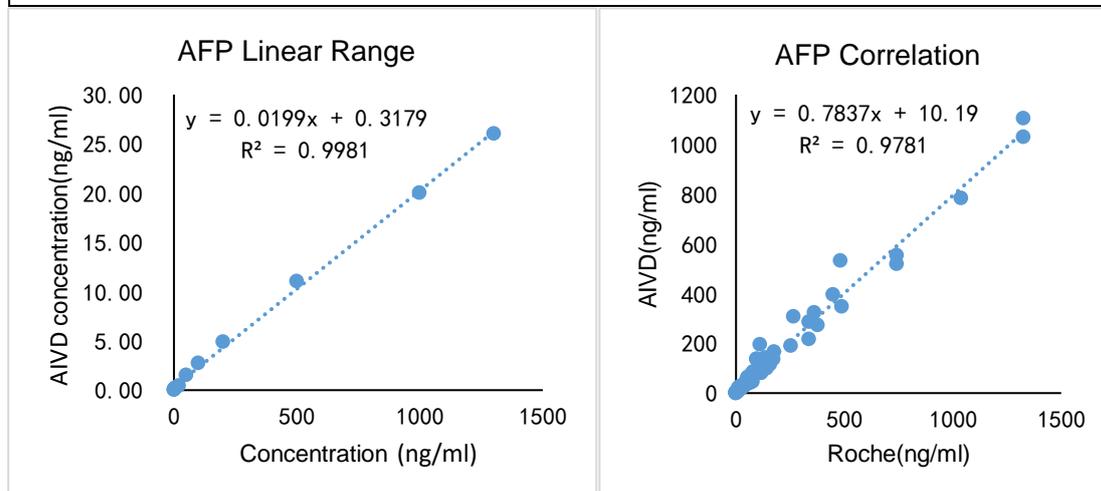
AIVD （ng/ml）
(200)
Beckman （ng/ml）

Tumor markers

Alpha Fetoprotein
AFP

Alpha Fetoprotein (AFP) is a kind of glycoprotein, the concentration of AFP is high in fetal blood circulation, and it declines after birth, it is basically replaced by albumin 2~3 months after birth. AFP is hard to detect in blood, so the concentration of AFP in adult serum is extremely low. AFP is closely related to the occurrence and development of liver cancer and various tumors, the concentration is high in various tumors, so it is used as a positive detection marker of various tumors. At present, AFP is mainly used as a serum marker of primary liver cancer in clinic for the diagnosis and curative effect monitoring of liver cancer. Normal range of AFP is <25ng/mL. The AFP level in adult serum increases in 60%~70% patients with primary liver cancer, also increases in patients with testicular cancer, ovarian tumor, malignant teratoma, pancreatic cancer, gastric cancer, bowel cancer, lung cancer. Generally, the AFP concentration increasement in benign tumor is transient, lasts about 2~3 weeks, while in cancer is continuous, so the dynamic observation of AFP concentration can not only identify the benign tumor and malignant liver diseases, but also diagnose liver cancer early.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFAFP001/IFAFP100	1-1000ng/ml	0.9981	0.9781	1ng/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type:</u> whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

AFP Linear Range

$y = 0.0199x + 0.3179$
$R^2 = 0.9981$

AFP Correlation

$y = 0.7837x + 10.19$
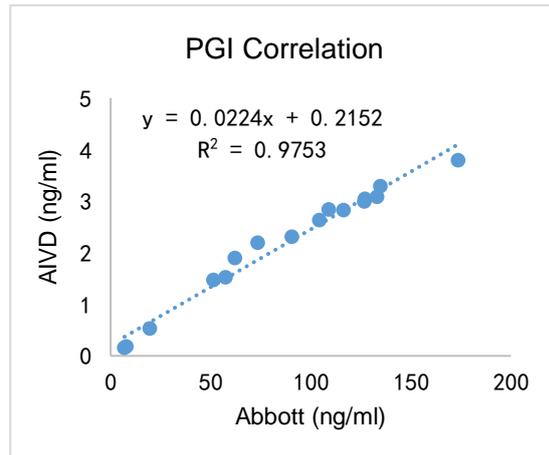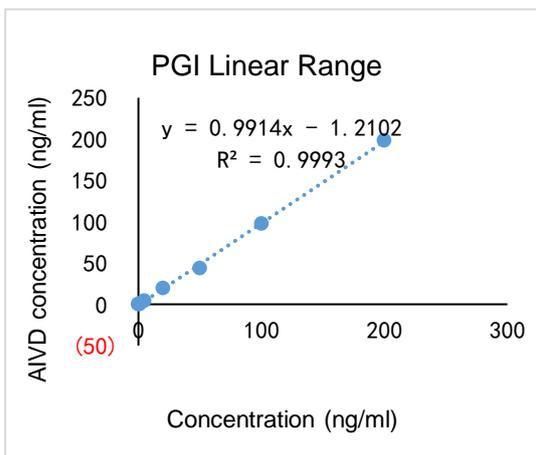$R^2 = 0.9781$

<div style="writing-mode: vertical">**Stomach's Function**</div>

Pepsinogen 1
PGI

Pepsinogen (PG) is precursor of pepsin which involved in digestion and secreted by stomach, usually about 1% of PG can enter the blood circulation through the gastric mucous membrane, and PG can be divided into 2 subtypes-PGI and PGII. PGI is secreted by chief cell of fundic gland. The normal range of PGI is 67~200 ng/ml, it is the indicator to detect oxyntic gland cell function, PGI concentration increases when the secretion of gastric acid increases, reduces when the secretion of gastric acid decreases or gastric mucosal glands atrophy.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFPGI001/IFPGI100	1-200ng/ml	0.9993	0.9753	1ng/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

PGI Linear Range

$y = 0.9914x - 1.2102$
$R^2 = 0.9993$

AIVD concentration (ng/ml) vs Concentration (ng/ml)

PGI Correlation

$y = 0.0224x + 0.2152$
$R^2 = 0.9753$

AIVD (ng/ml) vs Abbott (ng/ml)
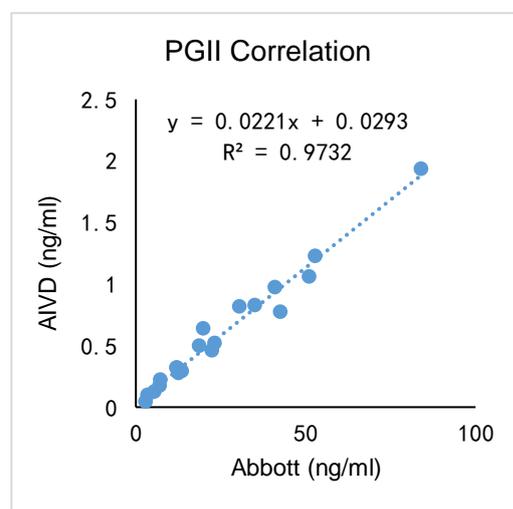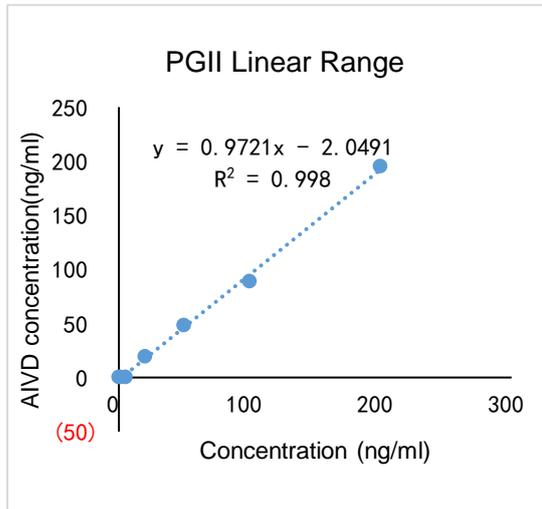
Stomach's Function

Pepsinogen 2
PGII

Pepsinogen II (PGII) is secreted by fundic glands, cardia glands, pyloric glands, brunner glands, the secretion of PGII is large but the concentration is low. Serum PGII can reflect the status and function of gastric mucosa more accurately. Normal range of PGII is 0~15ng/ml, PGII is more correlated with gastric mucosa lesions (compared with gastric mucosa). PGII increases when gastric fundus duct atrophy, gastric metaplasia or pseudopyloric gland metaplasia, atypia. With the development of stomach disease, both PGI and PGII in serum show an upward trend, but PGI decreases gradually and then maintains at a low lever, while PGII rises to a certain level and maintains this level until it becomes cancerous, so the ratio of PGI and PGII will be abnormal. A progressive decrease in the PGI and PGII ratio is associated with progression of gastric mucosal atrophy. Therefore the combo detection of PGI and PGII ratio can play the role of "serological biopsy" of gastric fundic gland mucosa. The ratio of PGI and PGII can be used to detect superficial gastritis and chronic atrophic gastritis, Helicobacter pylori infection and curative effect observation, primary screening of the gastric cancer.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFPGII001/IFPGII100	1-100ng/ml	0.998	0.9732	1ng/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

PGII Linear Range

$y = 0.9721x - 2.0491$
$R^2 = 0.998$

PGII Correlation

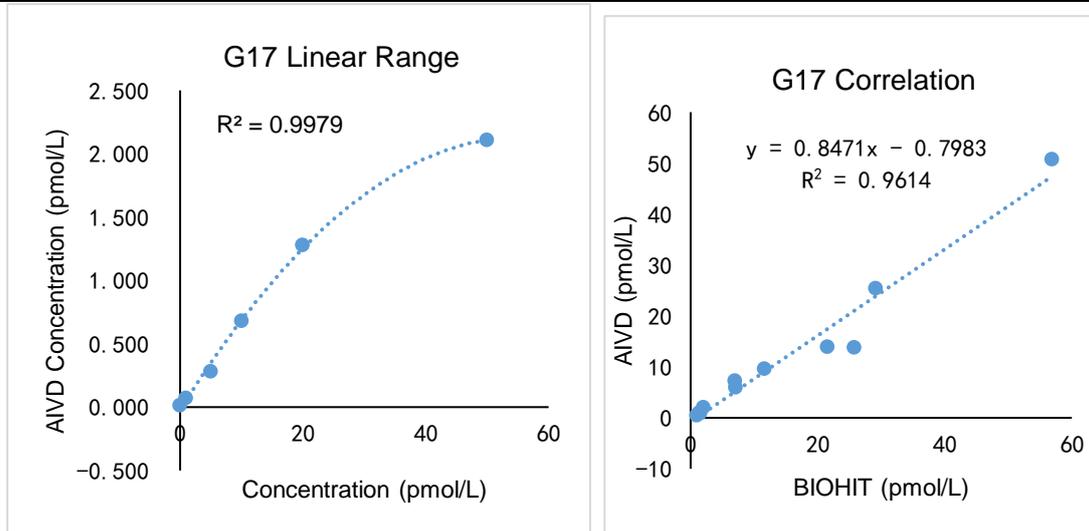$y = 0.0221x + 0.0293$
$R^2 = 0.9732$

Gastrin
G17

Gastrin is a gastrointestinal hormone mainly secreted by G cells of the gastric antrum and duodenum, it plays an important role in regulating the function of digestive tract and maintaining its structural integrity. In human body, more than 95% of the gastrin with biological activity is alpha-amidated gastrin, which mainly contains two isomers: G17 and G34, and 80%~90% of it are G17. G17 is only secreted by G cells in the gastric antrum, so it is a significant indicator to reflect the damage of gastric mucosa. Normal range of G17 is 1-15pmol/L when fasting, and 1-30pmol/L after meal. When G17 concentration is at low level in the human body, it usually indicates that there are some high acid conditions in the stomach, and there is risk of gastric inflammation, gastric antrum atrophy or even gastric cancer. When G17 is at high level, it indicates that there is some inflammation in the stomach, and some patients may have some symptoms of hypergastrinemia, which may be related to helicobacter pylori infection, gastric ulcer and drug effects. In addition, changes in G17 are also linked to the patient's stomach being stimulated by diet, and suffering from other diseases.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFG17001/IFG17100	1-50pmol/L	0.9979	0.9614	1ng/ml
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type</u>: whole blood, serum, plasma				
<u>Sample volume:</u> 80 ul				

G17 Linear Range

$R^2 = 0.9979$

AIVD Concentration (pmol/L) vs Concentration (pmol/L)

G17 Correlation

$y = 0.8471x - 0.7983$
$R^2 = 0.9614$
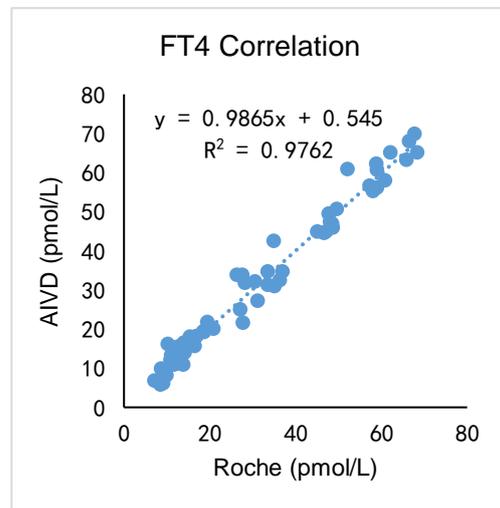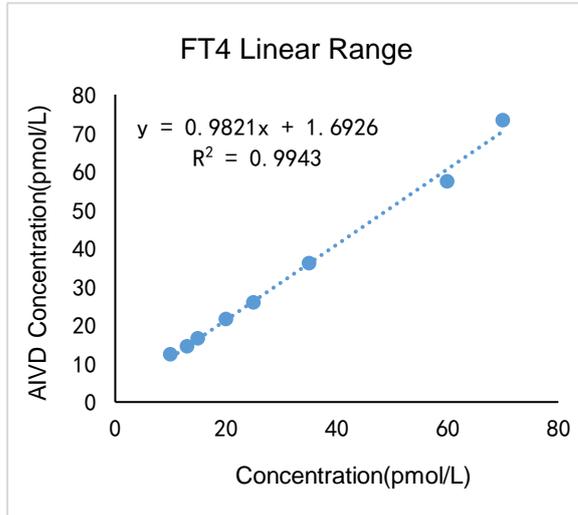
AIVD (pmol/L) vs BIOHIT (pmol/L)

Thyroid markers

Free Thyroxine
FT4

Thyroxine is a hormone synthesized and secreted by thyroid follicular cells. It is released into the blood circulation in free form, most of it is rapidly combined with plasma protein, thyroxine 3(T3) and thyroxine 4(T4) in the combined part have no biological activity, and their levels can't reflect the function state of the thyroid gland, only a small part of thyroxines is not bound to protein and is in a free state, so called free thyroxine 3(FT3) and free thyroxine 4(FT4). FT3 and FT4 can most directly reflect thyroid function status and aren't affected by changes in concentration and binding capacity of thyroxine-binding globulin in blood. Serum FT4 is a sensitive indicator of thyroid function in virtual test, even when the plasma thyroid binding capacity and concentration are changed under physiological and pathological conditions, it can still better reflect the thyroid function. Normal range of FT4 is 10～31pmol/L, FT4 concentration increases when patients have diseases like thyrotoxicosis, exophthalmos hyperthyroidism, subacute thyroiditis with hyperthyroidism, etc. FT4 concentration deceases in diseases like hypothyroidism(primary) transient hypofunction of pituitary or painless subacute thyroiditis, hypoalbuminemia.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFFT4001/IFFT4100	3.2-77pmol/L	0.9943	0.98	3.2pmol/L
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

FT4 Linear Range

$y = 0.9821x + 1.6926$
$R^2 = 0.9943$

AIVD Concentration(pmol/L) vs Concentration(pmol/L)

FT4 Correlation

$y = 0.9865x + 0.545$
$R^2 = 0.9762$

AIVD (pmol/L) vs Roche (pmol/L)
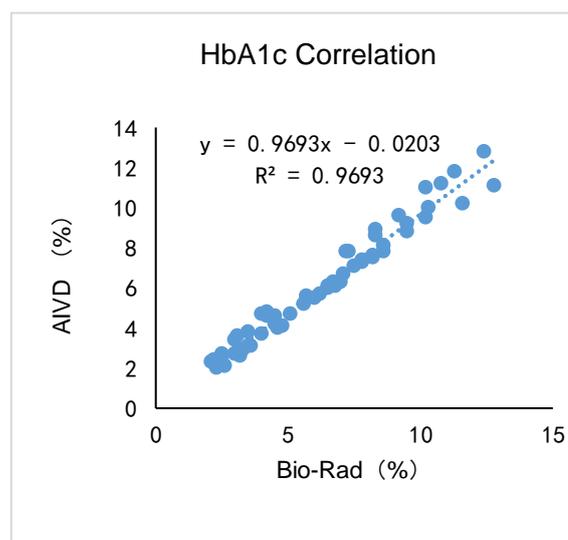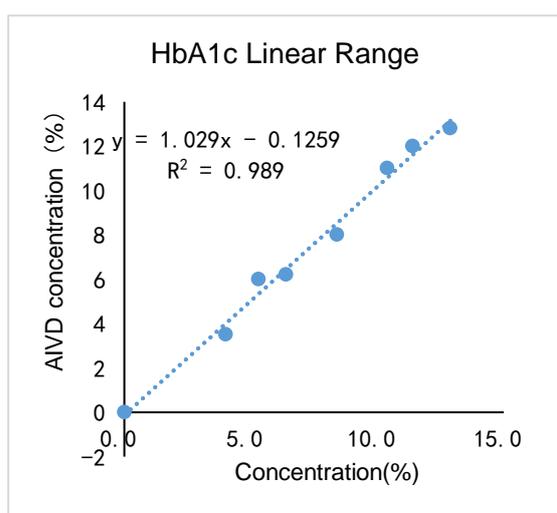
Other markers

Glycosylated hemoglobin
HbA1c

Glycosylated hemoglobin (HbA1c) is a product of the binding of the hemoglobin in red blood cells in the human blood and sugars in the serum. The non-enzymatic reaction which to form HbA1c has the characteristics of continuous, slow and irreversible, so HbA1c concentration can effectively reflect the blood glucose level during 1~2 month before blood collection, which is one of the diagnostic indicator of diabetes. The rational control target for most patients is HbA1c≤7.0%(53mmol/mol), with reference to the Diabetes Control and Complications Trial(DCCT)/United Kingdom Prospective Diabetes Study(UKPDS), where the upper limit is 6.0%.HbA1c level used to be a detection method to screen people at high-risk of diabetes, because of the continuity of risks associated with increasing HbA1c, those people with HbA1c level below the cut off points of diabetes but ≥6.0% should get effective preventive interventions. While patients with HbA1c level below 6.0% can also be in danger. HbA1c can be used to diagnose other diseases, for example, blood sugar increases but HbA1c not under stress states such as cerebrovascular emergency. In the management of gestational diabetes, it is not enough to control blood sugar, but also to control the HbA1c level, which would also have positive effect in preventing eclampsia, fetal macrosomia, teratology and stillborn foetus.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFHbA1c001/IFHbA1c100	4-14%	0.989	0.9693	4%
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 10-15 min				
<u>Specimen type</u>: whole blood				
<u>Sample volume:</u> 80 ul				

HbA1c Linear Range

$y = 1.029x - 0.1259$
$R^2 = 0.989$

AIVD concentration (%) vs Concentration(%)

HbA1c Correlation

$y = 0.9693x - 0.0203$
$R^2 = 0.9693$

AIVD (%) vs Bio-Rad (%)
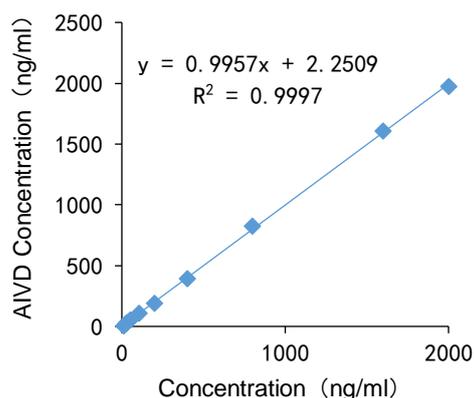
Other markers

Ferritin
Fer

Ferritin (Fer) is a protein contains 20% iron, usually it presents in almost all body tissues especially hepatocytes and reticuloendothelial cells, as a reserve of iron. Fer has special characteristics such as dilute acid resistance(PH 2.0), dilute alkali resistance(PH 12.0),and resistance to heat (invariance at 70~75℃ water temperature). In many researches, those characteristics are used to purify the Fer from animal tissues. Serum Fer is the most iron-rich protein in human body, Fer mainly reserves in the liver, spleen, red bone marrow and intestinal mucous, accounting for about 66% of the total iron in the body. The determination of serum Fer is a significant marker to judge the iron storage reserves in human body, it is of great importance in the diagnosis of iron deficiency anemia (IDA), iron overload and nutrition surveys. As a tumor marker, Fer also has certain reference value in clinical diagnosis of some malignant tumors. Normal range of Fer for men is <322 ng/ml, for women is <219 ng/ml. Decrease of Fer seen in IDA and body loss, iron deficiency: <24μg/L for men, <11μg/L for women; Increase of Fer seen in malignant tumors, acute hepatitis, acute infection, chronic kidney disease (CKD), hemochromatosis (HFE), Gaucher disease (GD), chronic inflammatory diseases, etc, iron overload: >336μg/L for men, >307μg/L for women.
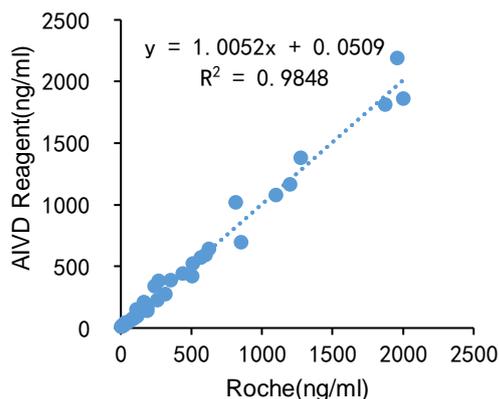
Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFFER001/IFFER100	1-2000ng/ml	0.999	0.985	1ng/ml
Available for order: uncut sheets, assembled tests, strips				
Reaction time: 15 min				
Specimen type: whole blood, serum, plasma				
Sample volume: 80 ul				

Fer Linear Range

$y = 0.9957x + 2.2509$
$R^2 = 0.9997$

Fer Correlation

$y = 1.0052x + 0.0509$
$R^2 = 0.9848$

Other markers

Microalbuminuria
MAU

Albumin is one of the important plasma protein, under normal circumstances, the molecular weight of albumin is too large to cross the glomerular basement membrane, so in the urine of health people, albumin concentration is very low, which is no more than 20mg/L, so it's also called microalbuminuria(MAU). MAU is a significant marker to evaluate early kidney disease and renal damage degree. Norman range of MAU is <20mg/L, pathological increase of MAU concentration is seen in diabetic nephropathy, hypertension, gestational preeclampsia. In the early stage, MAU is the signal and omen of the occurrence of kidney disease, when kidney damage can still be reversed, and if get treatment timely, the development of kidney diseases can be terminated or reversed. MAU detection can be the kidney function marker of systemic or local inflammatory reactions, such as early renal lesions caused by urine tract infection, etc, it is also a predictor of complications of acute pancreatitis. MAU can be tested when taking drugs which affect the kidney function to early observe the kidney function status and take early action. MAU can also be a toxicity indicator of some tumor treatment drugs, since some anticancer drugs have nephrotoxicity that limit the effectiveness of cancer treatment.

Performance Data

Catalog #	Linear range	Linearity	Correlation R^2	Detection limit
IFMAU001/IFMAU100	5 -1000 mg/L	0.9935	0.9953	5pmol/L
<u>Available for order</u>: uncut sheets, assembled tests, strips				
<u>Reaction time:</u> 15 min				
<u>Specimen type</u>: whole blood, serum, plasma				
<u>Sample volume: </u>80 ul				

MAU Linear Range

$R^2 = 0.9935$

AIVD Concentration (mg/L) vs Concentration (mg/L)

MAU Correlation

$y = 1.0228x + 2.4154$
$R^2 = 0.9953$

AIVD (mg/L) vs Orion(mg/L)