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## About Autobio & Bioyuan



Autobio Diagnostics Co., Ltd (Hereinafter called Autobio) founded in 1998, headquartered in National Eco & Tech Zone, Zhengzhou. Autobio specialized in R&D, Production, Marketing, and Service of Clinical diagnostic products, especially covering Immunoassay, Microbiology, Clinical Chemistry, and Molecular.

Shanghai Bioyuan Biotech Co., Ltd. was established in Shanghai in March 2016, and in the same year Zhengzhou Bioyuan Biotech Co., Ltd. was established by Shanghai Bioyuan Biotech Co., Ltd.

Bioyuan core business includes the Research and Development, Production, and sales of Quality Control products and intelligent quality control systems, as well as quality control education and ISO15189 accreditation services.

Corporate Vision: To become an internationally influential medical laboratory quality management service provider.

Enterprise Purpose: Committed to improving the quality management level of clinical laboratories, ensuring that every clinical test result is accurate and reliable in serving human health.



## Advantages

### **Bioyuan Quality Control**

Bioyuan offers independent quality control products to improve efficiency, reduce errors while maintaining compliance and increasing workflow and cost saving.

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### **Consolidation**

Bioyuan offers multiple analytes in one vial which effectively increases efficiency, helping labs streamline their workflow.

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### **Stability**

A shelf-life up to 36 months at 2-8°C, and the freeze-drying process ensures the stability of the analyte during transportation.

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### **Data Management**

The data management software (BIOAS) includes multiple functions such as automatic target setting, QC rule recommendation, interactive charts, out of control statistics, analysis, prompts, and quality control operation record to provide strong assistance in simplifying laboratory quality control operations, accelerating laboratory quality control management.

# Autobio & Bioyuan Controls

## Infectious Disease

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
ID0101	Infectious Disease Control	20 x 1.0mL	Level 1	Liquid	≤-20°C	36 months	14 days	Human Serum
ID0102		20 x 1.0mL	Level 2					
ID0103		20 x 1.0mL	Level 3					

### Analytes (1)

Hepatitis B Virus Surface Antigen (HBsAg)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
ID0201	Infectious Disease Control	20 x 1.0mL	Level 1	Liquid	≤-20°C	36 months	14 days	Human Serum
ID0202		20 x 1.0mL	Level 2					
ID0203		20 x 1.0mL	Level 3					

### Analytes (1)

Hepatitis B Virus Surface Antibody (HBsAb)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
ID0301	Infectious Disease Control	20 x 1.0mL	Level 1	Liquid	≤-20°C	36 months	14 days	Synthetic
ID0302		20 x 1.0mL	Level 2					
ID0303		20 x 1.0mL	Level 3					

### Analytes (1)

Hepatitis B Virus e Antigen (HBeAg)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
ID0401	Infectious Disease Control	20 x 1.0mL	Level 1	Liquid	≤-20°C	36 months	14 days	Human Serum
ID0402		20 x 1.0mL	Level 2					
ID0403		20 x 1.0mL	Level 3					

### Analytes (1)

Hepatitis B Virus e Antibody (HBeAb)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
ID0501	Infectious Disease Control	20 x 1.0mL	Level 1	Liquid	≤-20°C	36 months	14 days	Human Serum
ID0502		20 x 1.0mL	Level 2					
ID0503		20 x 1.0mL	Level 3					

**Analytes (1)**

Hepatitis B Virus Core Antibody (HBcAb)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
ID0601	Infectious Disease Control	20 x 1.0mL	Level 1	Liquid	≤-20°C	36 months	14 days	Human Serum
ID0602		20 x 1.0mL	Level 2					
ID0603		20 x 1.0mL	Level 3					

**Analytes (1)**

Human Immunodeficiency Virus Antibodies (Anti HIV)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
ID0701	Infectious Disease Control	20 x 0.5mL	Level 1	Liquid	≤-20°C	36 months	14 days	Human Serum
ID0702		20 x 0.5mL	Level 2					
ID0703		20 x 0.5mL	Level 3					

**Analytes (1)**

Hepatitis C Virus Antibodies (anti HCV)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
ID0801	Infectious Disease Control	20 x 1.0mL	Level 1	Liquid	≤-20°C	36 months	14 days	Human Serum
ID0802		20 x 1.0mL	Level 2					
ID0803		20 x 1.0mL	Level 3					

**Analytes (1)**

Syphilis Specific antibodies (Anti-TP)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
TOR0101		10 × 1.0mL	Level 1					
TOR0102		10 × 1.0mL	Level 2					
TOR0103		10 × 1.0mL	Level 3					
TOR0104	Infectious Disease Control (Neonatal)	10 × 1.0mL	Level 4	Lyophilized	2 °C~8 °C	36 months	14 days	Bovine Serum
TOR0105		10 × 1.0mL	Level 5					
TOR0106		10 × 1.0mL	Level 6					
TOR0107		10 × 1.0mL	Level 7					

#### Analytes (7)

Cytomegalovirus IgG Antibody (CMV IgG)      Herpes Simplex Virus Type 2 IgG Antibody (HSV-2 IgG)      Toxoplasma Gondii IgG Antibody (TOX IgG)  
Herpes Simplex Virus Type 1 IgG Antibody (HSV-1 IgG)      Rubella Virus IgG Antibody (RV IgG)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
TOR0201		10 × 1.0mL	Level 1					
TOR0202		10 × 1.0mL	Level 2					
TOR0203		10 × 1.0mL	Level 3					
TOR0204		10 × 1.0mL	Level 4					
TOR0205	Infectious Disease Control (Neonatal)	10 × 1.0mL	Level 5	Lyophilized	2 °C~8 °C	36 months	14 days	Human Serum
TOR0206		10 × 1.0mL	Level 6					
TOR0207		10 × 1.0mL	Level 7					
TOR0208		10 × 1.0mL	Level 8					
TOR0209		10 × 1.0mL	Level 9					

#### Analytes (9)

Cytomegalovirus IgM Antibody (CMV IgM)      Herpes Simplex Virus Type 2 IgM Antibody (HSV-2 IgM)      Toxoplasma Gondii IgM Antibody (TOX IgM)  
Herpes Simplex Virus Type 1 IgM Antibody (HSV-1 IgM)      Rubella Virus IgM Antibody (RV IgM)



Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
BIDI0101		6 x 3.0mL	Level 1					
BIDI0102	Infectious Disease Control	6 x 3.0mL	Level 2	Liquid	≤-20°C	30 months	14 days	Bovine Serum
BIDI0103		6 x 3.0mL	Level 3					
BIDI0104		6 x 3.0mL	Level 4					

#### Analytes (5)

Hepatitis B Virus e Antigen (HBeAg)      Hepatitis C Virus Antibodies (Anti HCV)      Treponema Pallidum Antibodies (Anti TP)  
Hepatitis B Virus Surface Antigen (HBsAg)      Human Immunodeficiency Virus Antibodies (Anti HIV)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
BIDII0101		6 x 3.0mL	Level 1					
BIDII0102	Infectious Disease Control	6 x 3.0mL	Level 2	Liquid	≤-20°C	30 months	14 days	Bovine Serum
BIDII0103		6 x 3.0mL	Level 3					
BIDII0104		6 x 3.0mL	Level 4					

#### Analytes (4)

Hepatitis B Virus Core Antibodies (Anti HBc)      Hepatitis B Virus Surface Antibodies (Anti HBs)      Human Immunodeficiency Virus p24 Antigen (HIV p24 Ag)  
Hepatitis B Virus e Antibodies (Anti HBe)

## Immunoassay

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
TM0201		6 x 3.0mL	Level 1				14 days	
TM0202	Tumor Marker Control (Immunoassay)	6 x 3.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	CA15-3 (7 days)	Human Serum
TM0203		6 x 3.0mL	Level 3					

#### Analytes (9)

AFP      CA19-9      Ferritin (Ferr)  
CA125      CA50      Prostate Specific Antigen (tPSA)  
CA15-3      CEA      free Prostate Specific Antigen (fPSA)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
TM0301		6 x 3.0mL	Level 1					
TM0302	Tumor Marker Control II (Immunoassay)	6 x 3.0mL	Level 2	Lyophilized	2 °C~8 °C	36 months	14 days NSE (1 day)	Human Serum
TM0303		6 x 3.0mL	Level 3					

#### Analytes (20)

Alpha Fetoprotein (AFP)	Carcinoembryonic Antigen (CEA)	Pepsinogen II (PGII)
Carbohydrate Antigen 125 (CA125)	Cytokeratin 19 fragment (CYFRA21-1)	Prostate Specific Antigen (tPSA)
Carbohydrate Antigen 15-3 (CA15-3)	Ferritin (Ferr)	Squamous Cell Carcinoma Antigen (SCCA)
Carbohydrate Antigen 19-9 (CA19-9)	free Prostate Specific Antigen (fPSA)	Thyroglobulin (TG)
Carbohydrate Antigen 242 (CA242)	Human Epididymal Protein 4 (HE4)	β2-Microglobulin (β2-MG)
Carbohydrate Antigen 50 (CA50)	Neuron Specific Enolase (NSE)	β- Human Chorionic Gonadotropin (β-HCG)
Carbohydrate Antigen 72-4 (CA72-4)	Pepsinogen I (PGI)	

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
HM0201		6 x 3.0mL	Level 1				14 days C-P (4 hrs) IGF-1 (3 days)	
HM0202	Endocrine Control (Immunoassay)	6 x 3.0mL	Level 2	Lyophilized	2 °C~8 °C	36 months	INS (7 days) HGH (10 days) ACTH (test immediately)	Human Serum
HM0203		6 x 3.0mL	Level 3					

#### Analytes (25)

17α- Hydroxyprogesterone (17α- OHP)	Human Growth Hormone (hGH)	T3 (Total)
25 Hydroxy Total Vitamin D (25-OH-VD)	Insulin (INS)	T4 (Free)
Adrenocorticotrophic Hormone (ACTH)	Insulin-like Growth Factor I (IGF-1)	T4 (Total)
Aldosterone (ALD)	Luteinizing Hormone (LH)	Testosterone (T)
C-peptide	Progesterone (P)	Thyroid Stimulating Hormone (TSH)
Cortisol	Prolactin (PRL)	Vitamin B12 (VB12)
Dehydroepiandrosterone Sulfate (DHEA-S)	T3 (Free)	β-Human Chorionic Gonadotropin (β-HCG)
Estradiol (E2)		

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
PCT0101	Calcitonin Control (Immunoassay)	10 × 1.0mL	Level 1	Lyophilized	2 °C~8 °C	24 months	3 days	Human Serum
PCT0102		10 × 1.0mL	Level 2					
PCT0103		10 × 1.0mL	Level 3					
PCT0104		10 × 1.0mL	Level 4					

**Analytes (1)**

Procalcitonin (PCT)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
CRP0101	C-reactive Protein control (Immunoassay)	10 × 1.0mL	Level 1	Liquid	≤0°C	24 months	14 days	Human Serum
CRP0102		10 × 1.0mL	Level 2					
CRP0103		10 × 1.0mL	Level 3					
CRP0104		10 × 1.0mL	Level 4					
CRP0105		10 × 1.0mL	Level 5					

**Analytes (1)**

C-reactive Protein (CRP)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
HF0101	Liver Fibrosis Markers Controls (Immunoassay)	5 x 3.0mL	Level 1	Lyophilized	2 °C~8 °C	24 months	14 days	Human Serum
HF0102		5 x 3.0mL	Level 2					
HF0103		5 x 3.0mL	Level 3					
HF0104		5 x 3.0mL	Level 4					
HF0105		5 x 3.0mL	Level 5					
HF0106		5 x 3.0mL	Level 6					

**Analytes (5)**

Glycyrrhetic Acid (CG)

Laminin (LN)

Type IV Collagen (Col IV)

Hyaluronic Acid (HA)

N-terminal Peptide of Type III Procollagen (P III NP)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
AMH0101		6 x 1.0mL	Level 1					
AMH0102	Anti-Mullerian Hormone Control (Immunoassay)	6 x 1.0mL	Level 2	Lyophilized	2 °C~8 °C	28 months	14 days	Human Serum
AMH0103		6 x 1.0mL	Level 3					

**Analytes (1)**

Anti-mullerian Hormone (AMH)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
DD0101		10 x 1.0 mL	Level 1					
DD0102		10 x 1.0 mL	Level 2					
DD0103	D-Dimer Control (Immunoassay)	10 x 1.0 mL	Level 3	Liquid	≤0°C	24 months	14 days	Human Serum
DD0104		10 x 1.0 mL	Level 4					
DD0105		10 x 1.0 mL	Level 5					

**Analytes (1)**

D-dimer

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
BMC0101		6 x 2.0mL	Level 1				7 days	
BMC0102	Inflammatory Marker Control (Immunoassay)	6 x 2.0mL	Level 2	Lyophilized	2 °C~8 °C	26 months	IL-6(1 day) PCT(3 days)	Human Serum
BMC0103		6 x 2.0mL	Level 3					

**Analytes (6)**

C-reactive Protein (CRP)

IL-6 (1 day)

Lipoprotein Associated Phospholipase A2 (Lp PLA2)

Myeloperoxidase (MPO)

PCT (3 days)

Serum Amyloid A (SAA)

## Clinical Chemistry

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
CB0101		6 x 5.0mL	Level 1				7 days	
CB0102	Clinical Chemistry Control	6 x 5.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	TBIL, DBIL, ALT remain stable for 3 days	Human Serum
CB0103		6 x 5.0mL	Level 3					

### Analytes (36)

Alanine Aminotransferase (ALT)	Creatinine (Cre)	Phosphorus (P)
Albumin (ALB)	Direct Bilirubin(DBIL)	Potassium(K)
Alkaline Phosphatase (ALP)	Gamma Glutamyltransferase (GGT)	Sodium (Na)
Alpha-Hydroxybutyrate Dehydrogenase (HBDH)	Glucose (Glu)	Total Bile Acid (TBA)
Amylase (AMY)	High Density Lipoprotein Cholesterol (HDL-C)	Total Bilirubin (TBIL)
Asparaginic Acid (AST)	Iron (Fe)	Total Cholesterol (TC)
Calcium (Ca)	Lactic Acid (LAC)	Total Protein (TP)
Carbon Dioxide (CO2)	Lactic Dehydrogenase(LDH)	Total Iron Binding Capacity (TIBC)
Chlorume (Cl)	Lipase (LPS)	Triglyceride (TG)
Cholinesterase(CHE)	Lithium (Li)	Urea
Copper (Cu)	Low Density Lipoprotein Cholesterol (LDL-C)	Uric Acid (UA)
Creatine Kinase (CK)	Magnesium (Mg)	Zinc (Zn)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
LIP0101		6 x 1.0mL	Level 1					
LIP0102	Lipid Control (Clinical Chemistry)	6 x 1.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	7 days	Human Serum
LIP0103		6 x 1.0mL	Level 3					

### Analytes (7)

Apo A1 (Apo A-1)	Lipoprotein a (Lp (a))	Total Cholesterol (TC)
Apo B (Apo B)	Low-density Lipoprotein Cholesterol (LDL-C)	Triglycerides (TG)
High-density Lipoprotein Cholesterol (HDL-C)		

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
SP0101	Protein Chemistry Control (Clinical Chemistry)	6 x 1.0mL	Level 1					
SP0102		6 x 1.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	10 days	Human Serum
SP0103		6 x 1.0mL	Level 3					

#### Analytes (22)

Albumin (ALB)	Immunoglobulin A (IgA)	Retinol Binding Protein (RBP)
Anti Streptolysin O (ASO)	Immunoglobulin E (IgE)	Rheumatoid factor (RF)
C-Reactive Protein (CRP)	Immunoglobulin G (IgG)	Total Protein (TP)
Complement C3 (C3)	Immunoglobulin M (IgM)	Transferrin (TRF)
Complement C4 (C4)	Kappa Light Chain (κ- LC)	α1 Antitrypsin (AAT)
Cystatin C (CysC)	Lambda Light Chain (λ- LC)	α1-Microglobulin (α1-MG)
Ferritin (Ferr)	Prealbumin (PAB)	β2-Microglobulin (β2-MG)
Haptoglobin (HPT)		

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
GLU0101	Blood Glucose Control	6 x 1.0mL	Level 1					
GLU0102		6 x 1.0mL	Level 2	Liquid	2 °C~8 °C	26 months	28 days	Synthetic
GLU0103		6 x 1.0mL	Level 3					

#### Analytes (1)

Glucose (Glu)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
GA0101	Glycated Albumin Control	6 x 1.0mL	Level 1					
GA0102		6 x 1.0mL	Level 2	Lyophilized	2 °C~8 °C	26 months	14 days	Human Serum
GA0103		6 x 1.0mL	Level 3					

#### Analytes (1)

Glycated Albumin (GA)



## Diabetes

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
TH0101	Diabetes Control	6 x 0.5mL	Level 1	Lyophilized	2 °C~8 °C	24 months	14 days	Human Whole Blood
TH0102		6 x 0.5mL	Level 2					

### Analytes (1)

Glycated Hemoglobin (HbA1c)

## Cardiac Marker

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
CM0101	Cardiac Marker Control	5 x 2.0mL	Level 1	Lyophilized	2 °C~8 °C	24 months	7 days	Human Serum
CM0102		5 x 2.0mL	Level 2				BNP, NT	
CM0103		5 x 2.0mL	Level 3				proBNP(3 days)	

### Analytes (11)

B-type Natriuretic Peptide (BNP)	Digoxin (Dig)	N-terminal B-type Natriuretic Peptide Precursor (NT proBNP)
C-reactive Protein (CRP)	Heart Type Fatty Acid Binding Protein (H-FABP)	Troponin T (cTnT)
Creatine Kinase (CK)	Homocysteine (HCY)	Troponin I (cTnI)
Creatine Kinase Isoenzyme (CK-MB)	Myoglobin (MYO)	

## Coagulation

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
NX0101		6 x 1.0mL	Level 1					
NX0102	Coagulation Controls	6 x 1.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	48 hours	Human Plasma
NX0103		6 x 1.0mL	Level 3					

### Analytes (5)

Prothrombin Time (PT)

Activated Partial Thromboplastin Time (APTT)

Thrombin Time (TT)

Fibrinogen (FIB)

Antithrombin III (AT III)

## Urine Chemistry

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
UCA0101		6 x 10.0mL	Level 1					
	Urine Chemistry Controls			Liquid	2 °C~8 °C	18 months	14 days	Human and Bovine Serum
UCA0102		6 x 10.0mL	Level 2					

### Analytes (10)

Specific Gravity (SG)

pH

Albumin (ALB)

Glucose (GLU)

Ketone Bodies (KET)

Blood (hemoglobin) (BLD)

Nitrite (NIT)

Bilirubin (BIL)

Urobilinogen (URO)

White Blood Cells (LEU)

# Unassayed - Autobio & Bioyuan Controls

## Infectious Disease

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID1001		10 × 1.0mL	Level 1					
FID1002	Infectious Disease	10 × 1.0mL	Level 2	Liquid	≤0°C	24 months	14 days	Synthetic
FID1003		10 × 1.0mL	Level 3					

### Analytes (1)

Hepatitis A Virus IgM Antibody (Anti HAV IgM)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID1201		10 × 1.0mL	Level 1					
FID1202	Infectious Disease	10 × 1.0mL	Level 2	Liquid	≤-20°C	24 months	14 days	Synthetic
FID1203		10 × 1.0mL	Level 3					

### Analytes (1)

Hepatitis E Virus IgM Antibody (Anti HEV IgM)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID1101		10 × 1.0mL	Level 1					
FID1102	Infectious Disease	10 × 1.0mL	Level 2	Liquid	≤-20°C	24 months	14 days	Synthetic
FID1103		10 × 1.0mL	Level 3					

### Analytes (1)

Hepatitis E Virus IgG Antibody (Anti HEV IgG)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID1401		10 × 1.0mL	Level 1					
FID1402	Infectious Disease	10 × 1.0mL	Level 2	Liquid	≤ -20°C	24 months	14 days	Synthetic
FID1403		10 × 1.0mL	Level 3					

**Analytes (1)**

HBV-PreS1 Ag

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID1500	Infectious Disease	10 × 3.0mL	negative	Liquid	≤ -20°C	24 months	14 days	Human Serum

**Analytes (14)**

Hepatitis A Virus IgM Antibody (Anti HAV IgM)	Hepatitis B Virus Surface Antigen (HBsAg)	Hepatitis E Virus IgM Antibody (Anti HEV IgM)
Hepatitis B Virus Core Antibody (Anti HBc)	Hepatitis B Virus e Antibody (Anti HBe)	Human Immunodeficiency Virus Antibody (Anti HIV)
Hepatitis B Virus Core Antibody IgM (Anti HBc IgM)	Hepatitis B Virus e Antigen (HBeAg)	Syphilis Non-specific Antibody (TRUST)
Hepatitis B Virus Pre S1 Antigen (HBV-PreS1 Ag)	Hepatitis C Virus Antibody (Anti HCV)	Syphilis Specific Antibody (Anti TP)
Hepatitis B Virus Surface Antibody (HBsAb)	Hepatitis E Virus IgG Antibody (Anti HEV IgG)	

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID0701		10 × 0.5mL	Level 1					
FID0702	Infectious Disease	10 × 0.5mL	Level 2	Liquid	≤ -20°C	24 months	14 days	Human Serum
FID0703		10 × 0.5mL	Level 3					

**Analytes (1)**

Hepatitis C Virus Antibodies (Anti HCV)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
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FHS0100	Infectious Disease Control	10 × 1.5mL	negative	Liquid	≤ -20 °C	24 months	7 days	Synthetic
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**Analytes (3)**

Hepatitis B Virus Deoxyribonucleic Acid (HBV DNA)	Hepatitis C Virus Ribonucleic Acid (HCV RNA)	Human Immunodeficiency Virus Type I Ribonucleic Acid (HIV-1 RNA)
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Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
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FHS0101	Infectious Disease Control	10 × 1.0mL	Level 1	Liquid	≤ -20 °C	24 months	7 days	Synthetic
FHS0102		10 × 1.0mL	Level 2					
FHS0103		10 × 1.0mL	Level 3					
FHS0104		10 × 1.0mL	Level 4					
FHS0105		10 × 1.0mL	Level 5					
FHS0106		10 × 1.0mL	Level 6					

**Analytes (1)**

Novel Coronavirus Nucleic Acid Ribonucleic Acid (2019 nCoV RNA)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
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FNCov0101	Infectious Disease Control	10 × 1.0mL	Level 1	Liquid	≤ -20 °C	24 months	7 days	Bovine Serum
FNCov0102		10 × 1.0mL	Level 2					

**Analytes (1)**

2019 nCoV IgG Antibody

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
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FNCov0201	Infectious Disease Control	10 × 1.0mL	Level 1	Liquid	≤ -20 °C	24 months	7 days	Human Serum
FNCov0202		10 × 1.0mL	Level 2					

**Analytes (1)**

2019 nCoV IgM Antibody

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FNCov0301	Infectious Disease Control	6 x 1.0mL	Level 1					
FNCov0302		6 x 1.0mL	Level 2	Liquid	2 °C~8 °C	12 months	10 days	Synthetic
FNCov0303		6 x 1.0mL	Level 3					

**Analytes (1)**

2019 nCoV Ag

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FHXD0101	Infectious Disease Control	10 × 1.0mL	Level 1					
FHXD0102		10 × 1.0mL	Level 2	Liquid	≤ -15 °C	24 months	14 days	Human Serum
FHXD0103		10 × 1.0mL	Level 3					

**Analytes (11)**

Adenovirus (AD)	Human Parainfluenza Virus 2 (HPV-2)	Mycoplasma Pneumoniae (MP)
Chlamydia Pneumoniae (CP)	Human Parainfluenza Virus 3 (HPV-3)	Rescued Human Virus (RhV)
Human Metapneumovirus (HMPV)	Influenza A Virus (Flu A)	Respiratory Syncytial Virus (RSV)
Human Parainfluenza Virus 1 (HPV-1)	Influenza B Virus (Flu B)	

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID0101	Infectious Disease	6 x 3.0mL	Negative	Liquid	≤ -15 °C	36 months	14 days	Bovine Serum

**Analytes (9)**

Hepatitis B Virus Core Antibody (Anti HBC)	Hepatitis B Virus e Antibody (Anti HBe)	Human Immunodeficiency Virus Antibody (Anti HIV)
Hepatitis B Virus Surface Antibodies (Anti HBs)	Hepatitis B Virus e Antigen (HBeAg)	Human Immunodeficiency Virus p24 Antigen (HIV p24 Ag)
Hepatitis B Virus Surface Antigen (HBsAg)	Hepatitis C Virus Antibody (Anti HCV)	Treponema Pallidum Antibody (Anti TP)



Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID0201		6 x 3.0mL	Level 1					
FID0202		6 x 3.0mL	Level 2					
FID0203		6 x 3.0mL	Level 3					
FID0204		6 x 3.0mL	Level 4					
FID0205	Infectious Disease	6 x 3.0mL	Level 5	Liquid	≤ -15 °C	36 months	14 days	Bovine Serum
FID0206		6 x 3.0mL	Level 6					
FID0207		6 x 3.0mL	Level 7					
FID0208		6 x 3.0mL	Level 8					
FID0209		6 x 3.0mL	Level 9					

#### Analytes (5)

Hepatitis B Virus Surface Antigen (HBsAg)

Hepatitis CVirus Antibodies (Anti HCV)

Treponema Pallidum Antibodies (Anti TP)

Hepatitis B Virus e Antigen (HBeAg)

Human ImmunodeficiencyVirus Antibodies (Anti HIV)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FID0301		6 x 3.0mL						
FID0302		6 x 3.0mL						
FID0303		6 x 3.0mL						
FID0304		6 x 3.0mL						
FID0305	Infectious Disease	6 x 3.0mL	Level 5	Liquid	≤ -15 °C	36 months	14 days	Bovine Serum
FID0306		6 x 3.0mL						
FID0307		6 x 3.0mL						
FID0308		6 x 3.0mL						
FID0309		6 x 3.0mL						

#### Analytes (4)

Hepatitis B Virus Core Antibodies (Anti HBc)

Hepatitis B Virus e Antibodies (Anti HBe)

Human ImmunodeficiencyVirus p24 Antigen (HIV p24 Ag)

Hepatitis B Virus Surface Antibodies (Anti HBs)

## Cardiac Marker

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FBNP0101		6 x 1.0mL	Level 1					
FBNP0102	Cardiac Marker Control	6 x 1.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	3 days	Human Serum
FBNP0103		6 x 1.0mL	Level 3					

### Analytes (2)

B-type Natriuretic Peptide (BNP)

N-terminal B-type Natriuretic Peptide Precursor (NT proBNP)

## Immunoassay

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FTM0101		6 x 3.0mL	Level 1					
FTM0102	Tumor Marker control II	6 x 3.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	Most projects remain stable for 14 days	Human Serum
FTM0103		6 x 3.0mL	Level 3					

### Analytes (21)

Alpha Fetoprotein (AFP)	Carcinoembryonic Antigen (CEA)	Pepsinogen I (PGI)
Carbohydrate Antigen 125 (CA125)	Cytokeratin 19 Fragment (Cyfra21-1)	Pepsinogen II (PGII)
Carbohydrate Antigen 15-3 (CA15-3)	Ferritin (Ferr)	Prostate Specific Antigen (PSA)
Carbohydrate Antigen 19-9 (CA19-9)	free Prostate Specific Antigen (fPSA)	Squamous Cell Carcinoma Antigen (SCCA)
Carbohydrate Antigen 242 (CA242)	Gastrin Releasing Peptide Precursor (proGRP)	Thyroid Globulin (TG)
Carbohydrate Antigen 50 (CA50)	Human Epididymal Protein 4 (HE4)	β 2-Microglobulin (β 2-MG)
Carbohydrate Antigen 72-4 (CA72-4)	Neuron Specific Enolase (NSE)	β- Human Chorionic Gonadotropin (β- HCG)

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FPS0101		6 x 1.0mL	Level 1					
FPS0102	Reproductive Control	6 x 1.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	14 days	Human Serum
FPS0103		6 x 1.0mL	Level 3					

**Analytes (4)**

β- Human Chorionic Gonadotropin(β- HCG)

free β Human chorionic gonadotropin (f)- β- HCG

Pregnancy Alpha Fetoprotein (P-AFP)

free Estriol (uE3)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FSAA0101		6 x 1.0mL	Level 1					
FSAA0102	Inflammatory Marker Control	6 x 1.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	7 days	Human Serum
FSAA0103		6 x 1.0mL	Level 3					

**Analytes (1)**

Serum Amyloid A (SAA)

## Clinical Chemistry

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FCYC0101	Chemistry Control	6 x 1.0mL	Level 1	Lyophilized	2 °C~8 °C	24 months	14 days	Human Serum
FCYC0102		6 x 1.0mL	Level 2					
FCYC0103		6 x 1.0mL	Level 3					

### Analytes (1)

Cystatin C (CysC)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FRBP0101	Chemistry Control	6 x 1.0mL	Level 1	Lyophilized	2 °C~8 °C	24 months	14 days	Human Serum
FRBP0102		6 x 1.0mL	Level 2					
FRBP0103		6 x 1.0mL	Level 3					

### Analytes (1)

Retinol Binding Protein (RBP)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FAFU0101	Chemistry Control	6 x 1.0mL	Level 1	Lyophilized	2 °C~8 °C	24 months	14 days	Human Serum
FAFU0102		6 x 1.0mL	Level 2					
FAFU0103		6 x 1.0mL	Level 3					

### Analytes (1)

A-L-Fucosidase (AFU)

Part Number	Product Category	Bottles & size	Levels	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FCB0201		6 x 3.0mL	Level 1				Free fatty acids (NEFA) and mitochondrial aspartate aminotransferase	
FCB0202	Chemistry Control	6 x 3.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	(mAST) can remain stable for 3 days, while other items can remain stable for 10 days	Human Serum
FCB0203		6 x 3.0mL	Level 3					

#### Analytes (20)

5'-Nucleotidase (5' - NT)	Glutamate Dehydrogenase (GLDH)	Pancreatic Amylase (P-AMY)
5-dehydrated Glucose Alcohol (1,5-AG)	Glycyrretinic Acid (CG)	Sialic Acid (SA)
Adenosine Deaminase (ADA)	Lactate (LAC)	Total Bile Acid (TBA)
Anti Cyclic Citrullinated Peptide Antibody (anti CCP)	Lactate Dehydrogenase Isoenzyme 1 (LDH1)	free Fatty Acids (NEFA)
Carbon Dioxide (CO2)	Leucine Aminopeptidase (LAP)	α-L-fucosidase (AFU)
Cystatin C (CysC)	Lipoprotein (a) (Lp (a))	β-Hydroxybutyric Acid (D3H)
Fructosamine (FMN)	Mitochondrial Aspartate Aminotransferase (mAST)	

## Coagulation

Part Number	Product Category	Bottles & Size	Level	Physical Status	Storage	Shelf Life	Open Vial Stability	Matrix
FNX0201		10 × 1.0mL	Level 1					
FNX0202	Coagulation Control	10 × 1.0mL	Level 2	Lyophilized	2 °C~8 °C	24 months	48h	Human Plasma
FNX0203		10 × 1.0mL	Level 3					

#### Analytes (7)

Activated Partial Thromboplastin Time (APTT)	Fibrinogen (FIB)	Prothrombin Time (PT)
Antithrombin III (AT III)	Fibrinogen Degradation products (FDP)	Thrombin Time (TT)
D-dimer (D-dimer)		

# BIQAS Quality Control Software

BIQAS quality control software is tailored to the actual needs of laboratory quality management work. The software adopts a B/S architecture mode, which simplifies the load on client computers while reducing the cost and workload of system maintenance and upgrade, providing a more convenient and optimized human-computer interaction experience for the laboratory.



## 01 Multidimensional QC data analysis

### a | QC Chart

- Qualitative/Quantitative Quality Control Chart
- Cumulative Sum Control Chart
- Patient-Based Real Time QC
- Youden Chart
- Westgard Method Decision Chart
- Power Function Graphs
- Out of Control Analysis Report

### b | QC Management

- Data monitoring
- Multiple L-J chart
- Performance Verification
- Retest Reserved Sample
- QC Screen

## 02 Various QC Report Statistics

- QC graphic data analysis report
- Monthly CV Statistical Analysis Report
- QC Rate Analysis Report
- Monthly Quality Control Data Analysis Report
- Out-of-control Record Statistical Analysis Report

## 03 Comprehensive QC Traceability Log

- Behavior log
- Result modification log
- Information modification Log
- Patient result evaluation log

## 04 Flexible QC settings

- Multiple targets setting methods.
- Multiple QC rule selection methods
- Customize out-of-control information settings

## 05 Intelligent user management

- Laboratory User Role Management
- Laboratory User Role Assignment
- Laboratory user login query

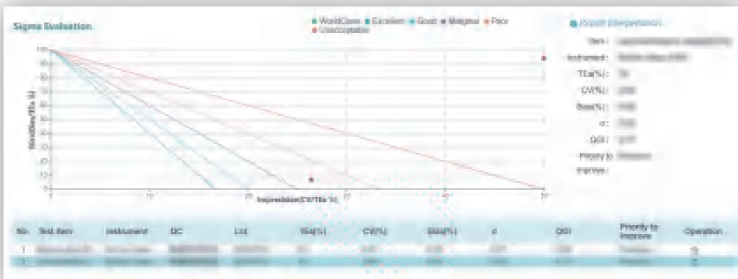




# Features

## Multi L-J chart

This function uses L-J plot overlay for project, quality control, and instrument testing comparisons to help evaluate the consistency between different instruments in the same project.

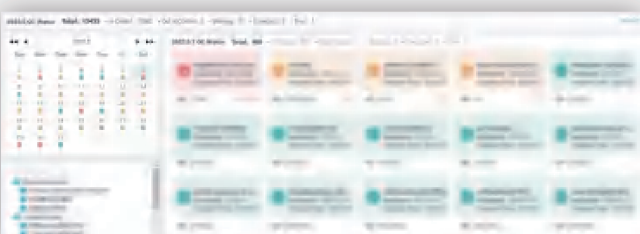
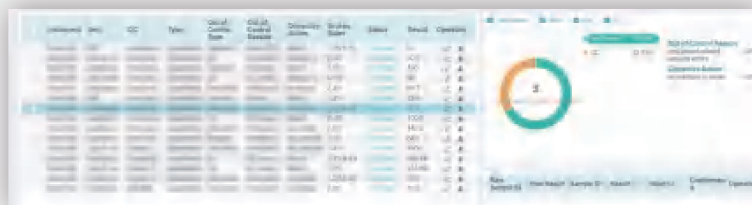


## Westgard method decision chart

This function uses the Six Sigma management to provide the lab with suitable QC rules.

## Out-of-Control Statistics and Analysis

Built-in common out-of-control information to get rid of manual filling. Record the process of losing control and evaluate patient samples for later statistics, analysis, and improvement.



## Data Monitoring

This function can display real-time QC status of different departments such as in control, out of control, and warnings. Assist the laboratory in quickly identifying abnormal items for targeted handling.

# Autobio & Bioyuan Control References

Product Category	Product Analyte	System						
		Autobio	Roche	Beckman	Abbott	Siemens	Canon	Other Platforms
Infectious Disease Control	HBsAg	AutoLumo Series						
	HBsAb	AutoLumo Series						
	HBeAg	AutoLumo Series						
	HBeAb	AutoLumo Series						
	HBcAb	AutoLumo Series						
	Anti-HIV	AutoLumo Series						
	Anti-HCV	AutoLumo Series						
	Anti-TP	AutoLumo Series						
	TOX IgG, HSV-1 IgG, CMV IgG, HSV-2 IgG, RV IgG	AutoLumo Series						Autobio Elisa
	TOX IgM, HSV-1 IgM, CMV IgM, HSV-2 IgM, RV IgM	AutoLumo Series						Autobio Elisa
Anti-HIV, Anti-HCV, Anti-TP, HBsAg, HBeAg	AutoLumo Series							
HIV p24 Ag, Anti HBs, Anti Hbe, Anti HBc	AutoLumo Series							
Tumor Marker Control	AFP, CEA, CA125, CA15-3, CA19-9, CA50, Ferr, tPSA, and fPSA	AutoLumo Series						
	AFP, CEA, CA125, CA15-3, CA19-9, CA50, Ferr, tPSA, fPSA, β2-MG, CA72-4, Cyfra21-1, SCCA, CA242, NSE, PGI, PGI1, HE4, β-HCG, TG	AutoLumo Series	Cobas e601,c701	DXI 800	Architect i2000SR	Advia Centaur XP		Maglumi 4000Plus, Luminex 200
Clinical Chemistry Control	K, Na, CL, Ca, P, Mg, Li, Cu, Zn, Fe, TIBC, GLU, Urea, UA, Cre, TBIL, DBIL, TBA, TC, TG, HDL-C, LDL-C, ALB, TP, ALT, AST, ALP, Amy, CK, LDH, GGT, HBDH, LPS, CHE, CO2, LAC		Cobas c501, c502, c701	AU5800, AU5400, AU680			TBA-120FR	
			Cobas c501, c701	AU5800, AU5400, AU680		TBA-120FR		
Lipid Control	Apo A-1, Apo B, TG, HDL-C, LDL-C, TC, Lp (a)		Cobas c501, c701	AU5800, AU5400, AU680			TBA-120FR	

Product Category	Product Analyte	System						
		Autobio	Roche	Beckman	Abbott	Siemens	Canon	Other Platforms
Protein Chemistry Control	PAB, IgE, IgA, IgG, IgM, CRP, RBP, α1-MG, β2-MG, RF, TRF, C4, C3, ASO, ALB, TP, λ- LC, κ- L, AAT, HPT, Ferr, CysC		Cobas c501, c502, c701, e601	AU5800, AU680		Siemens BN ProSpec	TBA-120FR	
Endocrine Control	FSH, PRL, LH, P, T, E2, β- HCG, TSH, T3, T4, FT3, FT4, TG, INS, C-peptide, IGF-1, HGH, ALD, Cortisol, ACTH, 17α- OHP, DHEA-S, FA, VB12, 25-OH VD	AutoLumo Series	Cobas e601,c701	DXI 800	Architect i2000SR	Advia Centaur XP		Autobio Elisa
Diabetes Control	HbA1c	AutoLumo Series	Cobas c501,	AU680				Bio-Rad D-10, ARKRAY HA-8180, Lifotronic H9
Cardiac Marker Control	CK, CK-MB, cTnI, cTnT, CRP,BNP, MYO, NT-proBNP, HCY,H-FABP, Dig	AutoLumo Series	Cobas c501, e601	Access 2, AU680	Architect i2000SR		TBA-120FR	Getein1100, Wondfo FS-112, i-CHROMATM Reader
Calcitonin Control	PCT	AutoLumo Series	Cobas e601					Wondfo FS-112, i-CHROMATM Reader, Maglumi 2000
C-reactive Protein Control	CRP	AutoLumo Series	Cobas c501					Getein1100, Wondfo FS-112, i-CHROMATM Reader
Liver Fibrosis Markers Controls	HA, LN, PIIINP, Col IV, CG	AutoLumo Series						
Coagulation Control	PT, APTT, TT, FIB, ATIII							Sysmex CS-5100, Sysmex CS-2000i, STA-R Evolution, Werfen ACL TOP 750
Urine Chemistry Control	BIL, BLD, NIT, KET, pH, LEU, GLU, URO, SG, ALB							Dirui H-500, URIT-1600

Product Category	Product Analyte	System						
		Autobio	Roche	Beckman	Abbott	Siemens	Canon	Other Platforms
Anti-Mullerian Hormone Control	AMH	AutoLumo Series	Cobas e601					Sysmex CS-2000i, Wondfo FS-112, Getein FIA8699
D-Dimer Control	D-dimer		Cobas c501				TBA-2000 FR, TBA-FX8	
Blood Glucose Control	GLU		Blood glucose meter		Blood glucose meter			Aikang blood glucose meter
Glycated Albumin Control	GA			AU680			TBA-120FR	
Inflammatory Marker Control	PCT, CRP, SAA, MPO, IL-6, Lp PLA2	AutoLumo Series	Cobas e601	Access 2, AU680			TBA-120FR, TBA-FX8	Wondfo FS-112





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