

华大吉比爱  
BGI · GBI

华大BGI | 华大吉比爱  
BGI · GBI

# BGI-GBI<sup>®</sup> Product Catalogue



Tel: +86 10 80492001 +86 10 80492002  
Fax: +86 10 80492118  
Add.: No.8 Building, 28 Yuhua Road, Airport Economic Core Zone,  
Shunyi District, Beijing, China 101300  
Email: bgi-gbiglobal@bgi.com  
Website: www.bgi.com.cn www.gbidiagnostics.com

GBI-MARKET-220727

## Ordering Information

### BGI-GBI COVID-19 Detection Holistic Solution

Product	Principle of Detection	Package Size	Catalogue No.	CE Registration No.
SARS-CoV-2 (COVID-19) Antigen Rapid Detection Kit (Fluorescence Immunochromatographic)	The fluorescent labeling and double antibody sandwich membrane chromatography method	5/50 tests/kit	0604010S/ 0604010	RPS/2239/2020
SARS-CoV-2 Total Antibody Detection Kit (Fluorescence Immunochromatographic)	The fluorescent labeling and double antigen sandwich membrane chromatography method	50 tests/kit	0604008	RPS/1774/2020
SARS-CoV-2 Virus IgM Antibody Detection Kit (ELISA)	IgM-Capture method ELISA	96 tests/kit	0601039	LMST ref. 2020033657
SARS-CoV-2 Virus IgG Antibody Detection Kit (ELISA)	Indirect method ELISA	96 tests/kit	0601038	LMST ref. 2020033656
SARS-CoV-2 Neutralizing Antibody Detection Kit (ELISA)	Competitive method ELISA	96 tests/kit	0601151	RPS/373/2021
SARS-CoV-2 (2019-nCoV) Detection Kit (PCR-probing)	Reverse transcription PCR	50 tests/kit	0603222	RPS/2486/2020

▲ 10,000 and 100,000 cleanliness GMP production workshop  
The first batch of high-tech enterprises approved by GMP in China



Founded in 1994, Beijing BGI-GBI Biotech Co., Ltd.(GBI) is the core subsidiary of BGI Group which is one of the largest genomic organizations in the world. GBI mainly focuses on the business including R&D, manufacture and sales of In Vitro Diagnostic (IVD) kits and clinical lab services. GBI is among the first batch of IVD enterprises who have obtained GMP certificate in China. All the blood-screening products have 100% passed inter-batch inspection of National Medical Product Administration(NMPA) for over 20 years in a row, and GBI has repeatedly ranked first with full marks in clinical quality assessment organized by the National Center for Disease Control and Prevention(NCDCP).

To improve people's health, we innovate medical detection model and enhance the efficiency of diagnosis and treatment. GBI is one of IVD enterprises which possesses the most comprehensive platforms. So far GBI has established methodological platforms such as mass spectrometry, nucleic acid testing, ELISA, CLIA, CMIA, POCT, gene sequencing and so on covering fields like reproductive health, cancer screening and medication, regular diseases, infectious diseases, blood screening, and nutrition detection. We have independently developed more than 100 categories of diagnostic kits approved by NMPA and have obtained EU-CE Markings for most products. In 2018, GBI undertook National S&T Major Project of China and One Belt One Road national research task. We have deep cooperation with hospitals in China, and we are also one of the largest reagent suppliers of large-scale physical examinations and healthcare centers. Not only have we focused on people's livelihood for a long run, GBI has also played an important role in providing aids against major disasters such as SARS, H1N1, and COVID-19.

#### International Orders

More than 10 million tests ordered  
from 89 countries and regions  
focused on epidemic prevention  
and control.

#### Global Deployment

China:  
Currently Operating:10, Developing Cooperation: 5, Under Construction: 1  
Overseas: Labs Started: 70+



Last Updated: May 6th, 2020



# BGI-GBI Chemiluminescence magnetic microparticle immunoassays (CMIA) POCT



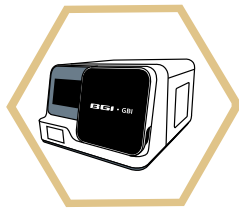
BGI-MAP 800



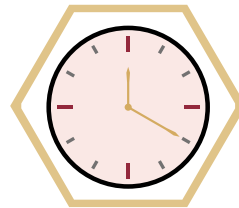
BGI-MAP 800Plus

Automatic Chemiluminescent Immunoassay Analyzer (POCT)  
BGI-MAP series

## Advantages



Small in size



Short testing time:  
results in 20 minutes



Simple operation



No waste

Product	Principle of Detection	Package Size	Catalogue No.	CE Registration No.
<b>Stomach Related POCT Tests</b>				
Pepsinogen I (PGI)	POCT CMIA	24/48 tests/kit	061601013	RPS/62/2022
Pepsinogen II (PGII)	POCT CMIA	24/48 tests/kit	061601014	RPS/63/2022
Gastrin-17 (G-17)	POCT CMIA	24/48 tests/kit	061601018	RPS/1942/2021

Product	Principle of Detection	Package Size	Catalogue No.	CE Registration No.
<b>Cardiovascular Disease Related POCT Tests</b>				
Cardiac Troponin I (cTnI)	POCT CMIA	24/48 tests/kit	061601001	RPS/169/2021
Myoglobin (Myo)	POCT CMIA	24/48 tests/kit	061601002	RPS/170/2021
Creatine Kinase-MB (CK-MB)	POCT CMIA	24/48 tests/kit	061601003	RPS/168/2021
N-terminal proBNP (NT-proBNP)	POCT CMIA	24/48 tests/kit	061601004	RPS/171/2021
Heart-type Fatty Acid Binding Protein (H-FABP)	POCT CMIA	24/48 tests/kit	061601015	RPS/1012/2021
D-dimer (DD)	POCT CMIA	24/48 tests/kit	061601006	RPS/1940/2021
High-sensitivity C-reactive Protein (hs-CRP)	POCT CMIA	24/48 tests/kit	061601005	RPS/546/2021
<b>Inflammation Related POCT Tests</b>				
High-sensitivity C-reactive Protein (hs-CRP)	POCT CMIA	24/48 tests/kit	061601005	RPS/546/2021
Procalcitonin (PCT)	POCT CMIA	24/48 tests/kit	061601007	RPS/1013/2021
Interleukin-6 (IL-6)	POCT CMIA	24/48 tests/kit	061601008	RPS/623/2021
Serum Amyloid A Protein (SAA)	POCT CMIA	24/48 tests/kit	061601009	RPS/1174/2021
<b>Pregnancy Related POCT Tests</b>				
$\beta$ -human Chorionic Gonadotropin ( $\beta$ -hCG)	POCT CMIA	24/48 tests/kit	061601010	RPS/1175/2021
Progesterone (PROG)	POCT CMIA	24/48 tests/kit	061601011	RPS/1402/2021
Anti Mullerian Hormone (AMH)	POCT CMIA	24/48 tests/kit	061601012	RPS/1941/2021
Luteinizing Hormone (LH)	POCT CMIA	24/48 tests/kit	061601016	RPS/1403/2021
Follicle Stimulating Hormone (FSH)	POCT CMIA	24/48 tests/kit	061601017	RPS/1404/2021

## BGI-GBI Chemiluminescence magnetic microparticle immunoassays (CMIA)




MAE-1200i



MAE-2000i

### Automatic Chemiluminescent Immunoassay Analyzer BGI-MAE series

Product	Principle of Detection	Package Size	Catalogue No.	CE Registration No.
<b>Tumor Marker Tests</b>				
 Alpha-Fetoprotein (AFP)	CMIA	100/500 tests/kit	0615023	RPS/726/2021
Carbohydrate Antigen 50 (CA50)	CMIA	100/500 tests/kit	0615024	00170076
Cytokeratin 19 Fragment (CYFRA21-1)	CMIA	100/500 tests/kit	0615025	00170084
Carbohydrate Antigen 242 (CA242)	CMIA	100/500 tests/kit	0615026	00170080

Product	Principle of Detection	Package Size	Catalogue No.	CE Registration No.
β 2-Microglobulin (β 2-MG)	CMIA	100/500 tests/kit	0615027	00170097
Squamous Cell Carcinoma Antigen (SCC)	CMIA	100/500 tests/kit	0615028	00170095
Human Growth Hormone (hGH)	CMIA	100/500 tests/kit	0615029	00170087
Neuron-Specific Enolase (NSE)	CMIA	100/500 tests/kit	0615030	00170089
Carbohydrate Antigen 19-9 (CA19-9)	CMIA	100/500 tests/kit	0615031	00170079
Carbohydrate Antigen 72-4 (CA72-4)	CMIA	100/500 tests/kit	0615032	00170081
Human Epididymis Protein 4 (HE-4)	CMIA	100/500 tests/kit	0615033	00170086
Carcinoembryonic Antigen (CEA)	CMIA	100/500 tests/kit	0615034	00170082
Carbohydrate Antigen 125 (CA125)	CMIA	100/500 tests/kit	0615037	00170077
Carbohydrate Antigen 15-3 (CA15-3)	CMIA	100/500 tests/kit	0615038	00170078
Ferritin (FERR)	CMIA	100/500 tests/kit	0615039	00170085
Pepsinogen I (PGI)	CMIA	100/500 tests/kit	0615040	00170091
Pepsinogen II (PGII)	CMIA	100/500 tests/kit	0615041	00170092
Pro-Gastrin Releasing Peptide (ProGRP)	CMIA	100/500 tests/kit	0615042	00170093
Total Prostate Specific Antigen (tPSA)	CMIA	100/500 tests/kit	0615035	Processing
Free Prostate Specific Antigen (fPSA)	CMIA	100/500 tests/kit	0615036	Processing



### Inflammation Related Tests

C-Reactive Protein (CRP)	CMIA	100/500 tests/kit	061601005	RPS/546/2021
Interleukin-6 (IL-6)	CMIA	100/500 tests/kit	061601007	RPS/1013/2021
Procalcitonin (PCT)	CMIA	100/500 tests/kit	061601008	RPS/623/2021
Serum Amyloid A Protein (SAA)	CMIA	100/500 tests/kit	061601009	RPS/1174/2021

# BGI-GBI Liquid chromatography tandem mass spectrometry (LC-MS)

The mass spectrometry detection platform kit is based on Triple Quadrupole Tandem Mass Spectrometric to study and detect target small molecules. At present, quantitative analysis and detection of target proteins, polypeptides and various small molecules are carried out. Most of the kits have been certificated in NMPA or CE.



BGI is responsible for the proteome study of chromosome-based HPP (Chromosome-HPP) of the Human Proteome Project (HPP).



Certified by the CDC for many years.



DEQAS assessment and certification (one of the world's authoritative vitamin D testing inter-laboratory quality assessment).



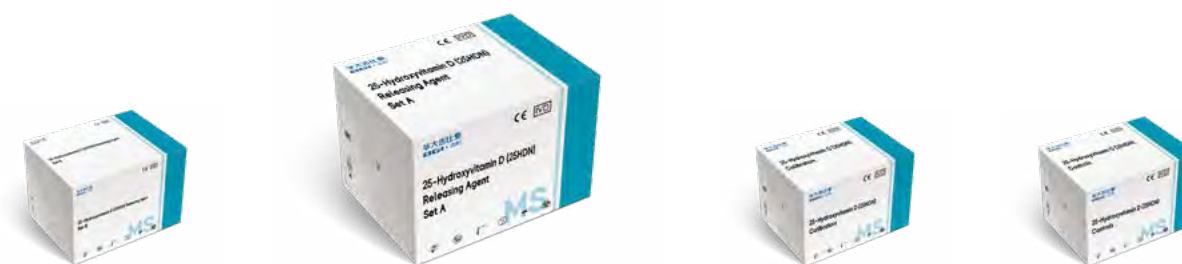
ISO 15189, ISO9001/14001, OHSAS18001 certification.



- 1 Linearity  $R \geq 0.99$
- 2 Sensitivity  $\leq 20\text{pg/mL}$
- 3 Matrix effects and accuracy 85%~115%
- 4 Intra-assay precision  $\leq \pm 6\%$ ;  
Inter-assay precision  $\leq \pm 15\%$
- 5 Methodological comparison Bias  $\leq \pm 15\%$ ;  
correlation coefficient  $R \geq 0.99$



Catecholamine (CA) and Metabolites



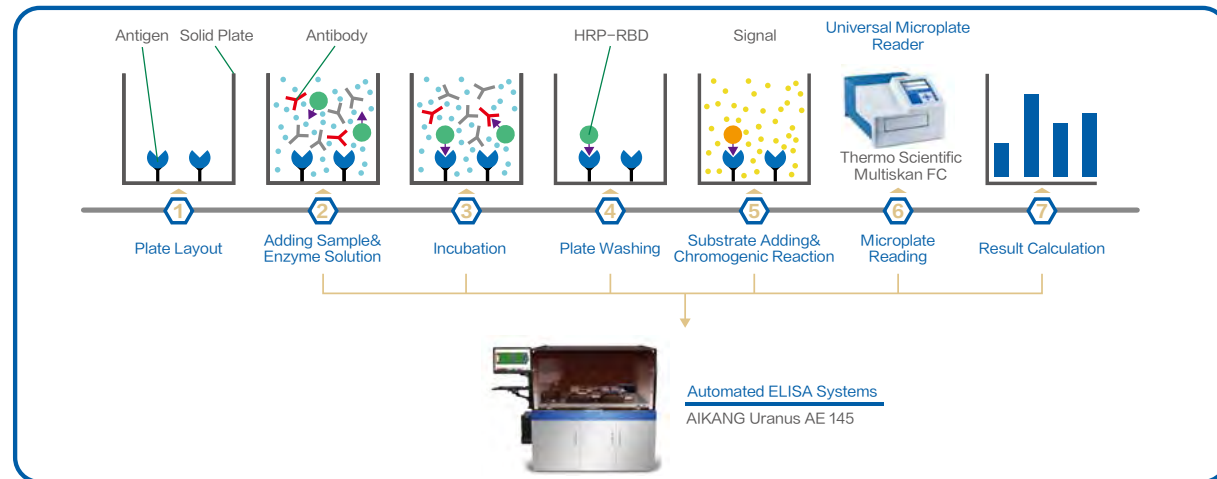
25-Hydroxyvitamin D (25HDN)

BGI-GBI LC-MS		
Product	Catalogue No.	CE Registration No.
25-Hydroxyvitamin D (25HDN) Releasing Agent	0612066	RPS/2585/2022
25-Hydroxyvitamin D (25HDN) Calibrators	0612067	RPS/2586/2022
25-Hydroxyvitamin D (25HDN) Controls	0612068	RPS/2587/2022
Catecholamine (CA) and Metabolites Releasing Agent	0612069	RPS/2580/2022
Serum Catecholamine (CA) and Metabolites Calibrators	0612070	RPS/2581/2022
Serum Catecholamine (CA) and Metabolites Controls	0612071	RPS/2582/2022
Urine Catecholamine (CA) and Metabolites Calibrators	0612072	RPS/2583/2022
Urine Catecholamine (CA) and Metabolites Controls	0612073	RPS/2584/2022



# BGI-GBI Enzyme-linked immunosorbent assay (ELISA)

## Protocol Diagram and Instruments



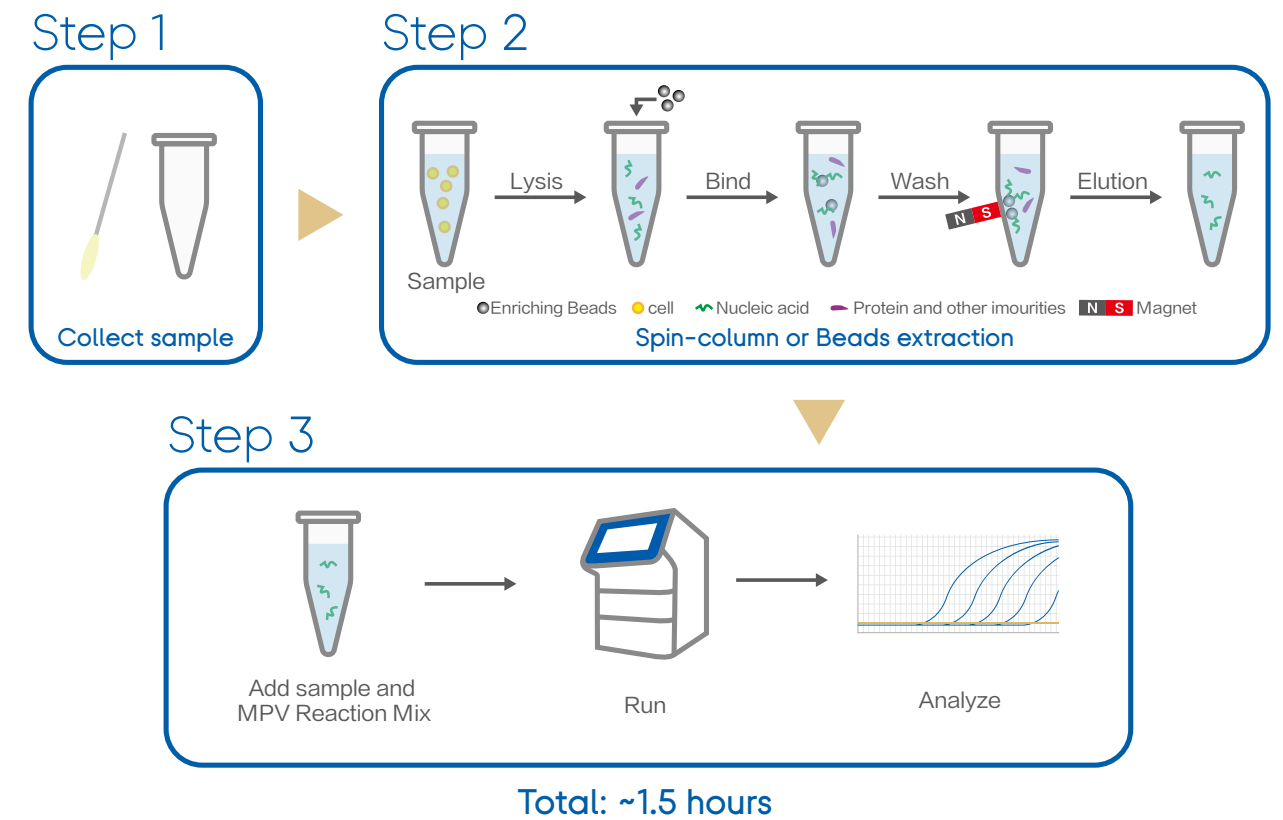
\*The above-mentioned content is only used as an example to illustrate the assay.



Product	Principle of Detection	Package Size	Catalogue No.	CE Registration No.
Dengue Virus IgG Antibody	Indirect Method ELISA	96 tests/kit	0601148	RPS/2237/2020
Japanese Encephalitis Virus IgM Antibody	IgM-Capture Method ELISA	96 tests/kit	0601147	RPS/2238/2020
Hepatitis E Virus IgG Antibody	Indirect Method ELISA	96 tests/kit	0601048	RPS/701/2021
Hepatitis E Virus IgM Antibody	IgM-Capture Method ELISA	96 tests/kit	0601049	RPS/702/2021

# BGI-GBI Nucleic acid RT-PCR

## Workflow



## Applicable Instruments

ABI 7500 fluorescence PCR instrument, Hongshi SLAN-96P fluorescence quantitative PCR instrument, etc.



\*The above-mentioned content is only used as an example to illustrate the assay.



The kits and equipments shown in here are for demonstration only, and the actual appearance and packaging is subject to the versions of each country and region.

Product	Principle of Detection	Package Size	Catalogue No.	CE Registration No.
EGFR-29 Mutations	PCR-Fluorescence Probing	24 tests/kit	0603219	RPS/2351/2020
K-ras-8 Mutations	PCR-Fluorescence Probing	24 tests/kit	0603220	RPS/2352/2020
Monkeypox Virus (MPV)	PCR-Fluorescence Probing	32 tests/kit	0603232	RPS/3934/2022
Mycobacterium Tuberculosis	PCR-Fluorescence Probing	32 tests/kit	0603218	RPS/2353/2020
Granular Corneal Dystrophy (GCD) SNP	PCR-Fluorescence Probing	32 tests/kit	0603226	00171479

## EX-48 Automatic Nucleic Acids Extraction Apparatus

The EX48 Automatic Nucleic Acids Extraction Apparatus is used in conjunction with the BGI-GBI® Viral DNA/RNA Nucleic Acid Extraction Reagent (Magnetic Bead Method), which is suitable for the extraction of viral nucleic acid from human serum and plasma.

Product Name	NMPA Registration No.	Catalogue No.
EX-48 Automatic Nucleic Acids Extraction Apparatus	Jinghai Machinery No. 20170051	0608018
Viral DNA/RNA Nucleic Acid Extraction Reagent	Jinghai Machinery No. 20160085	0603212



EX-48 Automatic Nucleic Acids Extraction Apparatus



Viral DNA/RNA Nucleic Acid Extraction Reagent

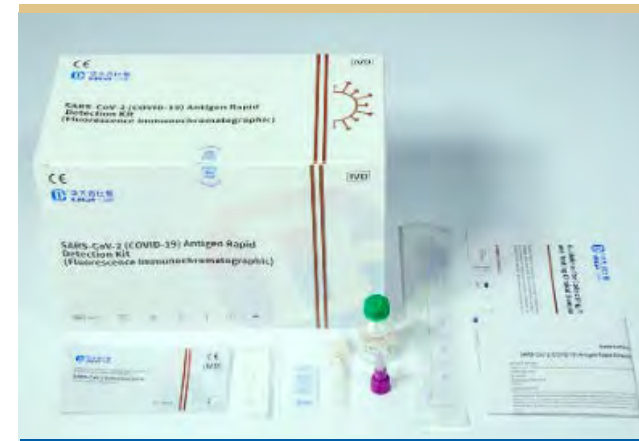
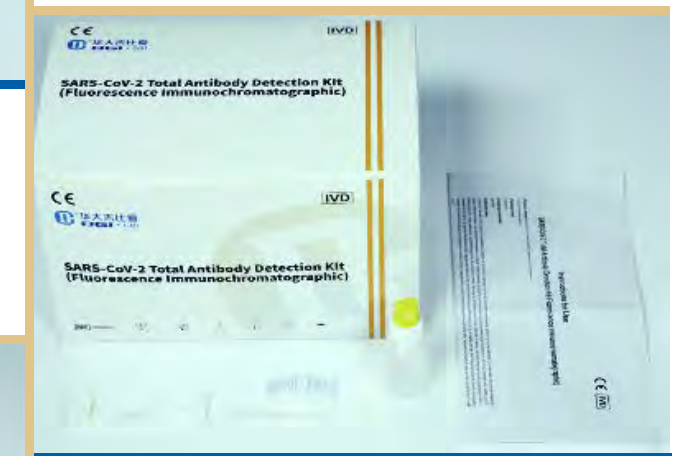
## BGI-GBI Immunochromatography

- Simple equipment
- Low cost
- Storage & transportation
- Flexible throughput
- Convenient operation
- Rapid detection
- Short incubation period
- High performance
- Patient-friendly sample collection types
- Easy sample processing



Sickle Cell Anemia (SCD)

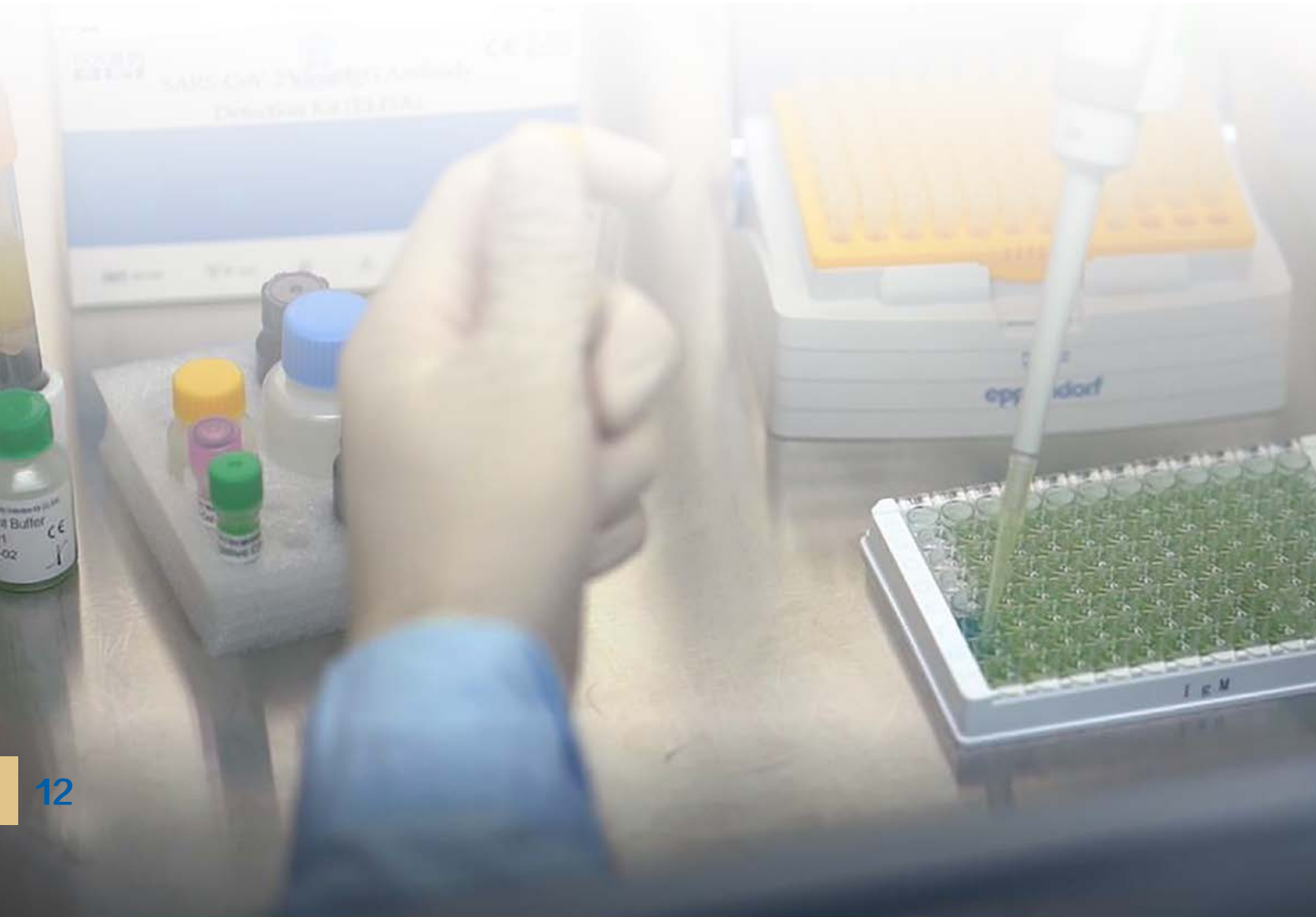
SARS-CoV-2 Total Antibody



SARS-CoV-2 Antigen



Product	Principle of Detection	Package Size	Catalogue No.	CE Registration No.
<b>COVID-19 POCT Tests</b>				
SARS-CoV-2 Total Antibody	The fluorescent labeling and double antigen sandwich membrane chromatography method	50 tests/kit	0604008	RPS/1774/2020
SARS-CoV-2 Antigen	The fluorescent labeling and double antibody sandwich membrane chromatography method	5/50 tests/kit	0604010S/0604010	RPS/2239/2020
<b>Anemia POCT Tests</b>				
Sickle Cell Anemia (SCD)	Colloidal Gold Chromatographic Immunoassay	50 tests/kit	0604012	00170096



## Quality Benchmark

Qualified national GMP certification and had a production plant with reverse osmosis combined with EDI purification water preparation system, automatic coating machine and liquid machine in 2000, which ensured the quality and stability of production. GBI is one of the main companies with all products passing "Batch-batch inspection" of NIFDC (The National Institute for Food and Drug Control). In 2017, a new IVD plant was constructed and GBI won "Best Quality Award" from BGI group.





The following kits are unregistered CE-qualified products and for research use only.

CMIA	
<b>Thyroid Function</b>	
Triiodothyronine (T3) Quantitative Assay Kit *	Free Triiodothyronine (FT3) Quantitative Assay Kit *
Thyroxine (T4) Quantitative Assay Kit *	Free-Thyroxine (FT4) Quantitative Assay Kit *
Anti-Thyroid Peroxidase Antibody (TPO-Ab) Quantitative Assay Kit *	Anti-Thyroid Microsomal Antibodies (TM-Ab) Quantitative Assay Kit *
Thyroid Stimulating Hormone (TSH) Quantitative Assay Kit *	Anti Thyroglobulin Antibody Quantitative Assay Kit (TG-Ab) *
<b>Sexual Gland Hormone</b>	
Estradiol (E2) Quantitative Assay Kit *	Progesterone (P) Quantitative Assay Kit *
Follicle stimulating hormone (FSH) Quantitative Assay Kit *	Beta Human Chorionic Gondotropin ( $\beta$ -hCG) Quantitative Assay Kit *
Luteinizing Hormone (LH) Quantitative Assay Kit *	Testosterone (T) Quantitative Assay Kit *
Prolactin (PRL) Quantitative Assay Kit *	
<b>Diabetes</b>	
Insulin (Ins) Quantitative Assay Kit *	C-peptide Quantitative Assay Kit *
Anti-glutamic acid decarboxylase Antibody Quantitative Assay Kit *	Anti-protein tyrosine phosphorylase Antibody Quantitative Assay Kit *
Anti-insulin Antibody Quantitative Assay Kit *	
<b>Communicable Diseases</b>	
Diagnosis of Communicable Diseases Assay Kits *	Human Immunodeficiency Virus (HIV) Antibody Assay Kit *
Hepatitis B Virus E Antigen Assay Kits *	Hepatitis B Virus E Antibody Assay Kit *
Hepatitis B Virus Core Antibody Assay Kit *	Hepatitis B Virus Core Antibody IgM Assay Kit *
Hepatitis B Virus Pre S1 Antigen Assay Kit *	Hepatitis B Virus Pre S1 Antigen Assay Kit *
Hepatitis C Virus Antibody Assay Kit *	Treponema Pallidum Antibody Assay Kits *
Hepatitis E Virus Antibody Assay Kit *	Hepatitis E Virus Antibody IgG Assay Kit *

Hepatitis B Virus Surface Antibody Assay Kit *	
<b>Others</b>	
Wash Buffer *	Trigger and Pre-Trigger Solution for the automatic immunoassay system*
<b>ELISA</b>	
<b>Hepatitis Virus</b>	
IgM Antibody to Hepatitis A Virus Assay Kit *	E Antibody to Hepatitis B Virus Assay Kit *
Hepatitis B Virus Surface Antigen Assay Kit *	Antibody to Hepatitis C Virus Assay Kit *
Surface Antibody HBsAb to Hepatitis B Virus Assay Kit *	Core Antibody HBcAb to Hepatitis B Virus Assay Kit *
Hepatitis B Virus E Antigen Assay Kit *	
<b>ToRCH</b>	
IgM Antibody to ToRCH Toxoplasma Assay Kit *	IgM Antibody to ToRCH Rubella Virus Assay Kit *
IgM Antibody to ToRCH Herpes Simplex Virus Type I Assay Kit *	IgM Antibody to ToRCH Herpes Simplex Virus Type II Assay Kit *
IgM Antibody to ToRCH Cytomegalovirus Assay Kit *	
<b>Respiratory Disease</b>	
IgG Antibody to SARS Coronavirus Assay Kit *	IgM Antibody to Measles Virus Assay Kit *
IgM Antibody to SARS Coronavirus Assay Kit *	IgA Antibody to EBV-VCA Assay Kit *
<b>Sexually Transmitted Disease</b>	
Antibody to Human Immunodeficiency Virus Assay Kit *	Human Immunodeficiency Virus Antigen Assay Kit *
Antibody to Treponema Pallidum Assay Kit *	
<b>Others</b>	
IgG Antibody to Tick-borne Encephalitis Virus Assay Kit *	IgG Antibody to Hantan Virus (Hantaan Virus) Assay Kit *
<b>Array-ELISA</b>	
<b>Tumor Biomarkers</b>	Six Tumor Markers Assay Kit *
<b>ToRCH</b>	IgG Antibody to ToRCH Assay Kit *
<b>Autoimmune Diseases</b>	ENA Antibody Profile to Autoimmune Diseases

<b>Mycobacterium</b>	IgG Antibody Profile to Mycobacterium Tuberculosis Assay Kit *
<b>CLIA</b>	
<b>Tumor Biomarkers</b>	
Ferritin Quantitative Assay Kit *	Alpha-fetoprotein (AFP) Quantitative Assay Kit *
Carbohydrate Antigen 72-4 (CA72-4) Quantitative Assay Kit *	Prostate Specific Antigen (PSA) Quantitative Assay Kit *
Cytokeratin 19-Fragment (CYFRA21-1) Quantitative Assay Kit *	Free Prostate Specific Antigen (f-PSA) Quantitative Assay Kit *
Carbohydrate antigen 242 (CA242) Quantitative Assay Kit *	Carcinoembryonic Antigen (CEA) Quantitative Assay Kit *
Carbohydrate Antigen 125 (CA125) Quantitative Assay Kit *	Carbohydrate Antigen 50 (CA50) Quantitative Assay Kit *
Carbohydrate Antigen 15-3 (CA15-3) Quantitative Assay Kit *	Human Epididymis Protein 4 (HE-4) Quantitative Assay Kit *
Carbohydrate Antigen CA19-9 (CA19-9) Quantitative Assay Kit *	Squamous Cell Carcinoma Antigen Quantitative Assay Kit *
Neuron Specific Enolase (NSE) Quantitative Assay Kit *	Beta-2 microglobulin (β-2-MG) Quantitative Assay Kit *
Human Growth Hormone Quantitative Assay Kit *	
<b>Hepatic Fibrosis</b>	
Laminin (LN) Quantitative Assay Kit *	Hyaluronic Acid (HA) Quantitative Assay Kit *
Precollagen Type III (PCIII) Quantitative Assay Kit *	Collegen Type IV (C-IV) Quantitative Assay Kit *
<b>Diabetes</b>	
Insulin (Ins) Quantitative Assay Kit *	C-peptide Quantitative Assay Kit *
<b>Thyroid Function</b>	
Triiodothyronine (T3) Quantitative Assay Kit*	Free Triiodothyronine (FT3) Quantitative Assay Kit *
Thyroxine (T4 ) Quantitative Assay Kit*	Anti-Thyroid Peroxidase Antibody (TPO-Ab) Quantitative Assay Kit*
Free-Thyroxine (FT4) Quantitative Assay Kit*	Anti-Thyroid Microsomal Antibodies Quantitative Assay Kit (TM-Ab) *
Thyroid Stimulating Hormone (TSH) Quantitative Assay Kit *	Anti Thyroglobulin Antibody Quantitative Assay Kit (TG-Ab) *

<b>Sexual Gland Hormone</b>	
Estradiol (E2) Quantitative Assay Kit *	Progesterone (P) Quantitative Assay Kit *
Follicle stimulating hormone (FSH) Quantitative Assay Kit*	Testosterone (T) Quantitative Assay Kit *
Luteinizing Hormone (LH) Quantitative Assay Kit *	Beta Human Chorionic Gonadotropin (β-hCG) Quantitative Assay Kit *
Prolactin (PRL) Quantitative Assay Kit *	
<b>Nucleic Acid Testing Assay</b>	
<b>Human Papillomavirus</b>	
Human Papillomavirus 16 and 18 Nucleic Acid Assay Kit *	16 types of high-risk Human Papillomavirus Nucleic Acid Assay Kit *
<b>Targeted Thrapy Genome Detection</b>	
Detection Kit for 20 EGFR Mutations Nucleic Acid Assay Kit *	
<b>Infectious Diseases</b>	
Severe Fever with Thrombocytopenia Syndrome Bunyavirus Nucleic Acid Assay Kit *	Xinjiang Hemorrhagic Fever Virus Nucleic Acid Assay Kit *
Hantan Virus (Hantaan Virus) Nucleic Acid Assay Kit *	Tick-borne Encephalitis Virus Nucleic Acid Assay Kit *
Neisseria Meningitides Nucleic Acid Assay Kit *	Encephalitis B Virus Nucleic Acid Assay Kit *
Dengue Virus type I/II/III/IV Nucleic Acid Assay Kit *	Dengue Virus I Nucleic Acid Assay Kit *
Dengue Virus II Nucleic Acid Assay Kit *	Dengue Virus III Nucleic Acid Assay Kit *
Dengue Virus IV Nucleic Acid Assay Kit *	Dengue Virus Nucleic Acid Assay Kit *
<b>Hepatitis Virus</b>	
Hepatitis A Virus Nucleic Acid Assay Kit *	Hepatitis E Virus Nucleic Acid Assay Kit *
Quantification of Hepatitis B Virus Nucleic Acid Assay Kit *	Quantification of Hepatitis C Virus Nucleic Acid Assay Kit *
<b>Reproductive Health</b>	
Chlamydia trachomatis and Ureaplasma urealytium Nucleic Acid Assay Kit*	Neisseria gonorrhoeae Nucleic Acid Assay Kit *
<b>Influenza Virus</b>	
Influenza Virus A Nucleic Acid Assay Kit *	Influenza Virus H1N1 Nucleic Acid Assay Kit *



Influenza Virus A H1N1 (pdm2009) Nucleic Acid Assay Kit *	Influenza Virus A H10 Subtype Nucleic Acid Assay Kit *
Influenza Virus H3N2 Nucleic Acid Assay Kit	Influenza Virus A H9 Subtype Nucleic Acid Assay Kit *
Influenza Virus H5N1 Nucleic Acid Assay Kit *	Influenza Virus B Nucleic Acid Assay Kit *
Avian Influenza Virus H7N9 Nucleic Acid Assay Kit *	Influenza A/B virus Dual Nucleic Acid Assay Kit *
Influenza Virus B Yamagata/Victoria Typing Nucleic Acid Assay Kit *	Avian Influenza Virus H5-H7-H9 Nucleic Acid Assay Kit *
Avian Influenza Virus H7N9 Dual Nucleic Acid Assay Kit *	
<b>Respiratory Diseases</b>	
SARS Nucleic Acid Assay Kit *	Mumps Virus Nucleic Acid Assay Kit *
Human Coronavirus OC43 Nucleic Acid Assay Kit *	Human Coronavirus HKV1 Nucleic Acid Assay Kit *
Human Coronavirus NL63 Nucleic Acid Assay Kit *	Human Coronavirus 229E Nucleic Acid Assay Kit *
The Middle East Respiratory Syndrome Assay Kit *	Rhinovirus Nucleic Acid Assay Kit *
The Middle East Respiratory Syndrome Assay Kit *	Rhinovirus Nucleic Acid Assay Kit *
Mycoplasma Pneumoniae Nucleic Acid Assay Kit *	Adenovirus Nucleic Acid Assay Kit *
Chlamydia Pneumoniae Nucleic Acid Assay Kit *	Rubella Virus Nucleic Acid Assay Kit *
Streptococcus Pneumoniae Nucleic Acid Assay Kit *	Measles Virus Nucleic Acid Assay Kit *
Legionella Pneumophila Nucleic Acid Assay Kit *	Rubella/Measles Nucleic Acid Assay Kit *
Respiratory Syncytial Virus Nucleic Acid Assay Kit *	Chlamydia Psittaci Nucleic Acid Assay Kit *
<b>Intestinal Microorganism</b>	
Enterovirus Nucleic Acid Assay Kit *	Coxsackie A16 Virus Nucleic Acid Assay Kit *
EV71 Virus Nucleic Acid Assay Kit *	Coxsackie A6 and A10 Virus Nucleic Acid Assay Kit *
Genal Type Enterovirus + EV71 and CoxA16 Viruses Nucleic Acid Assay Kit *	Enterovirus enteric universal/EV71/CoxA16 Nucleic acid triple Assay kit *
EV71/CoxA16 nucleic acid dual Assay kit *	Norovirus Nucleic Acid Assay Kit *
Norovirus Nucleic GI Acid Assay Kit *	Norovirus Nucleic GII Acid Assay Kit *
Human Poliovirus 1 Nucleic Acid Assay Kit *	Human Poliovirus 2 Nucleic Acid Assay Kit *
Human Poliovirus 3 Nucleic Acid Assay Kit *	Neisseria Meningitidis Nucleic Acid Assay Kit *
E.coli O157 Nucleic Acid Assay Kit *	Human Echovirus Nucleic Acid Assay Kit *

Vibrio cholerae O1 and enterotoxin gene Assay Kit *	Salmonella Nucleic Acid Assay Kit *
Mononucleosis Listeria Bacteria Nucleic Acid Assay Kit *	
<b>Others</b>	
Hemolytic Streptococcus B Nucleic Acid Assay Kit *	Pseudomonas Mallei Nucleic Acid Assay Kit *
Neisseria Meningitidis Nucleic Acid Assay Kit *	West Nile Virus Nucleic Acid Assay Kit *
Cryptosporidium Parvum Nucleic Acid Assay Kit *	Typhi Salmonella Nucleic Acid Assay Kit *
Eastern Equine Encephalitis Virus Nucleic Acid Assay Kit *	Venezuelan Equine Encephalitis Virus Nucleic Acid Assay Kit *
St. Louis Encephalitis Virus Nucleic Acid Assay Kit *	Streptococcus Suis Nucleic Acid Assay Kit *
Rickettsia Prowazekii Nucleic Acid Assay Kit *	Brucella Nucleic Acid Assay Kit *
Rickettsia Burneti Nucleic Acid Assay Kit *	Nipah Virus Nucleic Acid Assay Kit *
Hemorrhagic Fever with Renal Syndrome Nucleic Acid Assay Kit *	Western Equine Encephalitis Virus Nucleic Acid Assay Kit *
Pasteurella Multocida Nucleic Acid Assay Kit *	Cytomegalovirus ( CMV) Nucleic Acid Assay Kit *
Marburg Virus Nucleic Acid Assay Kit *	Yersinia Pestis Nucleic Acid Assay Kit *
Pseudomonas Melioides Nucleic Acid Assay Kit *	Francisella Tularensis Nucleic Acid Assay Kit *
Lassa Fever Virus Nucleic Acid Assay Kit *	Yellow Fever Virus Nucleic Acid Assay Kit *
Machupo Virus Nucleic Acid Assay Kit *	Zaire Ebola Virus Nucleic Acid Assay Kit *
Bacillus Anthracis Nucleic Acid Assay Kit *	Sudan Ebola Virus Nucleic Acid Assay Kit *
Reston Ebola Virus Nucleic Acid Assay Kit *	Chikungunya Virus Nucleic Acid Assay Kit *
Hendra Virus Nucleic Acid Assay Kit *	Rickettsia Tsutsugamushi Nucleic Acid Assay Kit *
Zika Virus Nucleic Acid Assay Kit *	Parvovirus B19 Nucleic Acid Assay Kit *
Chlamydia Psittaci Nucleic Acid Assay Kit *	
<b>Intestinal Cancer</b>	
Methylation Detection Kit for Septin9, ALX4 and SDC2 *	
<b>Nucleic Acid Isolation Machine and Reagents</b>	
EX-48 Automatic Nucleic Acids Extraction Apparatus *	Viral DNA/RNA Nucleic Acid Extraction Kit *

## Colloidal Gold

TP Strip \*

TP Card \*

Diagnosis of Treponema Pallidum \*

## LC-MS/MS

### Human Nutrition Metabolism Detection

Human Amino Acid Assay Kit (20 types)\*

Human Fat-soluble Vitamins Assay Kit (5 types)\*

Water-soluble Vitamins Assay Kit (5 types)\*

Steroid Hormone Assay Kit (14 types)\*

### Others

Catecholamine and its Metabolite Assay Kit \*

Therapeutic Drug Monitoring Assay Kit (TDM)\*

Human Bile Acid Assay Kit\*

Note: \*Product is for scientific research type\product is under development.  
This product catalog is for reference only, please refer to the actual product name and registration certificate.

## Development History

### Exploring

**1994:** Founded in Beijing, devoted to research HIV, HCV, HEV and EBV diagnostic kits

**1996:** Undertook the research and development of HIV antibody ELISA detection kit in the Country 9th Five-Year Scientific and Technological Project

**1997:** Innovated HIV detection kits, ending the history of no domestic detection kits

**1998:** Joined in and provided financial support for the International Human Genome Project

**2000:** Qualified GMP certification

**2001:** Innovated TP antibody ELISA diagnostic kits and won the new drug certification and patents in China

### Innovation

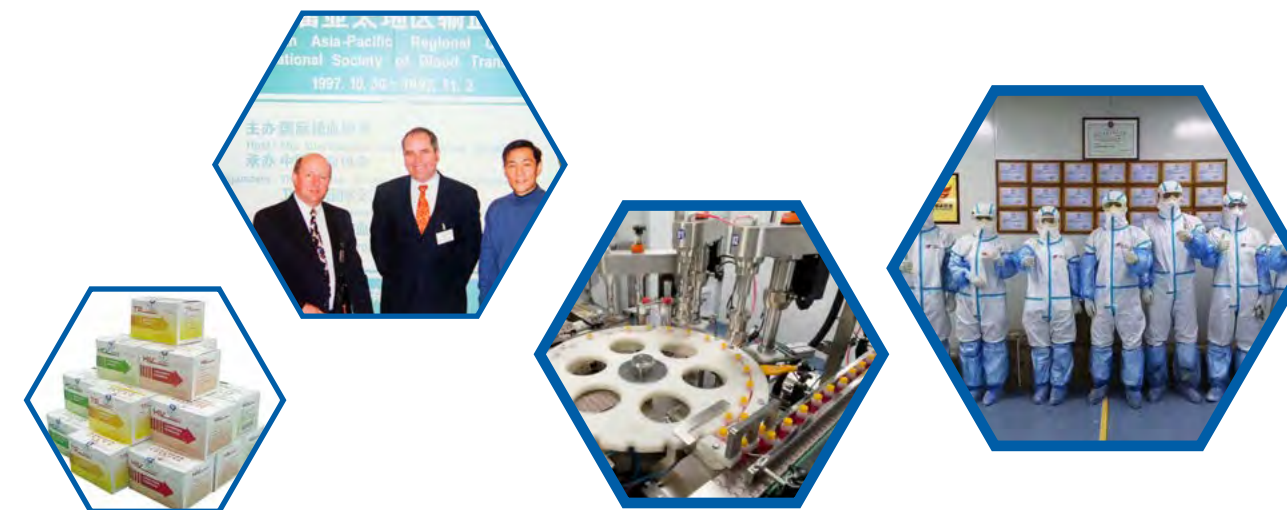
**2002:** Be awarded "High & New Technology Corporation"

**2003:** Innovated the SARS diagnostic kit approved by CFDA and denoted 300,000 detection reagent kits to Chinese government

**2004:** HIV1+2 type ELISA diagnostic kit had been funded by Beijing High-New Achievements Transformation Project and got the Technology Innovation Fund for small and medium-size enterprises of Ministry of Science and Technology

**2005:** Won the bid of Special Public Health Funds for Aids Prevention and Control Project organized by National Health Commission of China

**2006:** Accessed to national medical equipment production license and ranked the first in the clinical quality evaluation of HIV antibody diagnostic reagents organized by CDC





## Diversification

- 2007:** Passed ISO9001: 2000 Quality System Certification and developed Array-ELISA, a new innovation
- 2008:** Passed the field certification of category III and II IVD reagents organized by SFDA and Beijing FDA
- 2009:** Lead in developing the new H1N1 influenza virus diagnostic kits, Influenza A virus diagnostic kit and completed the detection of the first imported case in China. About 20 products such as thyroid function detection kit, gonadal hormone detection kit, insulin detection kit, liver fibrosis diagnostic kit had been certificated, which greatly enriched the product list and improve the company market competitiveness.
- 2010:** Passed the GMP field inspection and had the new GMP certification.
- 2011:** Got the Certificate of Pharmaceutical Product of HIV, HCV, TP, HBsAg. Some products had passed the Quality Management System Examination for Category 3 products by CFDA.
- 2012:** Awarded the certificates of nucleic acid diagnostic kits for EVs, HBV, TB virus and ELISA diagnostic kits for HEV and HAV.
- 2013:** Awarded the certificates of 16 type and 18 type HPV nucleic acid diagnostic kit.
- 2014:** Awarded the certificates of ToRCH IgG antibody, ToRCH IgM antibody, TB and the forth-generation HIV antigen and antibody diagnostic kits.

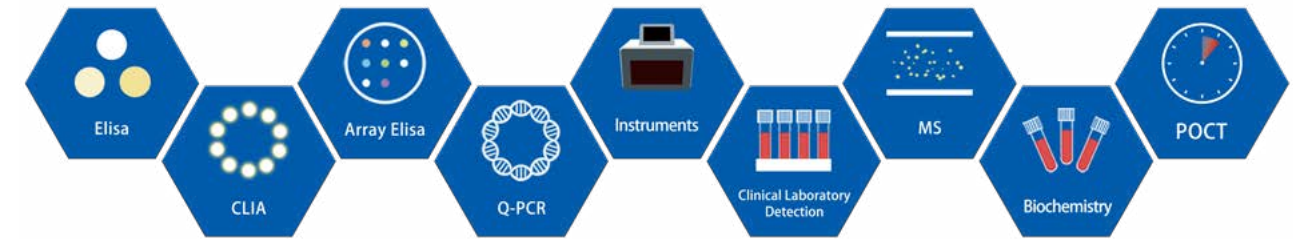
## Donation and Contribution for Society

- 2015:** Developed the new pattern of combination sales of kits and third party detection laboratory and awarded ISO13485 Quality System Certification.
- 2016:** Awarded the certificates of seventeen tumor markers which has been applied for the detections over 5 million samples, and also the certificates of EGFR and K-ras detection kits from nucleic acid platform in June 2016.
- 2017:** Undertook the hydatid disease antibody detection project of Tibet by detecting over 830,000 samples and won the "Best Quality Award" from BGI.
- 2018:** Took part in the "Zhejiang Province Two Cancer Screening Project" and "M. tuberculosis Major Specific Project" of the 13th Five-year Plan of Chinese government, R&D diagnostic kits for sudden acute infectious diseases, as the responsible unit in Chinese major national S&T projects, participated in research on improving the ability of prevention, control and disposal of important infectious diseases in China's peripheral areas and new HBV detection reagents and registration declaration organized by the Medical Science and Technology Development Research Center of CDC.
- 2019:** To promote school-enterprise cooperation, our company (GBI) signed an industry-university-research cooperation agreement with the School of Public Health of Lanzhou University. GBI and held the establishment ceremony of the "Lanzhou University Public Health and Preventive Medicine Teaching Research and Innovation Practice Base"; Human Immunodeficiency Virus (HIV) Antigen and Antibody Diagnostic Kit (ELISA), sample release agent, cleaning solution, and substrate liquid for automatic immunoassay system to obtain medical device registration certificate. GBI new product for Time of Light Mass Spectrometry (TOF) instrument and system are also launched.

## Industrial Pioneer

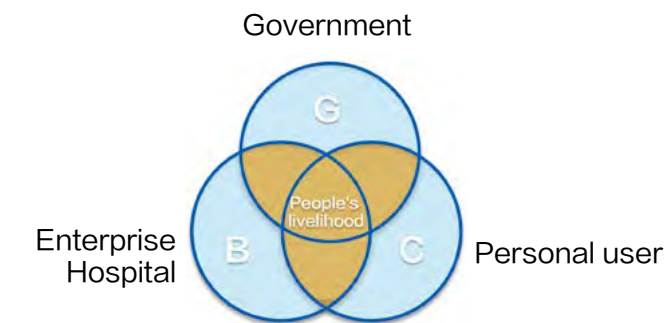
### Platform Development

Comprehensive products list



### Multiple end Markets

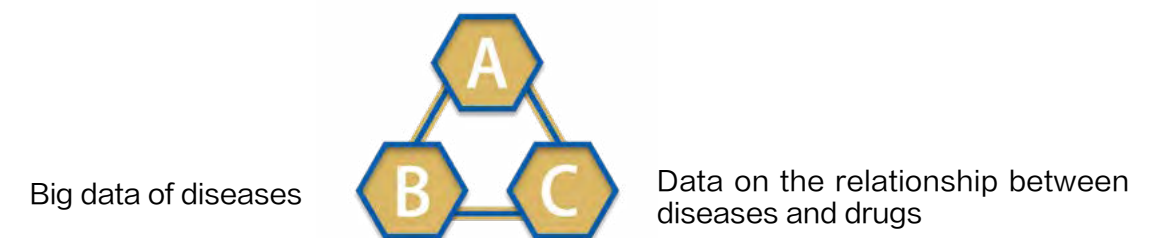
Diversified customer resources



### Data and Sample

Abundant samples and big data

Abundant and diversified samples



## Strong Research and Development Capability

Lead the industry and its development, Innovate the advanced technologies

GBI has funded and participated in many global projects, which strongly promotes the rapid development of the frontier scientific fields such as genome, protein and bioinformatics.

Projects Catalogue	Project Name
National Science Foundation of China	Mapping 1% of Human Genome Project
National Science Foundation of China	Whole Genome-Wide Screening SNP in Chinese People
Knowledge Innovation Program by CAS	Research on SARS Vaccine and Diagnosis
973 Project	Research on the Law of SARS-CoV Heredity and Variation
973 Project	Research on the Structure and Function of Nasopharyngeal Cancer-related Genes and Establishment of Information Database
International Cooperation by MOST	Domestic Pig Genome Project
Beijing Science and Technology Ministry	Construction of Drug-design-oriented Genomic Bioinformatics Data Analysis Platform
863 Project	Screening Anti-SARS Drug
863 Project	Super Hybrid Rice Genome Sequence
863 Project	Protein Expression Profile and Marker Protein Identification of Common Malignant Tumors in China
China-UK-US Cooperation Project	Thousand People Genome Project
Independent Project of BGI	Chinese Number One ( The First Chinese Genome Map ) , Chinese 99 Project, International Giant Panda Project
The Innovation Fund for STF	Diagnostic Kit for Autoimmune Disease ENA Antibody Spectrum
“The country’s 12th Five-year Plan” Major Project for Infectious Diseases	Declaration of Infectious Disease Diagnostic Reagent Industry Innovation Alliance in the HIV and HCV Major Infectious Diseases Specific Project
“The country’s 13th Five-year Plan” Major Project for Infectious Diseases	Evaluation of New Combined Detection Techniques for Latent Infection and Morbidity of Mycobacterium Tuberculosis
Major National Science and Technology Projects ( 2018 )	Research and Develop on Diagnostic Reagents for Sudden Acute Infectious Diseases R&D of New HBV Detection Reagents and Registration Declaration National S&T Major Projects.
One Belt One Road National Research Project	Research on Improving the Ability of Prevention, Control and Disposal of Important Infectious Diseases in China's Peripheral Areas organized by the Medical Science and Technology Development Research Center of CDC

## Social Responsibility

Social responsibility, one of the main corporate culture. GBI participated in wenchuan earthquake, SARS, Indian ocean tsunami, poor mountainous area, water cellar for mothers and many other public welfare projects.

People's life safety	In 2018, GBI undertook the Free Screening for Breast Cancer and Cervical Cancer project of Zhejiang province.
	In 2017, GBI undertook the hydatid disease antibody detection project for Tibet and detected 830 thousand samples.
	In 2009, GBI innovated the new H1N1 Influenza virus diagnostic kits and detected the first imported case to China.
	In 1996, GBI developed and produced HIV antibody ELISA diagnostic kits in 1996, ended the history of importing detection kits.
Public welfare and charity	During the Sichuan earthquake in 2008, GBI not only donated money and living materials to the disaster area, but also contributed HIV diagnostic kits to ensure the blood transfusion safety. GBI participated in the aseismic disaster emergency analysis and microbiological detection organized by China Ministry of Science and Technology.
	In 2003, GBI innovated the only SARS diagnostic kit approved by CFDA and denoted 300,000 detection kits to the national headquarters for SARS prevention and control of China Ministry of Science and Technology, the general office of the NPC standing committee, Guangdong provincial leading group on prevention and treatment of SARS and Institute of Microbiology Epidemiology, Military Academy of Sciences.
Production, education and science research	In 2019, to promote school-enterprise cooperation, our company (GBI) signed an industry-university-research cooperation agreement with the School of Public Health of Lanzhou University. GBI and held the establishment ceremony of the "Lanzhou University Public Health and Preventive Medicine Teaching Research and Innovation Practice Base".
	In 2018, GBI undertook the major research program of Chinese government for Mycobacterium tuberculosis infectious disease. In 2018, as the unit responsible for the project, GBI undertook the research and development of diagnostic reagents for sudden acute infectious diseases in major national science and technology projects organized by National Health Commission of the People's Republic of China. In 2018, Participated in research on improving the ability of prevention, control and disposal of important infectious diseases in China's peripheral areas organized by the Medical Science and Technology Development Research Center of CDC.
	In 2016, as the major research unit, GBI charged declaration of infectious disease diagnostic reagent industry innovation alliance in the HIV and HCV major infectious disease specific project of “the 12th Five-year Project” and obtained project special funding 19 million yuan.
	In 2007, GBI innovated the Array-ELISA detection method and products with high throughput and low cost application.
	GBI first developed TP antibody ELISA diagnostic kit and won the new drug certificates and domestic patent in 2001.
	GBI participated in and provided financial support for the International Human Genome Project in 1998.