One device with two different uses, more functions than what you see on this

GBIMToF-1000

About BGI Genomics Co., Ltd

On July 14, 2017, BGI Genomics was officially listed and became the 2001st listed company of the Shenzhen Stock Exchange. BGI Genomics is one of the world's leading genomics test and research service providers, providing genomics test and research services for medical institutions, research institutions, enterprises and institutions through genetic testing and other means. BGI Genomics is committed to helping and accelerating scientific innovation, strengthening the prevention and control of cancer and other genetic diseases, improving diagnostic tools for the rapid diagnosis of infectious disease and helping the development of precision medicine. Relying on cutting edge bioinformatics pipelines, advanced R&D, high-performance proprietary NGS sequencing technology, mass spectrometers,and underpinned by a decade of commercial experience, BGI Genomics provides its customers with expert and affordable clinical molecular diagnostic solutions and NGS services for research.

Wuhan BGI Biomedical Engineering Co.,Ltd is a subsidiary of BGI Genomics. Its business includes mass spectrometry platform, mass spectrometry automatic pretreatment system and mass spectrometry. R&D, production, sales of medical devices and provision of standardized clinical mass spectrometry laboratory overall solutions for supporting consumable products.

Big Data
1.45 million cases of genetic metabolic disease detection in newborns

Global cooperation
7300+ domestic universities and research institutes
100+covering countries and regions

Product registration
199 products have been approved for medical device registration or filing certificates

Product qualification

Medical device production license


ISO 13485:2016
Medical device quality management system certification


NMPA/CE

The company's mass spectrometry platform has been equipped with a full range of internationally advanced orbital ion trap mass spectrometers and Time-of-flight mass spectrometers, various types of liquid chromatography triple quadrupole mass spectrometers with high-throughput targeted protein and metabolite quantitative analysis, and other types of mass spectrometers such as inductively coupled plasma mass spectrometers and gas chromatography-mass spectrometers . Relying on the advantages of a comprehensive and advanced mass spectrometry platform, the company has actively developed a series of mass spectrometry in vitro diagnostic kits and neonatal disease screening management systems, and participated in the formulation of industry standards in clinical mass spectrometry related fields.

Industry-leading overall solution partner for clinical mass spectrometry laboratories

- Domestic self-developed clinical mass spectrometer
- Mass Spectrometry Automatic Pretreatment System
- Auxiliary equipment and consumables for mass spectrometer
- Clinical mass spectrometry detection kit
- Mass Spectrometry Medical Testing Services
- Customized mass spectrometry scientific research cooperation
- Professional clinical mass spectrometry laboratory Technical training system
- Perfect pre-sales and after-sales service support

Matrix-assisted laser desorption ionization time-of-flight mass spectrometer (MALDI-TOF MS) independently developed by Wuhan BGI Biomedical Engineering Co.,Ltd. The instrument is an automated medium-throughput mass spectrometry detection system specially designed for hospitals and clinical testing centers.

As a dual-function time-of-flight mass spectrometry detection system that can simultaneously perform microbial identification and nucleic acid detection and analysis, it is not only suitable for clinical isolation. It is also suitable for the qualitative detection of nucleic acid from human samples, including pathogens and human gene detection.

The time-of-flight mass spectrometry detection system is mainly composed of a target plate, a nucleic acid target plate adapter, a matrix-assisted laser desorption ionization source, a time-of-flight mass detector,Vertical ion flight tube, vacuum system, time-of-flight mass spectrometry detection system, microbial analysis and identification software BacTector (including database),The mass spectrometry detection system consists of nucleic acid detection and analysis software NuTyper and data acquisition card.

High fitness and high quality hardware system

Hardware performance characteristics

01	02	03	04	05
Double pulse delay extraction technology to ensure the full quality range **high resolution**	The modular design of the whole machine has a built-in backing pump, and the whole machine. More compact structure and easier maintenance	Using a solid-state laser, it can excite more than 2*10^9 times and the analysis speed is faster. Lifetime maintenance-free	The laser light path is close, vertical free introduction, vertical laser incident angle ⩽ 5°, effectively ensuring the number of ions reaching the detector and improving sensitivity	Intelligent, high pumping speed vacuum pump system.Sampling when entering the target without waiting

Detector
High Sensitivity Microchannel Plate (MCP) Electron Multiplier Detector

laser
Ultra-high frequency, long-life solid-state laser, maintenance-free for life

Ion Source
Integrated design, no-cleaning; double-pulse delay lead-out technology

Sample compartment
Ultra-fast inspection, single sample collection time only takes a few seconds

Flight tube
The length is 1002mm, ensuring the ion transmission efficiency

Backing pump
Built-in backing pump design, the whole machine structure is more compact

vacuum pump
High pumping speed molecular turbo pump, sampling can be done when entering the target

performance parameters

Quality range	mass resolution	sensitivity
1-200KDa For microbial identification: 2000~65000Da For nucleic acid detection: 4500~9000Da	For microbial identification: within the mass range,Mass resolution ⩾ 600 For nucleic acid detection: within the mass range,Mass resolution ⩾ 700	For microbial identification: detection absolute amount ⩽ 1pmol Bovine serum albumin BSA, signal to noise ratio ⩾ 10 For nucleic acid detection: detection absolute amount ⩽ 50 fmol standard, SNR ⩾ 10

mass accuracy	Quality repeatability	Quality stability
Mass-to-charge ratio maximum allowable error ⩽ 500ppm	Coefficient of variation of mass-to-charge ratio ⩽ 0.02%	The relative deviation of the mass-to-charge ratio within 8 hours does not exceed 300ppm

Fully automatic sample processing system MSP-96

[NMPA: No. 20210031]

Pretreatment according to the set process can be used for pre-analysis treatment and processing of medical clinical samples, and the processed products can be obtained for microbial identification and nucleic acid analysis and detection.

Strong Compatibility Double target board design

Compatible with nucleic acid samples (silicon target) and microbial samples (steel target), strong sample processing capabilities, and automatic time-of-flight mass spectrometry sample placement;

Multifunctional carrier, precise control

24-well reagent rack, which can accommodate up to 4 kinds of liquids; the design of the minimum dead volume at the bottom of the resin tank saves valuable reagents; the temperature control design of the target plate and sample area ensures precise control;

Advanced multi-channel, more accurate sample addition

The high-precision sampling tip cooperates with the 6-channel sampling arm to process multiple samples at the same time, and the sampling speed is faster, more accurate and more stable.

Fully automatic sample processing system EX-48

[NMPA: No. 20230020]

The automatic sample processing system EX-48 is used in conjunction with the virus nucleic acid extraction kit (magnetic bead method), and is suitable for the extraction of viral nucleic acids in human serum and plasma by clinical institutions.

high specificity

The specific combination of magnetic beads and nucleic acid makes the extracted nucleic acid high in purity and concentration; the optimized purification scheme and precise incubation time achieve efficient extraction;

fully automated

Fully automated; short time-consuming, 48 samples can be extracted at the same time in 20-30 minutes; independent operation, wizard-style operation interface, easy to operate;

Stable and effective

Strictly control the pollution between wells and batches; intelligently avoid errors and cross-contamination caused by human error, stable results and good repeatability;

Safe and reliable

Closed experimental cabin, disposable consumables, reduce operator contact with reagents; safe and non-toxic, no toxic reagents such as benzene and chloroform are used, reducing exposure hazards.

Basic parameters of automatic sample processing system EX-48

Sample throughput	48	Product Weight	36 kg	heating temperature	Cracking heating: room temperature ~+80 ℃
Processing volume	20 μL-1000 μL	Disinfection method	UV light	Oscillator module	Custom multi-mode multi-gear
Orifice Type	96 deep well plate (2.2mL)	Instrument interface	USB interface	operating time	20-30 minutes / time
Reagent type	Magnetic Bead Reagents	Rated voltage	AC220 V±22 V	Rated power	300 VA
extraction sensitivity	200 copies/mL positive sample detection rate	Rated current	50 Hz	Product Size	600 mm*420 mm*400 mm (L*W*H

Software system

Automated control acquisition software, whole-process intelligent monitoring of instrument status Provide two types of software for two-way service microbial identification and nucleic acid detection and analysis

Microbial Identification - **BacTector Software**

BacTector Software appraisal result interface

- Professional and convenient off-line analysis software, bacteria originate from the accumulation of CDC cooperative research of the Chinese Center for Disease Control and Prevention;
- Continuously update the database for free, and support users to create exclusive personalized databases
- Localized microbial database, providing professional Chinese names of strains, more suitable for Chinese users

Nucleic Acid Detection Analysis—NuTyper

NuTyper Software data collection interface

- NuTyper analysis software for data analysis of human genome SNP typing
- Modular application software, including data management, data analysis, data generation and other modules
- Automatically generate SNP allele type interpretation for each sample, intuitive and easy to understand
- It can display data results such as signal, genotyping and molecular weight, annotate spectral peak data, and judge peak intensity, resolution, and signal-to-noise ratio

Reagent application

BGI-GBI has carried out the following projects:

- Genetic testing for hereditary deafness
- Common respiratory virus joint testing
- Genetic testing for cardiovascular drugs
- Genetic testing for anti-tuberculosis drugs
- Genetic testing for anti-anxiety drugs
- Genetic testing for antidepressant drugs
- Genetic testing for antipsychotic drugs
- Genetic testing for anti-epileptic/emotional stabilizer drugs

Faster, more confident clinical application solutions

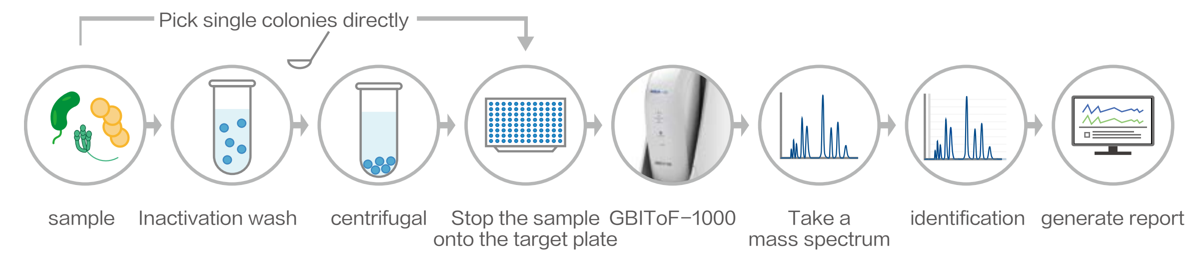
Microbial identification function

Technical principle

Protein is the material basis of life activities. Each microorganism is composed of its own unique protein, so its peptide mass fingerprint is also different; the mass number of the mixed peptide fragment sequence produced after protein enzymatic hydrolysis has obvious characteristics. The spectra obtained by measuring the mass numbers of these mixed peptides with the instrument are called peptide mass fingerprinting (Peptide Mass Fingerprinting, PMF).

The time-of-flight mass spectrometry detection system is used to detect the peptide mass fingerprint of the microbial ribosomal protein to be tested, and to match and compare with the microbial standard fingerprint in the equipped database, thereby completing the rapid identification of microbial strains.

Microbiological identification operation process



It only takes 20s to complete the identification of a single target detection, the bacteria identification report time is reduced from about 57 hours to about 27 hours, and the manual operation is reduced by 80%.

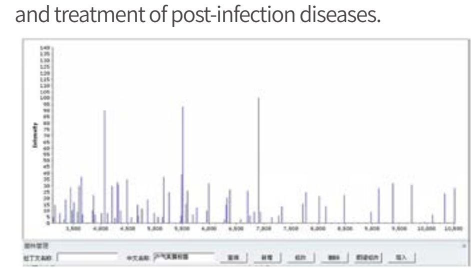
Microbial Profile Database

	Genus	Species	Strains
spectral database	＞480	＞3629	＞68000
Filamentous fungi	28	55	153
Mycobacteria	Mycobacterium	43	81

Improve the ability to identify anaerobic bacteria

It is difficult to clinically identify anaerobic bacteria, because most of them grow slowly due to the special culture conditions, and the identification takes a long time.

Clostridium perfringens (Clostridium perfringens) is a Gram-positive bacillus that is one of the main pathogens that cause necrotic enteritis, enterotoxemia and traumatic gas gangrene. Rapid and accurate identification of Clostridium perfringens It is of great significance for effectively preventing the infection of the bacteria and the prevention and treatment of post-infection diseases.



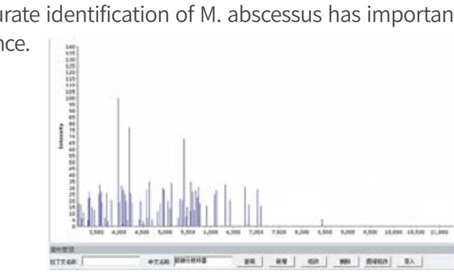
Schematic diagram of mass spectrum peaks for the identification of Clostridium perfringens

Identification score	latin name	Chinese name
2.81	*Clostridium perfringens*	产气荚膜梭菌

Improve the ability to identify rare bacteria

The pathogenic bacteria that are common in clinical practice can be easily diagnosed by etiology, but it is difficult to carry out early and correct clinical diagnosis and corresponding anti-infection treatment for the pathogenic identification of some clinically rare bacteria.

Mycobacterium abscessus is a non-tuberculous mycobacterium (NTM) that can cause human pathogenicity. It is one of the important pathogens that cause lung NTM disease worldwide. Patients with M. abscessus lung disease often have multidrug resistance to antibiotics, and clinical treatment is difficult. Therefore, rapid and accurate identification of M. abscessus has important clinical significance.



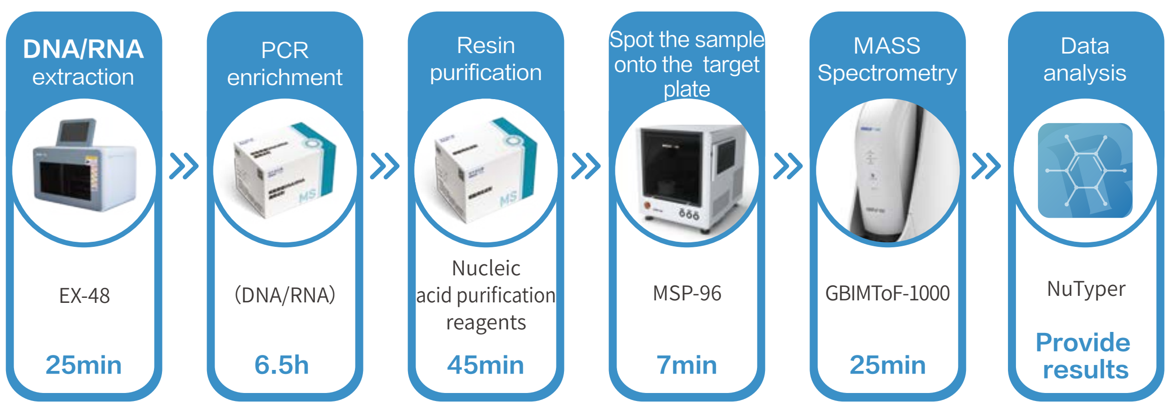
Schematic diagram of mass spectrum peaks for the identification of Clostridium perfringens

Identification score	latin name	Chinese name
2.78	*Mycobacterium abscessus*	脓肿分枝杆菌

Nucleic acid detection and analysis function

Technical principle

The principle of nucleic acid mass spectrometry detection is that the sample undergoes multiple PCR amplification and single base extension, and the genotype of the site to be tested in the sample is judged according to the difference in molecular mass before and after specific extension. The first step of the technical process is to design primers according to the site to be tested, and perform multiplex PCR to enrich the site to be tested; the second step uses shrimp alkaline phosphatase (Shrimp alkaline phosphatase, SAP) to process the PCR product of the previous step, Digest the remaining deoxyribonucleoside triphosphate; the third step is the single base extension reaction, design a single base extension primer for the detection site, add dideoxynucleoside triphosphate (ddNTP) and elongation enzyme in the reaction system , so that the extended primer extends one base at a specific single nucleotide site and then terminates the reaction; the fourth step is that the product is desalted and purified by ion exchange resin, and the product is targeted on the chip, and the sample combined with the matrix is irradiated by laser The ionization starts to fly in the vacuum tube and finally reaches the detector; the detector converts the electrical signal into a visible mass spectrum peak, and the mass of the extended single base can be detected by the mass spectrometer to determine the base at the site to be detected base type to get the results of genotyping and detection.



Twenty genetic deafness gene mutation detection

One-time detection of the most common 4 genes and 20 deafness gene defect sites in the Chinese population, assess whether the baby has the risk of hearing impairment as soon as it is born, and take care of the baby's hearing in the first time. Only need to collect 3 drops of heel blood or umbilical cord blood from newborn babies, and through time-of-flight mass spectrometry genetic testing and data analysis, we can accurately understand the baby's deafness genetic defect, predict the baby's risk probability of hearing impairment, and provide information for later clinical intervention. guide.

Four hotspot genes of hereditary deafness

Hotspot gene	Detection points	Clinical manifestations
GJB2	5	Non-syndromic deafness, prelingual deafness, full frequency deafness
SLC26A4	11	Nonsyndromic deafness, some with large vestibular aqueduct syndrome or Pendlay syndrome, prelingual/postlingual deafness, full frequency deafness
GJB3	2	Non-syndromic deafness, postlingual deafness, high frequency deafness
12sRNA	2	Aminoglycoside-induced deafness

Combined detection of common respiratory viruses

There are more than 100 pathogens causing community-acquired pneumonia, of which viruses account for about 30%. Pneumonia caused by other viruses is similar to common influenza virus, parainfluenza virus, adenovirus, respiratory syncytial virus, rhinovirus, and human metapneumonia. Viruses, SARS coronavirus, etc. have similarities, and it is difficult to distinguish from clinical manifestations and chest imaging alone, and it is necessary to rely on etiological detection to distinguish.

Detection of multiple targets

Multiple virus detection on the same sample, including RNA and DNA viruses

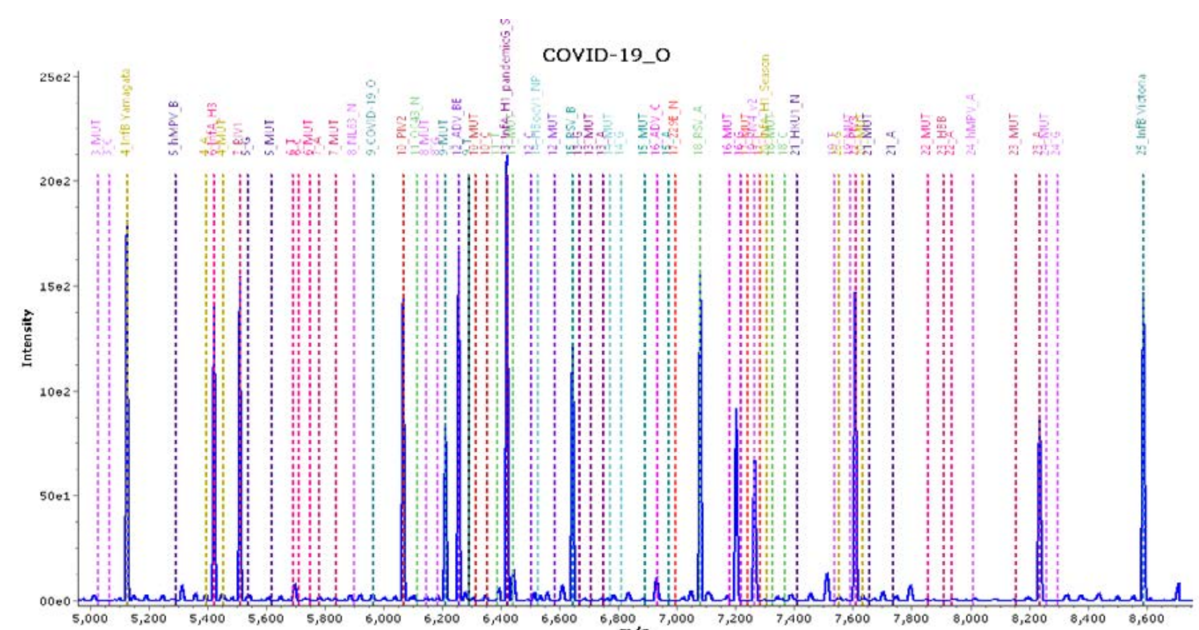
low cost

About half the cost of RT-PCR

high sensitivity

Stable detection range 25 copies/μL

No.	Detect pathogens	No.	Detect pathogens
1	Influenza B virus Yamagata	8	H3N2 influenza virus
2	Influenza B virus Victoria	9	Respiratory syncytial virus subtype A
3	Parainfluenza virus type 1	10	Respiratory syncytial virus subtype B
4	Parainfluenza virus type 2	11	Adenovirus C
5	Parainfluenza virus type 3	12	Adenovirus B/E
6	Parainfluenza virus type 4	13	COVID-19
7	H1N1 influenza virus		



Spectrum of joint detection results of common respiratory viruses

Pharmacogenomics (PGx) Genetic Testing

Pharmacogenomics aims at drug efficacy and safety, so as to study the relationship between various gene mutations and drug efficacy and safety. The FDA gradually revised the drug instructions, and gave warnings about the impact of genetic variation on the drug, and proposed the level of (genetic testing) evidence: clinical utility, FDA or academic research or other professional teams, clinical pharmacogenomics evaluation of drugs analyze. The use of time-of-flight mass spectrometry to realize clinical testing services for popular pharmacogenomics PGx precision medicine has become an industry consensus.

Drug metabolizing enzymes and drug target gene detection provide personalized customization services, and panel customization and gene loci can be added according to the genetic polymorphism sites of different types of drugs.

(1)Anti-tuberculosis drug target gene detection

《Guidelines for Chemotherapy of Drug-Resistant Tuberculosis》 (2019 Edition) recommends that individual differences in patients should be considered comprehensively during the treatment of tuberculosis, especially for drug-resistant tuberculosis. The test results provide medication recommendations.

Drug name	Detection gene	Drug name	Detection gene	Drug name	Detection gene
streptomycin	MT-RNR1	rifampicin	NAT2	ethambutol	NAT2
Isoniazid	NAT2		ABCB1		ABCB1
	ABCB1		AGBL4		CYP2C9
	BACH1		BACH1		CYP2C19
	CUX2		CYP2C9		TNF
	CYP2C9		CYP2C19	Pyrazinamide	NAT2
	CYP2C19		GSTP1		ABCB1
	GSTP1		NOS2		CYP2C9
	NOS2		RIPOR2		CYP2C19
	SLCO1B1		SLCO1B1		TNF
	TNF		TNF		
	XPO1		XPO1		

(2)Antipsychotic drug target gene detection

Mental illness has become a high-risk disease in our country. According to statistics, more than 17% of adults in our country suffer from mental illness such as depression and schizophrenia. Drug therapy is currently the main clinical intervention for mental illness, but it is still in the stage of trial and error, and the efficacy and adverse reactions of drugs also show significant individual differences. For clinicians, how to choose drugs reasonably, Dose adjustment, clinical monitoring and reasonable control of adverse reactions are particularly important.

	Drug name	Detection gene	Drug name	Detection gene
Antipsychotics	Chlorpromazine	CYP1A2	Piperidone	NUBPL
		EPM2A		CYP2D6
		DRD2		CELF4
	Clozapine	ANKK1/DRD2	Risperidone	CERKL
		HTR2C		DRD2
	Thioridazine	CYP2D6		CYP2D6
	Perphenazine	RGS4		MC4R
Anxiety and mood stabilizer medication	Carbamazepine	HLA-B	Phenobarbital	ABCB1
		HLA-A		SCN2A
		SCN1A		HLA-B
		EPHX1		CYP1A1
	Phenytoin	CYP2C9	Midazolam	POR
		HLA-B		CYP3A5
		SCN1A		CYP3A4
	Diazepam	CYP2C19	Oxazepam	UGT2B15
	Lamotrigine	UGT1A4	Lorazepam	UGT2B15

(3)Cardiovascular drug target gene detection

The morbidity and mortality of cardiovascular disease in China continue to rise, and it has become a major disease that endangers the lives and health of the people in our country. Anticoagulant drugs, antiplatelet drugs, lipid-lowering drugs, and vasodilators routinely used in clinical practice generally have individual differences. Choosing the right drug can greatly improve the safety and effectiveness of cardiovascular drug use.

Drug name	Detection gene	Drug name	Detection gene
Clopidogrel	CYP2C19	Warfarin	CYP2C9
Aspirin	GP1BA		VKORC1
	LTC4S		CYP4F2
Nitroglycerin	ALDH2	Simvastatin	SLCO1B1
Metoprolol	CY92D6	Atorvastatin, pravastatin, simvastatin	APOE
	ADRB1		
Captopril	ACE	Diuretic calcium/calcium ion antagonist	NPPA
Tacrolimus	CYP3A5	Losartan	CYP2C9

Human papillomavirus (HPV) nucleic acid typing test

Persistent high-risk human papillomavirus (Human Papilloma Viruses, HPV) infection is the main cause of cervical cancer. Cervical cancer is the second most common malignant tumor in women in the world after breast cancer. In China, there are about 150,000 new cases and 80,000 deaths from cervical cancer every year. Human papillomavirus is a spherical DNA virus with more than 110 subtypes. Clinically, according to the pathogenicity of HPV subtypes, HPV can be divided into high-risk, intermediate-risk and low-risk types. Cervical cancer is currently the only cancer with a clear etiology, early detection, early prevention, early diagnosis, and early treatment.

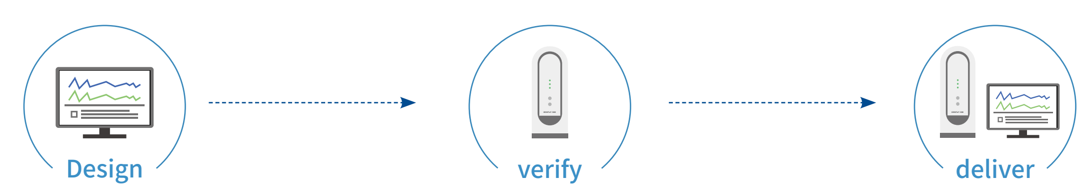
24 types of HPV genotyping test (24-type HPV typing test)

High-risk: HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68; mid-risk: HPV26, 53, 66, 73 ;

Low-risk: HPV6, 11, 42, 43, 81, 82, 83

Customized single nucleotide polymorphism (SNP) research plan

Time-of-flight mass spectrometry is a multifunctional genetic analysis tool that is not limited to each specific application; it can customize a personalized panel, add any SNP loci of interest, and carry out research in various fields such as pharmacogenomics, genetic diseases, and infectious diseases. Apply, design and validate specific research protocols.



Design SNP, insertion, deletion, translocation, copy number variation, somatic mutation, and methylation detection protocols.

Functional testing of the multiplex assay to determine its accuracy, robustness and performance.

Users accept ready-to-use and specified reporting software for immediate application in the laboratory.

Professional customization

Provide a technical route plan designed and developed by scientific research experts

Verification Guarantee

The technical route plans are all functionally verified in the laboratory

close collaboration

Provide comprehensive solutions such as technical training and technology transfer

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Service Hotline：400-666-8705

Telephone：010-80492001/02

Website：www.gbi.com.cn

Address：No. 8, Zone B, Airport Industrial Development Zone, Shunyi, Beijing（post code：101300 ）

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