



Dear value customers,

First of all, ABT Biological Solutions Co.,Ltd would like to express our sincere gratitude to you for using our products and hope this message finds you well.

We are a biotechnology company, who puts bio-research achievements into practice. We provide molecular biological testing and diagnostic Kits, especially in Covid19 pandemic prevention. Beginning as a startup, with our non-stop effort and hard-work, we have grown to become one of the leading company in applied biotechnology in Vietnam over the last two years.

The recent development of ABT is the result of both the internal effort and your great support and contribution. Thank you to always believe in and choose ABT as your partner. In addition, to sustainably maintain our products' quality and the brand reputation, we not only pay a lot of attention to our research and development activities but also try to apply the latest scientific achievements in improving our products and meet the market demand. We promise to always try our best in using biological sciences to provide quality products and services that meet international standards and solve daily medical issues.

We strongly believe that you will be satisfied when choosing our company. Once again, we wish you good health, happiness and further success in the future. Please feel free to contact us if you have any questions or need technical support.

Best regards!

General Director
ABT Biological Solutions Co.,Ltd

THE NEXT GENERATION OF BIOTECH SOLUTION



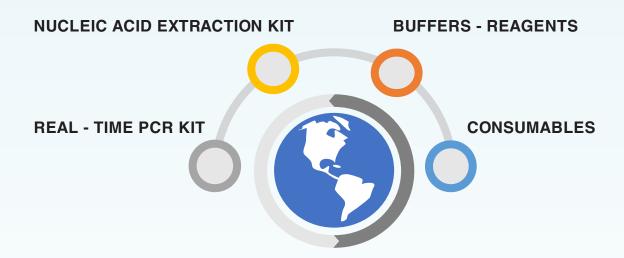




CHAPTER 1: ABT's Overview

OVERVIEW

"In 2019, ABT BIOLOGICAL SOLUTIONS COMPANY LIMITED was officially established, the headquarters is located in Ho Chi Minh City (Vietnam). We provide overall solutions in the bio-molecular diagnostics field:



Besides, We also provide overall solutions includes laboratory designing, technical transferring, and training for Molecular Biology laboratories in the fields of medical, industry, academic, etc.



"The factory is located in Long Hau Industrial Park"



CORE VALUES

"Responsibility - Creativity - Dedication"

Based on the foundations of "Responsibility - Creativity - Dedication", ABT set the first step into the market. These original principles have become our core values, which strongly influence our leadership and the mindset of our employees. Hence, we are willing to put in the work and dedication to bring our dream of one sustainable and prosperous ABT into life.



"ABT's strength is the Next Generation. At ABT, we believe the continual development of science leads to success.

We always implement product research and development activities, absorb science to provide comprehensive and best solutions to customers. We work together towards the goal of bringing science closer to everyday life."



ABT'S SOLUTIONS

Provide overall solutions including design, consultation, and training for molecular biology laboratories in the fields of medical, industry, academic, etc.





The overall solutions in diagnostic Covid-19

The overall solutions in diagnostic ASFV



The overall solutions in diagnostic disease on shrimp.



The overall solutions in detection GMO



Specimen Collection and Handling



Nucleic Acid Extraction



Real-time PCR

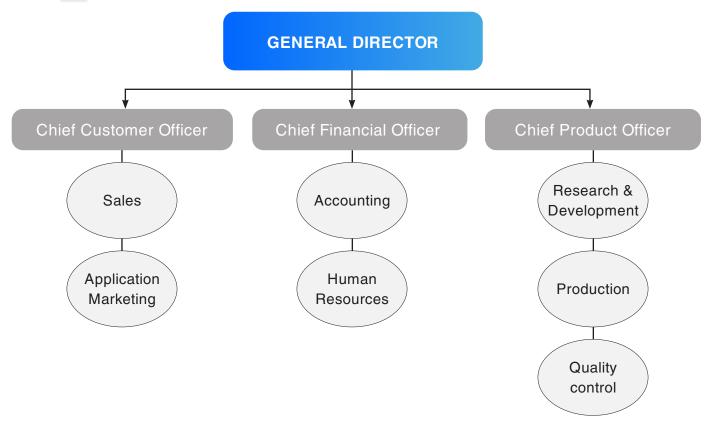


Results Analysis

Overall solution's procedure in pathogen diagnosis



ABT'S ORGANIZATIONAL STRUCTURE



Our company is operated under the leadership of a young board, who always stay enthusiastic, creative, and professional. Moreover, our employees and team of experts are highly specialized. Therefore, ABT commits the quality of our products will be maintained.

Our company consists of several distinct departments, those are responsible for the separated mission and contribute to the overall achievements.





HUMAN RESOURCE

QUALITY

The personnel of the ABT have been continuously improved with policies of recruiting, training and retaining talents. Besides, with investments in production systems and human resource training, our people follow to the standard ISO to help ABT commits to bring our customers good quality and services.



100 talented employees



100% bachelor and master degrees in biotechnology

OUR TEAM

More than 100 employees are working at ABT, 100% of them graduated with a bachelor or master's degree. The high quality human resources allows us to improve and guarantee the quality of our products can meet the market's demands.

OUR POLICY

ABT encourages and supports our staff to take a further education course such as master, doctorate degrees, or even short courses. This policy significantly improves our capacity in better handling our client's problems.

All procedures of ABT are strictly quality controlled follow to the standard ISO 9001 & ISO 13485





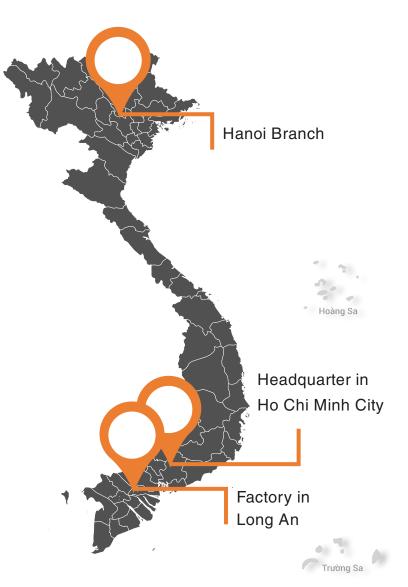














Headquarter in Ho Chi Minh City

No. 305/13/44 Le Van Quoi, Binh Tri Dong Ward, Binh Tan district, Ho Chi Minh city, Vietnam.



Factory in Long An

5.02 - 6.07, Lot L2, Long Hau-Hiep Phuoc Street, Long Hau Industrial Park, Long An Province, Vietnam.



Hanoi Branch

No. 20/63, Lane 218 Linh Nam Street, Linh Nam Ward, Hoang Mai, Ha Noi, Vietnam.

WORKING PLACES



The headquarter in HCMC includes Marketing, Accounting, Sales, Administration and Application.

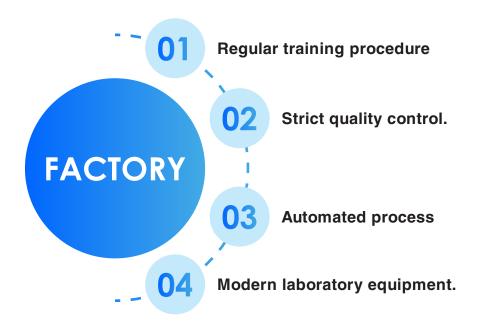
At the factory in Long An, R&D department and Production department are focus on producing main products such as extraction kits, diagnostic kits, transport medium for Covid-19 samples, and other chemicals for molecular biology laboratories.

Hanoi Branch is in charge of distributing products within the northern region.



MANUFACTURING CAPABILITIES AND FACILITIES

Our factory located in Long An province, here, we equipped the modern machines and production line, with massive productivity. To ensure to meet the client's demand. We are also setting up another manufactory to produce more products.







CERTIFICATIONS

High quality products with reasonable price are one of our remarkable features. We always yearn to provide high quality products with affordable price, proven by various domestic certificates such as ISO 9001: 2015 and ISO 13485: 2016. We understand that the quality is the foundation and good pricing is the tool to achieve success.







GIẤY CHỨNG NHẬN

Chứng nhận hệ thống quản lý chất lượng cho lĩnh vực thiết bị y tế của

CÔNG TY TNHH GIẢI PHÁP Y SINH ABT-CHI NHÁNH LONG HẬU

Địa chỉ: Xưởng 6.07, Lỗ L2, Đường Long Hậu, Hiệp Phước, KCN Long Hậu, Xã Long Hậu, Huyện Cần Giuộc, Tinh Long An, Việt Nam Địa điểm san xuất: Nhà xưởng 6.07 và 5.02, Lổ L2, Đường Long Hậu - Hiệp Phước, KCN Long Hậu, Ấp 3, Xã Long Hậu, Huyện Cần Giuộc, Tỉnh Long An, Việt Nam

Được đánh giá và phù hợp với các yêu cầu của tiêu chuẩn quốc tế

ISO 13485:2016

Cho lĩnh vực:

- Phát triển sản phẩm, sản xuất và kinh doanh kit chắn đoán, kit hỗ trợ chắn đoán
- Phát triển sản phâm, sản xuất và kinh doanh kit chân đoán, kit hỗ trợ chấn đoán sinh học phán tử, mỗi trường vận chuyển mỗu.
 Kinh doanh hóa chất hỗ trợ quá trình xét nghiệm.
 Thiết kế, sản xuất, kinh doanh nội thất phòng thí nghiệm và các thiết bị chuyên dụng cho ngành y tế (từ an toàn sinh học cấp 1 và 2, từ cấy dòng khí cháy tăng, từ hát khí độc, từ cách ly vô trùng, từ thao tác PCR, từ tiết trùng bằng tia UV, máy tách chiết tư động).
 Sản xuất ủy thác (OEM) và kinh doanh dụng cụ, vật tư tiêu hao trong lĩnh vực trang thiết bị y tế.

Số giấy chứng nhận Hiệu lực của giấy chứng nhận Chi tiết tại quyết định số Ngày

: TQC.08.3711 : Từ 22/06/2022 đến 21/06/2025 : 3711/2022/QĐ-TQC : 22/06/2022



TRUNG TÂM KN&CN CHẤT LƯỢNG TO William Control TH OLIANG HUNG

The Next Generation of Biotech Solution



SỞ Y TẾ TP HỎ CHÍ MINH

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM Độc lập - Tự do - Hạnh phúc

Số: 200000281/PCBSX-HCM

Tp Hồ Chí Minh, ngày 26 tháng 08 năm 2020

PHIẾU TIẾP NHẬN Hồ sơ công bố đủ điều kiện sản xuất trang thiết bị y tế

- 1. Tên cơ sơ công bố: CÔNG TY TNHH GIẢI PHÁP Y SINH ABT
- 2. Địa chỉ: Số 305/13/44 Lê Văn Quới, Phường Bình Trị Đông, Quận Bình Tân, Thành phố Hồ Chí Minh
- (Sản xuất tại: CÔNG TY TNHH GIẢI PHÁP Y SINH ABT; Địa chỉ: 305/13/44 Lê Văn Quới, Phường Bình Trị Đông, Quận Bình Tân, Thành phố Hồ Chí Minh)
- 3. Điện thoại: 02866826652 Fax: 4. Số văn bản đề nghị của cơ sở: 01/2020/CBSX-ABT Ngày: 20/08/2020

5. Tên trang thiết bị y tế cơ sở công bố sản xuất: Môi trường vận chuyển mẫu, TopPURE ® SERUM VIRAL EXTRACTION KIT, TopPURE ® Maga SERUM VIRAL EXTRACTION KIT (DNA/RNA), TopCARE ® HBV qPCR KIT, TopCARE ® HCV qPCR KIT, TopCARE ® HPV qPCR KIT, TopCARE ® HPV Genotype RDB Kit, TopCARE ® GBS qPCR KIT

6. Thành phần hồ sơ:

1	Văn bản phân công, bổ nhiệm người phụ trách chuyên môn của cơ sở sản xuất	X
2	Bản xác nhận thời gian công tác	x
3	Văn bằng, chứng chi đào tạo về kỹ thuật thiết bị y tế hoặc quản lý thiết bị y tế của người phụ trách chuyên môn	х
4	Văn bản công bố đủ điều kiện sản xuất	х
5	Bản kê khai nhân sự	х
6	Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng	x
7	Hồ sơ về thiết bị và quy trình sản xuất, kiểm tra chất lượng phù hợp với yêu cầu của loại trang thiết bị y tế mà cơ sở sản xuất	x

NGƯỜI TIẾP NHÂN HỎ SƠ

Ký bởi: Phạm Thị Thanh Huyển Email: ptthuyen.syt@tphcm.gov. vn Co.quan: Sô Y tế. Thành SỞ Y TẾ TP HỎ CHÍ MINH

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM

Độc lập - Tự do - Hạnh phúc

Số: 210000669/PCBA-HCM

Tp Hồ Chí Minh, ngày 21 tháng 09 năm 2021

PHIẾU TIẾP NHẬN

Hồ sơ công bố tiêu chuẩn áp dụng của trang thiết bị y tế thuộc loại A

- 1. Tên cơ sở công bố: CÔNG TY TNHH GIẢI PHÁP Y SINH ABT
- Địa chỉ: Số 305/13/44 Lê Văn Quới, Phường Bình Trị Đông, Quận Bình Tân, Thành phố Hồ Chí Minh
- 3. Số văn bản đề nghị của cơ sở: 04/2021/CBAD-ABTLH Ngày: 18/06/2021
- 4. Trang thiết bị y tế thuộc loại A

Tên trang thiết bị y tế: Môi trường vận chuyển mẫu

Chủng loại/mã sản phẩm: Theo phụ lục

Tên cơ sở sản xuất: Theo phụ lục

Địa chỉ cơ sở sản xuất: Theo phụ lục

Tiêu chuẩn chất lượng sản phẩm áp dụng: ISO 13485

5. Thông tin về chủ sở hữu trang thiết bị y tế :

Tên chủ sở hữu: CÔNG TY TNHH GIẢI PHÁP Y SINH ABT

Địa chỉ chủ sở hữu: Số 305/13/44 Lê Văn Quới, Phường Binh Trị Đông, Quận Bình Tân, Thành phố Hồ Chí Minh

Thông tin về cơ sở bảo hành:

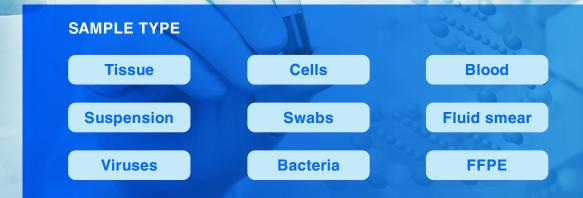
1	Phụ lục chi tiết trang thiết bị y tế	ı
2	Bản phân loại trang thiết bị y tế	Г
3	Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng còn hiệu lực tại thời điểm nộp hỗ sơ.	T
4	Giấy ủy quyền của chủ sở hữu trang thiết bị y tế	T
5	Giấy xác nhận đủ điều kiện bảo hành	Г
6	Tải liệu mô tả tóm tắt kỹ thuật TTBYT theo Mẫu số 1 (đối với TTBYT thông thường và IVD là máy, thiết bì), Mẫu số 2 (đối với TTBYT IVD là thuốc thứ, chất hiệu chuẩn, vật liệu kiểm soát in vitro) tại Phụ lục 8	
7	Giấy chứng nhận hợp chuẩn hoặc Bản tiêu chuẩn mà chủ sở hữu trang thiết bị y tế công bố áp dụng	Γ
8	Kết quá đánh giá các thông số hóa, lý, vi sinh và các thông số khác do cơ sở đũ điều kiện theo quy định của pháp luật về đánh giá sự phủ hợp cấp đối với trang thiết bị y tế sân xuất trong nước	
9	Tài liệu hướng dẫn sử dụng của trang thiết bị y tế	Г



CHAPTER 2:

Main Products

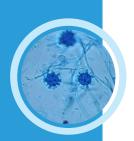
SAMPLE TYPES AND PRODUCTS





Nucleic acid Purification Kit

When you use TopPURE® kits of ABT, you will experience a simple, fast workflow that is designed to provide pure nucleic acid ready for downstream applications such as real-time PCR and sequencing...



Real - time PCR Kit

Kit for diagnosis & detection of pathogen provide a rapid diagnosis with high sensitivity and specificity. Specially designed and optimized reaction mixtures contain PCR primers that enable specific amplification of a particular gene fragment.



Buffers - Reagents

ABT provides a group of basic chemicals used in molecular biology to ensure prestige, quality and make every process in the laboratory easier. In addition, we are always developing and improving to meet the diverse needs of our customers.



Instruments

The unique feature of ABT is the modern equipment maintained by ABT's professional engineer team.

NUCLEIC ACID PURIFICATION KITS

FEATURES

- High quality and efficient extraction: the combination of the new generation of technology, buffer formulations, and optimized silica membrane to enhance DNA binding and release.
- **Easy and rapid operation:** the kit provides consumables and ethanol buffer for the convenience of users. The simple procedure reduces the contamination and workflow time.
- Stable and reliable: products are assured by a strict QC system.
- Safe & non-toxic.

LIST OF NUCLEIC PURIFICATION KITS

TopPURE SELECTION CHART	Genomic DNA	HPV DNA	Fluid Viral	Blood DNA	Serum Viral	FFPE DNA	Food DNA	Stool DNA	Viral DNA/RNA	Tissue Viral	Highpure Viral	Plant DNA	Plant RNA	PCR/Gel DNA	Plasmid DNA	Crude DNA
Animal Tissue	/									/						
Plant Tissue												/	/			
Whole Blood				/												
Serum, Plasma					/				/							
Cultured cells, bacteria	/	~	/		/				/							/
Suspension	/	/	/		/				/							
Buccal swabs (medical)	/	/	/		/				/							
Clean-up from surface	✓	/	✓		/				/							
Food (directly)												/				
Virus from tissue	/									/						/
Fungi, Yeast												/	\			
Plasmid from bacteria															>	
PCR Product & Gels														<		
Virus from Shrimp, Fish											/					/
Easy to grind bacteria	/															
FFPE tissue						/										
Fresh/frozen stool								✓								





TopPure® spin column extraction kit (manual solution)



TopPure® magnetic extraction kit (automation solution)

TopPURE Maga SELECTION CHART	HI-612	HI-612.A	HI-612.B	HI-612.C	HI-612.D	HI-612.E	HI-612.F	HI-612.N	HI-612.NB	HI-512	HI-512.A	HI-512.B	HI-812	HI-812.A	HI-812.B	HI-912.NA	HI-912.NB
Cultured cells, bacteria	/	/	/	/	>	>	/	>	/				\	/	/	>	/
Suspension	/	/	/	/	>	>	/	>	/				>	/	/	/	/
Buccal swabs (medical)	/	\	/	/	>	>	/	>	>				>	/	>	>	/
Clean-up from surface	/	/	/	/	>	>	/	>	/				>	/	/	>	/
Serum, Plasma										/	/	/	/	/	\		
Whole Blood										/	/	/	/	/	/		
Proteinase K	/	/	/							\	/	/	/	/	\		
32 test machine		/		/			/	/			/			/		/	
96 test machine			/			✓			/			/	/		/		/
32/96 test machine	/									/					/		
48/96 test machine					>												
Pre-filled		/	/			<		/	/		✓	/		/	/	✓	/





REAL-TIME PCR KITS

Real-time PCR is known as a highly sensitive technique, which allows the specific amplification and quantification of the target nucleic acid sequences and observation in real-time. In humans, this technique is highly utilized for a wide range of purposes, such as gene expression analysis, determination of viral load, pathogens identification, paternity testing, forensic investigation, diagnosis the inherited genetic disorders. In addition, this technique is also used in aquaculture, food, veterinary, GMO, and animal identifier.















I. TOPSENSI HUMAN

TopSensi Human qPCR Series Kit is a Real-time PCR test designed for the qualitative detection of disease with ultra-high specificity and sensitivity. It has been validated on all commonly real-time instruments in the market.

FEATURES

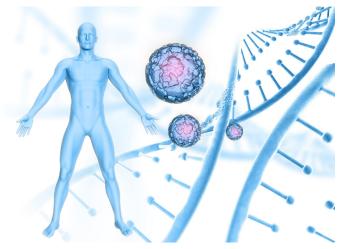






Easy to use

LIST OF PRODUCTS IN HUMAN KITS:





Quantitative Kit Series

- HBV qPCR Kit
- HCV qPCR Kit

Qualitative Kit Series

- HPV qPCR Kit
- GBS qPCR Kit
- CHT qPCR Kit
- NGN qPCR Kit
- Treponema Pallidum qPCR Kit
- CHT/NGN multilex qPCR Kit
- HSV1-2 multilex qPCR Kit
- Plasmodium spp. qPCR Kit
- · Helicobacter pylori qPCR Kit
- MTB qPCR Kit

Genotyping Kit Series

- HCV Genotype qPCR it
- HPV Genotype RDB Kit

Other disease

REAL-TIME PCR KITS

II. TOPSPEC AQUACULTURE

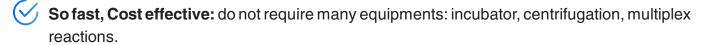
Shrimp and fish are important commodities that bring high economic efficiency. Diseases outbreak causes significant loss in aquaculture production, trade and negatively impacts on the economic development of many countries.

TopSpec Aquaculture Series Kit is a combination of the latest advances in buffer chemistry and PCR enhancers, together with an antibody mediated hot-start DNA polymerase and Tagman probes to ensure high sensitivity.

FEATURES







LIST OF TOPSPEC AQUACULTURE SERIES KIT

TopSpec Single	Kit Series	TopSpec Multiplex Kit Series
WSSV	TSV	WSSV - IHHNV
YHV	IMNV	YHV-TSV-IMNV
IHHNV	MrNV	MrNV-XSV
EHP	XSV	EMS-EHP
MBV	VNN	WSSV-EMS-EHP
AHPND/EMS	E.ictalurid	
HPV	DIV 1	HAV-NOV
NHPB		

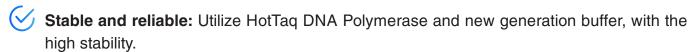


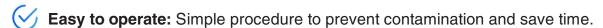
III. TOPSPEC FOOD SAFETY

In the recent years, with the improvement in quality of life, foodborne diseases have also become a problem in daily live, and foodborne pathogens are causing a growing number of them. Accurately detecting foodborne pathogens is the key link to effectively control the occurrence of foodborne diseases.

TopSpec Food Safety Kit Series Via using fluorescent quantitative PCR technology, primers and fluorescent probes are optimized for specific fragments of different foodborne pathogens, in order to find out the presence of foodborne pathogens from different sources.

FEATURES





High specificity: The design of specific primers and probes can avoid the false positive results.

LIST OF TOPSPEC FOOD SAFETY KIT SERIES

- Salmonella spp. qPCR Kit
- Listeria monocytogenes qPCR Kit
- Shigella spp. qPCR Kit
- Vibrio parahaemolyticus qPCR Kit



REAL-TIME PCR KITS

IV. TOPSPEC VETERINARY

Animals are considered as a potential pathogens carrier, they are often exposed to pathogens from various source of infection, resulting in significant morbidity, mortality and economic losses. Real-time PCR has become one of the most crucial tools in pathogens diagnostics with a simple procedure, high sensitivity and specificity.

TopSpec Veterinary Kit Series is the product line developed by ABT with premium quality molecular biology reagents to provide customer a game-changing solution for the detection various of pathogens in animals.

FEATURES



Rapid and reliable: Real-time PCR produces result within 1 hour. The primers and probes are optimized to avoid false positives.



Widely use: compatible with most quantitative PCR instruments.



High sensitivity: the latest advances in buffer and Tag Polymerase help improve the sensitivity of the reaction.

LIST OF TOPSPEC VETERINARY KIT SERIES

- ASFV qPCR Kit
- FMDV RT-qPCR Kit
- CSFV RT-qPCR Kit
- PRRSV RT-qPCR Kit
- Influenza virus A/B
- TGEV RT-qPCR Kit
- PEDV RT-qPCR Kit

- CDV RT-qPCR Kit
- Babesia qPCR Kit
- Ehrlichia qPCR Kit
- PPV RT-qPCR Kit
- JEV RT-qPCR Kit



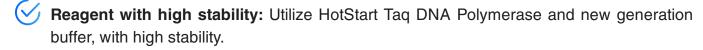


V. TOPSPEC GMO

Genetically modified foods are defined as plants or animals that have been genetically modified for human consumption to improve their quality. Genetically modified foods can be harmful to the environment or the consumer's health. With the advantages of sensitivity and high accuracy, real-time PCR is used as an important tool in the screening of GMO foods.

TopSpec GMO Safety Kit Series was developed to detect the presence of a GMO in a sample according to EU indications. It has been validated on all commonly real-time instruments in the market.

FEATURES



- Widely use: compatible with most quantitative PCR instruments.
- Quick protocol: nucleic acid extraction and the running time of PCR can be completed within 90 minutes.
- High specificity: The design of specific primers and probes can avoid false positive results.

LIST OF TOPSPEC GMO SAFETY KIT SERIES

- TNOS Terminator Detection Kit
- FMV Promoter Detection Kit



2

REAL-TIME PCR KITS

VI. TOPSPEC ANIMAL IDENTIFIER KIT

The increasing population is directly affecting the demand for fresh meat, which relates to several social and religious problems. In order to identify the animal meat ingredient, real-time PCR is used as the gold standard with high specificity and sensitivity.

TopSPEC Animal identifier Kit Series is the new product line developed by ABT. The kit uses primers and fluorescent probes for specific fragments of different sequences. It can be adapted to numerous other types of real-time PCR instruments.

FEATURES

- High sensitivity: the latest advances in buffer and Taq Polymerase can improve the sensitivity of reaction.
- Ultra-high specificity: the design of primers and probes helps detect only a specific animal nucleic acid sequence and avoid cross-reactions and false positives.
- Rapid and easy protocol: the simple procedure with only a few steps and the PCR running time can be completed within 1 hour.

LIST OF TOPSPEC ANIMAL IDENTIFIER KIT SERIES

- Porcin DNA Detection Kit
- Bovin DNA Detection Kit
- Ovine DNA Detection Kit
- Chicken DNA Detection Kit
- Goat DNA Detection Kit
- Horse DNA Detection Kit
- Donkey DNA Detection Kit





BUFFERS - REAGENTS

Viral transport medium: VTM

Universal transport medium: UTM

Virus transport medium (Inactivated): MT-001,

MT-002, MT-003

Lysis buffer for antigen test

Basic chemical for extraction

Basic chemical for RT/PCR

Basic chemical for electrophoresis

CONSUMABLES

Specimen Collection Swab

Tipcomb, Deep plate

Filter tip



Transport medium



Filter tip

AUTOMATIC NUCLEIC PURIFICATION SYSTEM



CHAPTER 3: Vietnam Market

The leading company in science services, We are constantly striving to bring the best quality products to meet the needs of our customer. We are present in 4 main markets throughout the country, including:

Overall solution:

We offer overall molecular biology laboratory solutions, including process improvement and laboratory consumables. We provide support to the diagnostics center to ensure that testing processes are safe and accurate.

Medical:

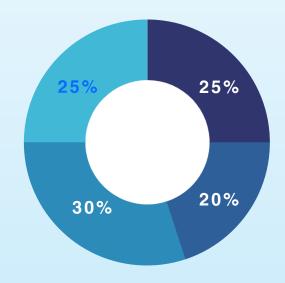
Providing hospitals and clinics with leading solutions in disease diagnosis

Industry:

We offer biological solutions for rapid pathogen detection. Businesses can minimize possible problems and save costs through detecting infections early.

Academic:

For their precision and consistency, many colleges rely on our goods. Downstream processes will benefit greatly from highly purified DNA or RNA. Many research papers will become more reliable with these exact findings.





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