TritaGene BIOTECH

Reality of Hi-Technology

Manufacturer of Hi-Tech Molecular *in vitro* diagnostic (IVD) Kits

About TritaGene:

TritaGene Biotech Co. is a Knowledge-intensive company that designs and manufactures molecular *in Vitro* Diagnostic (*IVD*) products intended to be used in medical genetic laboratories. Established in 2009, TritaGene has a team of talented and competent staff with more than one decade of scientific expertise that mainly dedicates its focus on design and development of innovative, robust, and easy-to-use molecular diagnostic kits based on the state-of-the-art technology, and maintains continuous product evolution in order to generate strong customer satisfaction and loyalty.

TritaGene is by researchers and for researchers. We welcome creative researchers, innovative ideas and high-Tech projects in the field of medical genetics and biotechnology. Customer orientation, Quality, Respect, Integrity and Innovation are the core concepts that drive our company culture. Here at TritaGene, we aim to make the world a better place and advance our business through hard work, high quality standards, and a steady-fast commitment to meeting our customer expectations.

TritaGene is ISO 9001:2015 and ISO 13485:2016 certified, and directly controls all parts of production and quality control processes to ensure high quality management system. We also proceed to meet the requirements of CE-marking and EU standards.

What TritaGene mainly stands for:

Mission

- Representing the fastest and easiest methods of molecular techniques
- Designing and manufacturing hi-tech molecular diagnostic kits based on the state-of-the-art technology in the field of medical Genetics and biotechnology.
- Maintaining a long-term expertise in developing innovative and easy-to-use IVD and RUO molecular kits.
- Continuous improvement in our production and quality control processes
- Production of high-tech molecular diagnostic kits within the quality management systems *accredited to ISO 9001:2015 and ISO 13485:2016, and proceeding to meet the* requirements of CE-marking and EU standards.

Competence and Team Spirit

- Employing a team of talented and competent staff
- Investing in training and creating good career opportunities
- Recognizing and encouraging researchers and/or research projects of high technology
- Behaving ethically in all our business and financial activities

Customer focus

- Demonstrating respect toward our customers and delivering customer satisfaction
- Giving value to our customers through quality management promotion
- Looking for innovative solutions to meet our customer expectations
- Enhancing customer loyalty and approval within the quality management systems accredited to ISO 10002:2018 and ISO 10004:2018 standards.

Why TritaGene?

Quality Assurance and conformity with international standards

All processes of TritaGene's quality management system including design and development, purchase, production, quality control, storage, sale and post-market surveillance (PMS) of *IVD* products are completely controlled according to the international quality management standards such as ISO 9001:2015 and ISO 13485:2016. Besides, all the manufacturing sites and sectors meet the requirements of Good Manufacturing Practice (GMP) in order to conform to the quality standards and increase customers' satisfaction.

Economical price

In recent years, along with the price increase of molecular diagnostic tests and lack of full insurance coverage in many countries, the request for clinical genetic tests has significantly decreased. Since genetic testing/screening can enhance population health through detecting individuals at high risk for common inherited conditions, TritaGene has provided the opportunity to get access to high quality molecular diagnostic kits with lowest price in order to be much more economical both for laboratories and genetic test applicants. Thus, a majority of population even low-income people can undergo their intended genetic tests.

Technical support and post-market surveillance

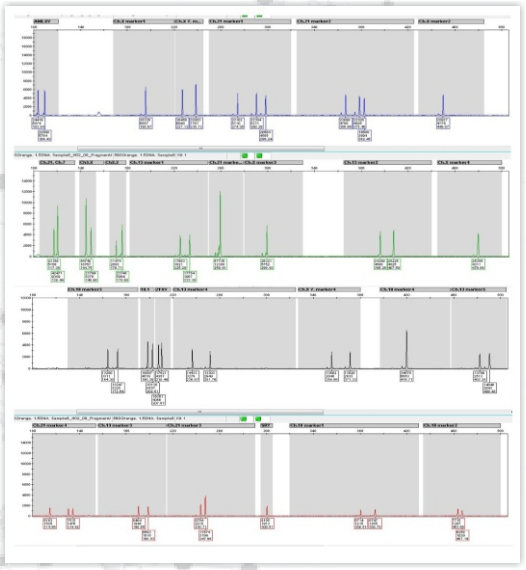
Customer orientation and customer support are among the core strategies of TritaGene. We develop and implement the processes of monitoring and measuring our customers' satisfaction and handle our customers' complaint according to ISO 10002:2018 and ISO 10004:2018 standards. We prioritize, improve or provide resources based on regular needs assessment, and plan to constantly develop products suitable enough to meet our customers' expectations all over the world. We are always ready to support our customers through providing professional consultation both before and after sale and align our business towards helping our customers reach successful results upon using our products.

Hi-tech technology

Here at TritaGene, Biotechnologists employ molecular techniques such as QF-PCR, Real-Time PCR, Strip Assay or develop a novel innovative technique called MFPA in order to design and produce high quality and more economical diagnostic kits with high sensitivity and specificity that not only decrease the rate of human errors in the lab, but also lead to accurate and reproducible results. TritaGene's scientific team continuously strive to promote the performance and quality of products along with state-of-the-art technology and updated international standards.

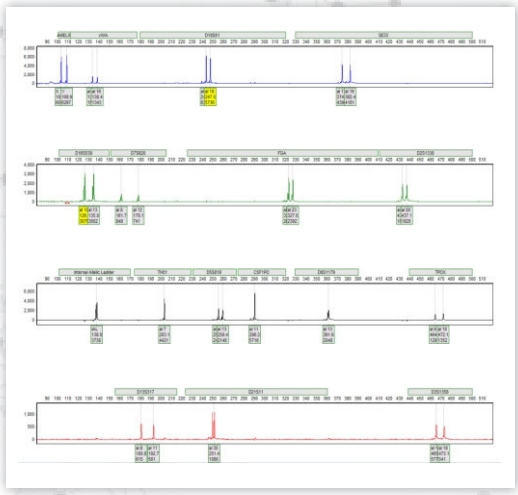
Trita FetusGene® Multiplex QF-PCR Diagnostic Kit

- Intended for prenatal determination of aneuploidies in chromosomes 13, 18, 21, X & Y.
- based on Quantitative Fluorescent-Polymerase Chain Reaction (QF-PCR) assay and capillary electrophoresis.
- Simultaneous amplification of 27 loci including STR, SD and SRY.
- Results analysis by professional softwares such as GeneMapper® or GeneMarker®
- Uses extracted DNA from amniotic fluid (AF) or Chorionic villus sampling (CVS)
- with %100 sensitivity and specificity
- Capable of detecting aneuploidies less than 5 hours after sampling.
- manufactured by TritaGene Biotech Co. within quality management systems accredited to **ISO 13485:2016** and **ISO 9001:2015.**

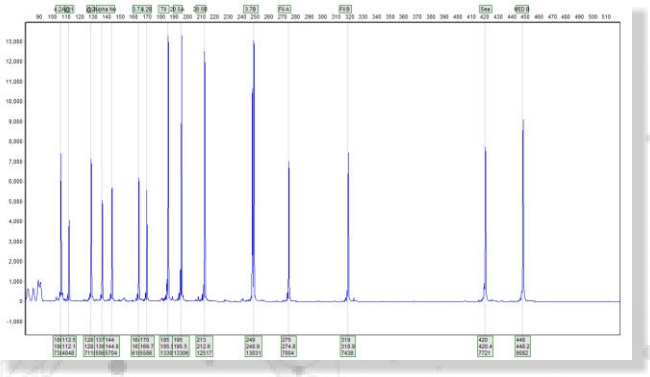


Trita® Human Identifier Kit

- Intended for human identification in forensics and DNA paternity testing.
- Simultaneous amplification of 13 original CODIS loci,1 marker from ENFSI, the SE33 locus and Amelogenin.
- Based on a single Multiplex fluorescent PCR amplification and Capillary electrophoresis.
- Efficient separation of the 15 STR loci and Amelogenin using a five-dye fluorescent system technology.
- Uses Extracted DNA from biological samples such as blood, hair, nail, *etc.*
- High discriminating ability due to SE33 locus analysis
- Highly sensitive to amplify and detect little concentration of temple DNA due to STR markers analysis.
- Results analysis by professional softwares such as GeneMapper® or GeneMarker®.
- manufactured by TritaGene Biotech Co. within quality management systems accredited to **ISO 9001:2015.**



Trita® α-thalassemia InDel Detection Kit



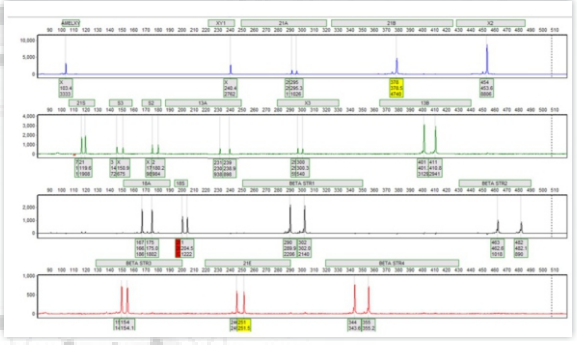
- Detection of common genetic deletions and duplications including -$\alpha^{3.7}$,-$\alpha^{4.2}$,-$\alpha^{20.5}$,--^{MED} ,--^{FIL} ,--^{SEA} ,--^{THAI} as well as α-triplication in alpha-globin gene cluster.
- Simultaneous amplification of all aforementioned deletions and duplications based on a novel method called Multiple Fluorescent Probe Amplification (MFPA) (first introduced by TritaGene Biotech Co.) and detection through a single run of Capillary electrophoresis.
- Capable of investigating for each deletion/duplication through amplification of two individual markers (Double checking the occurance of each InDel).
- Uses extracted DNA from human peripheral blood.
- Similar specificity and sensitivity with MLPA but even faster and more economical.
- Result analysis by professional software called T-Lyser® (first designed by TritaGene Biotech Co.).

Trita® β-thalassemia Linkage Analysis Kit

- Molecular diagnosis of beta-thalassemia based on fast, easy and indirect method of Linkage analysis.
- Detecting beta-thalassemia carrier or patient cases based on haplotype mapping
- Simultaneous amplification of 4 STR markers with high heterozygosity both in upstream and downstream of human beta-globin gene (*HBB*)
- Uses extracted DNA from human peripheral blood
- Marker detection based on five-dye fluorescent system technology
- Result analysis by professional softwares such as GeneMapper® or GeneMarker®

Trita® *Fetus* Thalassemia Diagnostic Kit

- Applying the fast and easy method of QF-PCR for simultaneous diagnosis of prenatal aneuploidy and beta thalassemia in a short time after sampling.
- Simultaneous amplification of 13 loci including STR and SD marker on chromosomes 13, 18, 21, X & Y as well as 4 STR markers with high heterozygosity in upstream and downstream of human beta-globin gene (*HBB*)
- Determining the status of being Beta-thalassemia carrier or patient in unborn child based on haplotype mapping
- Uses extracted DNA from amniotic fluid (AF), Chorionic villus sampling (CVS) or human peripheral blood
- Marker detection based on five-dye fluorescent system technology
- Result analysis by professional softwares such as GeneMapper® or GeneMarker®



Trita® f-HPV Detection Kit

- Detection of 14 high risk genotypes of human papilloma virus (HPV) based on a single Multiplex Fluorescent PCR and a single run of capillary electrophoresis
- With high sensitivity and specificity in qualitative detection of 14 oncogenic genotypes of HPV such as 16, 18, 31, 33, 35,39,45,51,52,56,58,59,66 & 68.
- Uses extracted DNA from human pap-smear or urogenital swabs and biopsies.
- Providing a fast and easy method with ready-to-use reagents that you only need to add sample DNA
- Using human beta-globin gene as internal control which allows to determine both the quality of the sample DNA and the presence of potential inhibitors
- Compatible with a various model of thermocyclers and Genetic analyzers
- Result analysis by professional softwares such as GeneMapper® or GeneMarker®

Trita® r-HPV Detection Kit

- Provides an *in vitro* Real-Time PCR-based assay for the qualitative detection of 14 oncogenic human papillomavirus (HPV) genotypes, *i.e.,* 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.
- With high sensitivity and specificity in detection and genotyping of high risk HPV DNA
- Using human beta-globin gene as internal control which allows to determine both the quality of the sample DNA and the presence of potential inhibitors.
- Uses extracted DNA from human pap-smear or urogenital swabs and biopsies.
- Compatible with a various models of Real-Time PCR machines
- Genotyping 14 high risk HPV genotypes based on a multiplex Real-Time amplification of 4 PCR tubes for each sample.

Channel	Categorization of HPV genotypes in Trita® r-HPV Detection Kit			
FAM	16	35	51	52
Cy5	18	31	39	56
HEX	45	33	66	-
ROX	IC	68	59	58

TritEx® Viral RNA Extraction Kit

- A Fast and easy methodology to isolate high-quality RNA from little amount of biological specimens
- Using human biological samples such as body fluids, serum, plasma, cell culture supernatant and virus-infected samples (Blood is not included)
- Employing silica-based technology using spin column and optimized buffer concentration
- Isolation of high purity RNA with A260 / A280 ratio between 1.7–1.9 in less than 30 minutes
- Reduced hands-on time and cross-contamination as well as safe control of potentially infectious specimens
- Applicable in molecular research and genetic laboratories
- Isolation of high-quality pure RNA to be used in downstream reactions such as RT-PCR, Real-Time PCR, Nested PCR, Viral detection, *etc.*

TritEx® Blood DNA Extraction Kit

- Easy and rapid methodology to isolate high-quality DNA from very little amount of biological specimens
- Using Fresh and frozen human whole blood treated with EDTA and citrate from common blood collection system
- Employing silica-based technology using spin column and optimized buffer concentration
- Isolation of high purity genomic DNA (40-60 ng/µl) with an A260 / A280 ratio between 1.7–1.9 within a short time (less than 30 minutes)
- Reduced hands-on time and cross-contamination as well as safe control of potentially infectious specimens
- Applicable in molecular research and genetic laboratories
- Isolation of high-quality genomic DNA to be used in downstream reactions such as PCR, southern blotting, *etc.*

TritEx® HPV DNA Extraction Kit

- Easy and rapid methodology to isolate high-quality HPV DNA from very little amount of biological specimens.
- Using Fresh and frozen human Pop-smear samples infected with HPV or cervical biopsy *samples* collected from *suspected* patients.
- Employing silica-based technology using spin columns and optimized buffer concentration
- Isolation of high purity viral DNA (40-60 ng/µl) from pop-smear samples with an A260 / A280 ratio between 1.7–1.9 within a short time (less than 30 minutes)
- Reduced hands-on time and cross-contamination as well as safe control of potentially infectious specimens
- Applicable in molecular biology research and virology laboratories
- Isolation of high-quality viral DNA to be used in downstream reactions such as PCR, southern blotting, *etc.*

FastPure® Amniotic Fluid DNA Extraction Kit

- Easy and fast methodology for isolation of high-quality DNA from very little amount of biological specimens
- Using amniotic fluid samples as biological specimens
- Employing precipitation-based method using alcohols at optimized buffer concentration
- Isolation of high purity genomic DNA (50–180 ng/µl) from ameniotic fluid within a short time (less than 30 minutes)
- With satisfactory purity ratio of extracted genomic DNA (A260 / A280 ratio between 1.7–1.9 & A260 / A230 ratio between 1.7–2.3)
- Reduced hands-on time and cross-contamination as well as safe control of specimens
- Applicable in molecular biology research and genetic laboratories
- Isolation of high-quality genomic DNA to be used in downstream reactions such as PCR, southern blotting, *etc.*

FastPure® HPV DNA Extraction Kit

- Easy and fast methodology for isolation of high-quality viral DNA from very little amount of biological specimens
- Using Fresh and frozen human Pop-smear samples infected with HPV or cervical biopsy *samples* collected from *suspected* patients.
- Employing precipitation-based method using alcohols at optimized buffer concentration
- Isolation of high purity viral DNA (50–180 ng/µl) form Pop-smear samples within a short time (less than 30 minutes)
- With satisfactory purity ratio of extracted viral DNA (A260 / A280 ratio between 1.7–1.9 & A260 / A230 ratio between 1.7–2.3)
- Reduced hands-on time and cross-contamination as well as safe control of potentially infectious specimens
- Applicable in molecular biology research and virology laboratories
- Isolation of high-quality viral DNA to be used in downstream reactions such as PCR, southern blotting, *etc.*

Certificates

CERTIFICATO N. 0839.2020

TRITAGENE BIOTECH

ISO 9001:2015

CERTIFICATE

TRITAGENE BIOTECH

ISO 9001:2015

Issued on: 2020 - 06 - 29
Expires on: 2023 - 06 - 28

Registration Number: IT - 130946

CERTIFICATE

TRITAGENE BIOTECH

ISO 13485:2016

Issued on: 2020 - 06 - 29
Expires on: 2023 - 06 - 28

Registration Number: IT - 130947

CERTIFICATO N. 0840.2020

TRITAGENE BIOTECH

ISO 13485:2016

CERTIFIED IQNet MANAGEMENT SYSTEM

ISO 9001

ISO 13485

Tel: +98 (21) 44180181-2
Website: www.tritagene.com

E-mail: info@tritagene.com
tritagene@gmail.com

Address: TritaGene Biotech Co, National Institute of Genetic Engineering and Biotechnology, Pajoohesh Blvd., Hakim (Hamedani) Hwy, Tehran, Iran.

TritaGene