

P real-time PCR 등 allergens DNA/RNA Extraction is feed AUTOMAT Set BIOTECON is feed AUTOMAT vetproof® foodproof® Diagnostics pharma spoilage organisms O liquid handling viruses KITS E technical service Dualo 32<sup>®</sup> On microproof<sup>®</sup> food



# Herzlich Willkommen | Bienvenido | Bienvenue : Welcome : The state of the state of



"Imagine a world where no one gets sick from food.

We contribute by supporting our customers' need for innovative safety testing by developing state of the art solutions."



We are

# **FOOD SAFETY EXPERTS**

Over 20 years of developing and marketing real-time PCR tests for the food, feed and pharmaceutical industry.

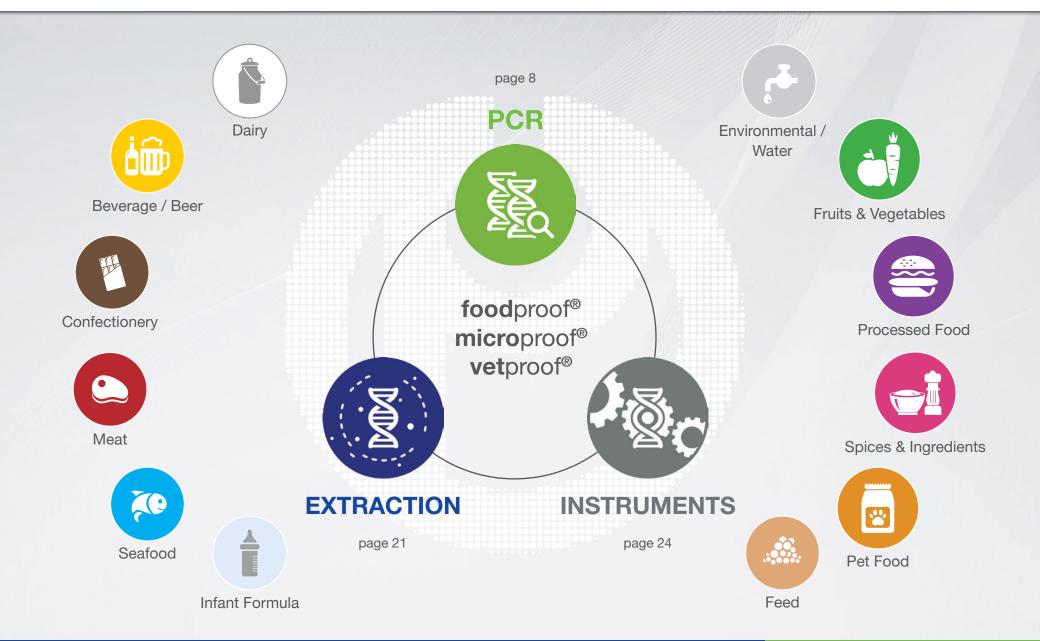
We welcome you to BIOTECON Diagnostics GmbH, situated on the beautiful peninsula of Hermannswerder in Potsdam, Germany. Our company was founded in 1998 and is established as a well-known and profoundly qualified partner for food, feed, beverage, pharma, water and veterinary testing. BIOTECON Diagnostics offers a complete portfolio of real-time PCR based kits, instruments (e.g. liquid handling systems, real-time PCR cyclers, MALDI-TOF MS), consumables, and software solutions as well as custom services and contract development.

In this age of globalization and ever increasing quality requirements, we have set up the right technology and

developed products which support our clients in the food and beverage industry to produce safe food. Our strengths are focused product development based on clients' needs, continuous quality control and unparalleled kit performance. Our vision is to further expand our position in the global market and to contribute to increased food safety through the use of our products.

We would like to warmly thank our clients and cooperation partners who have accompanied us in this pursuit. We are proud to present you the world of BIOTECON Diagnostics.

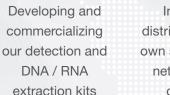
# The World of BIOTECON Diagnostics



# Business Strategy









International
distribution through
own sales force and
network of local
distributors



Setting up
PCR labs including all
needed equipment,
training, support and
automation according
to ISO 17025



Custom services and contract development



In- and outlicensing products and technologies for research and diagnostics

Our focus is on development, production and marketing of our PCR-based rapid **food**proof®, **micro**proof® and **vet**proof® detection kits. Our products provide customers with fast, reliable testing methods to screen for biological contamination. Our kits guarantee the highest quality standards for food, beverage, veterinary and

pharmaceutical industry. Additionally, the DNA extraction kits enable our customers to prepare nearly every matrix, especially difficult samples.

BIOTECON Diagnostics features a continuously growing network of local distributors.

# Competence, Experience and Success

	20 Years of Experience
1998	Spin-off BIOTECON Diagnostics GmbH
2000	Product launch <b>food</b> proof® kits
2001	Cooperation with Roche Diagnostics
2008	foodproof® 5'Nuclease kits
2009	Worldwide distribution network
2010	Pioneer in automated food analysis with the foodproof® RoboPrep Series
2011	Own software solutions for PCR and automation
2012	Setting up complete PCR labs for the industry
2013	foodproof® LyoKits KingFisher™ Flex
2015	Allergens, animal ID, yeast and mold
2016	Viral kits and MALDI-TOF MS
2017	Veterinary kits and RoboPrep Fusion®
2018	Dualo 32® cycler and environmental / water kits RoboPrep® 32 ELISA allergen kits

BIOTECON Diagnostics is a leading company in the field of real-time PCR for food safety testing. The high scientific competence of its international team builds the foundation that allows BIOTECON Diagnostics to offer complete solutions for sample preparation, DNA extraction and real-time PCR detection including cyclers, PCR lab equipment, robots, software solutions and consumables.

BIOTECON Diagnostics is certified by DIN EN ISO 9001:2015 and its service laboratory is accredited for analysis methods according to DIN EN ISO/IEC 17025.

The company is authorized to work with pathogenic organisms (L2, L3\*\*, §44 ff. Infection Protection Act) as well as genetically modified organisms.

Most of BIOTECON Diagnostics' pathogen test kits are successfully validated according to ISO 16140 and certified by internationally acknowledged validation authorities, such as AOAC, MicroVal and NordVal.

The quality and success of BIOTECON Diagnostics' products is reflected by a rapidly growing business and international distribution, both resulting in a profitable and sustainable business.



# Our Core Competence: Real-Time PCR

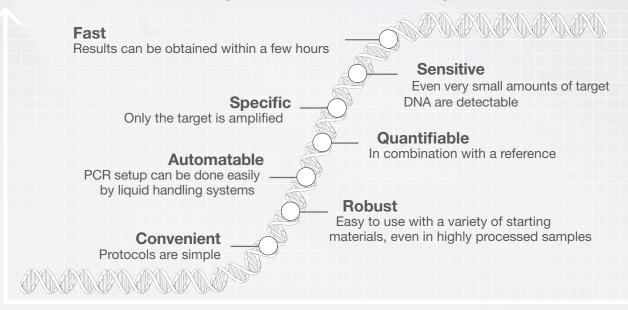


### Real-time PCR for food testing

Real-time PCR methods have been established and accepted in food analysis for many years now. They are used worldwide for the detection and quantification of bacteria, viruses, animal species, GMOs and allergens. Real-time PCR detects and amplifies a target DNA sequence using specific oligonucleotide primers and fluorescence probes. This technology enables a very specific, highly sensitive and – in combination with a suitable reference material – even quantitative detection of

the target organism. Since DNA is a very stable molecule, real-time PCR can be applied also in highly processed matrices. Sample preparation is comparable for all parameters. This enables time and cost saving workflows. In contrast to most other rapid detection methods, real-time PCR is faster - results can be analyzed within a few hours - more specific and sensitive, has a higher dynamic range for quantification and delivers more consistent results.

# **Advantages of Real-Time PCR Technology**



# Reagent D: elimination of DNA from dead cells

Matrices like powdered infant formula or processed seafood may contain a high background of dead target cells and free DNA, which may cause false-positive results or distort quantitative PCR assays. Reagent D is highly selective in penetrating only membranes of dead cells and can be used for live/dead differentiation to avoid false-positive results.

#### **Elimination Procedure**

Prior to performing the DNA extrac-

tion, Reagent D is mixed with the sample. Reagent D contains light sensitive substances that selectively penetrate cell membranes of dead cells. Brief exposure to visible light leads to covalent binding of Reagent D to dead cells and free DNA, preventing the masked DNA from being amplified in PCR. Reagent D has been validated in combination with BIOTECON Diagnostics' DNA extraction kits. Processing takes only a few minutes.



Reagent D: elimination of false-positive results due to dead cells and free DNA



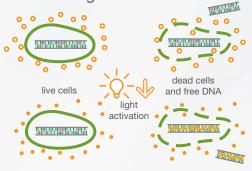
The **food**proof® D-Light instrument is designed for the use with Reagent D to eliminate false-positive PCR results from dead cells and free DNA

# foodproof® D-Light

- Fast: Up to 96 samples can be processed simultaneously
- Versatile: Allows use of different microplates and adapters in universal SBS format
- Convenient: Just insert sample plate, close lid and program will start automatically
- Safe: Secure sample workflow; no ice needed, no development of heat; reduced risk of cross-contamination
- Approved: Tested and certified for CE / FCC and product safety

# **PRINCIPLE**

1. Reagent D Treatment



2. After DNA Extraction

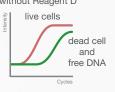


# 3. Real-Time PCR Run

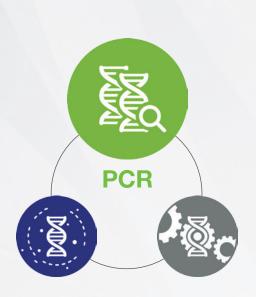
DNA of live cells dead cell and free DNA

amplification amplification blocked

without Reagent D with Reagent D



# Real-Time PCR Kits



Real-time PCR assays for detection, screening, identification and quantification



Sample Preparation / Sample Homogenization



**DNA / RNA Extraction** 



**PCR Setup** 



Real-Time PCR Run and Analysis



Foodborne Pathogens



Spoilage Organisms



**Yeast and Mold** 



**Viruses** 



**GMOs** 



**Animal ID** 



**Allergens** 



Veterinary



Pharma



**Environmental** 

**Instruments for Processing and Analysis** 



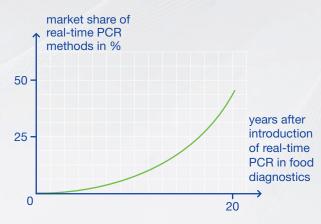
Microbial contamination by pathogenic bacteria is a predominant problem in food, feed and beverage manufacturing. Many foods and especially raw materials are not sterile, and unwanted bacteria, like pathogens, can colonize the product and lead to food poisoning or foodborne illness. Therefore, proper control of raw materials, products and environmental samples is necessary.

BIOTECON Diagnostics has designed a broad range of **food**proof® real-time PCR kits for precise and reliable detection, screening, identification and quantification. The assays are ready-to-use systems which represent fast and easy control solutions to guarantee a high level of safety for manufacturers and consumers.

## "Bad Bugs"

Several known pathogens (bacteria and viruses that cause disease) account for the vast majority of foodborne

illnesses, hospitalizations and deaths: e.g. *Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7 (and other STEC), *Campylobacter*, norovirus, *Yersinia*, *Staphylococcus aureus* and *Clostridium perfringens*.



Market share of real-time PCR based diagnostics in the food industry

BIOTECON Diagnostics' approvals for the most important foodborne pathogens.

Approvals for Kits	AOAC	NordVal	MicroVal	DAFF
Salmonella	+	+	+	+
Listeria monocytogenes	+	+	-	+
E. coli O157	+	+	-	+
Enterobacteriaceae plus Cronobacter	-	-	+	-

## **Parameters**

Bacillus cereus Brucella Campylobacter Clostridium botulinum Clostridium perfringens Cronobacter E. coli (O157, STEC) Enterobacteriaceae Listeria genus Listeria monocytogenes Salmonella Salmonella Typhimurium Salmonella Enteritidis Staphylococcus aureus Vibrio Yersinia

# Spoilage Organisms



BIOTECON Diagnostics offers real-time PCR-based test kits that allow detection spoilage bacteria and yeast at different stages during the production of food, beer and other beverages.

Monitoring to guarantee product consistency is traditionally accomplished using classical microbiological methods. As these methods are often very time-consuming and some are neither sensitive nor specific enough, BIOTECON Diagnostics developed rapid, sensitive and specific methods for the screening, detection and identification of relevant spoilage organisms in food and beverages.

### Beer-spoiling bacteria

The **food**proof® **Beer Screening Kits** allow real-time PCR detection of more than 30 different spoilage bacteria in one test. The liquid kit identifies the most important species, like *Lactobacillus brevis*, *Lactobacillus lindneri*, or *Megasphaera* by melting curve analysis. The lyophilized kit allows the identification of *L. brevis* and detection of hop-tolerance genes *horA* and *horC*. Kits contain all reagents needed for the detection of beer-spoilage bacteria, including UNG (Uracil N-Glycosylase) to prevent carry-over contamination and the internal amplification control (IAC) to avoid falsenegative results.

# Overview of detected beer spoilers by the foodproof® Beer Screening Kits

### Lactobacillus

L. lindneri

L. brevis

L. collinoides

L. paracollinoides

L. coryniformis

L. casei

L. parabuchneri (frigidus)

L. plantarum

L. perolens

L. harbiniensis (perolens)

L. rossiae

L. pentosus

L. paraplantarum

L. paracasei

L. buchneri

L. backii

L. acetotolerans



#### **Pectinatus**

P. cerevisiiphilus

P. frisingensis

P. haikarae

## **Pediococcus**

## Megasphaera

M. cerevisiae

M. paucivorans

M. sueciensis

- Carococa

P. damnosus P. inopinatus

P. clausenii

P. acidilactici

P. pentosaceus

P. parvulus

## Spoilage yeast

Yeasts play a central role in spoilage of beverages, particularly those with high acidity and high osmolarity.

BIOTECON Diagnostics now offers two specific kits to detect and optionally quantify the most important spoilage yeasts. The foodproof® Spoilage Yeast Detection 1 LyoKit detects the three genera Dekkera/Brettanomyces, Zygosaccharomyces and Saccharomyces in three different fluorescence channels in a single reaction.

Additionally, the foodproof® Spoilage Yeast Detection 2 LyoKit detects S. diastaticus, Wickerhamomyces anomalus, Kazachstania exigua and Schizosaccharomyces pombe individually in one test.

In combination with our **food**proof® DNA extraction kits, both LyoKits can be used to detect and quantify these spoilage yeasts in wine, beer and other beverages.

## Alicyclobacillus

For the prevention of spoilage by Alicyclobacillus in juices, tomato-based products and fruit preparations, BIOTECON Diagnostics has developed the foodproof® Alicyclobacillus Detection Kit. The kit detects all Alicyclobacillus species and additionally identifies Alicyclobacillus acidoterrestris, the most common juice spoiler, in a single reaction.

# **Overview of detected spoilers** by the foodproof® Spoilage Yeast Kits

## **Z**ygosaccharomyces

- Z. bailii
- Z. bisporus
- Z. gambellarensis
- Z. kombuchaensis
- Z. lentus
- Z. machadoi Z. mellis
- Z. parabailii
- Z. pseudobailii
- Z. pseudorouxii
- Z. rouxii

Z. sapae Z. siamensis

# Dekkera/ **Brettanomyces**

- B. naardenensis
- B. nanus
- D. anomala D. bruxellensis
- D. custersiana

Saccharomyces cerevisiae var. diastaticus Kazachstania exiqua



## **Parameters**

Dekkera / Brettanomyces

Zygosaccharomyces

Saccharomyces incl. diastaticus

Wickerhamomyces anomalus

Kazachstania exigua

Schizosaccharomyces pombe





# Yeast and Mold in Dairy



Growth of yeasts and molds is mostly undesirable in milk and dairy products. Especially dairy products with low pH and acidic dairy products are at a high risk of spoilage. Traditional colony count methods require 5-14 days to achieve a result. This is critical because many milk products, like yogurt, must be kept in the cold chain and typically have short lives of a few weeks only.

The foodproof® Yeast and Mold Quantification LyoKit provides a quick and safe solution for everyone who needs to quantify these potential spoilage organisms in dairy products. Within five hours including DNA extraction and live and dead cell differentiation, all yeasts and molds will be detected and quantified. Only living organisms are detected, and the results are expressed as cfu/g.



Aspergillus niger

High throughput testing is possible by a special protocol using 8-channel pipettes and deep-well plates. In the future the range of applications for this kit will be expanded to other food categories like beverages.

# **Workflow**



Sample Preparation 30 min



**DNA Extraction\*** 60 min



PCR Setup 10 min



Real-time PCR Run 160 min

Analysis Results in 4.5 h

\* including live and dead cell differentiation



Food- and waterborne outbreaks involving hepatitis A virus (HAV) and norovirus (NoV) are associated with different matrices, including berries, fruit and vegetables, seafood and fish, meat, dairy products and drinking water.

Since 2013, the use of real-time RT-PCR assays has been part of the ISO standard 15216 for the detection of viruses in food and water samples.

BIOTECON Diagnostics offers dedicated **food**proof® virus detection kits for NoV and HAV separately as well as together in a multiplex assay. The unique all-in-one multiplex real-time RT-PCR test, **food**proof® **Norovirus** (GI, GII) plus Hepatitis A Virus Detection Kit, allows simultaneous, qualitative detection and differentiation of



Norovirus is the #1 cause of diarrhea or vomiting outbreaks. It is spread by direct contact with an infected person or by contaminated food (14 % of all outbreaks are food-related).

CDC, 2017

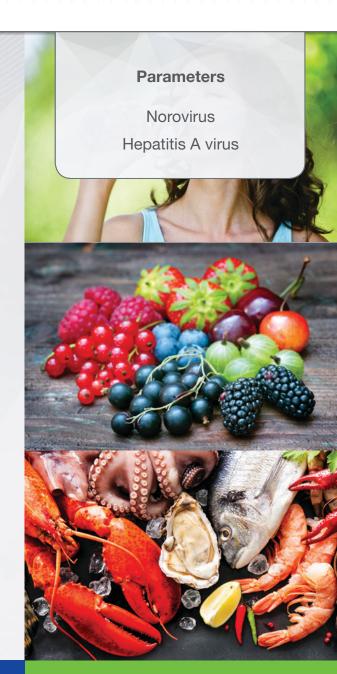


In the US, 3 out of 4 norovirus outbreaks occur in long-term care facilities. Elderly residents are more likely to get sick or die from norovirus.

CDC, 2017

HAV, NoV (separate answers for genogroups I and II) and a process control, bacteriophage MS2. Each kit includes a solution of the process control, which can be added to the sample. The virus kits allow simple and safe detection of viral RNA and process control for each sample in parallel. Additionally, we offer the **food**proof® **Sample Preparation Kit IV** for viral RNA extraction.

In the 2017 performance ring trial of the European Reference Laboratory for monitoring bacteriological and viral contamination of bivalve molluscs, the BIOTECON real-time RT-PCR assays showed 100 % accuracy!





# Screening:

P-35S, T-NOS, P-FMV
bar, P-35S-pat
CTP2-CP4-EPSPS
P-35S-nptII, P-NOS-nptII
CaMV

## Identification:

Maize

(e.g. Bt11, MON810)

Soya

(e.g. RR Soya, RR 2 Yield Soya)

## Quantification:

event-specific element-specific (e.g. soya, maize)

# The comprehensive GMO analysis solution

BIOTECON Diagnostics' GMO analysis strategy is a sophisticated combination of screening, identification and quantification assays for maximum coverage of the presence and identity of GMOs. The flexible GMO assays offer an easy and cost-effective approach for the analysis of genetically modified plants in food and feed.

## Global planting of soya and maize



source: ISAAA 2016

For every step of the analysis process, screening, identification and quantification, efficient solutions are available. Our screening approach with the **food**proof® **GMO Screening 1 LyoKit** and the **food**proof® **GMO Screening 2 LyoKit** targets 8 transgenic regulatory elements in total, reducing time, effort and costs to a minimum. The **food**proof® **GMO Soya and Maize Identification LyoKits** are multiplex identification assays that support precise event identification, including events not covered by screening. Exact and reliable quantification can be performed



Maize and soya are the most commonly genetically modified plants worldwide.

with the **food**proof® **GMO Quantification Kits**. The assays were developed according to the specifications of ISO-methods, the European Network of GMO Laboratories (ENGL) and the German Food Law § 64 LFGB.

# **Questions for GM Food and Feed Analysis**



- DOES A SAMPLE CONTAIN GMO?
   Can be answered by screening
- 2. WHICH EVENTS ARE IN THE SAMPLE?
  ARE THESE EVENTS AUTHORIZED?
  Can be answered by identification
- 3. IF IT IS AUTHORIZED, IS THE RELATIVE CONTENT ABOVE LEGAL LIMITS?

  Can be answered by quantification

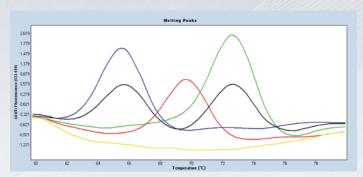


### Maintain product quality

Animal species testing is crucial for product quality control, whether to detect food adulteration or because of religious requirements. The detection, identification and quantification of potential contamination in processed and ready-to-eat food has become increasingly important.

### Horse Meat Scandal

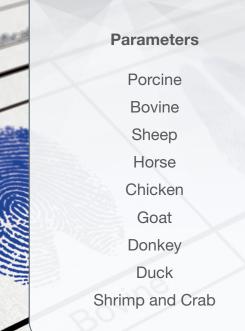
In 2013, the horse meat scandal took place in Europe, where meat, declared as beef, was found to contain horse meat. The scandal started in Ireland when food inspectors from the Food Safety Authority Ireland (FSAI) found traces of horse meat in burgers labeled as beef. This led to the recall of 10 million burgers from the market. Two weeks later, the UK Food Standards Agency (FSA) declared they had found up to 100 % horse meat in beef lasagna. In the following weeks, more products, e.g. frozen spaghetti meals, were found to contain up to 100 % horse meat, and more countries like France, Sweden, Germany and Austria were affected. Further tests found other unwanted components, e.g. pork meat or phenylbutazone. Although the horse meat scandal caused great public interest, two years later nearly nothing has changed: controls are still insufficient and in fact testing has declined nearly 15 % in the UK due to lack of funds. The meat trading companies responsible for the horse meat scandal renamed their businesses and today continue to manufacture food for the European market. The bottom line: food quality still must be maintained by the manufacturer.



Differentiation of equine species using melting curve analysis: differentiation of donkey (blue), zebra (red) and horse (green). Black line: control template. Yellow line: negative control.

Precise animal species identification methods are required to fight food fraud. Moreover, market demands for vegetarian products or food prepared according to religious guidelines, e.g. halal or kosher food, also require accurate testing.

BIOTECON Diagnostics offers a broad range of assays for the detection and identification of animal species in food samples. Real-time PCR is the method of choice, as even small traces in heavily processed matrices, like gelatin, should be declared. Lyophilized multiplex assays like the **food**proof® Animal Detection 1 LyoKit, which identifies porcine, bovine, horse, donkey, and zebra in a single reaction, help to reduce effort, time and cost.





# Allergens

**Parameters** (Real-time PCR) Celery Soya Peanut Hazelnut Walnut Gluten

220 - 250 million people are affected by food allergies





source: WAO, 2014

### The Kiss of Death!

In 2002, American physicians reported the case of a 20 year old woman with a known allergy to crustaceans. She nearly died due to allergic symptoms after kissing her boyfriend: He had consumed shrimp some hours before!

The kiss transferred traces of allergenic proteins and lead to an intense immune reaction. The symptoms were an angioedema of the lips, a swelling of the throat, diffuse flushing, urticaria, abdominal convulsion, respiratory filibuster and dyspnea.

Source: Steensma, DP: The kiss of death: a severe reaction to a shellfish induced by a good-night-kiss, Mayo Clinic Proceedings, 78(2002), P.221-222

To fulfill increasing market demand for allergen-free food, BIOTECON Diagnostics has developed high quality detection kits for food allergens. This extends the comprehensive portfolio of **food**proof® real-time PCR kits by another innovative group of parameters.

# Food allergens worldwide

Food allergen testing has become more important because the frequency of allergies in the population, especially in urban areas, has grown significantly in the last decade. The reasons are still unclear. Speculation of causes has focused on changing environmental influences and diet. Depending on the reference, worldwide prevalence of food allergies is between  $2-4\,\%$  for adults and  $4-8\,\%$  for children.

## Allergen real-time PCR kits

BIOTECON Diagnostics offers **food**proof® real-time PCR kits for the detection of celery, peanuts, hazelnut, soya and gluten. In combination with the **food**proof® Sample Preparation Kit III for manual and the **food**proof® Magnetic Preparation Kit III for automated extraction of plant DNA, the allergen kits allow simple and safe quantification of allergens in all kind of processed foods, raw materials and swab samples. To complete the portfolio, BIOTECON Diagnostics has developed a standardized reference material, Allergen RM 800, in order to create a reliable standard curve for exact quantification.

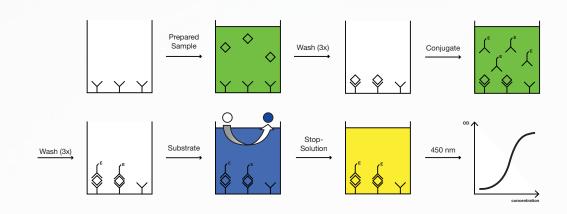
### Allergen ELISA kits

Enzyme-linked immunosorbent assay (ELISA) technology has been well established in laboratories worldwide for over 30 years. They are well-known and highly accepted by laboratory staff because they are robust, reliable, specific and highly sensitive.

Allergen testing with DNA detection methods is limited in its ability to distinguish between some animal products like milk or beef and eggs or chicken.

In contrast, ELISAs detect protein structures, thus eliminating this problem. Moreover, ELISAs are ideal for products which contain only minor amounts of DNA (e.g. egg white).

BIOTECON Diagnostics offers a wide range of ELISA diagnostic parameters from our partner Immunolab GmbH. With these assays, BIOTECON is enabling food laboratory users to establish a complete range of food allergen testing with a cost efficient and reliable method.



#### **ELISA**

A principle of ELISA technology is that specific antibodies are immobilized to a microtiter plate. The analyte (antigen) from the sample binds to the coated antibody, building an antibody-antigen complex. If antibody-antigen binding has taken place, this complex can be visualized using an enzyme that is linked to secondary antibodies. An added substrate is converted by the linked enzyme inducing a color change, which can be measured optically with a microplate reader.

# Parameters (ELISA)

Beta-Lactoglobulin

Casein

Cashew

Crustaceans (Tropomyosin)

Egg white

Fish (Parvalbumin)

Gliadin / Gluten

Lupine

Lysozyme

Milk

Mustard

Ovalbumin

Peanut

Sesame

Soya (Soy)

Tree nuts

# Pharma A Pharma

## **Parameters**

Staphylococcus
Micrococcus
Corynebacterium
Streptococcus pneumoniae



Since 2004, the use of more sensitive and specific tests has been recommended by the European Pharmacopoeia and by the FDA Aseptic Guideline with references to real-time PCR methods.

## **Environmental monitoring**

System offers the perfect solution for a fast and accurate screening of the three genera *Micrococcus*, *Staphylococcus* and *Corynebacterium* for pharma hygiene monitoring in clean rooms and other facilities. Additionally, some of the most important species like *Micrococcus luteus* and *Staphylococcus aureus* can be identified within the same test.

## Highest accuracy and specificity

An interlaboratory study was conducted with BIOTECON Diagnostics' microproof® Hygiene Screening System by eight international pharmaceutical companies. The PCR system was compared to their routine screening and identification methods. The results overwhelmingly showed that the microproof® system provided significantly better accuracy and specificity in a much shorter time frame.

### Contract development of rapid pharma methods

BIOTECON Diagnostics services include contract kit development of tailor-made solutions. With in-depth knowledge of development, manufacturing and lyophilization of PCR methods, BIOTECON Diagnostics provides a strategic partnership that can accelerate success.



Rapid hygiene monitoring of sterile production facilities.



### Water quality and environmental testing

Water quality control and environmental testing are a major concern for public health and thus subject to laws and regulations in many countries. Water systems may become contaminated with pathogens.

Legionella, for example, can grow in many building water systems and then spread by contaminated water droplets. Rising numbers of legionellosis outbreaks all over the world show the high need for diagnostic tools to monitor water systems such as in evaporative cooling systems, cooling towers or decorative fountains.



Inhalation of small water droplets contaminated with *Legionella*, like produced from shower heads, may lead to the contraction of Legionnaires Disease, which is fatal in 15 % of reported cases.

# Legionella: not a cold case

The Legionnaires' disease, an atypical form of pneumonia, is named after an outbreak at a meeting of US-veterans of the American Legion in a hotel in Philadelphia in 1976. 182 visitors of the hotel got hospitalized, 29 died. Investigations of the Centers for Disease Control and Prevention (CDC) led to the isolation and identification of *Legionella pneumophila*, the causative organism of the Legionnaires' disease. The bacterium was found within the cooling tower of the hotel's air conditioning system, which then spread it through the building. After an unprecedented and outstanding investigation of the CDC the causative agent was found.

BIOTECON Diagnostics' real-time PCR-based microproof® LyoKits play a trusted role in detection and quantification of pathogens in environmental samples and water, and offer reliable analysis with high sensitivity and specificity. The microproof® Legionella Quantification LyoKit detects and individually quantifies Legionella spp., Legionella pneumophila and Legionella pneumophila serogroup 1 in just one single test, using separate fluorescence channels. Results are provided in only four hours. Our well-proven Reagent D for live / dead differentiation is included in our method. All relevant sample types, like clear or turbid water samples, can be tested.

# **Parameters** Legionella Legionella pneumophila Legionella pneumophila serogroup 1



# 

# Parameters\* Salmonella Salmonella vaccines Mycoplasma \* Regulatory requirements vary by country; products may not be available in your geographic area

Our new **vet**proof® product portfolio focuses on animal health and the safety of products of animal origin. Human *Salmonella* infections may occur through contact with farm animals or consumption of raw and undercooked food. Advanced diagnostic testing of animal, environmental and food samples is key to animal health and high-quality animal-derived products.

BIOTECON Diagnostics has extensive experience in handling difficult samples for the analysis of *Salmonella* contamination, e.g. avian feces, dust, serum, plasma, blood, meat and environmental swabs.



Campylobacter is a bacterium that causes the disease campylobacteriosis. With about 200,000 human cases every year in the European Union (2014 data), this disease is the most frequently reported foodborne illness. Raw poultry is often contaminated with Campylobacter since the bacteria can live in the intestines of healthy birds. Handling of contaminated raw chicken or ready-to-eat food and eating undercooked chicken are the most common sources of infection.



Salmonellosis is a disease you get by eating contaminated food or by touching animals carrying *Salmonella* bacteria. According to the World Health Organization, eggs are a common source of human *Salmonella* infection. There are over 85,000 cases of human salmonellosis reported each year in the European Union (2015 data).

Our newest kits in this product line are the **vet**proof® **Salmonella Detection Kit** and a specialized identification kits for *Salmonella* live vaccine strain identification, e.g. **vet**proof® SE Vaccine Detection 1 Kit.

We further offer a wide selection of high quality molecular diagnostic solutions for the detection of *Campylobacter* spp. (including quantification), *Salmonella* Enteritidis and *Salmonella* Typhimurium, *Mycoplasma gallisepticum*, *M. synoviae*, *Listeria* spp. and *Listeria monocytogenes*.

In addition, the **food**proof® Magnetic Preparation Kit VI for automated extraction of viral RNA / DNA is suitable for starting material of different veterinary matrices, e.g. like serum, plasma, saliva, allantoic fluids or feces samples.

# DNA / RNA Extraction Kits



Sample Preparation / **Sample Homogenization** 



**DNA / RNA Extraction** 



**PCR Setup** 



**Real-Time PCR Run** and Analysis



**StarPrep Kits** 



**ShortPrep Kits** 

Fast and easy lysis by mixing samples with buffer



**Sample Preparation Kits** 



**Magnetic Preparation Kits** 

High purity DNA / RNA clean-up manual column based or automated magnetic bead based

**Instruments for Processing and Analysis** 



DNA / RNA extraction kits for different requirements e.g. convenience, speed, purity and complex matrices



# DNA / RNA Extraction Kits

## DNA / RNA extraction from:

Food

Feed

Beverages

Cosmetics

Environmental samples

Veterinary samples





foodproof® ShortPrep Kits



foodproof®
Sample
Preparation Kits



foodproof® StarPrep Kits



foodproof®
Magnetic
Preparation Kits

Reliable analysis of food and feed samples with real-time PCR require appropriate sample preparation. Optimized and validated methods for the extraction of nucleic acids from any kind of biological material are of high importance. The processed sample must be free of contaminants, especially inhibitors, while retaining even small amounts of the target's genetic information. The extraction method should be as fast and convenient as possible without compromising safety or reproducibility.

Optimized combination of extraction kit and PCR assay BIOTECON Diagnostics has developed a broad range of fast, safe and easy-to-use DNA and RNA extraction kits for any food, beverage or environmental sample. Our

extraction kits have been optimized in combination with our **food**proof® real-time PCR Kits. The isolated DNA/RNA can be used directly in all our real-time PCR assays.

# Direct lysis, column-based or automated

The **food**proof® ShortPrep, StarPrep, Sample Preparation and Magnetic Preparation Kits assist users in efficiently working with all types of sample matrices, including difficult complex samples e.g. cheeses, spices or cocoa powder.

Overcome the challenges of complex matrices, PCR inhibitors and hidden targets with BIOTECON Diagnostics' fast, straight-forward easy-to-use solutions.

The **food**proof® DNA / RNA extraction kits for all common matrices and parameters.

	Ra	pid	Highly purified		
Target	Bulk	Prefilled	Column based	Bead based/ Automated	
Gram-negative bacteria	StarPrep One StarPrep One 8-Strip*	ShortPrep I	Sample Preparation I	Magnetic Preparation I, V	
Gram-positive bacteria	StarPrep Two StarPrep Two 8-Strip*	ShortPrep II	Sample Preparation II	Magnetic Preparation II	
Enterobacteriaceae Cronobacter	StarPrep One	-	-	Magnetic Preparation IV	
Vibrio, STEC and Beer spoilage bacteria	StarPrep Three	-	-	-	
Legionella	StarPrep Two	-	-	-	
Dekkera, S. cerevisiae var. diastaticus	StarPrep Two	StarPrep Four	-	-	
Yeast and Mold	StarPrep Two StarPrep Six 8-Strip*	-	-	-	
GMOs and Allergens	-	-	Sample Preparation III	Magnetic Preparation III	
Animal ID	StarPrep Five	-	Sample Preparation III	Magnetic Preparation III	
Viruses	-	-	Sample Preparation IV	Magnetic Preparation VI	

<sup>\*</sup>high-throughput using multi-channel pipette

# WORKFLOW

e.g. StarPrep One



ADD SAMPLE
CENTRIFUGE 5 min
DISCARD SUPERNATANT



ADD LYSIS BUFFER



MIX



INCUBATE 10 min



MIX



CENTRIFUGE



SUPERNATANT FOR DETECTION



# Instruments



Instruments for processing and analysis e.g. cycler, automation, lab equipment and software



Sample Preparation /
Sample Homogenization



DNA / RNA Extraction



PCR Setup



Real-Time PCR Run and Analysis

# **Instruments for Processing and Analysis**



**Automation** 

**Real-Time** 

**PCR Cycler** 



**Software** 



**Devices** 



**MALDI-TOF MS** 

# Sample Enrichment / Processing









Food, feed, environmental and veterinary samples

# **DNA / RNA Extraction and PCR Setup**

RoboPrep® 32

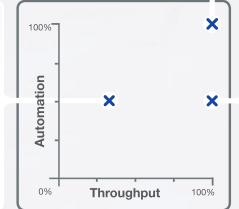
 Automated DNA / RNA extraction for 32 samples

- Low consumables costs



# RoboPrep Fusion®

- All-in-one solution for automated DNA / RNA extraction and PCR setup
- 96 samples simultaneously, sample tracking integrated



# ■ KingFisher™ Flex

- Automated DNA / RNA extraction
- Compact, robust system



Real-Time PCR Run and Data Analysis



Real-Time PCR Cycler and Diagnostic Interpreter



# All-In-One-System Automation



### The complete automation solution

The **food**proof **RoboPrep Fusion**® system achieves high throughput capabilities for automated sample handling and PCR setup. Together with its integrated KingFisher™ Flex unit, the system is a complete workstation for automated and fast extraction and PCR setup.

The protocol can be started using an integrated barcode reader, which ensures correct sample tracking. Up to 96 samples can be processed in one run automatically. The main advantage of the complete system is an automated, unattended proceeding, starting with sample preparations and ending with the final PCR setup in one single unit – the **food**proof **RoboPrep Fusion**<sup>®</sup>.

The innovative method of nucleic acids extraction by magnetic separation allows the generation of ultra-pure,

ready-to-use original DNA/RNA for enhanced performance in sensitive real-time PCR applications. Overall the system requires minimal user interaction and frees up your team for other value adding tasks.

The process begins with the liquid handling unit preparing the reagents and sample material for extraction. The integrated gripper arm then transfers plates to the KingFisher™Flex. After finishing the nucleic acid extraction protocol, the gripper arm moves the microtiter plate with the eluted sample DNA / RNA back to the liquid handling unit and continues with subsequent PCR setup.

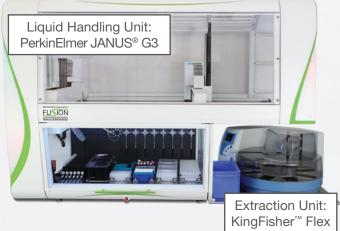
This unique combination allows the automation of almost all pipetting steps, frees up time of lab personnel and helps maximize lab productivity and efficiency.

# foodproof RoboPrep Fusion® Liquid Handling Unit: erkinElmer JANUS® G3 It is the perfect combination of a precise liquid handling robot with an attached and highly efficient DNA / RNA extraction system – the KingFisher™ Flex. The unique

features are:

Application guarantee (for specified parameters / protocols / support )

- Speed (e.g. Salmonella protocol of up to 96 samples takes only 96 minutes)
- Robustness (no air-displacement pumps, two separate instruments, can also work independently)
- Minimal consumption of tips and consumables





# Automated DNA / RNA Extraction





# The KingFisher™ Flex

As part of the **food**proof® RoboPrep® Series for high-throughput molecular testing, the KingFisher™ Flex offers fast and convenient DNA / RNA extraction. The applied technology is based on transferring magnetic beads rather than liquids. This provides a unique solution for quick and reliable automated extraction of plant DNA, animal DNA and viral DNA / RNA from food, feed, beverages, environmental samples and raw materials.

In combination with the **food**proof® **Magnetic Preparation Kits,** this instrument features many benefits that can increase lab productivity drastically.

# The foodproof® RoboPrep® 32

BIOTECON Diagnostics extended their **food**proof® RoboPrep® Series family: The **food**proof® RoboPrep® 32. With up to 32 samples per run, this small foot printed instrument allows to perform an isolation of high purified DNA / RNA from food and feed samples with the advanced magnetic bead technology. Due to its compact size and easy handling, the instrument will perfectly adapt to the laboratory workflow. The open platform allows to implement additional applications. BIOTECON Diagnostics already implemented validated protocols for bacteria (e.g. *Salmonella*) as well for isolation of GMO with the **food**proof® Magnetic Preparation Kits on the **food**proof® RoboPrep® 32 instrument.

**Fast** - High-throughput automated DNA / RNA extraction for 96 samples in 35 minutes

**Innovative** - GMO, allergen, animal ID and pathogen analysis

**Approved -** Validated and optimized protocols for food, feed and veterinary testing

**Convenient –** Simple process setup and easy-to-use software via touch screen

**Efficiency** - Compact and robust automated extraction device for up to 32 samples in less than one hour

Size - Small footprinted instrument: 40 cm (W) x 42 cm (D) x 44 cm (H)

**Economy** - Low cost per sample with a minimum of needed consumables

**Versatility** - Open system allows multiple applications



# Applications and Services for Automation

# **Technical Service**

As a pioneer in the field of automated molecular food diagnostics, BIOTECON Diagnostics has extensive experience in the care and maintenance of systems and applications. Our experienced team of certified service engineers provides installation and training, help desk support, as well as maintenance and repair of systems.

- Qualified Experienced and certified team of service engineers
- Comprehensive Repairs, preventive maintenance and upgrades of our automated systems in the field
- Flexible Service contract models suit individual customer specifications



# foodproof® Magnetic Preparation Kits

The foodproof® Magnetic Preparation Kits are based on magnetic bead technology and provide ultra-pure, ready-to-use DNA / RNA of bacterial, viral, plant or animal origin for enhanced performance in sensitive real-time PCR applications.

Salmonella Detection Kits using the automated protocol.

MicroVal and AOAC-RI certificate for foodproof®

Magnetic Preparation Kit I plus foodproof®

MICROVAL® W



Overview of **food**proof® Magnetic Preparation Kits

	MPK I	MPK II	MPK III	MPK IV	MPK V	MPK VI
Targets	Gram-negative bacteria, e.g. Salmonella spp.	Gram-positive bacteria e.g. <i>Listeria</i>	GMOs animal ID allergens	Enterobacteria- ceae Cronobacter Salmonella spp.	Salmonella spp.	Viruses
Matrices	food and feed	food and feed	food and feed	infant formula	food	serum, plasma, blood and feces
Approvals	AOAC and MicroVal	-	-	MicroVal	-	-
Additional Products	Consumable Pack (960 isolations)	Consumable Pack (960 isolations)	Consumable Pack (480 isolations)	Consumable Pack (480 isolations)	Consumable Pack (480 isolations)	Consumable Pack (480 isolations)
Instruments	foodproof RoboPrep Fusion®, KingFisher™ Flex, RoboPrep® 32	<b>food</b> proof RoboPrep Fusion®	KingFisher™ Flex, RoboPrep® 32	KingFisher™ Flex	KingFisher™ Flex	KingFisher™ Flex













Overview Real-Time PCR Cyclers							
Cycler	LightCycler® 480 II	LightCycler® 96	LightCycler® 2.0	AriaMx	Dualo 32® (MyGoPro)		
Capacity	96 samples / run	96 samples / run	32 samples / run	96 samples / run	32 samples / run		
Sample Volume	10 - 100 μΙ	10 - 50 μΙ	20 μl or 100 μl	10 - 30 μΙ	10 - 100 μΙ		
Profile	Low Profile	Low Profile	Capillaries	Low Profile	Low Profile		
Excitation (nm)	Broad spectrum LEDs	Broad spectrum LEDs	High brightness LEDs Broad spectrum LEDs		Full spectrum LEDs		
Emission	CCD camera	CCD camera	Photohybrid	Photo detectors	COS array		
Channels	6	4	6	4 (or 5)	120		
Dyes*	LC Cyan 500, SYBR Green I, <b>FAM</b> , <b>HEX/VIC</b> , <b>ROX</b> , <b>LC</b> Red 610 and 640 and <b>Cy5</b>	SYBR Green I, FAM, ROX, HEX/VIC, Yellow555, Cy5, Red 610 and Texas Red	SYBR Green I, HEX/VIC, <b>LC Red 610</b> , <b>640</b> , <b>670</b> and <b>705</b>	SYBR Green I, <b>FAM</b> , <b>HEX</b> , <b>ROX</b> , Cy3, <b>Cy5</b> and Atto425	SYBR Green I, FAM, Cy5, HEX/VIC, ROX and many more		
Color Compensation	Yes	Not necessary	Yes	Not necessary	Yes		
Supported Assay Format	Hybridization probes hydrolysis probes intercalating dyes	Hydrolysis probes intercalating dyes	Hybridization probes hydrolysis probes intercalating dyes	Hydrolysis probes intercalating dyes	Hybridization probes hydrolysis probes intercalating dyes		
<b>Melting Curve</b>	Yes	Yes	Yes	Yes	Yes		
Multiplexing	Yes	Yes	Yes	Yes	Yes		
Touchdown	Yes	Yes	Yes	No	Yes		

 $<sup>^{\</sup>ast}$  Highlighted dyes are used in BIOTECON Diagnostics' kits.



## microproof® Diagnostic Interpreter Software

BIOTECON Diagnostics has developed the **micro**proof® Diagnostic Interpreter Software as a tool to simplify the analysis and interpretation of real-time PCR data. It can be used as an extension to existing cycler-specific software.

# Simple workflow - reliable interpretation

The **micro**proof® Diagnostic Interpreter Software imports measured raw data from an experiment, performs a technical validation of the controls used in the assay, and finally interprets the results with validated, assay-specific algorithms. This way the interpretation of the results is not done by the cycler software only, increasing reliability and safety of the results and expanding the possibilities of final result reporting. The re-evaluated data is summarized in an easy-to-read report (tabular form or matrix report) and can be directly printed, saved or exported.

### Results summarized

### **Experiment status:**

- successful (controls passed)
- invalid (controls failed)

## Sample results:

- positive
- negative
- repetition (samples need to be repeated)

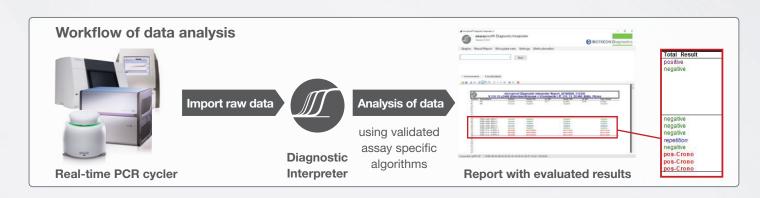
For multiplex tests, the results are reported like

- EB positive or
- Cronobacter positive

**Languages:** German, English, French and Spanish **Supported cyclers:** 

■ Roche Lightcycler® 480 II, Roche Lightcycler® 96, ABI 7500 and ABI 7500 Fast

Operating systems: Windows XP / 7 / 8 / 10





BIOTECON Diagnostics provides complete solutions for entry into PCR technology. Following extensive consultation with our team, tailored solutions for individual customer needs and laboratory requirements are implemented. The perfect device selection is made from a large portfolio of laboratory equipment.

We offer matching consumables for all equipment obtained through BIOTECON Diagnostics. All of our recommended products have been extensively validated in combination with our offered equipment and products.



## Centrifuges

- Centrifuge MicroStar 17
- Centrifuge Rotanta 460
- Centrifuge Perfect Spin for PCR Plates
- Microcentrifuges for Tube Strips
- Clinical Centrifuges
- Universal 320
- Centrifuge / Vortex-Multispin MSC-3000 or CVP-2



# Equipment for mixing, homogenization and cell disruption

- Disruptor Genie
- Vortex Genie
- BeadBug
- GeneReady
- Magnetic Stirrer
- Tube Mill Control
- Grindomix GM 200
- Swing Mill MM400



# **Heating blocks**

- TH 21 Heating Block Thermostat
- MRH13 Heating Thermomixer
- Heating Block, digital 1-block
- Heating Block Duo, digital 2-block

## Other

- Clean bench
- UV PCR cabinet
- Pipettes
- Microplate reader (BioTek ELx 808)

# **Devices**

D-Light
Centrifuges
Equipment for mixing,
homogenization, cell disruption
Heating Blocks
Clean benches
Pipettes
Microplate readers

## Consumables

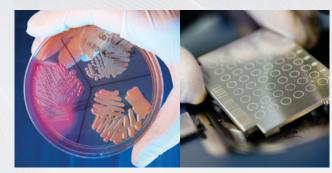


# MALDI-TOF MS .



The MALDI Biotyper system (microflex LT/SH) needs no special requirements for the laboratory. In the front, there is the sluice gate, which will transport the target with the samples into the instrument for measurement.

The MALDI Biotyper® (microflex LT/SH) as a molecular mass spectrometer is designed and developed for the rapid identification of a wide range of microorganisms. The



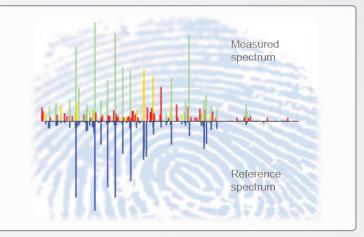
A colony from an agar plate is transferred to a target plate for identification by the MALDI Biotyper system.

microorganisms are identified by comparing recorded mass spectra to reference spectra from a valid database. Therefore, excellent and valid reference databases are important.

# Advantages of MALDI-TOF MS

- Very high identification potential (> 2,600 species)
- Provides additional information, e.g. after qualitative real-time PCR results
- Identification of Gram-negative / Gram-positive bacteria, yeast, mold and more
- Fast, high-throughput analysis
- Easy handling
- Robust benchtop instrument
- Low consumable costs

With MALDI-TOF MS (Matrix Assisted Laser Desorption / Ionization - Time of Flight Mass Spectrometry) technology, it is possible to identify microorganisms by their unique properties in the protein profile which is visible through a mass spectrum. With this characteristic mass spectrum as the proteomic fingerprint, an individual microorganism can be distinguished and identified. The characteristic spectrum is compared with the reference spectra of existing and evaluated database within minutes. The system is efficient and versatile for identification purposes in food and pharma industries. Other applications for the MALDI Biotyper® include mastitis analysis, environmental monitoring and others.



## **Automated colony picker**

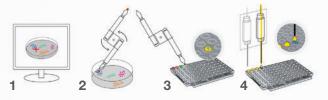
The MALDI Colonyst® is a robotic system that can automatically transfer colony material from agar plates to a MALDI target plate and deposit all the required reagents for sample preparation.

The Colonyst® increases the reproducibility and quality of sample preparation and therefore the identification.

Additionally, the instrument allows a complete documentation of the petri dishes before and after the preparation process in pictures. Finally, by using long-life colony picking system and robust liquid deposition needles, no picking and pipetting tips will be required.

The Colonyst® is designed to prepare target plates for MALDI measurement:

- 1. User selects colonies of interest from agar plates visible on the monitor
- 2. Automatic picking of the selected colonies
- 3. Transfer of sample to the MALDI target plate
- 4. Pipetting of the required matrix solutions to the single spots on the MALDI target plate





MALDI Colonyst®

#### **MALDI-TOF MS** databases

BIOTECON Diagnostics developed two MALDI-TOF MS databases for specific applications. The D-MASS  $^{\! \otimes }$  was

designed especially for the dairy industry. The database includes >300 additional validated entries of dairy relevant microorganisms.





The B-MASS® currently includes >100 entries of microorganisms which can be found in beverages. With the large strain collection of

BIOTECON Diagnostics, specialized new databases can easily be developed according to customer needs.

# **MALDI-TOF MS**

MALDI Biotyper system MALDI Colonyst®

## **Databases**

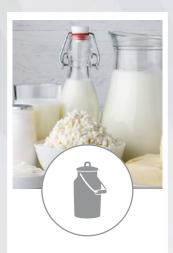
Dairy Beverages Custom databases

Reagents

Consumables



# foodproof® Solutions for different Markets



# **Dairy**

Bacterial
Pathogens
Yeast and Mold
Allergens
MALDI-TOF MS



# Beverage / Beer

Spoilage Bacteria

Spoilage Yeast

**Yeast and Mold** 

**Allergens** 

**GMO** 

**MALDI-TOF MS** 



# Confectionery

Bacterial Pathogens

**Spoilage Yeast** 

**Yeast and Mold** 

**Allergens** 

**GMO** 



# Meat

Bacterial Pathogens

**Animal ID** 

**Viruses** 

**Allergens** 



# **Seafood**

Bacterial Pathogens

**Yeast and Mold** 

**Viruses** 

**Allergens** 



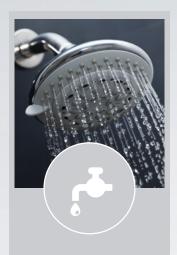
# **Infant Formula**

Bacterial Pathogens

**Yeast and Mold** 

**MALDI-TOF MS** 

For market specific enquiries please contact us: markets@bc-diagnostics.com



# Environmental/ Water

Bacterial Pathogens Viruses



**GMO** 



Processed Food

Bacterial Pathogens

**Spoilage Yeast** 

**Allergens** 

Viruses

**GMO** 



Spices & Ingredients

Bacterial Pathogens

**GMO** 

**Allergens** 

Yeast and Mold



**Pet Food** 

Bacterial Pathogens

**GMO** 

**Allergens** 



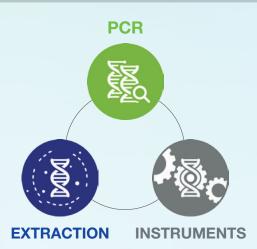
Feed

**GMO** 

Bacterial Pathogens

**Allergens** 

ATC GCTTCAT CATCCCTATC GCTTTTATCCATCCCTATC GCTTCCATCTGCT CGTATC GCCATCTTCATCCGTATCTGCCATCTTCATCCGTATC GCTTCCATC ATCCGTATCTCCAT TTCATCCGTATCCTTCCATCCTTCATCCGTATC CTATC GCTATCATCCATCCCTATCGCTTCCATCCCTATC GCTTCCATCC



For publications, references and certificates, please visit our website:

www.bc-diagnostics.com

Find the product you are looking for at: www.product-finder.bc-diagnostics.com

# **BIOTECON Diagnostics GmbH**

Hermannswerder 17 14473 Potsdam Germany

Phone: +49 (0) 331-2300-200 Fax: +49 (0) 331-2300-299

bcd@bc-diagnostics.com www.bc-diagnostics.com

real-time PCR 🗟 🗟 allergens BIOTECON S Vetproof® foodproof®Diagnostics pharma spoilage organisms O liquid handling O microproof®