ABOUT DUPONT NUTRITION & HEALTH

DuPont Nutrition & Health is a business dedicated to delivering a wide range of sustainable, bio-based ingredients and advanced molecular diagnostics to provide safer, healthier and more nutritious food. In addition to the leading diagnostic systems formerly available under the Qualicon name, we offer Solae[™] soy ingredients to provide a healthier and more sustainable source of proteins, and the DuPont[™] Danisco[®] range of ingredients to help provide enhanced bioprotection, an improved nutritional profile, and better taste and texture.

In the area of food protection, DuPont Nutrition & Health provides advanced molecular diagnostics such as the BAX° and RiboPrinter° Systems for microbial detection, identification and monitoring. These innovative systems enhance food safety and quality assurance programs, providing the superior speed, accuracy, convenience and customer support that food companies have come to expect from DuPont. In addition, we offer food companies a multitude of premier ingredients from the DuPont[™] Danisco[°] range that protect food from organisms such as *Listeria* and Yeast & Mold.

For more information on food safety and quality testing from DuPont, visit FoodDiagnostics.DuPont.com



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DUPONT[™] BAX[®] SYSTEM PRECISE AND POWERFUL MOLECULAR PATHOGEN DETECTION







HELPING PROTECT THE GLOBAL FOOD SUPPLY

Safe food for consumers and profitable growth for food companies are at the heart of diagnostic products from DuPont Nutrition and Health. Our food safety science is focused on continually developing state-of-the-art technologies that help companies around the world deliver safe food products to the market.

Food companies, service labs and government regulators around the world rely on the DuPont[™] BAX[®] System, which uses a powerful molecular technology for detecting unwanted bacteria in raw ingredients, finished products and environmental samples.

The automated, user-friendly system is easy to operate, utilizing polymerase chain reaction (PCR) assays, tableted reagents and optimized media to minimize hands-on time and free technicians for other tasks. And the electronic results are LIMS-compatible for convenient storage, sharing and retrieval.

With certifications and regulatory approvals in the Americas, Asia and Europe, the BAX[®] System is recognized globally as one of the most advanced pathogen testing systems available to the food industry.

SPEED AND ACCURACY

To lessen the risk of costly recalls or brand-damaging headlines, food testing labs need fast, accurate and convenient tools for detecting the presence of pathogens in their raw ingredients, environmental samples and finished products. For more than 15 years, many labs around the world have chosen the award-winning DuPont[™] BAX[®] System as their preferred method for food safety testing.

Ultimately, the value of this rapid, reliable and reproducible testing method appears on a food company's bottom line, where it matters most.

SIGNIFICANT TIME AND LABOR SAVINGS

One reason is that this molecular method performs as well as traditional culture plating, but with significant time and labor savings. BAX[®] System results are often available within 24 hours of taking the sample, instead of several days or weeks later, after colonies have grown.

EXCEPTIONAL SENSITIVITY

Another reason is the exceptional sensitivity of the BAX° System. Internal and external studies have shown that this DNA-based technology can detect as low as one colony forming unit per sample, in volumes ranging from 25 g to 375 g.

SUPERIOR SPECIFICITY

The BAX° System also delivers superior specificity. Where phenotypic tests can cross-react with bacteria exhibiting similar behavior or traits, the BAX° System addresses the unique genetic structure of the target for fewer false positive results.

IMPROVED OPERATIONAL EFFICIENCIES

Accurate results mean fewer re-tests, shorter storage time for products on hold, and less waste of truly safe food. Put another way, the BAX° System helps to improve the operational efficiencies of testing labs by enabling fast and confident product release decisions.



PROVEN PERFORMANCE

In the food industry, microbial testing is a critical part of Hazard Analysis and Critical Control Point (HACCP) plans for quality assurance. The DuPont[™] BAX[®] System provides food companies with a certified method for detecting many pathogenic organisms, such as *Salmonella*, STEC, *Listeria*, and more.

Because third-party certifiers, such as AOAC and AFNOR, require extensive validation of BAX° System performance before granting their seal of approval, food labs get the assurance of demonstrated accuracy and reliability. Government labs in Canada, Brazil, Denmark, China and other countries have also validated the BAX° System as an approved method for detection.

And for companies whose food products are regulated by the United States Department of Agriculture (USDA), the BAX[®] System can be utilized for routine testing with the confidence of using the same method adopted by the USDA Food Safety & Inspection Service (FSIS) for monitoring meat and poultry.

HISTORY OF INNOVATION

For more than 200 years, DuPont has been the leader in technological solutions with powerful business value. DuPont Food Diagnostics is part of that strong tradition and has grown—in technology, understanding and size—to become a global leader in advanced microbial diagnostic solutions.

Over the years, DuPont diagnostic products have earned a reputation for innovation and received numerous awards, including the R&D 100 Award, IAFP Black Pearl Award and *The Wall Street Journal* Technology Innovation Award. More importantly, our innovations—including the first commercial application of PCR technology for food safety testing—have helped revolutionize the industry.

As technology evolves and the needs of industry change, we will continue to develop, improve and advance diagnostics to deliver unparalleled customer value to the marketplace.







DUPONTTM BAX[®] SYSTEM HELPS POULTRY BUSINESS REDUCE CONTAMINATION

A large poultry processing company routinely tested carcass rinses for *Salmonella* using standard rapid method immunoassays. Toward the end of the summer, they noticed a disturbing upward trend in positive results that could not be explained by seasonality.

Staff immediately began examining their products and procedures. Did the plant have a true contamination problem or were the testing methods faulty? The processor introduced a few interventions and the quality control lab used classical culture plating methods to monitor the effects of each. But this quickly became problematic. The processor could not afford to wait five to seven days to determine whether or not a single intervention had worked.

After investigating alternative testing methods, the company decided to try the BAX° System for its DNA-based detection and next-day results. With the BAX° System in place, the lab was immediately able to increase its weekly sample throughput by 25%. Lab personnel also found that they could determine Most Probable Number (MPN) counts in approximately 34 hours by testing dilutions with the BAX° System instead of plates. This cleared the way for accelerated interventions.

As the company introduced new interventions to sanitize and prevent contamination along the entire process, the fast turnaround for BAX° System results let the company confirm the effectiveness of each change in a systematic way.

It didn't take long to see improvement. In just two months, the rate of *Salmonella* positive results fell from 18% to 5%. And in the following two months, the plant saw no positives at all.

Encouraged by this success, the processor began examining feed, the hatchery and other special projects to reduce the incidence of *Salmonella* in all affected areas.

An unexpected benefit of taking positive action to control *Salmonella* is that other pathogens, such as *E. coli*, have also been reduced in the plant. Thanks to the BAX[®] System, the company is now several steps ahead of U.S. federal regulations.



BENEFITS OF THE DUPONT[™] BAX[®] SYSTEM

CONFIDENCE

Clear and reproducible results, independent of operator technique.

RELIABILITY

Automated cycling, detection and analysis without the need for expert skills.

EASE OF USE

Simplified sample prep with minimal hands-on time.

SPEED

High capacity load, up to 96 samples per batch.

CONVENIENCE

Pre-packaged PCR reagent tablets provide consistency, stability and long shelf-life.

ELECTRONIC DATA

LIMS-compatible system allows for easy storage, retrieval and printing.

SUPPORT

World-class customer-focused assistance to answer your questions and keep your operation running smoothly.

START-UP PACKAGE

Heating & cooling blocks Capping/decapping tools Cluster tubes and holders Pipettes and tips User documentation





SYSTEM COMPONENTS

BAX° System cycler/detector Computer work station BAX° System application and Microsoft° Windows° OS Installation and training



(optional upgrade to analog heating/ cooling blocks)

The BAX[®] System uses either real-time or end-point technology to detect amplified product, if it's there, and deliver straightforward positive or negative results.

The BAX[®] System simplifies PCR by combining the requisite reaction reagents, including fluorescent dye and internal positive control, into a stable, dry tablet, which is hydrated with prepared sample and processed in a BAX[®]System instrument.

HOW IT WORKS

The DuPont[™] BAX[®] System uses PCR technology to amplify (replicate) specific fragments of bacterial DNA, which are stable and unaffected by growth environment. These fragments are genetic sequences that are unique to the targeted organism.

In a typical application, sample DNA is combined with DNA polymerase, nucleotides and primers. Primers are specific for a given nucleotide sequence and determine the specificity of the reaction.

This mixture then undergoes a series of timed heating and cooling cycles. Heating denatures the DNA, separating it into single strands. As the mixture cools, the primers recognize and anneal (bind) to the targeted DNA sequence. The polymerase then uses the nucleotides to extend the primers, thus creating two copies of the fragment (amplification). Repeating the cycle of denaturing, annealing and extending produces an exponential increase in the number of target DNA fragments, creating millions of copies in a very short time.

If the target sequence is not present, no detectable amplification takes place.

If the target sequence is present, the BAX[®] System detects amplified fragments by measuring fluorescent signal, either through probes in real-time or through intercalating dye in a subsequent phase. See next section for details on detection.

DUPONT[™] BAX[®] SYSTEM PCR AMPLIFICATION



Unique DNA fragment found only in the target organism.

As temperature rises, doublestranded DNA separates.

As temperature cools, primers anneal to single DNA strands and polymerase extends the primers.

At the end of the first cycle, two new fragments are formed.

With each successive cycle of heating, binding and extending, each existing fragment splits to form two new fragments.

DUPONT[™] BAX[®] SYSTEM REAL-TIME DETECTION WITH PROBES



"This automated system reduces the hold time for release of analyzed products. It gives us speed and great confidence in the results. I would definitely recommend this system to other companies that perform pathogen testing."

SYLVAIN GUEGUEN, QUALITY LABORATORY MANAGER, BIGARD

REAL-TIME DETECTION

The PCR tablets in BAX[®] System real-time assays contain targetspecific, dye-labeled probes that correspond to multiple target fragments.* Probes are short oligonucleotides with quencher dye at one end and fluorophore dye at the opposite end. The probes are designed with the two ends in close proximity, so that the signal from the fluorophore dye is restricted by the quencher dye.

During PCR, the probe binds to a specific area of the targeted fragment in such a way that the fluorophore is separated from the quencher, allowing for signal emission. The BAX° System uses dye-specific filters to measure signal at the end of each cycle and report positive/negative results for each target in the assay.

* Some BAX[®] System real-time PCR assays use structured probes called Scorpions", whose mechanism for fluorescent detection is illustrated on the next page. Other BAX[®] System real-time PCR assays use linear TaqMan[®] probes, which utilize a different mechanism (not illustrated) to cleave the probe for increased fluorescent signal.

Unique DNA fragment found only in the target organism.

As temperature rises, double-stranded DNA separates.

As temperature cools, primers anneal to single DNA strands and polymerase extends the primers.

At the end of the first cycle, two fragments are formed-one with and one without an attached scorpion.

As the temperature rises, the scorpion unwinds. This will allow the probe section to attach to the fragment during cooling in the next step.

Greater distance between the two dyes allows the fluorophore to emit signal on that fragment as the other fragments repeat the extension.

With each successive cycler, increasing numbers of strands contain the unwound scorpion, increasing the signal to detectable levels in less than an hour.

DUPONT[®] BAX[®] SYSTEM END-POINT DETECTION WITH INTERCALATING DYE

Unique DNA fragment Primer Polymerase L HUNBORD HUTELE

"A technician performing the assay can do a lot of other things while the system is running, which improves flexibility in the lab. Training needs are minimal."

Lene Johansen, Laboratory Manager, Lantmännen Danpo A/S

END-POINT DETECTION

The PCR tablets in BAX° System standard assays contain intercalating dye, which binds with double-stranded DNA and emits a fluorescent signal in response to light. After amplification is complete, the BAX° System program begins a detection phase. A reading of the fluorescent signal is taken, then the temperature is raised to separate the DNA strands, releasing the dye and reducing the signal. This change in fluorescence is plotted against temperature to generate a melting curve, which is interpreted by the application as positive or negative results. Unique DNA fragment found only in the target organism.

The first heating cycle separates the DNA into single strands.

During the first cooling cycle, primers from the PCR tablets bind to one end of the fragments, and the polymerase enzyme uses nucleotides to finish extending the fragment.

The highly specific fluorescent dye binds to double-stranded DNA. (At this point, the dye is not emitting signal.)

Repeated heating and cooling cycles continue to replicate the fragment exponentially. At the end of amplification (about 3 hours), a separate 90-minute detection phase begins by exposing the fragments to light, which excites the dye into emitting signal.

As the temperature rises, the DNA fragments separate, releasing the dye and reducing the signal. These measurements are plotted as "melting curves" that are unique for each target.

WIDE RANGE OF TARGETS*



BAX° SYSTEM ASSAY

PRODUCT NUMBER

PCR Assay for <i>Salmonella</i> PCR Assay for <i>Salmonella</i> 2 Real-Time PCR Assay for <i>Salmonella</i>	D11000133 D14368501 D14306040
Real-Time PCR Assay for <i>E. coli</i> O157:H7 Real-Time PCR Assay: STEC Screening for <i>stx</i> and <i>eae</i> Real-Time PCR Assay: STEC Panel 1 for <i>E. coli</i> O26, O111, O121 Real-Time PCR Assay: STEC Panel 2 for <i>E. coli</i> O45, O103, O145 PCR Assay for Screening <i>E. coli</i> O157:H7 MP	D14203648 D14642964 D14642970 D14642987 D12404903
PCR Assay for <i>L. monocytogenes</i> 24E PCR Assay for <i>L. monocytogenes</i>	D13608125 D11000157
PCR Assay for Genus <i>Listeria</i> 24E PCR Assay for Genus <i>Listeria</i>	D13608135 D11000147
Real-Time PCR assay for Vibrio cholerae/papahaemolyticus/vulnificus	D12863877
Real-Time PCR Assay for <i>Campylobacter jejuni/coli/lari</i>	D12683449
Real-Time PCR Assay for Staphylococcus aureus	D12762689
PCR Assay for Screening Enterobacter sakazakii	D11801836
PCR Assay for Screening Yeast and Mold (with 1 supplement kit) PCR Assay for Screening Yeast and Mold (with 3 supplement kits)	D12778644 D12685005

* And more in development. Please visit FoodDiagnostics.DuPont.com for the most current list of BAX® System assays.



EASY-TO-USE PROCESS





Transfer lysate to the tablet in each PCR tube.





Place the PCR tubes into the BAX° System instrument. You can then work on other tasks while the BAX° System amplifies and detects.
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6 REVIEW

Results are displayed as clear yes or no icons in about one hour for most assays. "In today's market, there is no room for error and with the BAX° System, we have confidence in our testing and results."

Clint Willis, VP Operations, South Georgia Pecan

26 Core



DUPONTTM BAX[®] SYSTEM HELPS PROCESSED MEAT PRODUCER REDUCE FALSE POSITIVES

A producer of processed beef, pork and poultry products was experiencing a very high percentage of false positives during routine *Listeria* testing. The quality assurance (QA) director was pleased that the production facility did not have contamination problems, but was very concerned about the negative impact that these false positives were having on both the bottom line and the company's credibility with its customers.

Standard practice at this production facility was to test for contamination in-house, then send samples with positive results to a third-party laboratory for confirmation. The QA department was dismayed to find that nearly all of these samples were being returned as false positives.

This indicated that although the production facility had good HACCP plans in place and was implementing necessary measures to significantly reduce the risk of pathogens, its testing method in the QA laboratory was not meeting the company's needs.

Sending a high volume of false positive samples to a third-party laboratory cost the company a significant amount of money and caused major delays in shipping finished product. Perhaps even more important was the damage to the company's reputation caused by false alarms. To improve its QA procedures, the company needed to invest in a testing method with a proven track record for reliability and accuracy. The QA director knew that the third-party contract laboratories he depended on were using the DNA-based BAX° System. After some additional research, he decided to bring a BAX° System in-house.

As the QA laboratory staff started using the BAX° System to distinguish whether a positive result was true or false, they saw dramatic improvements. Now, only 1 in 10 positive results needs to be sent to a third-party laboratory for confirmation because the BAX° System shows the other 9 to be false. And, with the BAX° System on site, the company has this valuable information faster than ever before.

Incorporating the BAX° System into routine testing has made a tremendous difference for this company. The faster turnaround time and fewer positives sent out for third-party confirmation translate into improvements in the company's bottom line. Most importantly, renewed credibility with its customers and with inspectors from the USDA FSIS has strengthened the company's reputation.



"Next-day results will mean that we can alert our customers to potential risks before the product is on supermarket shelves. Not only will this protect the health of the consumer, but it will also have obvious economic advantages for the manufacturer."

Jennifer Newton, Company Director, Express Microbiology Ltd.