

WHITE PAPER

RapidBio Systems Pathogen Detection System Overview

Introduction

Food borne illness is a costly and deadly global concern. According to the CDC and WHO, millions of people a year die from food and water borne illnesses related to pathogen contamination. In the US, it is estimated that every year one in six people contracts a foodborne illness. In 2013, Tyson and Zachey Farms both had to recall over 4 million pounds of chicken due to systemic Salmonella contamination. In 2012, Sunland, Inc. was forced by the FDA to shut down their New Mexico processing plant due to a widespread Salmonella contamination issue in their peanut and seed products. This resulted in a massive recall affecting over 240 brands across the US and internationally. The famous *Escherichia coli* (E coli) outbreak in 2006 and 2007 cost the spinach industry an estimated +\$100 million. ConAgra's Sylvester, GA Grocery/Snack Foods division's \$150 million in annual sales was nearly wiped out with a Salmonella outbreak at its plant. Not only are products and people significantly affected, companies' lose sales and more importantly their brand equity. These and other related costs impact companies by 100's of millions of dollars. Some companies never recover. Peanut Corporation of America, Topps Foods, and Jensen Farms are just a few examples of companies that saw their food safety crises end in financial ruin.

These devastating losses have driven many companies and governments globally to strengthen the screening protocol in order to protect consumers. In January 2010, President Obama signed into effect the Food Safety Bill, one of the most sweeping overhauls of America's food safety system since 1938. This legislation gives the federal Food and Drug Administration the authority to impose new rules to prevent contamination and allows the agency to order, rather than simply suggest, the recall of tainted foods. This further increases pressure on all growers and manufacturers to take extra measures in preventing food contamination.

Key Issues and Problems

A critical factor in the food safety testing market is the time to obtain a pathogen test result. Based on the long lead times to get samples from the field or processing plant to the laboratory and then to a final test result, the total time can be in excess of 30 hours! An example of the impact of "time to result" is at Dole Fresh Foods, they hold in quarantine over \$1.0 million of green leafy vegetable inventory every day just waiting for test results. The capital losses as well as delays in the food supply chain cost the industry \$100's of millions annually. Additionally, the delay in getting test results cuts into the short shelf life of fresh produce and meats.

Unfortunately, all of the current pathogen detection products have many disadvantages. They cannot provide immediate on-site results, and most tests require users to send the samples to a separate testing location. The tests are also

time consuming; even the fastest technology today requires more than four hours of turn-around time from the moment the sample is collected to when the results are received. The more sophisticated products like Polymerase Chain Reaction (PCR) are also expensive, and this limits market adoption due to cost constraints. Additionally, specially trained scientific personnel are required to run the test as well as the need for expensive laboratories.

These significant issues have led Tom Mack, VP of Quality at Dole Fresh Foods, stated what the market needs is the following: ***“We need a fast, easy-to-use, accurate, reliable and portable system for food-borne pathogen detection”.***

Market Dynamics

The global food safety testing industry has become a sizable industry with over 600 million pathogen tests performed per year and generating revenues approaching \$9 billion annually. There is a substantial global demand for an accurate and efficient pathogen detection modality that can safeguard the food supply every step of the way from raw material collection sites to processing and packaging facilities. The food safety testing market is divided into six market categories based on the testing target. These segments are: Produced (Fresh & Processed Vegetables), Beef/Poultry, Dairy, Eggs, Seafood/Fish and Grains

The current practice of pathogen screening consists mainly of three methods: cultured media, antibody-based rapid assay and PCR based rapid assay. PCR based rapid assay is the most specific and sophisticated test currently in the market. PCR systems work by amplifying bacterial DNA and then matching the test sample DNA sequence to any pathogen of interest. The reaction is complicated and requires a trained technician to perform. PCR based devices also require an enrichment process step to ensure that the sample collected is not too diluted and to prevent loss of bacterial DNA in the testing process. The actual PCR reaction time can range from 4 to 8 hours and the enrichment time can be up to 12 to 18 hours. Unfortunately, due to the speed of food processing, by the time a test results are available, the product from which the sample was initially collected is aging while sitting in quarantine, inventory or is likely already on the way to market.

In 2010 the US GAO stated that imports account for nearly 2/3 of fruit and vegetable and 80% of seafood eaten in the US. The growth of imported products is coming from Mexico, South America, China, Asia, India and Africa. Less than 10% of this is tested, leading to a significant need for a more widely available fast testing method.

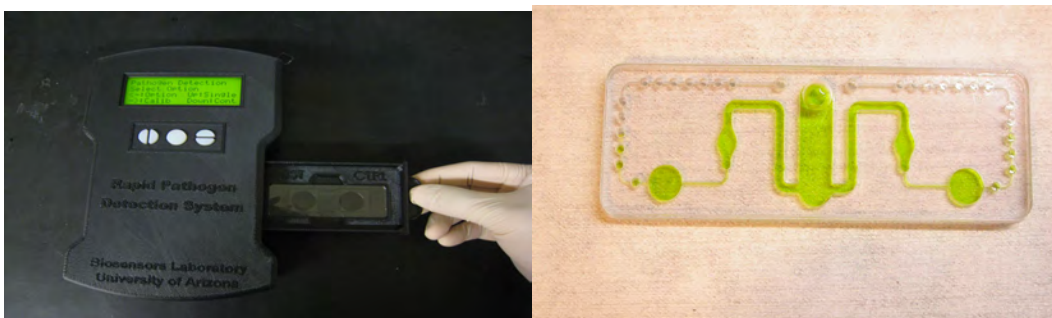
The global pathogen testing market is dominated by three main companies with over 55% of the market: Qualikon (DuPont), 3M and BioMerieux. The rest of the market is made of numerous companies supplying culture media, as well as DNA based and antibody based rapid assays. Other companies that play a more significant role outside of the U.S. include EMD Chemicals (Merck), BD Diagnostics, Neogen and Bio-Rad Laboratories, etc. Most companies offer the tests as adjuncts to their more lucrative life sciences and pharmaceutical activities.

RapidBio Systems Solution

In response to the clear market need for a: simpler, faster and accurate pathogen (bacteria) testing system, RapidBio Systems is developing a fast (~10 minutes), accurate, easy to use, handheld and field deployable pathogen detection system. It also offers high sensitivity (down to 10 cfu/ml) and high specificity due to utilization of highly specific antibodies. This patent pending system will allow growers, processors, distributors and end-users to obtain results faster than the current technology thereby improving overall food safety and moving product faster through the food distribution system. The net of all this is significant system cost savings, better process control and a safer food supply. The RapidBio Systems product can be used in concert with PCR testing systems when a confirmation test is required by requisite quality systems. The system is based upon the work out of Professor Jeong-Yeol Yoon's laboratory at the University of Arizona. RapidBio Systems has complete freedom to operate and has a technology license agreement in place with the University of Arizona.

The system integrates six distinct technologies to obtain a pathogen test result. The product utilizes: laser light detection (based on Mie Scattering), coated microspheres, specific antibodies, proprietary reagents, highly sensitive electronics, and microfluidic slide cartridges.

The RapidBio Systems business model is based on the “razor/razorblade or printer/ink” model whereby the user purchases the device and uses single use consumable slide cartridges for testing. (See pictures of both the prototype device and slide cartridge below) Currently, single pathogen per cartridge is in development, though, it maybe possible to test for more than one pathogen per cartridge in the future.



Based on development work to date the system is very close to finalization and will be able to satisfy the market need for a fast, portable, accurate pathogen detection system. For additional support of RapidBio Systems efforts, please see the attached Letter of Interest From Dole Foods. RapidBio Systems strongly believes it is developing the right product at the right time with the right strategy.

May 1, 2014

Dole Foods Letter of Interest



Fresh Vegetables, Inc.

Post Office Box 2018, Monterey, CA 93942 Phone (831) 641-4200

January 16, 2014

John Erickson
President & CEO
RapidBio Systems

Dear John,

As we discussed in our last conversation, Dole is very interested in having RapidBio Systems finalize the development of your rapid pathogen (food-borne bacteria) detection system. As targeted in your development plan the key features for the systems are:

- Portable – field use deployable
- Fast – less than 15 minutes
- Accurate – limit of Detection (LOD) close to PCR
- Easy-to-use - icon driven and minimal training required

Dole is interested in supporting this development program with financial support to ensure development gets finalized. Due to the current Dole stock repurchase/buy-back program we are unable to make an investment into RapidBio Systems at this time but we will consider doing so after seeing first quarter results. Dole also will look to actively support the field-testing of the system both for initial testing and for AOAC pathogen protocols.

The need for this system is great and will have a significant impact on how, where and when we screen for food-borne pathogens in support of our HACCP plan.

Best


Dr. Roger Billingsley
Senior VP R&D