Food-Safety Testing Gets a Much-Needed Makeover

Food poisoning. The impact on consumers can range from an inconvenient bout of gastrointestinal discomfort to hospitalization or even death. Every year in the U.S., one in six people suffers a food-related illness. Foodborne pathogens were responsible for 3,000 deaths reported in the U.S. in 2013. To help protect consumers, food producers and manufacturers follow rules promulgated by the U.S. Food and Drug Administration (FDA) and test food for pathogens. However, as they wait for time-consuming test results before releasing food products for shipment, valuable inventory languishes. It is estimated that, worldwide, approximately one-third of all perishable food ($35 billion worth) is lost in this manner every year.

Despite the large demand for safe and nutritious food, more than 75% of the world's food testing continues to rely on 120-yr-old cell-culture methods. Even though these methods take days to produce results, they have become ingrained in the industry because they are easy to use and do not require highly skilled personnel or specialized equipment.

Although time-consuming and insensitive cell-culture methods continue to dominate much of the world's food testing, considerably more-sensitive molecular-detection methods, which detect specific DNA sequences unique to individual pathogens using polymerase chain reaction (PCR) analysis, are rapidly gaining ground. The main stumbling block to their widespread use is the necessary sample preparation and analysis, which involves multiple steps by highly trained personnel using multiple pieces of expensive equipment.

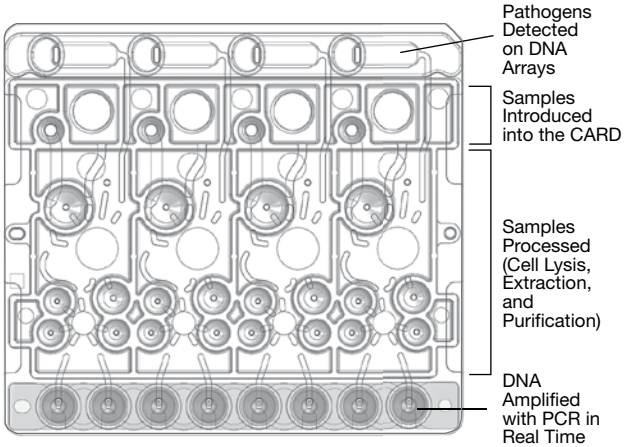
New technology developed by scientists at Rheonix Inc., based in Ithaca, NY, is enabling a portable unit that greatly simplifies the testing through automation, providing results in hours instead of days and reducing costs. Thermo Fisher Scientific Inc. has incorporated the Rheonix technology into a new generation of PCR-based rapid analysis for the food- and beverage-testing markets.

Original funding from the National Science Foundation was intended for the development of a rapid biosensor for recreational water testing, but the project took an interesting and unexpected turn. (Beach water testing uses time-consuming cell-culture methods, and decisions to close or reopen beaches can take several days.) Rheonix realized that the underlying technology developed for recreational water testing could also be used for food and beverage testing.

At the heart of the Rheonix technology is the unique, disposable Chemistry and Reagent Device (CARD). The size of a credit card, the CARD uses pneumatically driven diaphragm valves to move fluids through microchannels. In the newly developed Thermo Fisher instrument, the CARD automatically performs all of the required sample preparation, analysis, and read-out steps without any user intervention. And, the system has the ability to perform multiple assays simultaneously.

Rheonix employed several of its patented technologies in the development of the CARD. It used its lamination technology to form components such as discrete pumps, valves, and microchannels and to integrate those with other plastic components to create a user-friendly disposable device capable of performing complex assay steps such as sample extraction, DNA purification, amplification, and detection. Its injection-molding process created the CARD's plastic parts, thereby lowering manufacturing costs to below those of fabrication methods such as etching techniques. Together, these patented technologies provide a cost-effective way to perform simply what would otherwise be highly sophisticated PCR-based assays.

Rheonix will continue working with Thermo Fisher to introduce modern molecular-detection methods into the food and beverage market, potentially transforming how food and beverages are tested for safety.



▶ The CARD, which consists of fluidic microchannels and reservoirs, can perform fully automated assays. Four separate samples are introduced; processed through cell lysis, DNA extraction, and purification; and then amplified in real time through PCR. The amplified DNA sequences are then detected on DNA arrays. Image courtesy of Rheonix.

This technology was funded through the NSF Small Business Innovation Research Program.

This article was prepared by the National Science Foundation in partnership with *CEP*.