



Rapid Bacterial Pathogen Identification (RAPID-B) Food Safety Applications: Bacterial Pathogen Screening and “Fingerprinting”

Overview

“Fingerprinting” of bacterial pathogens is a technique that employs the use of analytical instrumentation, the application of various chemicals and biological solutions, and specialized software to enable identification of the bacterial pathogens of interest to food safety sector organizations (e.g. a food processing plant).

RAPID-B has the ability to rapidly (<20 minutes) and accurately recognize specified bacteria cells and provide a count of viable (live and injured) and dead cells for a given sample.

RAPID-B’s capabilities have been independently validated “side by side” tests using the current standard; solid culture on enrichment and selective media. RAPID-B provided results in less than 2 minutes after sample preparation (15 minutes for preparing a batch of multiple samples) whereas the traditional method required a minimum of twenty-four hours to provide results. In addition, not only was RAPID-B significantly faster, RAPID-B proved to be more accurate than the traditional methods because not only could it determine whether cells were dead or alive, it could also detect injured or stunned cells. Injured or stunned cells are those that will either eventually die or recover and grow. Because traditional methods can only count cells that grow, these methods are not able to detect these cells (potentially a false negative). Furthermore, RAPID-B has the ability to provide exact count of the number of cells over a broad range versus the traditional method that uses the acronym TMC (“To Many to Count”) when cell counts exceed 400 or so.

The technology that RAPID-B employs for food safety testing was jointly developed by LITMUS and scientists from FDA’s National Center for Toxicological research (NCTR) under the auspices of a Cooperative Research and Development Agreement (CRADA). The IP was jointly developed and is jointly owned by FDA and LITMUS, with LITMUS having the exclusive world-wide rights to commercialize the technology.

Kinds of RAPID-B Tests and Pathogens Detected

LITMUS offers two different kinds of RAPID-B tests:

1. PC (“Process Control”) Test:

This test corresponds to a standard “Total Plate Count” test, where all live bacterial cells regardless of type are counted. This RAPID-B test is primarily used to enable personnel to monitor selected sites for abnormal spikes in bacterial growth. This information can indicate processes that are not “in control”, provide a forensic tool to determine the source and path of contamination, be used for “auditing” cleaning procedures to ensure they are effective, and to confirm that an area has been properly cleaned prior to actual utilization.

2. PS (Pathogen Specific) Tests:

LITMUS has developed the following five PS tests that are of specific interest to the Food Safety industry. LITMUS has the expertise to develop bacterial pathogen tests that would be of interest for any given market sector. Based upon discussions with several different healthcare companies and professionals, LITMUS believes MRSA is of special interest and presents a significant opportunity for LITMUS and a selected partner to address an unmet need through the introduction of its RAPID-B technology.

For the Food Safety industry, the following five individual pathogen-specific tests can be run to identify: *Salmonella spp.*, *Listeria monocytogenes*, *Campylobacter jejuni*, *E. coli*, or *Staphylococcus aureus*. If different pathogens present a specific problem (e.g. – *E. coli* O157 or *Bacillus anthracis*) Rapid-B tests can be readily modified to detect them.

How Fast is RAPID-B’s Test?

The bulk of the identification process involves sample preparation, which takes approximately 15 minutes. Mitigating this time is the fact that multiple samples can be prepared in parallel during this process. Once sample preparation is complete, each individual test takes two minutes.

From sample delivery to pathogen identification and quantification takes less than 20 minutes.

Traditional methods require a minimum of twenty-four hours and can require as long as three days to provide definitive bacteria identification and cell counts.

Installation and Environment

The installation and calibration of the equipment require a day. The instrument will operate in a standard QA/QC lab environment as long as procedures are in place to preclude cross or inadvertent sample contamination

Personnel Requirements

Existing QC/QA personnel can be trained in less than a day.

What does it cost?

LITMUS' charges a flat monthly fee from each customer that covers: 1) the use of the instrument, 2) its maintenance, 3) Level 1 technical support, and 4) consumables not associated with sample testing. LITMUS charges a per test fee that covers a sample test kit used either for sample preparation or for generating the test results.

Value Proposition

LITMUS' RAPID-B bacterial pathogen tests are a disruptive technology that enables companies to change the way they conduct bacterial testing. The speed of the tests enable companies to quickly identify when and where there are safety issues and minimize the loss of product and production time, potentially saving millions of dollars that go directly to the bottom line. The increased accuracy and ability to "see" injured cells reduce the potential for a "false negative" and potential product liability.

RAPID-B's potential value to a company is best understood through real examples such as the following article appearing in the July 31, 2006, issue of the London's Telegraph publication describing in detail the financial impact of a recall due to a bacterial pathogen (*Salmonella*) to a major producer of chocolate in England, Cadbury Schweppes.

Cadbury Schweppes will admit this week that the cost of the salmonella contamination of its chocolate has risen to around **£20m**, compared with the original estimate of £5m. It will confirm that the scare is hitting sales and will affect profits. **The impact on profits could be £40m**, according to the company's own broker. Cadbury discovered salmonella at its Marlbrook plant in Herefordshire in January but did not inform the Food Standards Agency until June, when it was ordered to recall 1m products.

The recall came just one week before the half-year accounts were signed off and the impact on the interim results Cadbury presents on Wednesday is therefore limited. However, the greater impact will be in the second half of the year and, after pressure from investors, Cadbury will this week indicate how it is being hit. **A major decontamination of Marlbrook demanded by the foods agency is expected to cost about £5m and the company will spend up to £10m on a marketing campaign to restore sales.**

Although Todd Stitzer, the chief executive, will admit that second-half **sales have been hit by the bad publicity**, he will say it is too early to provide figures. He will point out that the hot weather has also hit sales.

However, Cadbury's own stockbroker, ABN Amro, estimates **the fall in sales at £25m, with a £15m reduction in profit**. "Historically, prolonged hot summer weather has reduced sales by some 10 per cent and we would not be surprised if the **salmonella recall reduced sales by a further similar amount**," said Julian Hardwick, an ABN Amro analyst.

Note: Currently, the £ is roughly equivalent to US\$1.87