Lancaster Laboratories INCORPORATED

October 2, 1987

U.S. Nuclear Regulatory Commission Region I
Nuclear Material Section B
631 Park Avenue
King of Prussia, PA 19406

ATTENTION: Mr. Jack Davis

Dear Mr. Davis:

THIS IS A REQUEST THAT OUR APPLICATION FOR A SPECIFIC LICENSE BE GIVEN PRIORITY TREATMENT BASED ON THE FACT THAT THERE MAY BE A HUMAN HEALTH ISSUE INVOLVED.

Our laboratory is applying to use microcurie amounts of ^{32}P which is incorporated in the GENE-TRAK Salmonella and Listeria Assays. The in vitro diagnostic tests will be used to detect the presence of these pathogenic bacteria in food products.

The GENE-TRAK Assays have proven to be faster and more accurate in detecting bacterial pathogens in foods, thus reducing the possibility that contaminated food will be released to the market.

Any assistance you can provide will be greatly appreciated.

Sincerely,

Fred R. Albright, Ph.D.
Vice President

FRA:glh

License Fee Information on Application

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2425 New Holland Pike, Lancaster, Pa. 17601 • (717) 656-2301

GENE-TRAK SYSTEMS

31 New York Avenue
Framingham, Massachusetts 01701
617-872-3113

LISTERIA FACT SHEET

Description

Listeria is an emerging foodborne pathogen of special significance since, in contrast to common food poisoning agents which generally cause gastrointestinal disease, infection with Listeria can produce severe disorders such as meningitis, septicemia and abortion. Of the seven recognized species of Listeria, only one, L. monocytogenes, has been implicated as a foodborne pathogen. At this time, only L. monocytogenes is of regulatory significance from the perspective of the FDA, although the other species of Listeria have possible importance as indicators of food plant sanitation conditions.

Where Present

Listeria is widely distributed in nature. Fecal carriage is common among wild and domestic animals, and has been reported in healthy humans as well. The organism has also been isolated from soil, improperly fermented silage, and leafy vegetables. Historically, listeriosis has been considered primarily a disease of animals, chiefly livestock. Events within the past five years have implicated Listeria as a significant cause of foodborne disease in man. Of particular importance from the viewpoint of the food sanitarian is the organism's ubiquitous presence in nature and its ability to survive and multiply at refrigeration temperatures. These characteristics stress the importance of prevention of post-process contamination of food products. Foods of animal origin, including meat, poultry, and dairy products, are those most likely to be contaminated with Listeria. Standard pasteurization processes are believed sufficient to kill Listeria, although there are some data indicating that milk contaminated with high numbers of Listeria may yield some viable organisms after minimum high-temperature short-time pasteurization. This remains a controversial topic.

Clinical Symptoms

In healthy adults, listeriosis is most frequently manifested as a self-limiting "flu-like" illness. However, infection of pregnant women has severe consequences for the fetus, including neonatal sepsis or memingitis, often resulting in abortion, stillbirth, or delivery of acutely ill infants. Immunocompromised adults constitute a second susceptible population. Mortality in diagnosed cases is on the order of about 30%, with mortality occuring most frequently among newborns and patients over 70 years of age.

Foodborne Outbreaks

In recent years, a number of foodborne listeriosis outbreaks, with high mortality rates, have been reported. Incriminated products were cole slaw, pasteurized milk, and soft cheeses. The most well-publicized outbreak occured in Southern California in 1985, in which soft Mexican-style cheese was identified as the vehicle of infection. Approximately 200 cases of listeriosis were identified, with a mortality rate of about 40%.

Conventional Testing Methods

Current testing methods for identification of *Listeria* in foods depend upon basic microbiological procedures including cultural enrichment and biochemical identification. The method in widespread use for the analysis of dairy products, the "FDA method", requires a minimum of 9 days of analysis time before a sample can be identified as *Listeria* - free. Identification of positive samples requires approximately 7-18 days of analysis time. Another culture method has been developed by the USDA for the analysis of raw and processed meat products.

GENE-TRAK Listeria Assay

The GENE-TRAK Listeria Assay utilizes highly specific DNA probes to identify the presence of Listeria species in dairy products and environmental samples following an abbreviated cultural enrichment procedure. Listeria-free samples can be identified within 48 hours. Confirmation of positive samples is accomplished by standard cultural techniques. In addition to the obvious benefit to the food producer of decreased analysis time and therefore earlier product release, preliminary results of field trials have indicated that the GENE-TRAK Assay is more effective than the FDA culture procedure in identifying the presence of Listeria in test samples.

/2020b

GENE-TRAK SYSTEMS

31 New York Avenue
Framingham, Massachusetts 01701
617-872-3113

SALMONELLA FACT SHEET

Description

Salmonella is probably the most important cause of foodborne illness on a worldwide basis. The organism is widely distributed in nature, the most important reservoirs being wild and domestic animals. There are approximately 2,000 different Salmonella serotypes; all serotypes are considered potentially pathogenic for man.

Where Present

Foods of animal origin, including red meats, poultry, eggs, and raw dairy products, are major sources of human salmonellosis. Salmonellae are very heat sensitive and are readily destroyed by proper cooking of raw foods and pasteurization of milk. Consumer mishandling of raw products is a major contributing factor to the salmonellosis problem in the United States. Considering the ubiquitous nature of Salmonella in the environment, there also exists the possibility of post-process contamination of processed food products. Thus, a multitude of food products have the potential for Salmonella contamination and ultimately the possibility of being vehicles in foodborne salmonellosis outbreaks. For this reason, many food manufacturers routinely test finished products for the presence of Salmonella. Other important contributing factors in human salmonellosis include cross-contamination between raw and cooked products, and improper cooling and storage of cooked food.

Clinical Symptoms

In foodborne salmonellosis, the organisms multiply in the intestinal tract, producing symptoms including diarrhea, cramps, vomiting, and elevated temperature. In otherwise healthy individuals, the illness is of relatively short duration and mortality is low. High risk groups include the very young,

the aged, and individuals with underlying disease and/or a compromised immune system. In these populations, the disease can be very severe and death may result. Only recently recognized is that salmonellosis may produce serious diseases as sequelae, including rheumatoid disorders, possibly with cardiac involvement.

Foodborne Outbreaks

Documented foodborne outbreaks of salmonellosis are not uncommon. In the past decade, there have been several outbreaks of foodborne salmonellosis in the U.S. causing hundreds to thousands of cases of illness. Products including cheddar cheese, pasteurized milk and precooked roast beef have been implicated as sources of infection. One of the more recent and well-publicized outbreaks, involving pasteurized milk in the Chicago area, resulted in an estimated 20,000 cases of illness.

Conventional Testing Methods

Conventional methods of analysis of food products for Salmonella contamination involve microbiological culture procedures and biochemical and serological identification. These microbiological procedures generally require four to seven days for complete analysis.

GENE-TRAK Salmonella Assay

The GENE-TRAK Salmonella Assay utilizes DNA probe technology to accurately and rapidly identify the presence of Salmonella in food products. Total analysis time is approximately 48 hours, thus reducing analysis time by two days or more compared to conventional culture procedures. Advantages to the food producer include reduction in inventory carrying costs and lessened response time in the event of a contamination problem. The GENE-TRAK Salmonella Assay also offers increased accuracy. In independent studies comparing the GENE-TRAK Assay and the most widely used conventional culture procedure, the GENE-TRAK Salmonella Assay has exhibited superiority in detecting Salmonella contamination in food products.

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