

ABOUT COMMONWEALTH BIOTECHNOLOGIES, INC.

COMPANY BACKGROUND

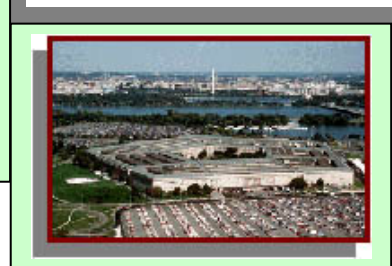
Commonwealth Biotechnologies, Inc., working for the good of all, is a full service comprehensive contract research organization providing research and development services to the biotechnology industry, academic institutions, pharmaceutical companies and government agencies. Operating on both short- and long-term contractual bases, CBI serves nearly 2,000 customers worldwide. CBI has been providing state of the art biological and technical services for commercial and government agencies for the past 10 years. Services includes DNA analyses, Genomics, Proteomics, Biochemical Analysis, Mass Spec Analysis, Microbiological Services, Pathogen Testing (Select Agents), Food Microbiology, Peptide Services, and Protein Sequencing, and Drug Discovery. The company also has a DNA reference laboratory that specializes in forensic genetic identity, molecular diagnostics and paternity testing. CBI holds laboratory accreditations by the American Association for Blood Banking, CLIA and the National Forensic Science Technology Council. In addition, CBI operates a BSL III facility for work with Human pathogens. This facility is licensed to receive and work with select agents as defined by the CDC.



CBI's State of the art 32,000 ft² facility

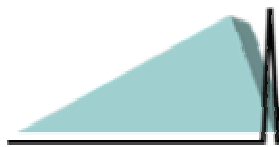


CBI *cutting edge science*

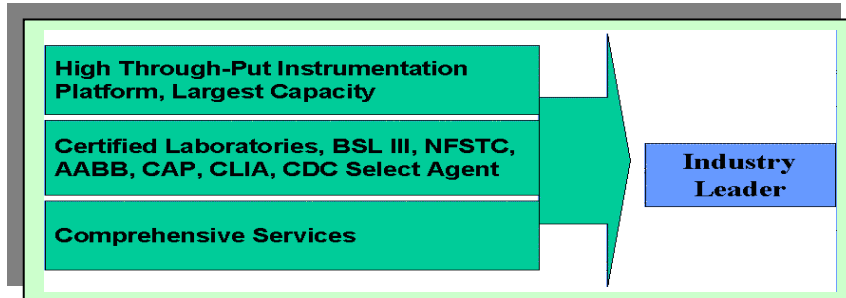


Serving the Biodefense sector

In the Biodefense arena, CBI has made a name for itself as a provider of ***cutting edge science and technology*** to government agencies and the military over the past five years. CBI operates in a secure environment with staff holding security clearances and credentials. Strong program management and quality science have been CBI's hallmark and driving force behind our success and rapid expansion into the Biodefense business sector. CBI has developed a strong program in microbial Genomics of pathogenic organisms and has developed an extensive catalog of molecular diagnostic capabilities. Novel science has driven this program and enabled CBI to provide the answers to some of the most difficult problems facing detection of bioterrorist agents. This is illustrated by CBI's Mass Spec Analysis program for the study of biowarfare CB agents including bacteria and toxins. CBI's renowned toxin laboratory contains an extensive library of information on toxin data.



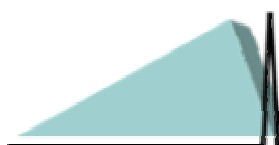
CBI has a long history of service to government agencies and has provided program management for long-term contracts. CBI has formed research CRADAs with numerous US government research facilities and agencies. This experience and our record of outstanding technical service have leveraged CBI into the position as a leader in the industry.



Overview of CBI

Four experienced research scientists to provide sophisticated research and development support services on a contract basis to the biotechnology industry founded CBI in 1992. CBI's customers consist of private companies, academic institutions, and government agencies, all of which use biological processes to develop products for health care, agricultural, and other purposes. CBI has developed a strong reputation as a leading provider of biotechnology research and development analytical services. Providing a wide range of services is an important element of our strategy. There are few major competitors which offer integrated DNA/RNA and protein/peptide technologies, and none that offer these technologies combined with sophisticated biophysical techniques, such as calorimetry, spectroscopy, and mass spectral analysis.

Thus, CBI can provide "one stop shopping" for biotechnology services.



Resources

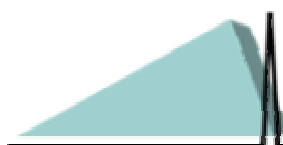
CBI Facilities: CBI is currently located in a new, 32,000 ft² state-of-the-art facility located in the Gateway Centre Office Park, Chesterfield County, Virginia (schematic is shown in Appendix 1). This facility houses all of CBI's equipment and personnel. Each laboratory at CBI is fully equipped with necessary power, water, fume and/or bio-safety hoods. **CBI operates a fully equipped and certified 500+ square ft BSL-3 laboratory. The laboratory contains all the proper equipment to grow, isolate and manipulate restricted organisms in a safe manner. The BSL-3 laboratory is equipped with a bio-vestibule (190 sq ft) for changing, all the necessary safety equipment, autoclave, incubators, water baths, and analysis equipment.**

CBI operates a CLIA certified clinical DNA Reference lab in which TaqMan[™] PCR analyses are done using ABI 7700 or 7900HT Real Time PCR instruments. With regard to DNA services, CBI operates a high throughput DNA sequence laboratory, which is designed for genomic sequencing and boast 6,000 square ft of continuous flow through workspace. Housed in this production lab are the (1) DNA synthesis facility which contains 5 automated high throughput synthesizers; the (2) DNA prep lab which contains Qiagen 9600 bio-robots, centrifuges, shakers and other equipment for template prep work; (3) the DNA reaction prep lab featuring hood and pipette area, a Beckman Biomek multi-pipette Robot for 96 well plates, 2 MJ Research Tetrad 96 well thermal cyclers (8 heads total) and 1 MWG 96 well thermal cycler; (4) the DNA sequencing facility with 10 ABI 377XL sequencers, high density 96 well plate speed-vacs, a separate wash room for plate preparation and clean up; and (5) the bioinformatics computer room housing Macintosh and PC based computers for sequence analysis. Interspersed throughout the production laboratory are offices for senior scientists in charge of the production work and each office is outfitted with PC and Macintosh computers for analysis of data.



CBI's computer center is ~500 ft² of space and houses SGI, UNIX and PC based servers for sequence analysis. CBI has a Sun Ultra Sparc 450 UNIX based server containing the Wisconsin package GCG programs, PRED/PHRAP/CONSED package, GenBank, which is maintained and updated weekly, GRAIL, GLIMMER as well as other programs. SGI servers house Sybil and BioSyms Protein folding and analysis programs. A Microsoft SEQL server contains our "Star Fruit" DNA database and project tracking software for DNA molecular applications, and other PC based programs such as Sequencer Primer express, and Vector NTI

CBI houses individual laboratories for peptide synthesis, preparative RP HPLC, bioorganic chemistry, N- and C-terminal protein sequence analysis, amino acid analysis, general



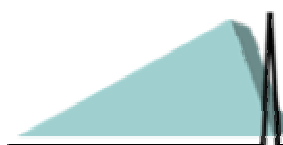
biochemistry, immunology and immune-chemistry, cell and bacterial culture, calorimetry, and toxin analysis,

CONTRACT RESEARCH AND DEVELOPMENT

CBI has developed a strong reputation as a leading provider of biotechnology research and development analytical services. CBI's unique custom service platforms provide the flexibility required for today's high technology research and development programs while also providing a multifaceted integrated approach to research and project support. Providing a wide range of services is an important element of our strategy. There are few major competitors which offer integrated genetics, molecular biology, genomics, DNA services, and microbiology services with proteomics, protein/peptide technologies, and none that offer these technologies combined with sophisticated biophysical techniques, such as calorimetry, spectroscopy, and mass spectral analysis. Thus, CBI is unique in the field because it can provide "one stop shopping" biotechnology services. With its newest platform technology on board, Drug Development and Clinical management, CBI is now able to take projects from ***"concept to clinic"***.

Cutting edge technology





CBI PRODUCTS AND SERVICES

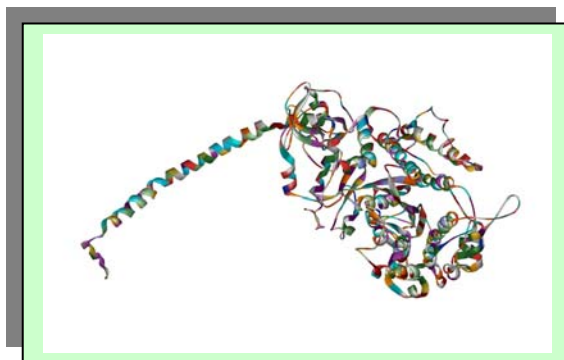
CBI Comprehensive Proteomics, Immunology, Bioorganic and Biochemistry Services.

CBI has comprehensive protein, peptide and amino acid analysis services, including:

- ◆ MALDI-TOF mass spec
- ◆ Peptide synthesis,
- ◆ Amino Acid Analysis
- ◆ Peptide and protein sequencing, both N and C terminal
- ◆ Protein purification,
- ◆ Bacterial and mammalian cell culture for overexpression,
- ◆ Biochemistry, 1D and 2D gel, Calorimetry,
- ◆ Bioorganic chemistry
- ◆ Immuno-chemistry

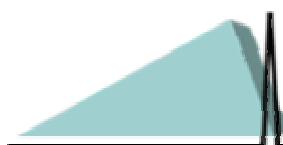
In addition, CBI has put in place a state of the art proteomics program including automated 1D and 2D gel analysis, MALDI mass spec analysis, Biomarker identification, whole cell protein identification and mapping.

CBI has the ability to synthesize milligram to hundred gram quantities of homogenous peptides incorporating any of the conventional amino acid residues, as well as modified amino acids and chromogenic, fluorogenic, or radiometric reporter groups. Both t-BOC and FMOC chemistries are available, and we can modify our coupling techniques to suit the individual investigator's needs.



Instrumentation includes fully automated peptide synthesizers, multiple peptide synthesizers, and a synthesizer for preparation of peptide libraries. The synthesized peptides are routinely purified by preparative reverse-phase high performance liquid chromatography, and are characterized by amino acid analysis, RP-HPLC and/or mass spec protocols.

CBI offers **comprehensive immunochemistry services**. CBI has the ability to synthesize or purify your immunogen, prepare polyclonal or monoclonal antibodies, purify your antibodies from cell culture, ascites fluids, or from whole serum, prepare monospecific polyclonal antibodies by ligand affinity chromatography, or we can help develop novel routes of immunoassay.



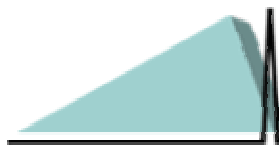
Genomics, Bioinformatics, DNA, Molecular Biology, and Synthesis Services.

CBI is a leading provider of complete DNA sequencing services, genome analysis and Bioinformatics of microbial and viral genomes, as well as comprehensive molecular biology services. These include:

- ◆ DNA sequencing, single reaction, GLP, FDA submission, shot gun
- ◆ DNA/PNA/RNA synthesis, scales from 50 nMol to 15 μ Mol
- ◆ Plasmid preps, from mini preps up to 100 mg (cGLP grade)
- ◆ Whole Gene synthesis
- ◆ Genotyping
- ◆ PCR
- ◆ TaqMan services
- ◆ Assay development
- ◆ Mutagenesis,
- ◆ Recombinant manipulations, cloning, library construction
- ◆ Southern and Northern analysis
- ◆ Expression analysis
- ◆ SNP detection
- ◆ Genome analysis
- ◆ Bioinformatics

At CBI, we are committed to providing accurate, high quality sequence data in a timely manner. We are equipped to carry out any size sequencing project from beginning to end. We provide template preparation, oligonucleotide synthesis, sequencing reactions, and data analysis/bioinformatics. CBI has a number of laboratory certificates including CLIA, National Forensic Science Technology Council (NFSTC), AABB, CDC as well as others and therefore you are assured of quality throughout the program of work. Our current capacity in the sequencing lab is >20,000 reactions a day. Automated reaction preparation is achieved using our Beckman Biomek robotic system. All sequencing reactions are tracked via Accutrac™ reagent system and data via a LIMS program providing results tracked throughout the project. CBI runs internal pgem controls on every gel and high standards are set to assure quality gel runs. CBI has current capacity to perform millions of sequencing reactions per year. We are confident we can perform your project in a timely fashion. Personnel at CBI will be available to confer with you on the best approach to your projects as well as to troubleshoot any problems that may arise during the project through phone or on site consultation.

The Comprehensive service package includes all of the sequencing required to obtain 100% accurate (publication quality) sequencing. Comprehensive DNA sequencing service package is a standard service offered by CBI since its inception in 1992. The service has several levels of detail including standard sequencing as well as GLP documented report for support of FDA submissions or patent work.



Biodefense Related Services

CBI has developed considerable strength in the bio-defense field over the past three years with on-going multi-year contracts with numerous Government agency Sponsors. The CDC to receive and transport restricted pathogens accredits CBI. CBI is also a secure facility with STU capabilities. The Senior Management of CBI and selected senior scientist hold various security clearances. With the credibility to meet the high degree of oversight required by the agencies and a reputation of providing the highest level of technical and customer support, CBI is widely recognized for its abilities in bio-defense and its abilities to complete projects in a timely cost-efficient manner.

By virtue of it being a secure facility with BSL-3 capabilities and the combination of its extensive integrated technology platforms with accreditations from the USDA, AABB, CDC, CLIA, and National Forensic Science Technology Council (NFSTC), make CBI a uniquely qualified CRO.

CBI Pathogen Testing Service

CBI has developed expertise over the past five years in biodefense related contracts to both government and industry. The horrific events of September 11th and the subsequent anthrax related events heightened the awareness of every US citizen to the global threats of terrorism and bioterrorism. CBI has recognized the growing concerns over domestic chemical, biological or radiological (CBR) terrorism and has responded with innovative services, which rapidly respond to those on the front lines of the war on terrorism at home.



CBI has developed services for pathogen detection, on-site sampling and monitoring solutions to provide effective means for detecting and identifying pathogenic agents including Anthrax. CBI's support combines expert consultation with rapid response and results.

DNA Sequencing for Identification of Bacteria and Fungi

CBI uses 16 Ribosomal DNA sequence analysis for bacterial identification. This technology is the most accurate and fastest means of identification of bacteria. CBI uses proprietary primers to amplify sequences within the 16s Ribosomal gene and then BLASTs the data against private, commercial and public databases for a comparative sequence analysis. Identification occurs when the query sequences matches the sequence in the database. CBI offers a state of the art microbiology facility to isolate pure colonies for analysis.

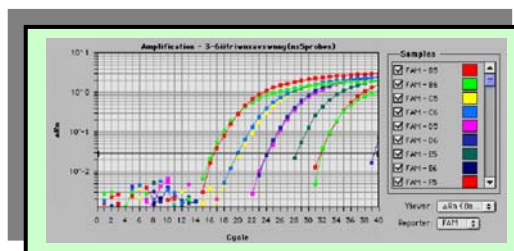
Alternatively, you can send us a pure isolate and CBI will perform the requisite DNA extraction, amplification of the 16S rRNA gene, sequencing and comparison. Results for this service have a typical 3-5 day turnaround time depending on the nature of the study. DNA can typically be isolated from viable, damaged, and non-viable cells. Sample identification reports consist of the comparative analysis obtained from the data base search, in order of decreasing genetic distance. The sample id is included in the report. A phylogenetic tree analysis can be included along with the results showing closest near neighbors. Raw sequence data, sequence line-ups and blast search results will also be part of the report. Reports can be made to suit upon request.

Fungi

The same technology listed above can also be used to obtain comparative DNA sequence data for identification of Fungi. Identifications of both yeasts and filamentous fungi are provided. This technology provides the most accurate and rapid method for identification.

Real Time PCR Detection of Pathogen

CBI has developed real time PCR methods for detection and identification of viral and bacterial pathogens. CBI is an industry leader in developing novel technology for rapid of detection of microbial and viral agents in environmental and complex samples. CBI has combined these technologies, with robust extraction procedures, that supplies a unique and responsive service. CBI operates a state-of-the-art licensed BSL III facility and can receive restricted agents from facilities under CDC licensure. A list of some of the assays CBI has developed is shown below:



E coli 0157

Salmonella arizonae

Listeria monocytogenes

West Nile virus

SLE virus

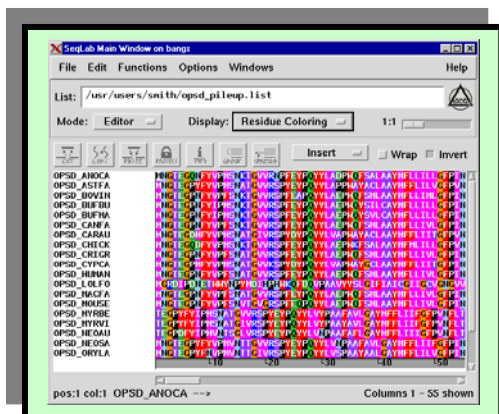
Human Herpes Virus (1-8) including 6a & b

Dengue virus 1-4

VEE virus

Clostridium perfringens

Computer assisted assay design



Our expert molecular biologists can develop specific assays for your project or can use one of the many standard assays in place at CBI. CBI maintains a powerful suite of sequence analysis software and can provide customized bioinformatics services to "design" your assay. CBI offers custom synthesis of TaqMan primers and probes and can incorporate the latest technological advances in the design of the probes.

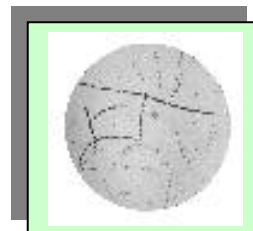


ANTHRAX TESTING SERVICE

CBI provides a full service capability for Microbial Pathogen testing here or on site.

CBI laboratories, following

the protocols developed by the CDC, APHL, and the Laboratory Response Network, offers testing services for suspect samples or environmental monitoring. All samples which test positive at CBI are forwarded to the appropriate public health laboratories, appropriate government agencies or law enforcement laboratories for confirmation.



CBI utilizes the facilities and expertise it has developed over the past ten years to provide the critical analysis necessary to identify bacteria in suspect environmental samples. Through many years of contract government work, CBI has advanced the knowledge and understanding of detection in complex samples.

Powders

Lab testing of powders or other materials suspected of harboring the anthrax bacteria can be performed. CBI can accept appropriately packaged and labeled samples through Fed Ex or can collect samples onsite and ship to CBI laboratories. CBI will perform the tests using a two-phase approach. Phase I includes initial characterization, growth and identification by molecular diagnostics. Phase II testing includes a series of biochemical and microbiological confirmation analysis and is only performed if positive results are obtained in Phase I. Positive tests will be reported and the appropriate government laboratories for confirmatory analysis.

Powder Testing continued:

Phase I tests include:

- ◆ Culture of suspected materials.
- ◆ Microscopic examination
- ◆ Gram Stain.
- ◆ Evaluation of growth in broth
- ◆ PCR (polymerase chain reaction) test that amplifies DNA at three sites.

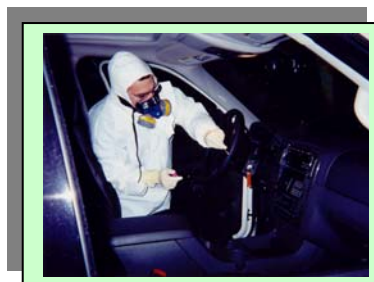
Phase II tests for confirmation:

- ◆ Microbiological analysis
- ◆ Hemolysis,
- ◆ AP ID testing,
- ◆ Morphology analysis.
- ◆ Other specialized tests to confirm the identification of the bacteria.



Environmental testing. During the course of investigation important information may be obtained from sampling the environment where the exposure may have occurred. Testing of the environment is useful for detecting trace amounts of anthrax spores. Specimens obtained may include:

- ◆ Swabs on contamination of various surfaces
- ◆ Samples of the air (off filters)
- ◆ Paper samples
- ◆ Soil samples
- ◆ Cloth
- ◆ water



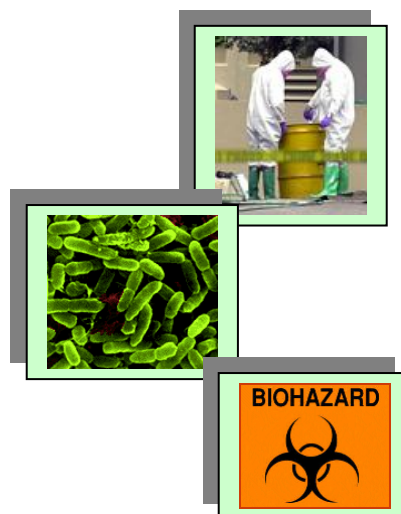
These samples are processed in the laboratory to promote growth of any spores, if present. If suspicious bacteria grow, additional testing will be performed.
Licensed BSL III facility

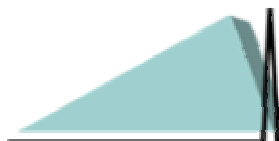
Monitoring

CBI experts can work with you to devise continual monitoring of your facility or place of business for detection of anthrax or other agents. CBI's monitoring program can include post-decontamination surface testing and viability testing of decontaminated materials. CBI specialists will visit your facility for an onsite consultation. A specific monitoring program will be set up to address your needs.

CBI can monitor

- ◆ Receiving/shipping areas
- ◆ Offices
- ◆ Air handling systems
- ◆ Manufacturing areas
- ◆ Mailrooms
- ◆ Environmental testing

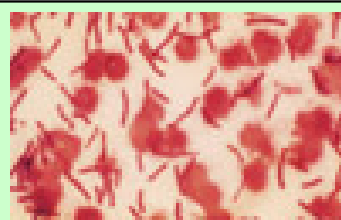




Biodefense Related Mass Spec Analysis

CBI has been in the forefront of MALDI-TOF mass spectrometry performing foundation studies in toxin research as well as in the pathogen identification field. CBI is the recognized leader in peptidic toxin analysis MALDI-TOF mass spectrometry and has significant libraries of mass spectra obtain from these studies. MALDI-TOF mass spectrometry has been used to study a wide variety of bacteria. CBI has analyzed protein extracts of bacteria and is able to determine genus, species, and generate **strain specific biomarkers** for several different species. Studies to differentiate the bacterial pathogenic species from non-pathogenic counterparts have been undertaken.

MALDI-TOF mass spectrometry has also been successfully used to identify different strains of the same bacterium in an efficient, reproducible manner. In these experiments, the strains were differentiated according to the unique mass spectra obtained using whole intact bacterial cells, rather than using a bacterial lysate. The basis for identification can be obtained by visualization of ions due to unique secondary metabolites or membrane specific biomarkers (peptides in the m/z range of 500-5000) which are present in individual bacterial strains. Daughter ion analysis (PSD analysis) is used with subsequent primary sequence to determine the peptides on the cell surface which distinguished one strain from the other. Further, once the mass spec fingerprint of a target bacterium is established, the identity of each and every component in the fingerprint can be determined by the method of daughter ion analysis. CBI has been at the forefront of this technology to generate a library of fingerprints of the target bacteria and then use these libraries to identify the unique molecular elements characteristic of each bacteria.



Gram Stain of Bacteria



Mass Spec Analysis of Pathogens

Thus, potentially, in a single experiment, MALDI gives us the ability to distinguish one bacterial strain from another and to absolutely identify the biomarkers allowing the strains to be distinguished.



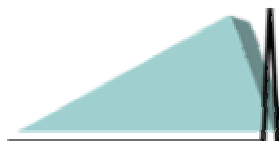
Vaccine and Biopharmaceutical Development/Clinical Support

CBI provides support for Vaccine development and Biopharmaceuticals, by offering an array of clinical Biosafety testing services, assays and protocol development under GLP and 21 CFR guidelines. CBI's focus has been laboratory analysis throughout the process of manufacture of pre-clinical and early-stage (Phase I/II) clinical trial materials for vaccines and biopharmaceuticals cultivated by mammalian cell culture or bacterial overexpression fermentation. Being fully integrated, CBI can work with a client from the initial research and development stage (concept) provide molecular biology support, cell culture, synthesis, and developing the genetically engineered cell lines, all the way through final biopharmaceutical product Biosafety testing and stability studies prior to distribution to clinical trial sites (clinic). CBI has worked with JVAP to develop assays and protocols for bulk vaccine testing to assure product safety.

CBI has developed a battery of tests and assays for product stability testing and safety testing, including assays for adventitious agents, viral plaque assays, PCR and PERT assays, TaqMan assays, HIV, HTLV, and HHV assays, as well as biochemical and sterility testing. Strategic alliances have been made with partners for testing in animal models. CBI has tissue culture facilities and provides primary cell culture and banking services for study support. Meeting FDA compliance and quality assurance guideline is imperative for final acceptance of the vaccine. CBI quality assurance and compliance group offer timely and professional support throughout the process. CBI has been audited by many different agencies and private companies and has a spotless record of compliance with FDA regulations.

CBI offers GLP sequencing of viral vaccines for FDA submission. Guidelines call for DNA sequencing data to be obtained at key points through the development and production process.





Commonwealth Biotechnologies Food Safety Program and RAMP

Exclusively at CBI, we offer Risk Assessment Management Program (RAMP) as well as a complete Microbiology Laboratory featuring a state-of-the-art testing service, specializing in food safety and sterility testing. The long-term goal is to develop an accurate, practical and cost effective method to ensure food safety from farm to table with a screening process that can be utilized at all levels. We propose to develop and implement a standardized process to diminish or eliminate the impact of potential contaminants to the food supply through terrorist agents. RAMP will ultimately result in optimal safety and security at the lowest possible cost. While risk can never be completely eliminated, use of risk management systems will reduce the hazards to an acceptable level.

CBI Food Safety Program offers technical consulting and a full array of bacterial and viral testing including Mycoplasma and Hepatitis A. CBI has initiated a rapid and sensitive food safety-testing platform to detect pathogens in foods and production facilities.

Currently at CBI we use PCR-based kits combined with the latest in microbiological and molecular biological assays to improve the continued safety of the nation's food supply.

We can help answer two questions:

- 1. Is the background level of microorganisms in your food a cause for worry?**
- 2. Are there any specific pathogens present in your foodstuffs?**

CBI has aligned with Richter International, Inc. ([Richter International, Inc.](#)), a world leader in food quality and safety research, to commercialize these services and technologies. CBI technicians and scientist stand ready to provide complete customer support including, testing, research, consulting and data management services.

CBI tests products for microbiological quality on a regular basis. This includes monitoring by FDA accepted methods of pathogens. Rapid (Standard PCR or TaqMan) or Classical methods (Standard Biochemical and Microbiological) are used in compliance with AOAC, BAM, and other official compendia to detect the following pathogens:

PATHOGENS

Bacillus cereus

Escherichia coli O157:H7

Listeria monocytogenes

Salmonella enteridis and species

Staphylococcus aureus

Campylobacter jejuni and species

Yersinia enterocolitica and species

Hepatitis A

Mycoplasma species

Others

We can work with your company to help assure food safety by monitoring your environment and work areas for pathogens. This can be done by either CBI or your staff. Rapid turnaround time, which is so important to the food industry, is a hallmark at CBI.



How CBI Can Help You

CBI can design and perform a personalized program to ensure your company or vendor's food safety, quality and Hazard Analysis Critical Control Points (HACCP) programs. CBI has developed sensitive microbiological methods coupled with PCR and TaqMan assays (ABI *E. coli* 0157 and *Salmonella* assays currently available) to rapidly identify potential pathogens, spoilage organisms, and many toxins in food matrix. CBI can provide testing on a regularly scheduled basis or as a single event. Organisms detected include the most common causes of food-borne illnesses.

The same organisms can be detected by PCR-based assays with a **rapid** turn-around-time using our quantitative assay platform (TaqMan). This is a quantitative assay that will generate data to determine the real numbers of organisms present in a food sample.

Other standard microbiological identification and custom PCR-based assays not mentioned above available by quotation.

FOOD SAFETY SERVICES WE OFFER

HAACP Auditing

HAACP Training

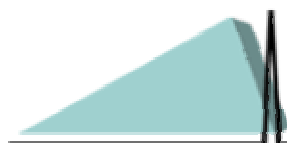
GLP/SOP Auditing

GLP Compliant Testing

Risk Assessment and Management Program (RAMP)

Technical Consulting

Sterility Testing and Monitoring



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