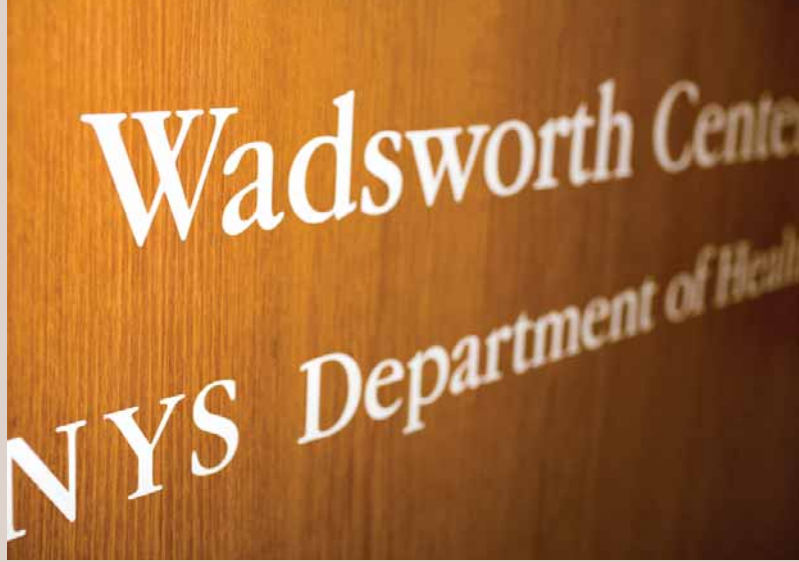


# Wadsworth Center

NEW YORK STATE DEPARTMENT OF HEALTH



**Science in the Pursuit of Health<sup>®</sup>**



## WADSWORTH CENTER

Innovative, multidisciplinary research. Complex diagnostics and novel detection methods. High-tech instrumentation and state-of-the-art laboratory services. All are components of the dynamic scientific community that is the Wadsworth Center of the New York State Department of Health.

Building on a century of excellence as the state's public health laboratory, the Center entered the 21st century as a premier biomedical institute that merges clinical and environmental testing with fundamental, applied and translational research.

Today, Wadsworth scientists use both classical and contemporary approaches to study environmental and biological sciences related to human health and disease. They develop advanced methods to identify microbial or chemical threats; study drug resistance and emerging infections and environmental exposures; manage the country's most comprehensive laboratory permit program; oversee extramural research programs on stem cells, breast cancer and spinal cord injury; and train the next generation of scientists through undergraduate, graduate, postdoctoral and visiting scientist programs. Their efforts embody *Science in the Pursuit of Health*.®

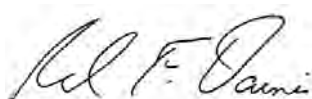
[www.wadsworth.org](http://www.wadsworth.org)

## Message from the Commissioner

The Department of Health's laboratories have a long and rich history. Under the early leadership of Augustus B. Wadsworth, the laboratories set a precedent for excellence in diagnostics and original research. By mid-20th century, this tradition led to a "translational medicine" milestone, the discovery of the first antifungal antibiotic, named Nystatin for New York State.

In subsequent decades, staff developed methods to analyze complex environmental mixtures or detect a pathogen's DNA fingerprints; used computational and imaging tools to visualize cells and biomolecules; initiated the first state laboratory permit program and the country's largest newborn screening program; and responded to natural and intentional disease threats.

Today, the Wadsworth Center laboratories stand at the forefront of biomedical and environmental sciences and their interplay. As such, they continue to serve a vital role in the Department's efforts to protect and promote the health of New York's citizens.




**Richard F. Daines, M.D.**  
*Commissioner*  
*New York State Department of Health*

## Message from the Director

Wadsworth Center displays many faces to the world. To the scientific community, Wadsworth is a research institute; to the laboratory community, a reference laboratory and quality check; to the general public, a responder to public health threats; to students and postdocs, a training opportunity; and to the Department of Health, a resource for laboratory data and scientific information.

To our 1,100 staff, Wadsworth is a multi-site scientific community of diverse individuals, laboratories and programs. Wadsworth Center succeeds because of our staff's commitment to "science in the pursuit of health." These dedicated, talented individuals are the laboratory's most valuable resource, and the source of its expertise and accomplishments.

More than any other time in history, science is moving at an accelerated pace, making it difficult to capture individual projects or progress for more than a brief moment in time. What follows, then, is a snapshot of Wadsworth Center in the early years of its second century.



**Lawrence S. Sturman, M.D., Ph.D.**  
*Director, Wadsworth Center*  
*New York State Department of Health*

# Landmark Achievements

Syphilis test standardized with the chemically defined antigen, cardiolipin (Dr. Mary Pangborn)



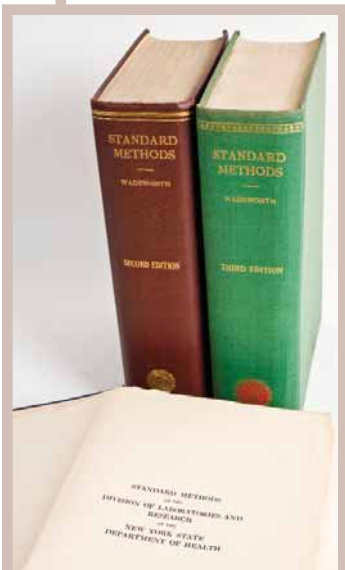
Nystatin discovered, the first safe and effective antifungal antibiotic (Drs. Elizabeth Hazen and Rachel Brown)



1926

1941

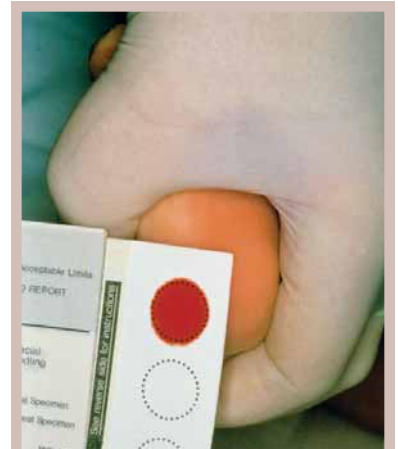
1948 1950



First *Standard Methods* of analysis for public health testing published



Coxsackie virus isolated and characterized



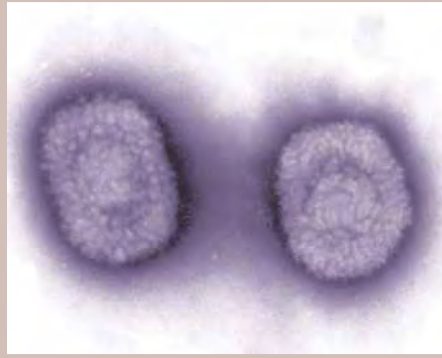
A model state newborn screening program established

The country's first state clinical laboratory permit program launched



1965

Vaccinia virus served as a recombinant vector to express selected genes from pathogens to make vaccines



1978-80

1981

1983 1984

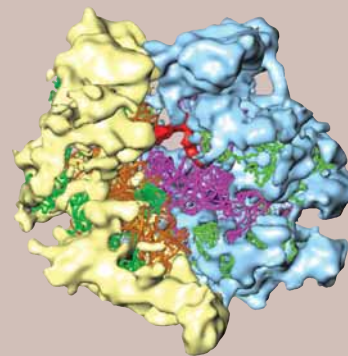
Brain-computer interface system translated electrical signals from the brain into a novel communication and control device



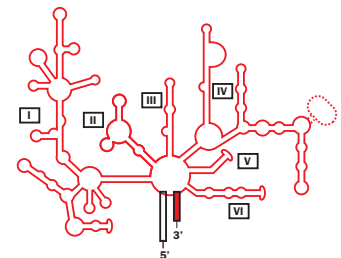
1991



Sophisticated methods developed to assess toxicity of complex environmental mixtures



Electron microscopy and computer processing used to analyze the 3D structure of large biomolecules



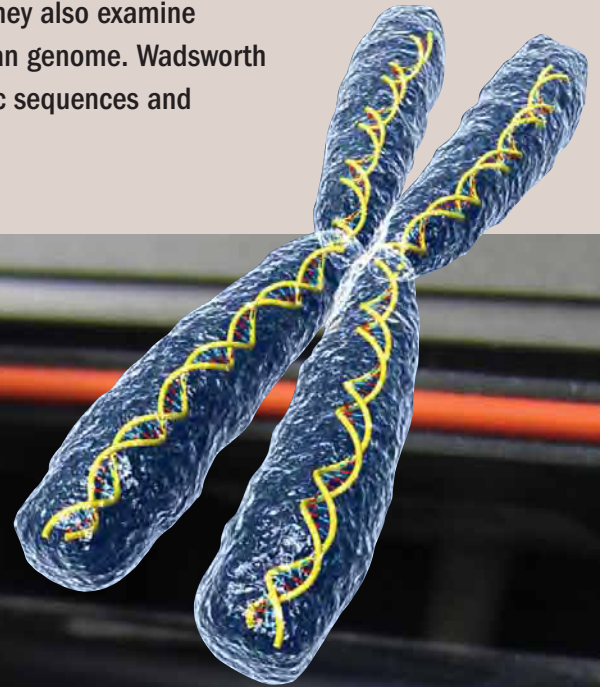
**Group II Intron Structure**

The catalytic RNA of a group II intron consists of six domains, I-VI

Mobile genetic elements known as introns discovered in bacteria

# Genes and Genomes

The human genome sequence is the driving force of 21st century genetic research and molecular medicine. Investigators explore the roughly 20,000 human genes for clues to how they orchestrate the development and function of a healthy person, and how mutations in the genetic code can lead to disease. They also examine non-coding regions that constitute a large portion of the human genome. Wadsworth scientists study how the interplay of genes, non-coding genetic sequences and the environment contributes to individual and public health.





## MOLECULAR GENETICS

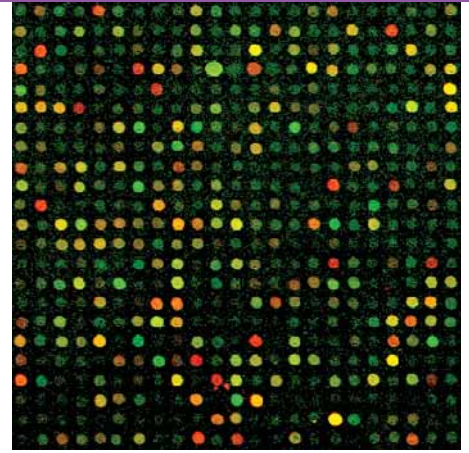
Control of gene expression is critical to the normal functioning of an organism. Novel computational approaches devised by Wadsworth scientists are uncovering DNA and RNA sequences that regulate gene expression in diverse organisms, dictating when, where and how much protein to manufacture. Molecular geneticists build on this regulatory information as they investigate cellular processes that cause genomes to alter or adhere to genetic instructions. Knowledge about genome evolution and conservation informs studies of development, inherited disorders and cancer. Similarly, an understanding of non-coding DNA reveals how these sequences create diversity within and among species, while retaining a blueprint for development and function.

## DEVELOPMENT

Wadsworth scientists rely on simple organisms, such as fruit flies and yeast, which lend themselves to genetic studies, to decipher the fundamental mechanisms at play in early human development. They interrogate these model systems about cell identity during embryonic development; for example, what signals a cell to mature into a nerve cell versus a muscle cell, and the consequence of signaling errors. They also delve into the molecular details of how genes are turned on and off, including how the packaging of genes into chromosomes modulates gene expression, and how their protein products function.

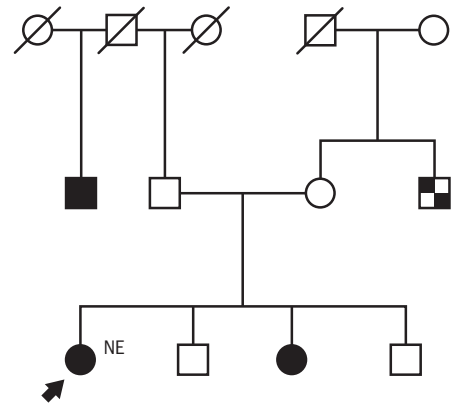
## MAMMALIAN GENOMICS

Wadsworth researchers use transgenic mouse models of human disease, microarrays that compare gene expression in healthy versus diseased cells, and other tools to probe the impact of genetic and environmental factors on disease susceptibility or severity. They investigate genes involved in processes that broadly affect health, and examine learning and memory disorders, Parkinson's, and other neurological diseases from several perspectives, including gene-environment interactions and gene therapy.



## POPULATION GENETICS

Wadsworth scientists apply gene chips, microarrays and nano-technology to population-wide studies. These include screening newborns for rare genetic disorders; discerning the genetic basis of common conditions through molecular genetic epidemiology; and predicting individual responses to drug treatments, the province of pharmacogenomics. Population studies extend to other species. Infectious disease genomics includes deciphering patterns of population structure, gene flow and infectivity of malaria- and West Nile virus-infected mosquitoes.







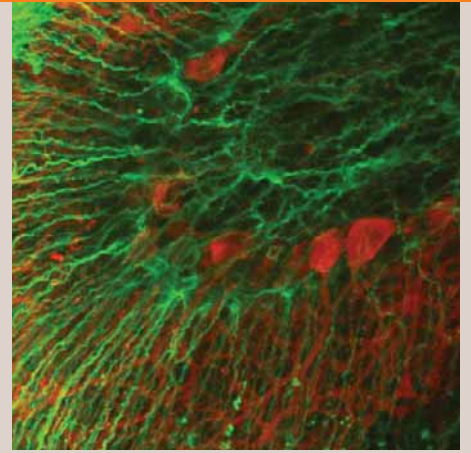
Newborns' blood specimens collected from a heel prick onto filter paper forms are "punched" to remove samples for processing

## Newborn Screening: By the Numbers

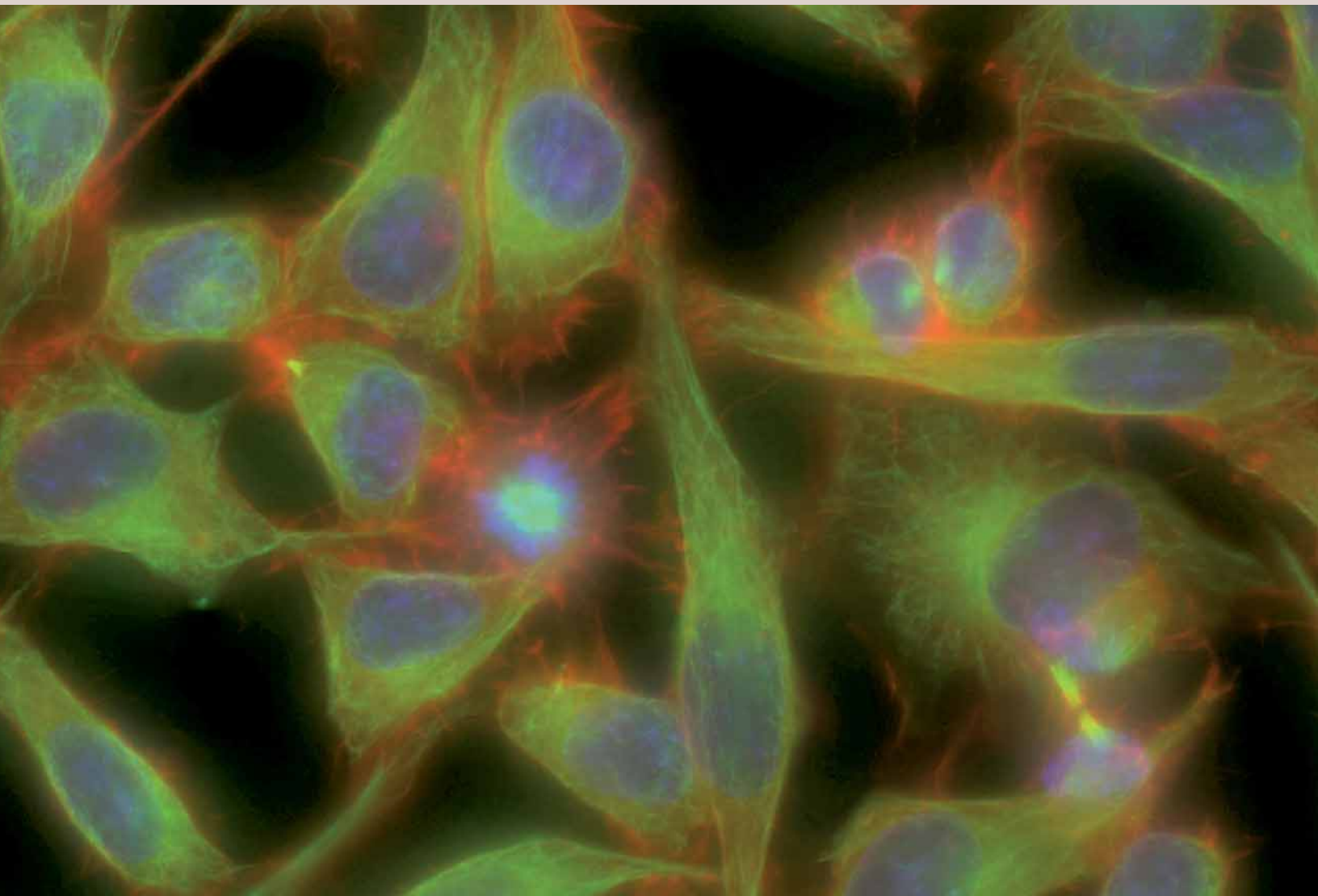
New York's smallest citizens get off to a healthy start thanks to a comprehensive program that screens all infants for detectable, treatable conditions. An acknowledged leader in newborn screening, Wadsworth Center capitalizes on technological and medical advances, making newborn screening the Center's largest program.

- **45** conditions screened for using **5** methodologies
- **75** staff operating **10** hours each weekday
- Around **250,000** infants screened and over **11** million results reported annually
- Around **25,000** requests for results answered monthly via a voice response system
- Around **7,000** phone calls monthly related to referrals and follow-up with physicians or the public
- **70** specialty treatment centers to which infants are referred

# Molecular and Cellular Basis of Disease



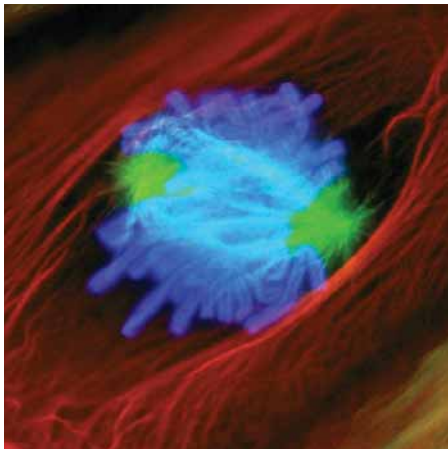
A cell's DNA contains genes that code for large molecules (proteins and RNAs) that do everything from regulating cell growth and division to maintaining cellular energy supplies. Most of these macromolecules only function as part of larger and more complicated structures, such as membranes, filaments and molecular machines like the ribosome, the factory that fabricates proteins. Advances in the diagnosis, prevention and treatment of diseases such as cancer and autoimmunity rely heavily on technology. For example, the intricate details of the cell's molecular machines can now be imaged in three dimensions at the highest resolution.





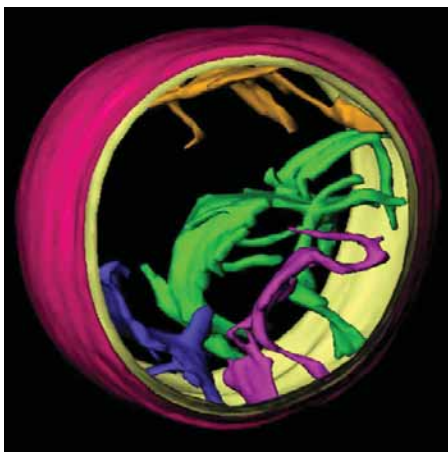
### CELL GROWTH AND DIVISION

All disease starts at the level of the cell. Wadsworth scientists investigate how cells communicate with one another, regulate growth and proliferate, age or die. Problems in any of these areas can lead to disease, from birth defects and autoimmune disorders to cancer, diabetes and infertility. Researchers use high-resolution light and electron microscopy, molecular biology, genetics and chemistry to probe these processes. Some explore the cytoskeletal and motor machinery within cells that are responsible for movement, secretion and division, while others study hormones and chemical pathways that dictate what cells do and when. Information gleaned from such basic studies can aid in detecting diseases very early in their development, as well as in designing better drugs to ameliorate abnormal cell behaviors.



### BIOMOLECULAR MACHINES

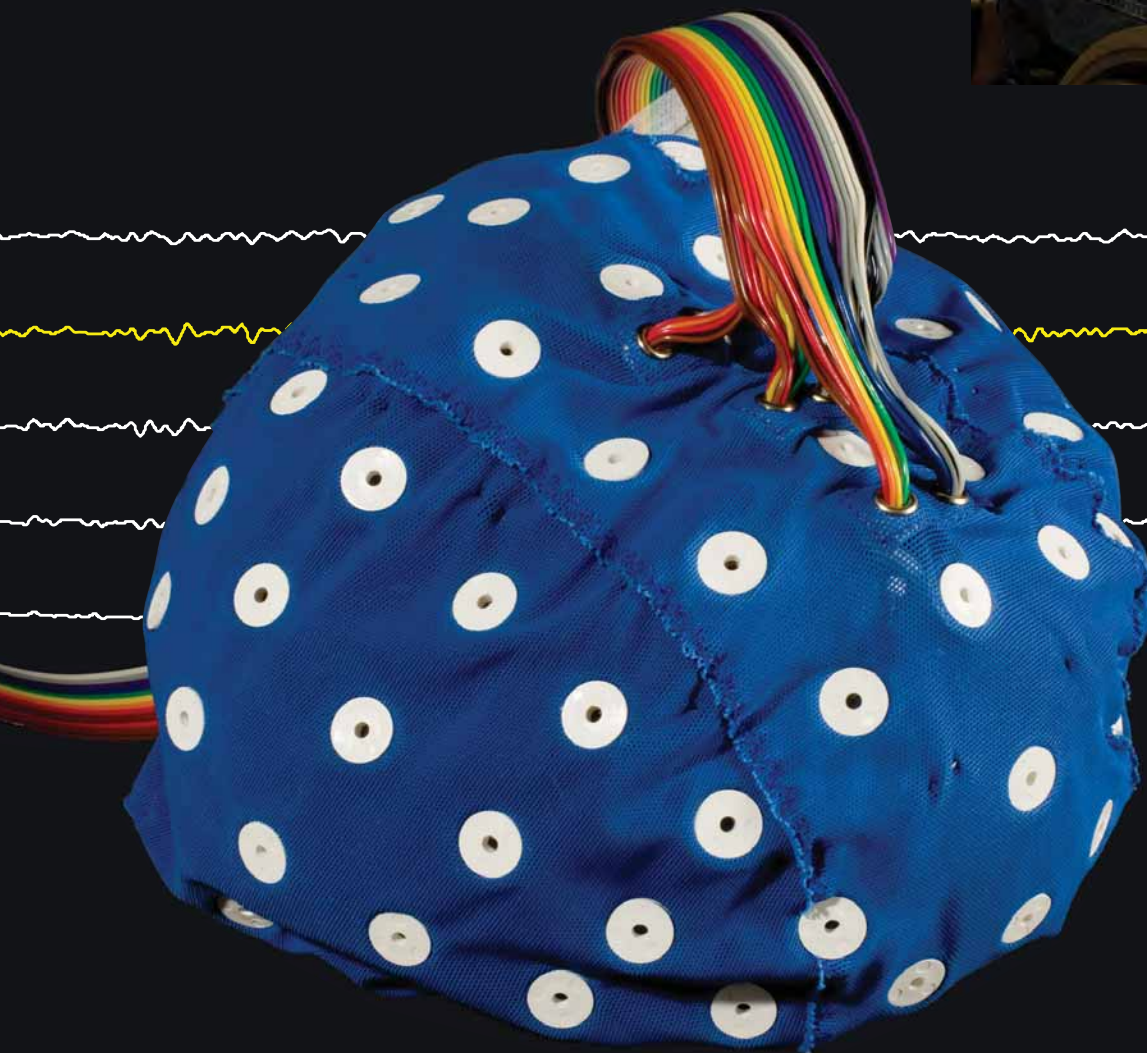
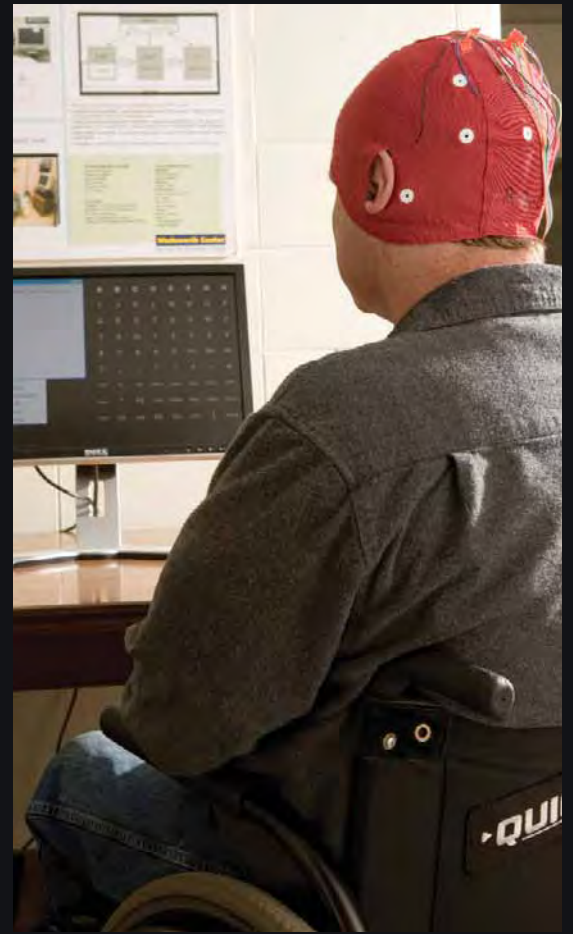
Molecular machines perform essential cellular work. These complexes of proteins and nucleic acids carry out cell replication, translate genes into functional proteins, transport macromolecules, and govern cell communication and movement. They are the primary targets of antibiotic and antiviral drugs, and are key to the development of cancer and neurological disease therapeutics. Wadsworth scientists study molecular machines using a highly multidisciplinary approach: imaging technologies to reveal structure, including cryo-electron microscopy, X-ray crystallography and nuclear magnetic spectroscopy; biochemical and genetic data to identify features necessary for operation; and computational methods to predict structures and model their dynamic states.

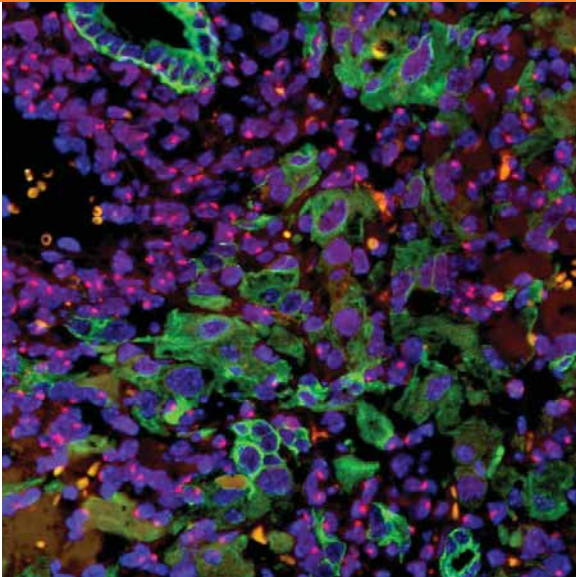


## You Think. You Can.

By simply thinking, severely disabled users of a brain-computer interface (BCI) pioneered at Wadsworth can compose and send e-mails, converse using a voice output utility, and control their environment, such as turning on a light. The award-winning BCI system translates electrical signals detected from the scalp into users' commands, giving keyboard-like control of computer-based functions.

The non-invasive system consists of an electrode cap that detects electroencephalographic (EEG) activity from the scalp, an amplifier that records key brain waves, a computer and sophisticated software. The research project has moved from laboratory to living room, with the development of a portable, affordable system useful for everyday tasks for the target population, the most severely disabled. The first home-based user, a working neuroscientist with ALS (Lou Gehrig's disease), uses BCI to communicate by e-mail with his research team.



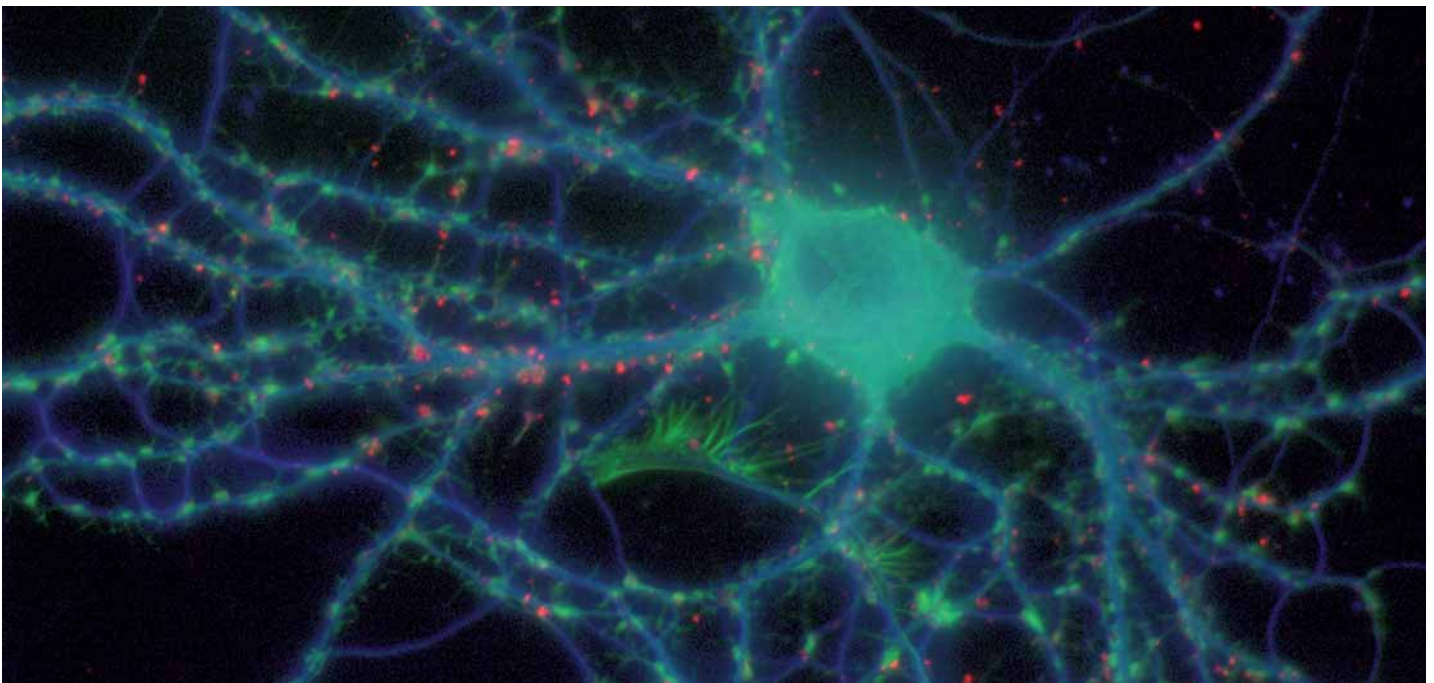


## CANCER

Cancer's hallmark of uncontrolled cell division serves as a framework in which to ask how cancer begins and progresses, what type of specialized cells give rise to tumors, and what opportunities exist to interrupt the process. For example, can enzymes involved in cell division be exploited to damage or kill cancer cells without harming normal cells? Wadsworth scientists study the origins of cancer cells and the mechanisms by which these cells evade chemotherapy, and consider how these same biological pathways might be co-opted to improve treatment. Also investigated are disease susceptibility and drug resistance, and the role of cancer stem cells, including their implications for the development of effective cancer treatments.

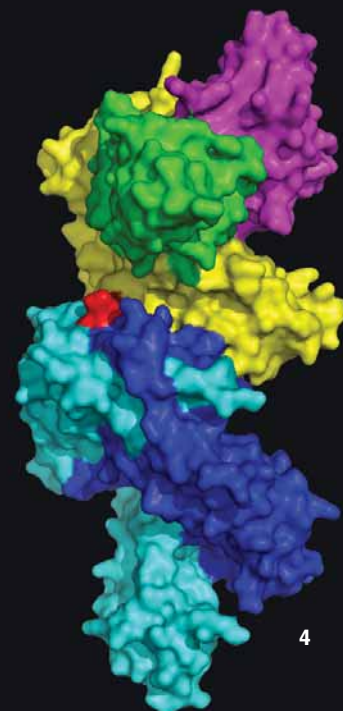
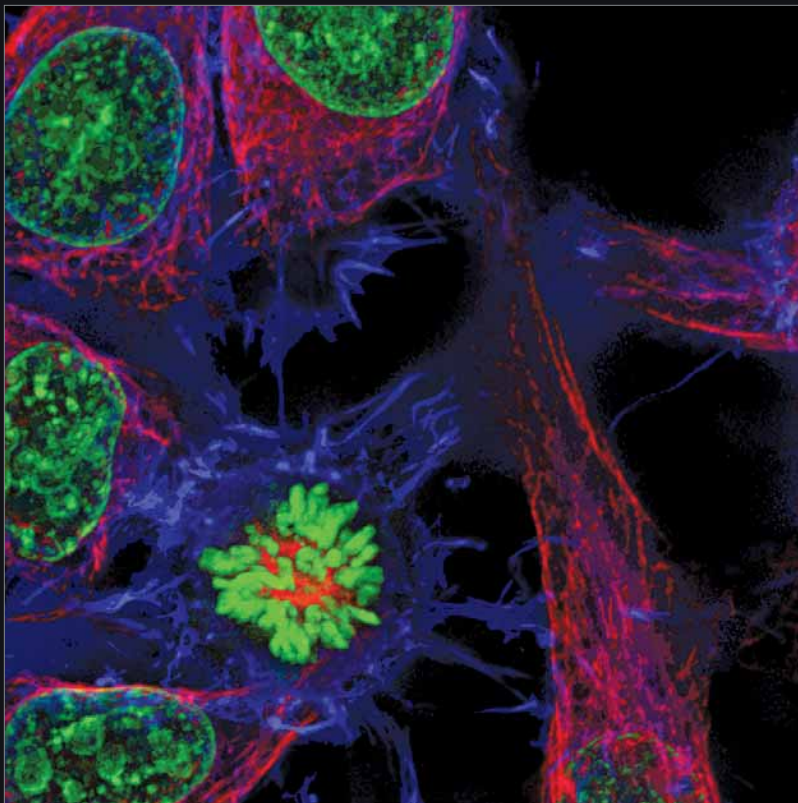
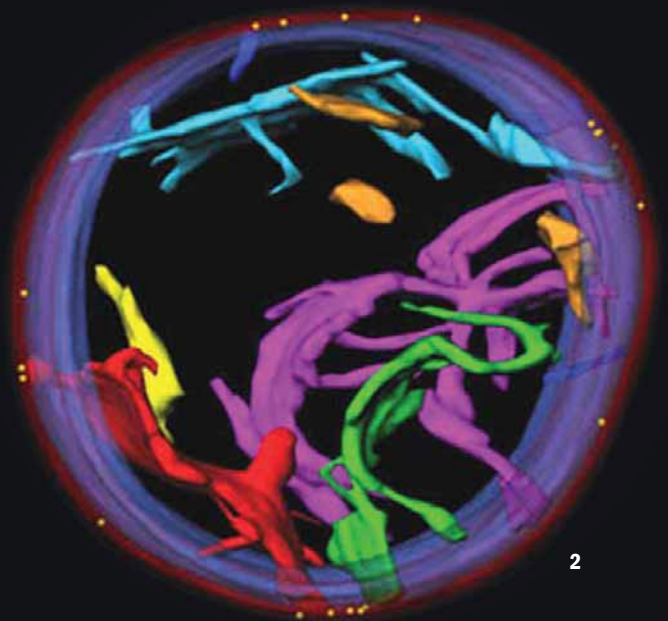
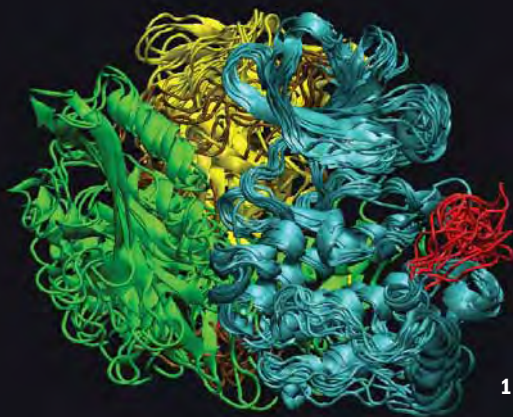
## NEUROBIOLOGY

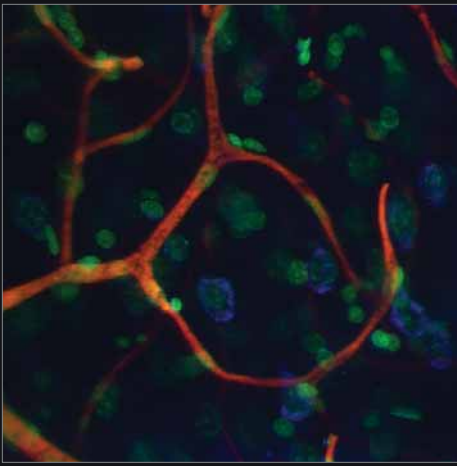
An understanding of fundamental neurobiological processes underlies the development of better means of restoring function lost to neurological trauma or disease. At Wadsworth, such efforts range from using experimental models to study novel therapies for Parkinson's disease, to testing devices that can supplement or circumvent damaged neurons. Scientists use neurochemistry, cell biology and 3-D cell and tissue analysis to optimize function of nano-fabricated brain implants that treat neurological disorders. Another approach employs sophisticated software to translate the brain's electrical activity into control of a computer cursor or robotic arm. The nervous system's remarkable capacity to alter circuits and synapses after injury also is explored for its potential to assess spinal cord injuries and possibly aid in recovery.



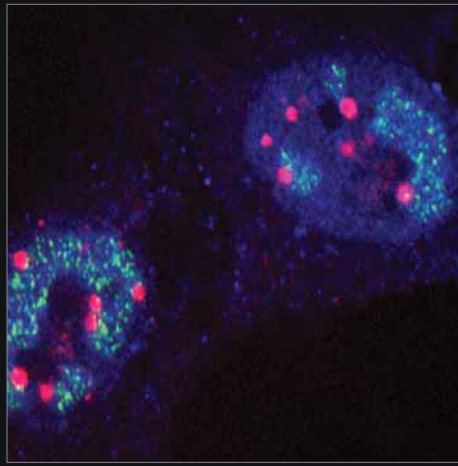
## Life Science as Art

Image isn't everything, but for some scientists visualizing their pathogen, protein or process of interest can yield new insights. At Wadsworth, cell biologists, structural biologists and other life scientists produce data that are visually arresting as well as scientifically meaningful. Using sophisticated instrumentation, they generate representations of cells and biomolecules to better understand their function – pathogens invading host cells, cells caught in the act of dividing, organelles mapped in three dimensions, or proteins and nucleic acids bound in macromolecular complexes. These colorful, information-rich images have won international awards, been featured on note cards, and graced the covers of textbooks and prestigious journals, including *Science*, *Cell* and the *Proceedings of the National Academy of Sciences*.

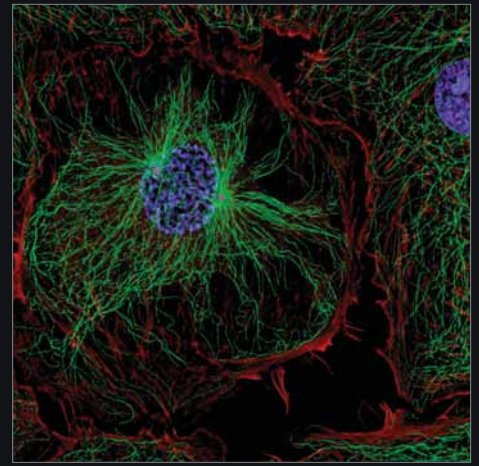




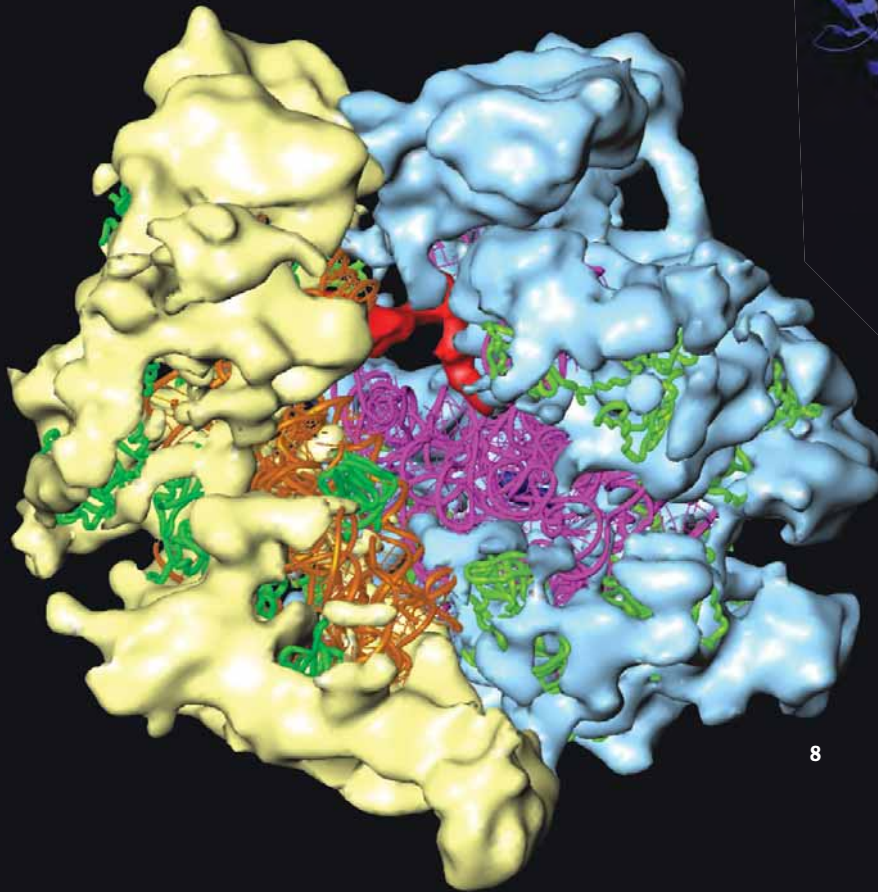
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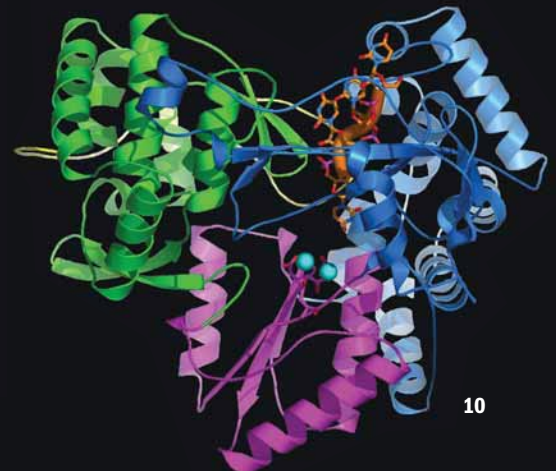
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8



9



10

1 Cell signaling enzyme dynamics predicted by simulation  
 2 Electron tomogram of frozen-hydrated mitochondrion  
 3 Confocal image of cervical cancer-derived (HeLa) cells

4 Structure of super antigen-immunoreceptors ternary complex  
 5 Confocal image of neurons in cerebral cortex  
 6 Relocation of chaperone proteins in herpes virus-infected cells  
 7 Vertebrate somatic cell initiates cell division (prophase)

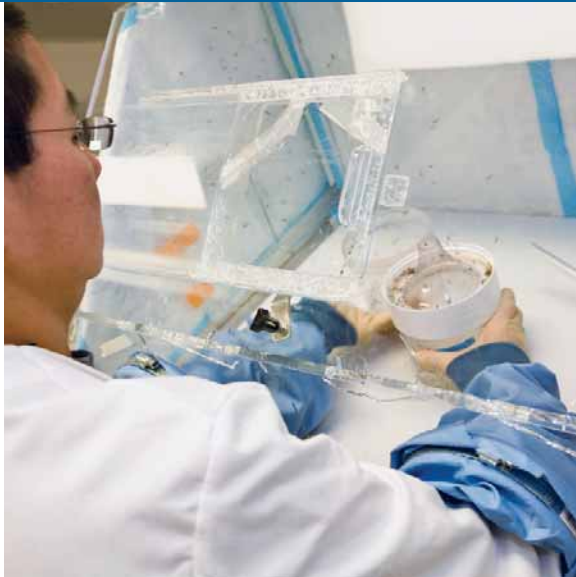
8 Mammalian mitochondrial ribosome by 3D cryo-electron microscopy  
 9 Crystal structure of HIV reverse transcriptase and inhibitor  
 10 X-ray structure of hepatitis C virus RNA polymerase substrate complex

# Infectious Disease and Host Defense

Public health and basic research programs converge on infectious agents, with Wadsworth scientists seeking to improve detection of disease-causing organisms and understand their fundamental properties. Staff develop and validate assays to identify pathogens in order to monitor and manage disease outbreaks. While not abandoning traditional methods, they embrace modern molecular technologies that rapidly determine the source of disease transmission. At the same time, researchers dissect the lifestyles of bacteria, viruses and parasites to understand how microbes infect and interact with their human host. For example, details about key proteins and cellular machinery that pathogens require for virulence can aid in the development of novel drugs or vaccines that interrupt the disease process.







## VIROLOGY

Wadsworth scientists probe the mechanisms that viruses use to hijack a human host's replication machinery, causing diseases from AIDS to hepatitis C. They examine viral proteins that help assemble genetic material into infectious particles and analyze how changes in these proteins allow the SARS coronavirus and other pathogens to adapt to new hosts. West Nile virus researchers concentrate on the ecology and evolution of the virus and its insect vectors, while clinical virologists test for West Nile infection. The clinical program also conducts outbreak investigations, performs surveillance, develops assays for emerging pathogens and collaborates with the World Health Organization to detect the earliest appearance of new strains of influenza. Other laboratories chart the prevalence and spread of viruses to alternate hosts, including rabies in bat species.

## IMMUNOLOGY

The immune system sometimes misses the mark, either failing to mount a response against foreign elements or mistakenly targeting host cells, leading to autoimmune diseases. Wadsworth investigators parse the immune system, studying its component cells and the mechanisms involved in host defense against bacterial and viral infections. Researchers consider factors that modulate immune response, including diet, aging, hormones and genetic makeup. Avenues for novel therapeutics are assessed, such as the properties of mucosal antibodies that inhibit infection and the structure of immune molecules that mediate a protective response. Scientists develop assays to measure specific serum antibody levels for emerging and newly epidemic diseases, among them Powassan encephalitis, Lyme disease and ehrlichiosis.



**Zoonotic diseases transmitted directly to people from vertebrate hosts such as bats, or by mosquitoes, ticks and other vectors, account for half of all human pathogens.**



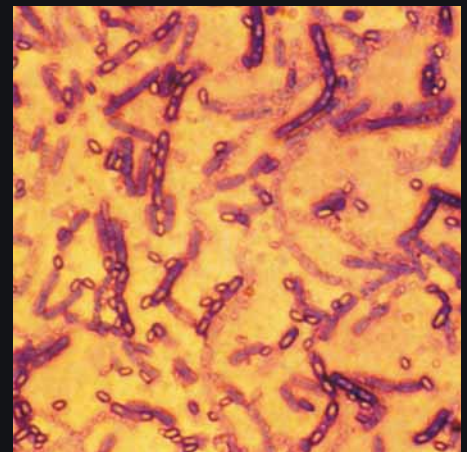
## Reference, Readiness and Response

Rapid identification of disease threats is an everyday event at New York State's public health reference laboratory.

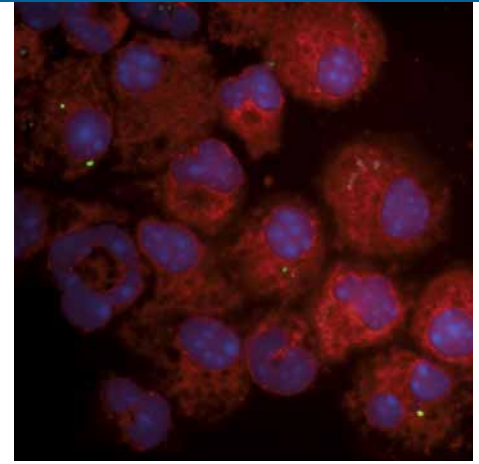
- Staff have identified more than 30 emerging and re-emerging disease-causing organisms in recent years, including West Nile virus, Hantavirus, Legionella, Listeria and Cryptosporidium.
- In a single year, bacteriologists implemented almost two dozen new molecular-based methods and tested more than 10,000 specimens using such assays, in some cases linking New York State patients with nationwide foodborne disease outbreaks.
- Virologists developed a molecular assay to simultaneously detect 11 respiratory viruses in a single reaction, and used archived influenza specimens to demonstrate the evolution of the influenza virus over a single flu season.
- Rabies specialists developed and licensed a novel approach to producing a biological reagent used by all public health laboratories as part of the gold-standard rabies diagnostic test.
- The biodefense laboratory analyzed more than 1,000 suspicious materials and clinical specimens for the presence of *Bacillus anthracis* following the anthrax attacks in the fall of 2001, and continues to assess potential biotreats.
- The federal government designated Wadsworth as one of only two sites to evaluate prototype mobile units for screening environmental samples to rule out potential hazards, such as chemicals, radiation or harmful vapors, prior to biological testing.



Training for preparedness takes place at the laboratory bench and in the field with first responders and other critical partners.



*Bacillus anthracis*



### PARASITOLOGY AND MYCOLOGY

Fungal and parasitic infections that debilitate the young, aged and immunocompromised patients, especially those with AIDS, highlight the need for more effective treatments. Wadsworth researchers study yeasts, molds and other medically important fungi using recombinant DNA technology and animal models to understand how the pathogens cause disease. Their ultimate goal is to identify genes or proteins useful for diagnosis or development of novel drugs. Similarly, scientists investigate pathogenic parasites to find metabolic pathways or cellular components that may serve as parasite-specific drug targets. Parasitic protozoa of particular interest are the causative agents of malaria, toxoplasmosis and cryptosporidiosis, the latter a potentially life-threatening gastrointestinal illness. Traditional and molecular diagnosis of molds, yeasts and parasites from clinical specimens and the environment is performed, as well as more complex confirmatory testing.

### BACTERIOLOGY

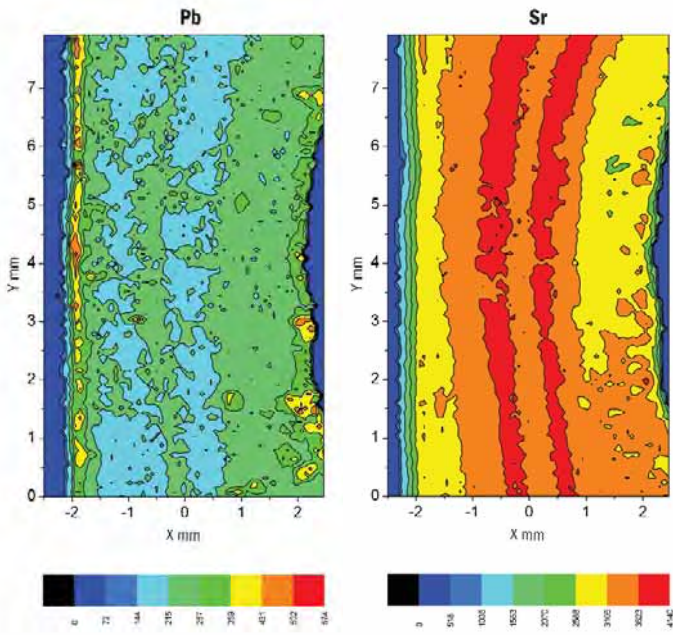
The study of bacterial pathogens incorporates conventional and molecular diagnostics, surveillance, strain typing and research. Investigators focus on *Mycobacterium tuberculosis* to understand how the bacterium that causes tuberculosis lies dormant within the lungs, then overcomes the host's immune defenses to initiate disease. Wadsworth scientists develop and validate molecular tools to detect and identify bacteria in complex clinical and environmental samples, methods that have helped address disease outbreaks caused by *E. coli* O157:H7 and *Mycoplasma pneumoniae*. This expertise also aids in the assessment of bioterror samples for infectious agents that may have been deliberately disseminated. Naturally occurring outbreaks are tracked with DNA typing (bacterial fingerprinting) to confirm links between organisms causing human disease and their presence in implicated food or other products. This information is incorporated into a national database to proactively identify outbreaks that may affect neighboring states.

# Environmental Health Science



Scientific and technological advances of the last century allowed for the detection of minute quantities of contaminants in complex environmental samples. Complementing that capacity today is the emerging ability to directly measure environmental chemicals or their by-products in clinical specimens. At Wadsworth, scientists employ these and other approaches to monitor the environment for public health threats, assess individual exposures, and investigate the relationships between environmental, occupational and dietary exposures and health effects. Their studies also examine the underlying interactions of environmental toxicants with immune, endocrine, neurological and genetic systems.

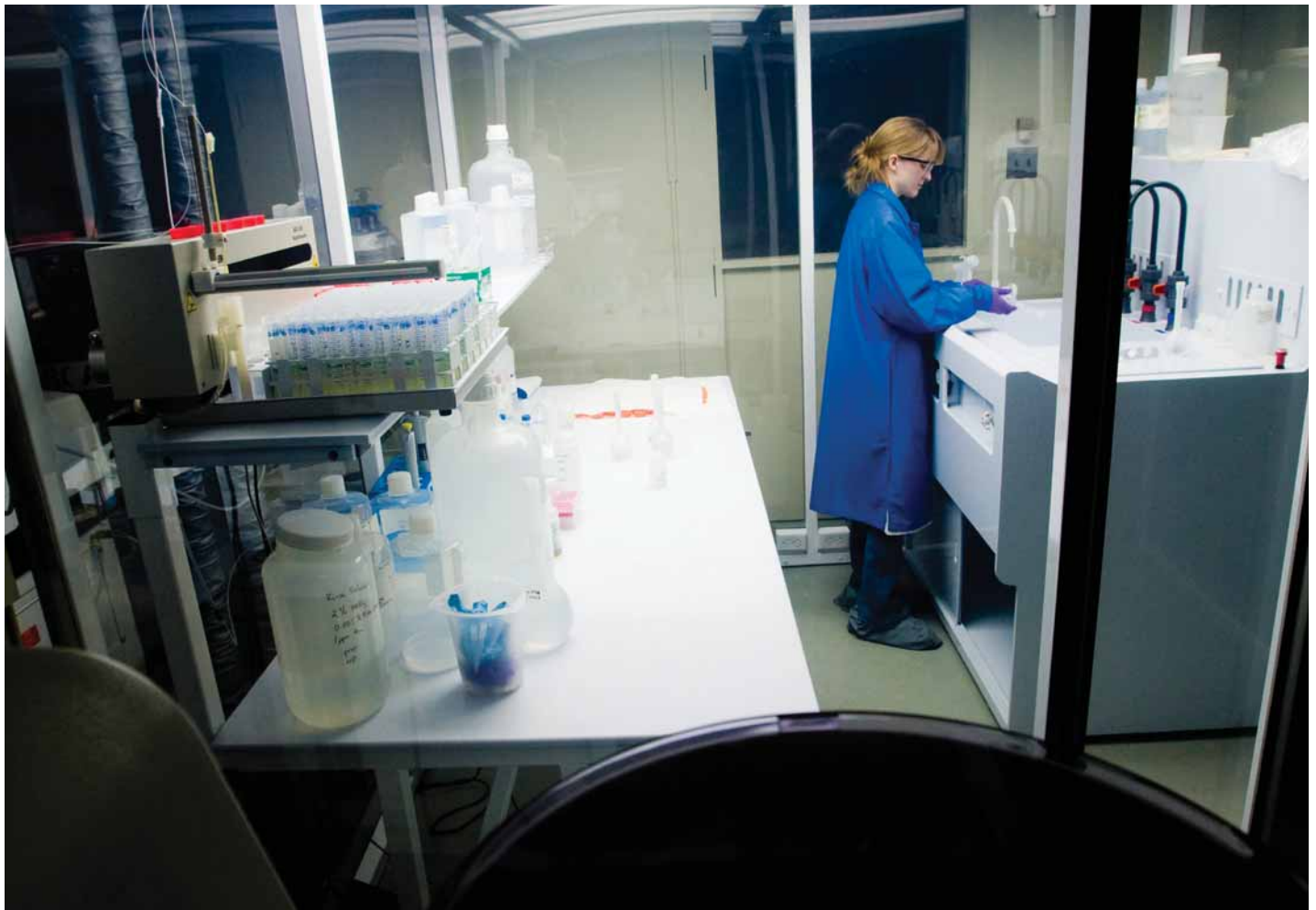




**A novel X-ray fluorescence instrument detects lead (Pb) and strontium (Sr) concentrations in goat shin bone, while other trace metal analyses take place in a clean-room environment.**

## TOXICOLOGY

Differences in how chemicals are metabolized can be explained, in part, by an organism's own chemical make-up. Variant forms of enzymes that bioactivate foreign compounds, whether therapeutic drugs or environmental pollutants, can predispose individuals to toxic or beneficial effects. Wadsworth scientists study variants of a complex metabolizing system known as cytochromes P450. They investigate the influence of metals, fluoride, nanoparticles and other foreign substances on P450 function, and study the enzyme's differential expression in multiple tissues. Other efforts to identify environmental triggers of disease examine alterations in nervous system function produced by exposure to such contaminants as PCBs, pesticides and methylmercury. A trace element program both conducts research on non-invasive *in vivo* bone lead measurements, and performs trace metal analyses in support of public health lead screening programs.



## Biomonitoring in Action

- Measurement of nicotine metabolites to determine the effect of smoking law changes on exposure of bar and restaurant workers to secondhand smoke.
- Assessment of fish-borne exposure to bioaccumulated flame retardant compounds in anglers.
- Evaluation of potentially cancer-causing compounds that form on well-cooked meat to induce DNA damage.
- Response to accidental or deliberate release of toxic chemicals to identify agents, determine exposure and assess re-occupancy.
- Analysis of specimens from state employees and National Guard personnel stationed near the World Trade Center, post-disaster, to identify possible biomarkers of exposure to support investigations of long-term health effects.



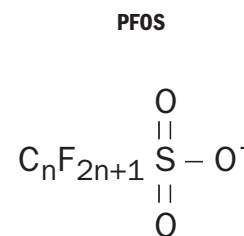
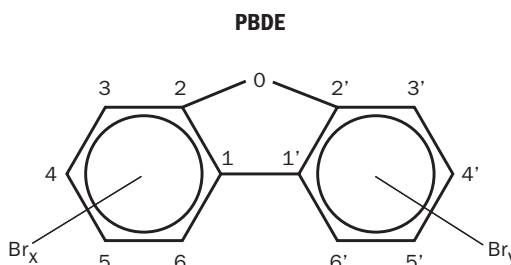
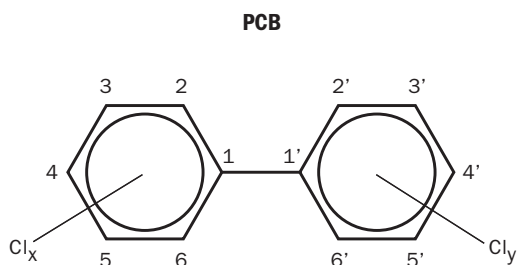
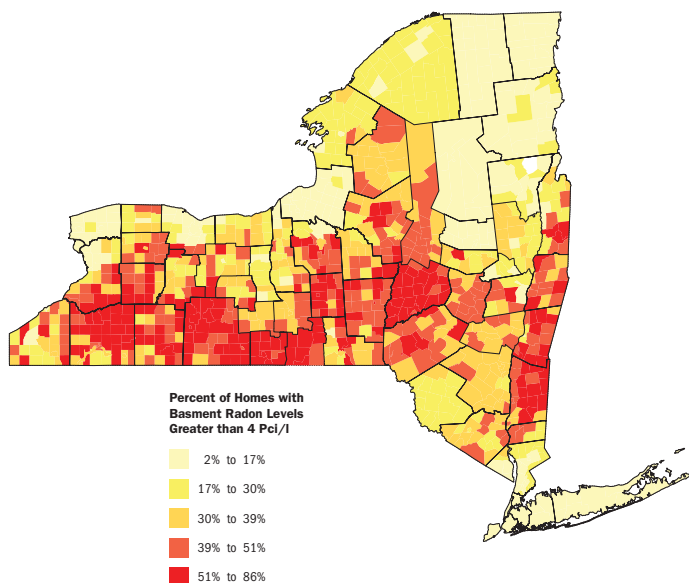


## BIOMONITORING

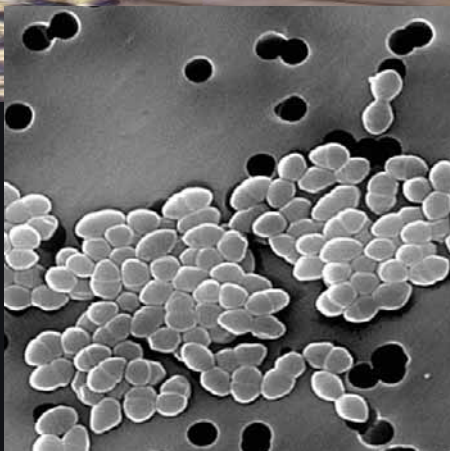
Biomonitoring measures personal environmental exposures, rather than inferring exposure from chemical concentrations in air, water or soil. This approach directly quantifies the suspect chemical, its metabolites or reaction products in human specimens. Wadsworth scientists are developing non-invasive methods to measure biomarkers in blood, urine and tissue in order to identify individuals at risk. Biomonitoring can help determine the relationship between exposure and disease, and target prevention and remediation efforts more appropriately. For example, an objective measure of exposure to emissions from the World Trade Center disaster in state employees and National Guardsmen will support investigations of future health effects.

## ENVIRONMENTAL CHEMISTRY

Accurate measurement of radioactivity and chemical contaminants is essential for surveillance of drinking water supplies, nuclear power plants and indoor air, or for response to public health emergencies. Programs to characterize occurrence and exposure to natural radioactivity largely focus on radon, with the development of township-level maps indicating indoor radon-potential. Community water supplies around nuclear power reactors are monitored for radioactivity, and preparedness drills are conducted to improve response to potential accidents or terrorism. In addition to monitoring regulated chemicals in the environment, Wadsworth scientists develop novel methods to detect contaminants of concern, such as flame retardants, pesticides and pharmaceuticals present in the environment and food. Studies aim to evaluate the bioaccumulation, food-chain transfer, and human exposures of emerging chemical toxicants, and to develop biomarkers of human exposure.



Persistent organic pollutants found in everyday products from flame retardants (PBDE) to stain repellents (PFOS), and even those banned decades ago (PCB), are studied for potential health effects.



*Enterococcus* bacteria

## Do (or Don't) Jump in the Water

Micron-sized organisms whose presence in recreational waters indicates bacterial contamination take time to identify. The gold standard for detecting *Enterococcus* and other disease-causing bacteria that flourish in animal and human intestines is the culture method, with a 24-hour turnaround.

The lag between sample collection and reporting results means that day-old data, at best, inform decisions on beach closings. Wadsworth Center is one of only 11 laboratories in the country to have participated in assessing a molecular-based assay against the gold standard. This Environmental Protection Agency-developed test amplifies a segment of an *Enterococcus* gene, giving rapid, accurate and sensitive results. This approach gives beach communities and bathers the news they need to hear faster.



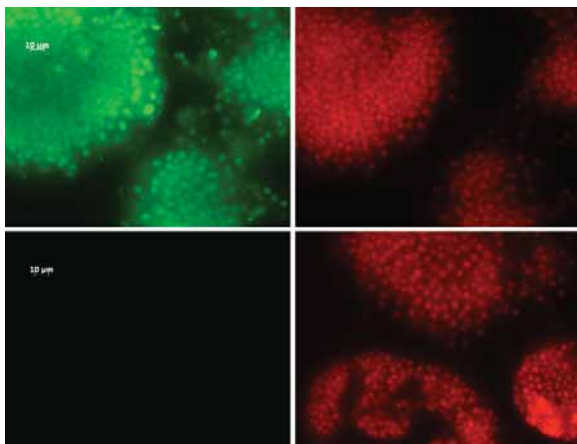


### ATMOSPHERIC SCIENCE

The earth's atmosphere is a mixture of particles and gases from natural and man-made sources, including airborne products of combustion and manufacturing. Ultra-fine particles are a special concern for their association with cardiac and pulmonary disease, and climate change. Wadsworth scientists identify the chemical constituents of these fine particles and identify their sources. Secondary aerosols formed from chemical reactions also affect air quality, producing acid rain and altering ozone levels. Wadsworth researchers study reactions in cloud, ice and snow environments to understand the production of stratospheric ozone; analyze clouds for the occurrence and production of acidic sulfate, the cause of acid rain; and characterize indoor pollutants to understand the relationship between chemical exposure and asthma.

### MICROBIOLOGY AND AQUATIC CHEMISTRY

Wadsworth scientists develop state-of-the-art methods to quantify the sources, distribution, fate and transport of waterborne toxicants, including persistent organic pollutants (e.g., PCBs and dioxins) and perfluorinated compounds. These rapid and accurate analytical tools aid routine monitoring of water resources and improve response to public health emergencies. Examples are a molecular method to discriminate between human and agricultural sources of fecal pollution in watersheds, and a rapid assay to differentiate between toxin-producing species of blue green algae and their non-toxic counterparts.



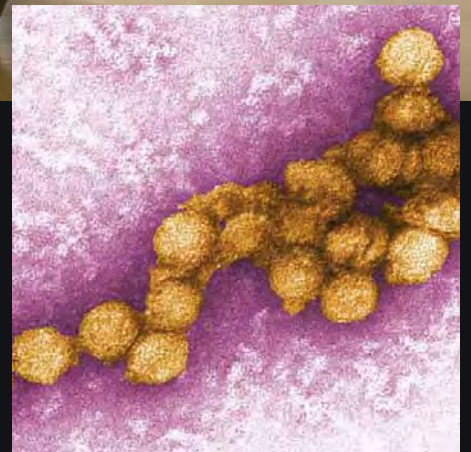


## Crossing Corridors, Crossing Disciplines

Scientists at Wadsworth Center don't work in isolation. They confer and collaborate, whether their laboratories are separated by hallways or miles. They also bridge scientific divides, drawing upon their disparate fields to wrestle with a particular challenge.

For example, multiple lines of work focus on West Nile virus (WNV) and other arthropod-borne agents. Clinical laboratory groups test for WNV and related viruses to aid decisions on patient treatment and vector control activities. Research groups concentrate on the transmission and pathogenesis of WNV, and on the ecology and evolution of the virus and its insect hosts. Molecular biological research is geared toward understanding the machinery that replicates the viral RNA genome, with the goal of identifying molecular targets for antiviral therapy and screening prospective drugs.

It is this synergy of clinical science combined with basic and applied research that uniquely describes New York's public health laboratory.



West Nile virus



Saliva collection from West Nile-infected mosquito

## Public Health Science from A to Z

**A** Alzheimer's  
Anthrax  
Antibiotic resistance  
Autism  
Autoimmune disorders  
Avian influenza

**B** Bacterial infections  
Batten disease  
Biomarkers  
Birth defects  
Blood disorders  
Breast cancer

**C** Chagas' disease  
Chemical pollutants  
Cryptosporidiosis  
Cystic fibrosis  
Cytomegalovirus

**D** Developmental disorders  
Diabetes  
Drug toxicity

**E** *E. coli* O157:H7  
Ehrlichiosis

**G** Giardiasis

**H** H1N1 influenza (Swine flu)  
Hepatitis  
Hereditary disease  
Herpes simplex virus  
HIV

**I** Influenza

**L** Lead poisoning  
Listeriosis  
Lung cancer  
Lyme disease

**M** Malaria  
Memory loss  
Meningitis

**N** Neural regeneration

**O** Olfaction

**P** Parasitic infections  
Parkinson's  
Plague  
Pneumonia

**R** Rabies  
Radon

**S** Salmonella  
SARS  
Sickle cell anemia  
Streptococcal infections  
Stem cells

**T** Tuberculosis

**V** Vaccine development  
Viral infections

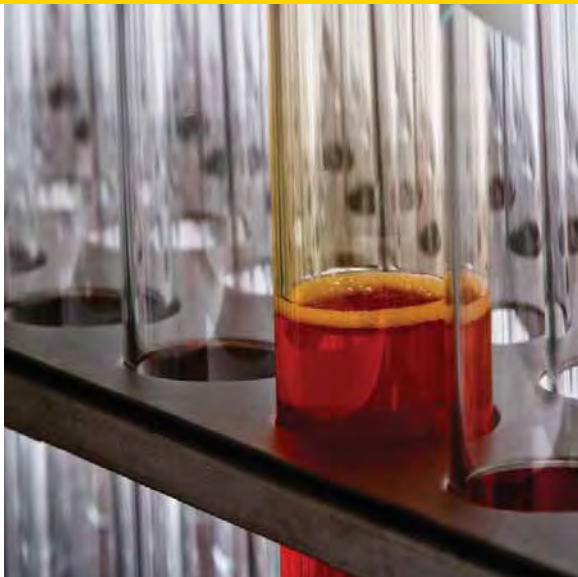
**W** West Nile virus

**Z** Zoonoses

# Ensuring Quality of Laboratory Services

The quality assurance and regulatory oversight programs that reside in Wadsworth Center assure the development and implementation of laboratory methods that yield accurate, reliable, reproducible test results. The analysis of human clinical specimens or samples collected from the environment provides information that is essential to health assessment and disease or exposure prevention.





## CLINICAL LABORATORIES

Certification and permitting of laboratories testing human specimens are overseen by Wadsworth's Clinical Laboratory Reference System. The reference system validates and approves laboratory methods and materials, provides consultation and reference testing, conducts cooperative research relevant to methods and materials, and inspects laboratories and administers proficiency tests. Clinical laboratories increasingly are developing in-house diagnostics, known as home-brew assays, which are not subject to approval of the Food and Drug Administration. Wadsworth's reference system requires that their performance claims be documented before the new assays may be used. The reference system is a multifaceted program that is integrated throughout Wadsworth Center, as well as with other New York State Department of Health entities and governmental agencies.

## ENVIRONMENTAL LABORATORIES

Any environmental laboratory testing samples collected in New York must be certified by Wadsworth's Environmental Laboratory Approval Program. Laboratories are certified for testing chemical and bacteriological pollutants in a range of sample types, including drinking water, natural waters, waste effluents, soils, sediments, chemical waste and air. Certification is based on successful participation in proficiency testing, on-site inspection of facilities and appropriate staffing. Perhaps unique among state accreditation programs is ELAP certification for detecting Biological Critical Agents in environmental samples, such as the causative agents of anthrax, botulism and plague.

**Summa® canisters collect ambient air and the samples are analyzed for the presence of volatile organic compounds.**



## BLOOD AND TISSUE BANKS

The Blood Resources Program provides support to the New York State Council on Human Blood and Transfusion Services, which is empowered to enact regulations governing human blood in New York, subject to approval by the State Health Commissioner. The regulations provide quality oversight for blood banks, and blood collection and transfusion sites. The Tissue Resources Program oversees the operation of facilities collecting or using human tissue for transplantation or in medical education and research through on-site inspections, review of staff credentials and issuance of guidelines and regulations. Tissues included are sperm and embryos, skin, bone, hematopoietic (blood) stem cells and human milk. The program also investigates incidents with potential to endanger donor or recipient safety, and provides technical assistance to the involved facilities.

## PHYSICIAN OFFICE LABORATORIES

In New York State, laboratory testing performed in physician offices for that clinician's own patients is exempt from state clinical laboratory permit requirements. However, the federal Clinical Laboratory Improvement Amendments of 1988 require that all entities performing laboratory procedures register with the federal Centers for Medicare and Medicaid Services and adhere to quality control and assurance, testing personnel, record keeping and other technical requirements. Wadsworth Center provides certification of these facilities through the Physician Office Laboratory Evaluation Program, under contract to the Centers for Medicare Services and Medicaid.

## REGULATORY AFFAIRS

Wadsworth's quality oversight activities are coordinated through review and input from the Regulatory Affairs Office. The Office drafts and reviews new and amended regulations pertaining to Wadsworth's regulatory programs; evaluates rules and legislative initiatives proposed by other Departmental or state agency programs; advises regarding interpretation of regulatory and statutory provisions as they pertain to oversight program responsibilities; investigates consumer complaints and allegations of misconduct related to the laboratory entities and makes appropriate referrals for legal sanctions as warranted; and manages Wadsworth's response to requests for public records made under the Freedom of Information Law.



## **CORE FACILITIES**

Core facilities provide scientific staff with access to shared instrumentation, services and expertise that would normally be beyond the fiscal means of an individual investigator or program. Thus, core facilities eliminate needless duplication of high-end analytical equipment and specialized personnel services. Wadsworth's cores are grouped into three general themes:

### **IMAGING**

Advanced Light Microscopy and Electron Microscopy, including various modes of image analysis

### **STRUCTURAL BIOLOGY**

Biochemistry Instrumentation, Crystallography, Mass Spectrometry and Nuclear Magnetic Resonance Spectroscopy; Membership in the New York Structural Biology Center affords access to additional facilities

### **GENOMICS/INFORMATICS**

Transgenic Mice, DNA Sequencing, Microarray Analysis, Genotyping, Immunology and Computational Molecular Biology

## **NATIONAL MICROSCOPY RESOURCE**

For more than 25 years Wadsworth Center has been the site of a federally supported national biotechnology resource in microscopy. The resource employs advanced methods of three-dimensional imaging with electron microscope and computation to look at different levels of biological architecture, and to integrate this information with existing data toward a comprehensive understanding of biological systems.

## **HEALTH RESEARCH, INC.**

Health Research, Inc. (HRI), a 501(c)(3) not-for-profit corporation affiliated with the Department of Health, administers external grant support received by Wadsworth Center investigators, and disseminates the benefits of the laboratory's expertise through programs such as technology transfer.

## **GRADUATE PROGRAMS**

Wadsworth Center houses the University at Albany, School of Public Health's Departments of Biomedical Sciences and Environmental Health Sciences. Master's and doctoral degree students prepare for technical, teaching and research careers in academia, government and industry.

## **EXTRAMURAL FUNDING**

Wadsworth Center administers legislatively authorized extramural funding programs that support New York State investigators studying specific topics, including:

### **STEM CELLS**

The Empire State Stem Cell Board makes awards in fields related to stem cell biology.

### **BREAST CANCER**

The Health Research Science Board supports breast cancer research and education.

### **SPINAL CORD INJURIES**

The Spinal Cord Injury Research Board distributes research awards to find a cure.

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