



# LabLink

Michigan Department of Community Health  
Bureau of Laboratories

Vol. 6 No. 2

Fall 2000

## The Human Genome Project Nears Completion

Frances Pouch Downes, Dr.P.H.  
Laboratory Director

The Human Genome Project, originally scheduled for complete sequencing of the human genome in 2005, is now scheduled for completion in 2003. This spring a working draft comprising 90% of the human gene sequences was introduced. The billion base pair blue print of the human genome is not only finishing early but also under budget. Advances in sequencing and informatics technology and an urgent need for the information have enabled collaborators at the National Institute of Health, DOE Sanger Centre in Cambridge England and sequencing centers around the world to accelerate completion of the project goals.

The goals of the Human Genome Project are not limited to sequencing the human genome. Early objectives included gene mapping, technology development and characterization of the genomes of organisms commonly studied in the laboratory. Development of gene maps and physical maps make possible location and identification of individual genes of interest. All information generated by collaborators is made accessible through public data bases at no charge. From the inception of the project it was appreciated that society would confront ethical, legal and social issues due to the newly-acquired knowledge. An additional goal of the project was to address ethical legal and social issues.

When all of the approximately 100,00 human genes are identified, it will be possible not only to identify the gene variant associated with rare inherited disorders, but also those that make an individual more susceptible to common diseases.

As the science of genetics evolves from primarily a study of single gene disorders which largely affect individual families to a study of more complex diseases and multiple gene interactions (e.g., cancers, diabetes, heart disease, depression), the focus of disease prevention might evolve from individual or family genetic counseling and single gene testing to testing for a wide array of disease genes, developing individual risk profiles and individualized treatment (pharmacogenetics) or prevention plans.

Before this new era is realized, clinical and public health laboratories face a great challenge in incorporating genetics testing into the traditional test menus. Prior to introduction of a test the analytical validity (how sensitive and specific is the test in predicting the variant gene or genotype?), clinical validity (how reliably does the test predict the development of the disease?), and clinical utility (what risks and benefits accrue for the genetic tests and ensuing interventions?) must be determined. Population-based studies incorporating multiple data sources will be needed to evaluate test performance.

Development and evaluation of genetic testing quality assurance programs will be particularly challenging. The rate of test introduction and public demand for testing may outpace methodical, well-designed evaluations of test performance and availability of proficiency testing. Recruiting and training testing personnel and managers with current knowledge of the rapidly evolving field of genetics will be challenging. Post-analytical monitoring of use of test results will be needed in

an era when most health care providers have only the most rudimentary genetics education. Government policies on accreditation of genetics testing under CLIA, reimbursement for testing and the role of public health laboratories in genetics testing field are still evolving. It is enticing to approach genetics tests as just any new molecular pathology test. But the interpretation of results and ethical and social issues in making this information available to the patient present an entirely different set of challenges.

Although completion of the human Genome Project is an exciting event in human knowledge with its potential for improving preventative health, there are still many unresolved issues for applying this knowledge to practice of medicine. For the laboratory community the challenges are even greater.

For more information on genetic testing and the Human Genome Project:

Human Genome Research Institute  
[www.nhgri.nih.gov](http://www.nhgri.nih.gov)

U.S. Department of Energy Office of Science,  
Human Genome Program  
[www.ornl.gov](http://www.ornl.gov)

U.S. Centers for Disease Control and Prevention  
[www.cdc.gov/genetics](http://www.cdc.gov/genetics)

Secretary's Advisory Committee on Genetic  
Testing (SACGT)  
[www.od.nih.gov/oba/sacgt.htm](http://www.od.nih.gov/oba/sacgt.htm)

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Societal Consequences of the Human Genome  
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needed partnership for genetic policy. *Public  
Understand. Sci.* 3(8): 241-254.



## **New Test for MSUD**

Marilyn Boucher  
Newborn Screening

MSUD or Maple Syrup Urine Disease, so named from the characteristic odor of an afflicted infant's diaper, is a defect in leucine metabolism. The buildup of leucine, iso-leucine, valine and keto acids in blood and urine can cause overwhelming metabolic acidosis, vomiting, CNS depression and respiratory failure. Affected infants can die in as little as two days.

The newborn screening laboratory at MDCH runs interference on this killer by testing for leucine in whole blood as part of the newborn panel. New technology has replaced the Bacterial Inhibition Assay (BIA). The BIA required overnight incubation and exact temperature regulation to deliver a semi-quantified result. The new test is the NeoNatal Leucine by P.E. Wallac. It is a fluorometric, enzymatic assay, with quantitative results in a faster turnaround time.

The goal of MDCH is to screen every newborn Michigan infant quickly and accurately for MSUD and six other hereditary disorders. The new leucine technology will help accomplish this goal.

## **NEW BOVINE TUBERCULOSIS WEB PAGE**

[www.bovinetb.com](http://www.bovinetb.com)

A new joint web page has been established to provide comprehensive information on bovine tuberculosis in Michigan. Contributing partners in this page are: MDCH, the Michigan Department of Agriculture, the Michigan Department of Natural Resources, the Michigan Bovine Tuberculosis Eradication Project, Michigan State University and the United States Department of Agriculture. The object of this site is to provide comprehensive information on the issue of bovine tuberculosis in Michigan farm animals and wildlife. Contents of this site include wildlife surveillance information, feeding ban and baiting restriction information, livestock, captive deer and elk herd surveillance information, testing procedures, bovine TB research, disease information, maps, photos, press releases and more.

## **Laboratory Detection of *Bordetella pertussis***

Despite an era in which routine childhood immunizations should have made whooping cough only a memory, cases continue in both infants and adults. In Michigan, as of October 21, 2000, 66 cases of pertussis have been reported. This is a 37.5 percent increase over the 48 cases reported in the same period in 1999. Highest levels of immunity are achieved only after three doses of vaccine and may wane in adulthood. Providers are unlikely to consider a diagnosis of pertussis in older children and adults with persistent cough but who lack the characteristic whoop. Recognition of this agent has been hampered by low levels of suspicion among practitioners and by the fastidious nature of the organism which requires special media and handling in the laboratory.

In order to enhance the laboratory detection of *Bordetella pertussis*, the molecular biology section is offering a new test procedure in conjunction with routine culture. Polymerase chain reaction (PCR) is targeted against a 153 base pair (bp) unit of *Bordetella pertussis* DNA present in about 80 copies in the chromosomal DNA, and will detect viable as well as nonviable organisms. PCR will supplement rather than replace culture, but is expected to increase detection of this fastidious agent.

Only nasopharyngeal aspirates (NPAs) are acceptable for testing, with the same sample being used for both PCR and culture. Nasopharyngeal swabs are unacceptable as the charcoal in the transport medium will interfere with the enzyme system used in PCR. It is recommended that NPAs be transported to MDCH without delay and kept at 2-8°C while in transit. Specimens should be received within 24 hours of collection. Specimens should not be frozen as they are rendered unsuitable for culture.

NPA specimen collection kits for Pertussis PCR and culture (Unit 16) can be ordered from MDCH at (517)335-8059, by faxing a shipping unit requisition (DCH 0568) to (517)335-9039, or from the website ([www.mdch.state.mi.us](http://www.mdch.state.mi.us)).

These kits contain instructions and all the materials necessary to collect the NPA, including syringe and butterfly infusion set used for the wash or aspiration.

Detection of *Bordetella pertussis* by either culture or PCR in symptomatic individuals is indicative of current or recent infection. Failure to detect viable organisms or *B. pertussis* DNA does not exclude infection; sampling error is an issue with this as with most laboratory tests.

Please contact either the microbiology section (517-335-9641) or the molecular biology section (517-335-8850) prior to submission of samples for diagnosis of pertussis so that your sample can receive prompt and careful attention.

This article was a collaboration of the following:

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## **New Employees and Promotions**

The Bureau of Laboratories would like to welcome two new employees. Cheryl Ballard has joined the Division of Chemistry and Toxicology as the division secretary. Ballard transferred from DEQ. Albert Johnson has joined the microbiology section as a laboratory technician in the reference bacteriology unit. Johnson was previously a student assistant in the environmental lead testing laboratory.

Santiago Rocha of the laboratory support unit has been promoted to laboratory assistant.

## **MDCH, CLIA Regulations and Specimen Submissions**

Trish Somsel, Dr.P.H.  
Division of Infectious Diseases

It may come as a surprise that the state laboratory labors under Clinical Laboratory Improvement Act (CLIA) regulations just as you do. MDCH is required by CLIA to receive specific items of information on specimens submitted for testing. Without this minimal information, processing of samples is suspended while missing information is sought from submitters. It may be only a single test request from any given facility that lacked the required information last month, but consider that MDCH receives 15,000 samples per month and nearly 2 percent have incomplete information. About 300 specimens each month require follow-up before they can be processed. The delay in processing means reporting will be delayed and care for patients will be delayed. On occasion the sample may be too old to process by the time it is determined what test was needed. Neither outcome is acceptable.

In an effort to reduce and eventually eliminate these delays, please review the basic minimum information which CLIA requires for processing of samples. Instruct whoever fills out the test requests in your facility about the importance of completing the form. It will speed reports to you and reduce the time spent trying to 'fix' a form completed in haste.

Required by CLIA regulations:

- Agency/Submitter name and address
- Patient full name or unique identifier (must match specimen label exactly)
- Specimen source
- Date collected
- Test requested
- Any information needed to perform test properly (e.g. time collected in some instances)

MDCH laboratories appreciate your efforts to help reduce preanalytic delays and improve service to you, your patients and physicians. Please do not hesitate to call with questions or comments.

**Division of Infectious Diseases  
Welcomes New Director**

Trish Somsel, Dr. P.H., has been appointed as director of the Division of Infectious Diseases. The division includes the microbiology, virology and molecular biology sections.

Somsel received her Dr. P.H. in 1994 from the University of Michigan with a concentration in hospital and molecular epidemiology. For the last 14 years Somsel was the head of the microbiology department and an epidemiologist for the Regional Medical Laboratories in Battle Creek, Michigan.

Somsel is currently a clinical associate in the department of health and human services at Eastern Michigan University and an instructor in the clinical microbiology intern rotation portion of the medical laboratory technician program at Kellogg Community College in Battle Creek. Somsel was the chair of the Calhoun County Board of Health and an inspector for the College of American Pathologists laboratory certification program. As a registered specialist microbiologist (ASCP 1979), Somsel has been active in the South Central Association for Clinical Microbiology, the American Society for Microbiology and has been an investigator on numerous antimicrobial trials.

The Bureau of Laboratories wishes to welcome Dr. Somsel to MDCH. Somsel may be reached at (517) 335-8064.

## **New Communicable Disease Handbook**

Sonja Hrabowy  
Division of Communicable Disease

In September 2000, each county's Communicable Disease unit and each medical director received the new 2000 Communicable Disease Handbook. This replaces the February 1989 version. In it are the following sections: Communicable Disease Administrative Rules, current MDCH reporting forms for all communicable diseases and immunizations, the National Case Definitions for Infectious Diseases, contact names and numbers for communicable disease and immunizations, Bureau of Laboratories, including MDCH lab forms. Many of the MDCH forms have been updated. CDC forms are also included.

Feel free to make additional copies of the forms or any other portion of the handbook. It is not copyrighted. Any questions on the new CD handbook, please contact Sonja Hrabowy at (517)335-8165 or [HrabowyS@state.mi.us](mailto:HrabowyS@state.mi.us). CD units should have received the new Gastrointestinal Case Investigation Form DCH-0622. If it has not been received, call Gladys Simon at (517) 335-8050.

## **A Change in STD Testing Methodology**

William Sottile, Ph.D.,  
Houghton Laboratory  
and  
William Schneider  
Enteric/STD/Chromatography

The MDCH Bureau of Laboratories is changing its testing system for gonorrhea and *Chlamydia*. For the past 10 years Michigan has been using the PACE 2 assay by GenProbe, a DNA:RNA probe technology. For the past three years all low level positive tests have been confirmed by this procedure. The procedure has served MDCH well, but newer technologies are now available which should markedly increase ability to identify *Chlamydia* infections. The ProbeTec by Beckton Dickinson uses a DNA amplification step called Strand Displacement Amplification, (i.e. generating multiple copies of DNA from a single cell) prior to applying a DNA probe. This process greatly improves the ability to detect infections and is capable of greater sensitivity and specificity for *Chlamydia* than was available with the GenProbe. The sensitivity and specificity for gonorrhea are equivalent to GenProbe.

Starting January 2001, the entire public sector STD and family planning testing system throughout Michigan will be converted to ProbeTec. The sample collection technique is very similar to that used for the GenProbe, but the transport medium will be different. The ProbeTec automatically tests for both gonorrhea and *Chlamydia*. Test request forms will be converted to reflect this change. Separate testing for gonorrhea and *Chlamydia* will no longer be available.

An advantage of the ProbeTec is the ability to test urine for gonorrhea and *Chlamydia*. Urine testing is limited to samples transported to the laboratory within two days. This testing will be available only to those sites with courier services. This is not an option for much of rural Michigan as MDCH is unable to provide courier service throughout the state. Those submitters having a courier service and wishing to submit urine specimens, need to order a special shipping kit for that purpose. There is a urine processing packet (UPP) that

needs to be added to each urine specimen when it is collected. The UPP is necessary to remove inhibitors commonly found in urine specimens. The urine test is not expected to be widely used once we convert to ProbeTec because of the two-day limitation. Urine specimens are not to be mailed to the laboratory.

Training materials will be provided within the next two months as conversion to the ProbeTec proceeds. In the meantime, keep supplies for GenProbe to one month's worth of specimen collection kits so there is not a large surplus inventory of supplies at the time of converting to ProbeTec. GenProbe collection kits cannot be used with the ProbeTec assay.

The collection of the specimen by swab is very similar to that with GenProbe but with different transport medium. ProbeTec uses a Culturette, dry swab system rather than a liquid transport as is used with GenProbe. New collection kits for ProbeTec will be made available mid-December.

## **Bureau of Laboratories Has New Bioterrorism Coordinator**

James T. Rudrik, Ph.D., has joined the Bureau of Laboratories as the bioterrorism laboratory coordinator. Rudrik will direct the overall operation of the biological laboratory portion of the CDC bioterrorism cooperative agreement. This includes training the level A and B laboratories in procedures of isolation, identification and referring possible bioterrorism organisms.

Rudrik received his Ph.D. in immunology and microbiology from Wayne State University School of Medicine in 1982. Rudrik then completed a two-year postdoctoral fellowship in medical microbiology and public health at St. Joseph Mercy Hospital in Ann Arbor, Michigan.

Before joining MDCH, Rudrik held the positions of microbiologist and acting research and development coordinator at the Asheville Veterans Affairs Medical Center in Asheville, North Carolina. Most recently he was the assistant laboratory director at the Great Smokies Diagnostic Laboratory also in Asheville.

MDCH welcomes Dr. Rudrik. Rudrik may be reached at (517) 335-8183.

## Fatal Cases of Rocky Mountain Spotted Fever and Tularemia in Michigan Residents

Mary Grace Stobierski, D.V.M.  
Division of Communicable Disease  
and Immunization

In June 2000, a fatal case of Rocky Mountain Spotted Fever occurred in a 3-year-old child who was a resident of Cass County. The child had been ill with a fever and rash in the week preceding his death and had been seen twice by a physician, but confirmation of the illness did not occur until tissues obtained at autopsy were analyzed by the Centers for Disease Control and Prevention (CDC). The child spent most of his time in and around his home, where the exposure is believed to have occurred. An ecologic study done as a follow up demonstrated the presence of one of the classic vectors, *Dermacentor variabilis*, the American dog tick, on the property.

At the end of May 2000, a 74-year-old resident of Ottawa County died of tularemia after a 2-day illness. Her illness was not diagnosed before she expired. When her family was contacted for the epidemiologic follow up, they denied knowledge of exposure to any animals, nor did they recall the deceased mentioning any tick or fly bites. Travel history was limited to her own local area, thus acquisition of illness is believed to be local. The MDCH laboratory identified an autopsy isolate as *Francisella tularensis*, which was further identified by CDC to be a type B strain of the organism.

These two fatalities underscore the need for health care providers, including physicians, to be aware that these rare diseases do occasionally occur in Michigan. The vectors of both these illnesses are endemic in the state, thus Michigan-acquired infections do indeed occur.

## Quirky Bugs...

The reference bacteriology units column Quirky Bugs will return next issue. The topic will be the isolation and identification of *Francisella tularensis*.

## Some Observations on Accreditation of Regional Laboratories

William Sottile, PhD, ABMM,  
Regional Laboratory Coordinator

Local public health departments have progressed through a year of accreditation visits and most have done well. Every facility wants a perfect score, but unfortunately that may not always occur. If the system works the way it is intended, there will always be more to work on. The surveyor will bring that to your attention. If you accept that inspections are a means of identifying areas where quality can be improved, the inspector becomes your colleague and consultant. The accreditation process in Michigan allows local health departments 90 days to develop a plan of corrections and a year to implement those corrections. Corrective action means implementing changes into the system as part of the day-to-day process.

The laboratory inspection team from MDCH prepared a list of the most common errors found in the laboratory (F5, sec 1, 2, & 3). They are listed below with thoughts on appropriate action.

1. No written Chemical Hygiene Plan: A sample chemical hygiene plan can be obtained from the Michigan Department of Consumer and Industry Services, MIOSHA section. Relevant portions may be used to develop a plan. A chemical hygiene plan is a working program, not a document used to pacify the inspector. A good chemical hygiene plan will have, at minimum, the following elements:
  - Hazard Communications Plan: This details who is going to communicate what, to whom, on what schedule and where documents are to be kept. This includes use of signs and labels.
  - Persons in charge of different areas that use chemicals.
  - Specific precautions: A list of chemicals and a standard operating procedure (SOP) for each chemical that will detail storage, use and clean up.
  - Safety equipment: What kinds of equipment (e.g. fire extinguishers, safety glasses, masks, lab coats, rubber gloves) and when they should be used.
  - Spill cleanup procedures: Who is going to do what, when, and where everyone else will be while cleanup is occurring.
  - Training records: Training is required annually and the records of training must be retained for three years minimum.
2. No evidence of review of MSDS files: Material Safety Data Sheet (MSDS) must be on file for every chemical. The MSDS must be reviewed and checked by supervisors and the persons working with the chemicals. A yearly review and sign-off sheet, including initials and dates, should be available during inspection.
3. No written Blood Borne Pathogens plan: This document is separate from the Chemical Hygiene Plan. This document must detail:
  - The nature of the hazards and the instances where they would be encountered

- Who is at risk
- What measures to take to avoid exposure
- Medical records: Must be kept for length of employment plus 30 years (CFR 1910.20)
- Training records: Keep for at least three years.

If the health department is to have one manual, there must be sections specific to each clinical area (e.g. WIC, Family Planning clinics).

4. Documentation of training: A file documenting all training must be available. This includes who, what, when and where. This must be current and kept at least three years or the minimum time determined in the Federal Register (29CFR1920.20). Chemical hygiene and blood borne pathogens training must take place annually for all staff members and must be documented. A record of all in-service training related to laboratory testing must also be maintained.
5. Discrepancy and Problem Solving Logs:
  - Discrepancy Logs are a file of corrective actions related to medical information (e.g. incorrect reports, physician complaints, lost data, lost specimens). The corrective action is an investigative report which details who, what, when, where, why the incident occurred and actions taken to prevent it from reoccurring. This is an incident report that is related to testing and the resultant data.
  - The Problem Solving Log is a collection of forms or memos to the supervisor or lab director regarding QC failures and corrections. This log documents action taken regarding equipment performing incorrectly. It is an incident report that details what was wrong and what was done to correct the situation. If no clients were tested while the equipment was out of control, this needs to be included in the report. Documentation is required regarding clients that were tested with a procedure that was not within accepted control limits.
6. Equipment Logs: Log sheets must be kept for each piece of equipment. The log sheet must specify the piece of equipment, where it is located, the acceptable range of performance, who to call if it is out of acceptable range and the routine preventative maintenance. It should also include model number, serial number, asset tag number or another means of uniquely identifying the piece of equipment.
7. A Quality Assurance Manual: This is a complex document that outlines the quality assurance program at your particular institution. This details policies and guidelines not found in other documents, but references other manuals (e.g. Chemical Hygiene Plan, Lab Procedure Manual)

for specifics. Do not duplicate information found in other documents. The manual would detail the following:

- Statements of purpose, mission, goals and objectives.
  - Personnel: A copy of your HCFA 209 which is site specific. A listing of all testing personnel and a copy of the organization's structure.
  - Means of proficiency testing and competency testing. Note where the records are kept and for how long (minimum of two years).
  - Laboratory facility description and any policies that pertain to the use of the facility
  - Instrumentation: A list of instruments and the programs in which they are used. This includes non-instrumented tests like pregnancy and dipsticks for urine
  - Test Procedures: A list of procedures and their purpose. Sample collection and analytical methodologies should be listed, but the actual procedural documents would be in the Procedure Manual. Reference the procedure manual.
  - Records: A list of records that are generated, how are they reviewed and where and how long they are retained.
  - General quality control activities: This section discusses the general aspect of the quality control processes that are applied to the tests performed. The method-specific procedures will be included in the procedure manual and so do not need to be included in this section. A copy of the current QC logs should be inserted here or in an appendix.
  - Data Review: How you review the laboratory process to assure effective service. This includes a chart review activity, randomly pulling clinic test logs to evaluate the percent of data that actually made it to the clients chart or whether the quality control was in fact done for the week (or day) your clinic was held, or how many corrective actions resulted from routine quality control activities and what kinds of actions were needed.
  - Health and Safety: This section can refer to the Chemical Hygiene Plan and the Blood Borne Safety Plan. It should also detail the who, where, how and when of your employee health activities.
8. Review: Review all manuals and procedures on an annual basis. Review includes a date and signature. Evaluate any changes that need to be made. If interim changes are made in procedures, the supervisor and the testing persons all sign the interim changes. All testing personnel involved in proficiency testing should sign the report that comes back with the correct results. If a written communication about a corrective action is sent to the laboratory director, all testing personnel and the supervisor must initial the report.

**Antimicrobial Resistance Trends, Regions One ( Rg 1 Detroit Area) and  
Two to Twelve (RG 2-12 Outstate Michigan)  
Penicillin Resistant Study-site<sup>1</sup> Isolates of *Streptococcus pneumoniae*  
and Vancomycin Resistant Sterile-site<sup>2</sup> Isolates of *Enterococcus spp.*  
Michigan Sentinel Hospital Laboratory Survey, Fourth Quarter, 1995 through First Quarter, 2000**

**Percent Resistant<sup>3</sup>**

Microorganism	Resistance Classification <sup>3</sup>	1995 Quarters		1996 Quarters		1997 Quarters		1998 Quarters		1999 Quarters		2000 Quarters	
		Third/ Fourth Rg 1	Rg 2-12	First to Fourth Rg 1	Rg 2-12	First to Fourth Rg 1	Rg 2-12	First to Fourth Rg 1	Rg 2-12	First to Fourth Rg 1	Rg 2-12	First Rg 1	Rg 2-12
<i>Str. pneumoniae</i>	Moderate or High	20	14	25	18	24	22	21	23	22	25	27	27
<i>Str. pneumoniae</i>	High Level only	5	4	7	3	11	5	5	7	9	6	13	11
<i>E. faecalis</i>	Resistant	1	0	2	1	2	1	3	1	3	1	5	1
<i>E. faecium</i>	Resistant	34	7	41	9	49	9	56	40	68	37	73	42
<i>All Enterococcus</i>	Resistant	8	1	10	2	13	4	14	7	17	7	19	11

<sup>1</sup> Study sites = blood, CSF, deep surgical wound, pleural fluid(fl.), peritoneal fl., respiratory specimens or synovial fl.

<sup>2</sup> Sterile sites = blood, CSF, deep surgical wound, pleural fluid(fl.), peritoneal fl., or synovial fl.

<sup>3</sup> NCCLS, Performance Standards for Antimicrobial Susceptibility Testing, M100 - S8.

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printed at each with a total cost of  
DCH-0096

**LabLink** is published quarterly by the Michigan Department of Community Health, Bureau of Laboratories, to provide laboratory information to Michigan health professionals and the public health community.

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