

PERFORMANCE AUDIT  
OF THE

**BUREAU OF LABORATORIES**

COMMUNITY PUBLIC HEALTH AGENCY  
DEPARTMENT OF COMMUNITY HEALTH

June 2003



Michigan  
*Office of the Auditor General*  
**REPORT SUMMARY**

*Performance Audit*  
*Bureau of Laboratories*  
*Community Public Health Agency*  
*Department of Community Health*

Report Number:  
39-680-02

Released:  
June 2003

*The Bureau of Laboratories provides a wide range of multidisciplinary diagnostic and analytical services to support public health initiatives related to the surveillance and control of communicable diseases, to support detection of genetic and metabolic errors in newborns, and to support activities related to environmental concerns.*

***Audit Objectives:***

1. To assess the effectiveness of the Bureau's controls over samples received from local units to ensure that the receipt of the samples was properly recorded, that samples were directed to the appropriate division for testing, and that the results of the testing were accurately reported.
2. To assess the effectiveness of the Bureau's controls over laboratory tests in ensuring that the tests were performed in accordance with established procedures and within established time frames.
3. To assess the effectiveness of the Bureau's Newborn Screening Program in providing accurate testing of all Michigan newborns.

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***Audit Conclusions:***

1. We concluded that the Bureau's controls effectively ensured that the receipt of samples from local units was properly recorded, that samples were directed to the appropriate division for testing, and that the results of the testing were accurately reported. Our report does not include any reportable conditions related to this audit objective.
2. We concluded that the Bureau's controls over laboratory tests were generally effective in ensuring that the tests were performed in accordance with established procedures and within established time frames. Our report does not include any reportable conditions related to this audit objective.
3. We concluded that the Bureau's Newborn Screening Program was effective in providing accurate testing

of Michigan newborns. Our report does not include any reportable conditions related to this audit objective.

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**Noteworthy Accomplishments:**

The Department of Community Health (DCH) has met federal requirements for clinical laboratory licensure by the Centers for Medicaid & Medicare Services' Clinical Laboratory Improvement Amendment (CLIA) program. In addition, the laboratory voluntarily applied for and received certification by the American Industrial Hygiene Association. DCH has responded to several public health emergencies, including the anthrax issues after the September 11, 2001 terrorist attacks on America and the emergence of the West Nile virus in Michigan in 2002. Along with responding to public health emergencies, the laboratory has made significant strides developing capacity to test for biological and chemical agents of bioterrorism. The laboratory is one of five in the nation identified by the Centers for Disease Control and Prevention as a chemical terrorism response laboratory.

DCH reported that the Bureau of Laboratories has an active and progressive quality assurance program and has established a Continuous Quality Improvement Committee to promote quality services, innovations, and efficiency. DCH also reported that it has provided high quality and rapid testing services while maintaining the same standards of performance for ongoing testing and attending to other public health emergencies, such as anthrax and the West Nile virus. Furthermore, DCH reported that the laboratory continues to bring technological innovations into service for the citizens of Michigan by adopting new instrumentation and providing technical training to personnel.

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A copy of the full report can be obtained by calling 517.334.8050 or by visiting our Web site at: [www.state.mi.us/audgen/](http://www.state.mi.us/audgen/)



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THOMAS H. MCTAVISH, C.P.A.  
AUDITOR GENERAL

June 18, 2003

Ms. Janet Olszewski, Director  
Department of Community Health  
Lewis Cass Building  
Lansing, Michigan

Dear Ms. Olszewski:

This is our report on the performance audit of the Bureau of Laboratories, Community Public Health Agency, Department of Community Health.

This report contains our description of agency; audit objectives, scope, and methodology and prior audit follow-up; comments; and a glossary of acronyms and terms.

We appreciate the courtesy and cooperation extended to us during this audit.

AUDITOR GENERAL

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## Description of Agency

The Bureau of Laboratories, Community Public Health Agency, Department of Community Health, was established under Section 333.9601 of the *Michigan Compiled Laws*. The Bureau provides a wide range of multidisciplinary diagnostic and analytical services to support public health initiatives related to the surveillance and control of communicable diseases, to support detection of genetic and metabolic errors in newborns, and to support activities related to environmental concerns. The Bureau conducted approximately 1.4 million tests on approximately 330,000 specimens received during fiscal year 2001-02.

The Bureau consists of two divisions and one section: the Division of Infectious Diseases, the Division of Chemistry and Toxicology, and the Quality Assurance Section.

As of September 30, 2002, the Bureau had 118 full-time equated positions. The Bureau was appropriated approximately \$12 million for the fiscal year ended September 30, 2002.

## **Audit Objectives, Scope, and Methodology and Prior Audit Follow-Up**

### Audit Objectives

Our performance audit\* of the Bureau of Laboratories, Community Public Health Agency, Department of Community Health, had the following objectives:

1. To assess the effectiveness\* of the Bureau's controls over samples received from local units to ensure that the receipt of the samples was properly recorded, that samples were directed to the appropriate division for testing, and that the results of the testing were accurately reported.
2. To assess the effectiveness of the Bureau's controls over laboratory tests in ensuring that the tests were performed in accordance with established procedures and within established time frames.
3. To assess the effectiveness of the Bureau's Newborn Screening Program\* in providing accurate testing of all Michigan newborns.

### Audit Scope

Our audit scope was to examine the program and other records of the Bureau of Laboratories. Our audit was conducted in accordance with *Government Auditing Standards* issued by the Comptroller General of the United States and, accordingly, included such tests of the records and such other auditing procedures as we considered necessary in the circumstances.

### Audit Methodology

Our audit procedures, conducted from July 2002 through January 2003, included examination of Bureau records and activities primarily for the period October 2001 through September 2002.

We conducted a preliminary review of the Bureau's operations to gain an understanding of its activities. Also, we reviewed applicable laws and regulations, management plans, and policies and procedures related to management control\*.

\* See glossary at end of report for definition.

To accomplish our first objective, we reviewed the system for recording and distributing specimens received and for reporting test results. Also, we conducted audit tests to determine whether the Bureau's system was operating as intended.

To accomplish our second objective, we reviewed the certification and accreditation of the laboratory and corrective actions suggested by outside reviewers and verified compliance with federal Clinical Laboratory Improvement Amendment\* (CLIA) competency requirements for laboratory personnel. We tested controls and procedures to ensure that the Bureau performed the required preventive maintenance on laboratory equipment and to ensure that the Bureau conducted laboratory tests according to procedures and within the established time frames.

To accomplish our third objective, we evaluated the process for determining which tests the laboratory will perform as part of the Newborn Screening Program.

#### Prior Audit Follow-Up

The Bureau complied with the three prior audit recommendations included within the scope of our current audit.

\* See glossary at end of report for definition.

# COMMENTS

## EFFECTIVENESS OF CONTROLS OVER SAMPLES RECEIVED FROM LOCAL UNITS

### COMMENT

**Audit Objective:** To assess the effectiveness of the Bureau of Laboratories' controls over samples received from local units to ensure that the receipt of the samples was properly recorded, that samples were directed to the appropriate division for testing, and that the results of the testing were accurately reported.

**Conclusion:** **We concluded that the Bureau's controls effectively ensured that the receipt of samples from local units was properly recorded, that samples were directed to the appropriate division for testing, and that the results of the testing were accurately reported.** Our report does not include any reportable conditions\* related to this audit objective.

**Noteworthy Accomplishments:** The Department of Community Health (DCH) has met federal requirements for clinical laboratory licensure by the Centers for Medicaid & Medicare Services' Clinical Laboratory Improvement Amendment (CLIA) program. In addition, the laboratory voluntarily applied for and received certification by the American Industrial Hygiene Association. DCH has responded to several public health emergencies, including the anthrax issues after the September 11, 2001 terrorist attacks on America and the emergence of the West Nile virus in Michigan in 2002. Along with responding to public health emergencies, the laboratory has made significant strides developing capacity to test for biological and chemical agents of bioterrorism. The laboratory is one of five in the nation identified by the Centers for Disease Control and Prevention as a chemical terrorism response laboratory.

DCH reported that the Bureau of Laboratories has an active and progressive quality assurance program and has established a Continuous Quality Improvement Committee to promote quality services, innovations, and efficiency. DCH also reported that it has provided high quality and rapid testing services while maintaining the same standards of performance for ongoing testing and attending to other public health emergencies,

\* See glossary at end of report for definition.

such as anthrax and the West Nile virus. Furthermore, DCH reported that the laboratory continues to bring technological innovations into service for the citizens of Michigan by adopting new instrumentation and providing technical training to personnel.

## **EFFECTIVENESS OF CONTROLS OVER LABORATORY TESTS**

### **COMMENT**

**Audit Objective:** To assess the effectiveness of the Bureau's controls over laboratory tests in ensuring that the tests were performed in accordance with established procedures and within established time frames.

**Conclusion:** We concluded that the Bureau's controls over laboratory tests were generally effective in ensuring that the tests were performed in accordance with established procedures and within established time frames. Our report does not include any reportable conditions related to this audit objective.

## **EFFECTIVENESS OF THE NEWBORN SCREENING PROGRAM**

### **COMMENT**

**Audit Objective:** To assess the effectiveness of the Bureau's Newborn Screening Program in providing accurate testing of all Michigan newborns.

**Conclusion:** We concluded that the Bureau's Newborn Screening Program was effective in providing accurate testing of Michigan newborns. Our report does not include any reportable conditions related to this audit objective.

## Glossary of Acronyms and Terms

<b>Clinical Laboratory Improvement Amendment (CLIA)</b>	A federal statute (the Clinical Laboratory Improvement Amendment of 1988) establishing quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed.
<b>DCH</b>	Department of Community Health.
<b>effectiveness</b>	Program success in achieving mission and goals.
<b>management control</b>	The plan of organization, methods, and procedures adopted by management to provide reasonable assurance that goals are met; resources are used in compliance with laws and regulations; valid and reliable data is obtained and reported; and resources are safeguarded against waste, loss, and misuse.
<b>Newborn Screening Program</b>	A program mandated by Act 368, P.A. 1978, as amended, that tests newborns for seven different diseases.
<b>performance audit</b>	An economy and efficiency audit or a program audit that is designed to provide an independent assessment of the performance of a governmental entity, program, activity, or function to improve public accountability and to facilitate decision making by parties responsible for overseeing or initiating corrective action.
<b>reportable condition</b>	A matter that, in the auditor's judgment, represents either an opportunity for improvement or a significant deficiency in management's ability to operate a program in an effective and efficient manner.