

Our Lady of Lourdes Health Care Services, Inc. and Affiliates

Administrative and General Policy

**POLICY NUMBER:** AS0019LAB

**PAGE NUMBER:** 1 of 16

**TITLE:** Clinical Laboratories Compliance Plan

**ACCOUNTABILITY:**

President and Chief Executive Officer

**OBJECTIVES:**

**RELATION TO MISSION:**

Our Lady of Lourdes, a Catholic Health System – a member of Catholic Health East – dedicated to its Franciscan Tradition of serving all, will demonstrate the value of **Stewardship** by establishing this Clinical Laboratories Compliance Plan.

**RELATION TO OPERATION:**

It is Our Lady of Lourdes Health Care Services, Inc. and Affiliates (OLLHCS, Inc.'s) policy to abide by all Federal, State and agency laws and regulations in regards to the clinical laboratories.

The laboratory ensures compliance with applicable state and local laws and regulations by educating staff and management to follow all laws and regulations pertaining to healthcare and by also ensuring that required documentation and reporting takes place. *Applicable state and local requirements may include but are not limited to the following areas: shipping infectious or diagnostic materials, personnel qualifications, retention of specimens and records, hazardous waste disposal, fire codes, medical examiner or coroner jurisdiction, legal testing, acceptance of specimens only from authorized personnel, handling controlled substances, patient consent for testing, confidentiality of test results, and donation of blood*

**I. POLICY:**

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Our Lady of Lourdes Health Care Services, Inc. and Affiliates

**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 2 of 16

**TITLE:** Clinical Laboratories Compliance Plan

The Board of Trustees, Senior Associate Leadership and Staff of Our Lady of Lourdes Health Care Services, Inc. and Affiliates (OLLHCS, Inc.) believe the provision of health services and the conduct of business require a keen sense of, and attention to, business and professional ethics. This is central to the Mission of any reputable health care provider, and it is the responsibility of all associates and others connected with OLLHCS, Inc. to embrace the highest ethical standards in the conduct of OLLHCS, Inc.'s business. Therefore, this Clinical Laboratories Compliance Plan (The Plan) has been adopted by the Board of Trustees of OLLHCS, Inc., and all associates and agents of OLLHCS, Inc. have been instructed to use the Plan as a guideline in the performance of laboratory procedures.

## II. Related Policies:

- A. Clinical Laboratories Compliance Plan (OLLHCS, Inc.'s policy A0019LAB)
- B. Clinical Laboratories – Corporate Compliance Code of Conduct (OLLHCS, Inc.'s policy A0020LAB)
- C. Clinical Laboratories – Advance Beneficiary Notice (OLLHCS, Inc.'s policy A0021LAB)
- D. Clinical Laboratories – Auditing and Monitoring Activities (OLLHCS, Inc.'s policy A0022LAB)
- E. Clinical Laboratories – Billing for Automated Multichannel Chemistry Tests (OLLHCS, Inc.'s policy A0023LAB)
- F. Clinical Laboratories – Custom Profiles (OLLHCS, Inc.'s policy A0024LAB)
- G. Clinical Laboratories – Marketing / Pricing of Laboratory Services (OLLHCS, Inc.'s policy A0025LAB)
- H. Clinical Laboratories – Medical Necessity Documentation (OLLHCS, Inc.'s policy A0026LAB)
- I. Clinical Laboratories – Notice to Physicians (OLLHCS, Inc.'s policy A0027LAB)
- J. Clinical Laboratories – Reflex Testing (OLLHCS, Inc.'s policy A0028LAB)
- K. Clinical Laboratories – Standing Orders (OLLHCS, Inc.'s policy A0029LAB)

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 3 of 16

**TITLE:** Clinical Laboratories Compliance Plan

### III. Definition/Purpose

- A. **Clinical Laboratories Compliance Plan:** A “code of conduct” which sets forth written guidelines for acceptable business practices with reasonably designed protocols to prevent and detect violations of law or business ethics.
- B. **Reasons for a Plan:**
1. It may reduce exposure to fraud and abuse investigations;
  2. It establishes internal accounting controls to reduce the likelihood of fraud;
  3. The cost of Plan development and operation are allowable expenses under both Medicare and Medicaid (cost reporting);
  4. It encourages the provision of high quality, well documented patient care;
  5. It meets or exceeds the guidelines of payors for accurate billing and documentation of services rendered;
  6. It encourages fiduciary responsibility among management and others;
  7. It is the right thing to do, reflecting good corporate citizenship.

### IV. Compliance Standards and Procedures

It is the intent of this Plan to establish compliance standards and procedures – to be followed by all associates and other agents of OLLHCS, Inc.’s Clinical Laboratories – which are reasonably capable of reducing the potential for criminal conduct or other unethical business behavior. These standards and procedures are specific to OLLHCS, Inc.’s Clinical Laboratories, and the areas in which there is the greatest risk of noncompliance (especially billing, contractual agreements, subcontractor activities, etc.).

A. **Audit of Existing Policies and Procedures**

1. **Billing and Clinical Records**

- ◆ Coverage determinations
- ◆ Improper billing for non-covered services
- ◆ Over utilization
- ◆ Billing for services not provided

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Our Lady of Lourdes Health Care Services, Inc. and Affiliates

**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 4 of 16

**TITLE:** Clinical Laboratories Compliance Plan

- ◆ Improper diagnosis
- ◆ Lack of documentation
- ◆ Prospective Payment System issues which may evolve in the future
- ◆ Other

2. **Administration, Accounting & Finance**

- ◆ Contracts, including contractor compensation
- ◆ Purchasing policies and procedures, including vendor selection

This initial audit will be outsourced under the guidelines of the Medicare program, with input from other OLLHCS, Inc. staff as requested.

B. **Implementation of New or Revised Policies and Procedures**

1. **Billing:** When such do not exist, billing policies and procedures will be developed which document every step of the billing process. These manuals will be written/edited by associates representing every step of the billing process, from first contact by the Admitting function to final collection of Accounts Receivable. After these Policies and Procedures are developed, all associates affected by each section of the manual will be required to sign a statement indicating they have reviewed and are familiar with the appropriate handling of their portion of the billing process.

2. **Clinical:**

- ◆ Once every three months, the Clinical Laboratories Manager and the System Compliance Officer will present a regulatory/compliance “update” to the Clinical Laboratories Compliance Committee. This presentation will address changes in federal regulations related to reporting, billing and payments, and will identify and discuss any issues that have developed since the prior monthly report.

C. **Specific Policies Which Shall be Adopted or Amended as Necessary:**

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Our Lady of Lourdes Health Care Services, Inc. and Affiliates

**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 5 of 16

**TITLE:** Clinical Laboratories Compliance Plan

1. **Standards of Conduct:** The Clinical Laboratories have developed standards of conduct for all associates, which clearly delineate the policies of the Clinical Laboratories with regard to fraud, waste and abuse and adherence to all guidelines and regulations governing federally funded healthcare programs. These standards shall be published and made available to and understandable by all associates.
  
2. **Medial Necessity:** Only claims which laboratory staff believes to be medically necessary shall be submitted for payment. To help ensure submitted claims reflect services which are medically necessary, the following shall be implemented:
  - ◆ **Requisition Design:** The Clinical Laboratories shall standardize its test offerings and use common, uniform requisition forms which emphasize physician choice and encourage physicians to order, to the extent possible, only those tests they believe are necessary to the care of each patient. The forms shall require physicians to document the need for each test ordered, by inserting a diagnosis code or narrative description for each test. A printed statement shall appear on every requisition reiterating that when ordering tests for which Medicare reimbursement will be sought, physicians (or others authorized to order tests) should only order tests which are medically necessary for the diagnosis or treatment of a patient.
  
  - ◆ **Notices to Physicians:** The Clinical Laboratories shall provide annual written notices to all its clients, which set forth a) the Medicare medical necessity policy; b) the individual components of every laboratory profile which includes a multichannel chemistry test or other automated multiple test result; c) the CPT/HCPCS codes which the laboratories use to bill the Medicare program for each such profile; d) the Medicare National Limitation Amount for each CPT/HCPCS code used to bill Medicare for each profile and its components; e) a description of how the laboratories will bill Medicare for each profile; and f) the Medical Director's phone number, noting that he/she is available to discuss appropriate testing and test ordering. As a matter of policy, the

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 6 of 16

**TITLE:** Clinical Laboratories Compliance Plan

OLLHCS, Inc. Clinical Laboratories shall not offer customized profiles to physicians and other clients.

- ◆ **Test Utilization Monitoring:** OLLHCS, Inc. Clinical Laboratories shall retain and analyze test utilization data, by CPT/HCPCS code, for the top 30 tests (by volume) performed for Medicare beneficiaries. This data will be used to compute the percentage growth in claims submitted for each of the top 30 tests from year to year. When utilization increases by more than 10 percent from one year to the next, an inquiry shall be initiated to ascertain the cause of the growth. If the reason(s) for such growth are due to actions of the Clinical Laboratories, they shall be corrected. (See also OLLHCS, Inc.'s policy "Clinical Laboratories – Auditing and Monitoring Activities," number A0022LAB.)

3. **Billing:** The following protocols are intended to assure that all claims for testing submitted to Medicare are accurate, and correctly identify the services ordered by the physician (or other authorized individual) and performed by the Clinical Laboratories.

- ◆ **Selection of CPT/HCPCS Codes:** Codes will be selected which most accurately describe the service that was ordered and performed. Intentional "upcoding" is prohibited.
- ◆ **Selection of ICD-9-CM Codes:** The Clinical Laboratories shall only submit diagnostic codes and descriptions that were obtained from the physician ordering the test. When a diagnosis code or description is received after the requisition and specimen, documentation of the late receipt of that information shall be maintained.
- ◆ **Tests covered by Claims for Reimbursement:** OLLHCS, Inc. shall submit claims for payment only for those procedures that were ordered and performed. When an order is ambiguous, or subject to multiple interpretations, the physician shall be contacted for clarification before the procedures are performed.

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Our Lady of Lourdes Health Care Services, Inc. and Affiliates

**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 7 of 16

**TITLE:** Clinical Laboratories Compliance Plan

- ◆ **Billing of Automated Multichannel Chemistry Tests (“AMCT”) and Calculations:** Effective April 1, 1998, AMCT panels, other than those panels specifically approved by Medicare, shall neither be offered nor performed by OLLHCS, Inc. Clinical Laboratories. Calculations (such as LDLs, T7s and indices) shall not be billed if the tests necessary to calculate these results were billed.
  
- 4. **Reliance on Standing Orders:** Standing orders may be followed when executed in connection with an extended course of treatment. However, the Clinical Laboratories shall monitor existing standing orders to ensure their continuing validity.
  - ◆ Nursing homes using standing orders shall be required to confirm the validity of all standing orders at regular intervals.
  - ◆ Standing orders from physician offices and “draw stations” shall be verified with the physician or his/her designee.
  
- 5. **Compliance with Applicable HHS OIG Fraud Alerts:** Management shall carefully consider all fraud alerts issued by the OIG. When conduct applicable to Clinical Laboratories is criticized in a Fraud Alert, it shall be the Clinical Laboratories policy to cease such actions immediately, identifying a non-offensive alternative when possible.
  
- 6. **Marketing:** All marketing related to Clinical Laboratories services shall be honest, clear, fully informative and non-deceptive in nature.
  
- 7. **Retention of Records:** All records required by federal and/or state law, or by this plan, shall be created and maintained for the period mandated by those laws.
  
- 8. **Compliance as an Element of a Performance Plan:** The promotion of, and adherence to, this Compliance Plan shall be an element in evaluating the performance of all involved managers, or supervisors whether or not

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 8 of 16

**TITLE:** Clinical Laboratories Compliance Plan

they are assigned to the Clinical Laboratories. The adherence to this Compliance Plan shall be an element in evaluating the performance of all involved managers, supervisors and associates as well.

9. To ensure this requirement is met, the responsibility to adhere to the Plan shall be included in all management and supervisory Job Descriptions. Additionally, all managers and supervisors involved in the sale, marketing, or billing of Clinical Laboratory services, should:
- ◆ Discuss with their associates the compliance policies and legal requirements applicable to their functions.
  - ◆ Inform all supervised personnel that strict compliance with those policies and requirements is a condition of employment.
  - ◆ Disclose to all supervised staff that the Clinical Laboratories will take disciplinary action up to and including termination for violation of these policies or requirements.

**D. Monitoring Protocols:**

Periodic testing of compliance is a required component of this Compliance Plan. Management will determine how much monitoring is necessary, based on the perceived risk within OLLHCS, Inc. See OLLHCS, Inc. policy Clinical Laboratories – Auditing and Monitoring Activities (A0022LAB.)

**V. Clinical Laboratories Compliance Committee:**

A Clinical Laboratories Compliance Committee shall be appointed by Administration to oversee compliance with these standards and procedures. This Committee has substantial influence over OLLHCS, Inc. and its policy making process, in order to minimize the risk of establishing any policy, procedure or process which is contrary to the intent of this Plan.

**A. Authority and Reporting of the Clinical Laboratories Compliance Plan**

The Clinical Laboratories Compliance Committee operates autonomously, and is immune from punitive action that might be taken by Management or the Board of

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 9 of 16

**TITLE:** Clinical Laboratories Compliance Plan

Trustees, when acting within the scope of its designated responsibilities under this Plan. It is intended that the members of the Committee will feel free to take any action necessary to ensure OLLHCS, Inc. and its associates agents comply with this Plan and the spirit/letter of the law.

1. Once per quarter, the chairperson of the Clinical Laboratories Compliance Committee will report to the Corporate Compliance Sub-Committee all Clinical Laboratories Compliance statistics for the prior quarter, while maintaining the confidentiality of affected associates.
2. Once per quarter, the Corporate Compliance Sub-Committee will forward the quarterly report to the Corporate Compliance Committee of the Board of Trustees.

**B. Structure/Functions of the Clinical Laboratories Compliance Committee:**

1. Membership: The Clinical Laboratories Compliance Committee shall consist of at least the following individuals:
  - Clinical Laboratory Manager, Chair
  - Director of Compliance and Privacy Officer
  - Director of Admissions
  - Director of Business Office
  - Various Clinical Laboratory Supervisors
2. **Primary Duties of the Committee:**
  - a. To manage the training of all affected associates in the key elements of this Plan;
  - b. To identify areas of concern within OLLHCS, Inc., and suggest policies and procedures (or other actions) to address those concerns;
  - c. To respond to incidents of apparent wrongdoing;
  - d. To review, at the request of the Clinical Laboratory Manager or Administration, any allegations made against any associates or agent of OLLHCS, Inc. under this Plan. Such review is not a

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 10 of 16

**TITLE:** Clinical Laboratories Compliance Plan

requirement prior to disciplinary action being taken, and the Committee's review, if any, is merely advisory in nature.

3. In order to prevent duplication of committee functions, and possible conflicts between similar committees, the Clinical Laboratories Compliance Committee will communicate with the OLLHCS, Inc. Corporate Compliance Sub-Committee.

## **VI. Personnel Issues:**

Due care must be taken not to delegate substantial discretionary authority to individuals who OLLHCS, Inc. knew, or should have known (through the exercise of due diligence) to have an inclination to engage in illegal activities. (Refer to the OLLHCS, Inc. Policy "Prohibition Against Contracting with Sanctioned Individuals or Companies – Policy" (A0036CCP) further guidance on this matter.)

## **VII. Associates Communication and Training**

The process of communicating the Clinical Laboratories Compliance standards, policies and procedures to clinical laboratory associates and other agents of OLLHCS, Inc. shall include but is not limited to the following:

1. An initial presentation of the Plan's purpose and Management's expectations;
2. Ongoing (no less than once per year) associates educational seminars in the areas of Clinical Laboratory Compliance and business ethics;
3. Routine circulation of materials which discuss current regulatory and compliance issues;

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 11 of 16

**TITLE:** Clinical Laboratories Compliance Plan

4. Internal publications, including articles in the associates Compliance newsletter, which reinforce the concepts and principles expressed in the Plan.

The specific actions taken to orient all OLLHCS, Inc. associates to the principles of Clinical Laboratories Compliance shall include at least the following:

1. All present Clinical Laboratories associates will undergo a one-hour seminar, during which Management will present the essential points of this Plan and will stress its consistent application to all OLLHCS, Inc. business dealings. This program will be repeated annually for all OLLHCS, Inc. Clinical Laboratories associates /; annual attendance is a condition of continued employment. These training sessions shall be conducted by the Clinical Laboratory Manager/designee and others.
2. All new Clinical Laboratory associates will receive a one-hour seminar on the Plan, which will be incorporated into the New Clinical Laboratory Associates Orientation.
3. Those Clinical Laboratory associates who are in a position to make decisions regarding the operations or expenditures of OLLHCS, Inc. will participate in additional training as specified by the Clinical Laboratories Compliance Committee, during which their special responsibilities to support the Plan will be stressed. Individuals who must attend this additional training include Supervisors, Directors and anyone else who has the authority to negotiate contracts, make purchases, select vendors, etc. This training shall be conducted annually, and annual attendance shall be a condition of continued employment for these individuals.
4. External publications will be routed to all Management staff. Thereafter, the publications will be stored in the Laboratory Manager's office for one year, allowing full associates access. These publications typically have information regarding the various anti-fraud initiatives, and it is important that all associates have the opportunity to read about these activities.

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 12 of 16

**TITLE:** Clinical Laboratories Compliance Plan

5. All internal newsletters will include one or more references to OLLHCS, Inc.'s commitment to ethical business practices. It shall be the responsibility of the Clinical Laboratory Manager to approve the "copy" of all internal publications regarding the Plan and its contents.

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 13 of 16

**TITLE:** Clinical Laboratories Compliance Plan

**VIII. Monitoring and Reporting Systems:**

OLLHCS, Inc. shall utilize auditing systems, designed simultaneously with the development of policies and procedures, which will help to detect criminal conduct by associates and other agents, to help achieve compliance with this Plan and the expectations of Management and the Board of Trustees.

- A. A system of internal audits, encompassing all phases of the billing process, shall be developed, implemented and reviewed on an ongoing basis. These audits may be augmented by external operations (“clinical”) or accounting audits from time to time, as Management or the Board of Trustees deems necessary.
- B. OLLHCS, Inc. associates and others may use the Corporate Compliance Hotline (**1-877-215-5697**) to report suspected wrongdoing, anonymously and without fear of retribution or disclosure. Additionally, complaints or other reports of suspected wrongdoing under this Plan may be made verbally, in writing, by e-mail or voicemail (if applicable) directly to any member of the Clinical Laboratories Compliance Committee.
- C. Any associates, who uses one or more of these methods to report suspected wrongdoing, is immune from any retaliation or disciplinary action as a result of using these reporting mechanisms. Additionally, his/her identity will remain confidential.

**IX. Enforcement/Discipline Mechanisms:**

It is imperative that this Plan’s compliance standards are consistently enforced throughout OLLHCS, Inc., through appropriate disciplinary mechanisms determined on a case-specific basis.

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 14 of 16

**TITLE:** Clinical Laboratories Compliance Plan

- A. Any associate, who is responsible for an offense under this Plan, shall be subject to discipline up to and including termination, on the first offense.
- B. Any non-employed physician or contractor who is responsible for an offense under this Plan, shall be subject to corrective or disciplinary action including suspension of staff privileges or contract suspension.
- C. Any associates who knows of an offense under this Plan, and does not report it to the Director of Compliance & Privacy Officer or a member of the Clinical Laboratories Compliance Committee, shall be subject to discipline up to and including termination, on the first offense.
- D. As with all associates disciplinary matters all relevant Human Resources policies and procedures will be followed.

**X. Response to Potential Offenses:**

OLLHCS, Inc. Management shall take all reasonable steps to respond appropriately and immediately once a potential offense has been detected. At least the following steps will be taken in each case:

- A. OLLHCS, Inc. Management will consult with legal counsel to evaluate OLLHCS, Inc.'s legal obligations, including any required disclosure to government officials.
- B. When indicated, this Plan will be modified to address the identified offense.
- C. When a charge of wrongdoing is directed against any member of Administration or any Director, the Director of Compliance & Privacy Officer will work directly with the Vice President of Human Resources and the ranking, unaffected Administrator to reach resolution, including the appropriate disciplinary action if applicable. When the charge of wrongdoing is directed against any other Clinical Laboratory associates or agent of OLLHCS, Inc., the Chairperson of the Clinical

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 15 of 16

**TITLE:** Clinical Laboratories Compliance Plan

Laboratories Compliance Committee will work directly with the Director of Compliance & Privacy Officer and Vice President of Human Resources to reach resolution, including the appropriate disciplinary action, if applicable.

- D. When a charge of wrongdoing is directed against the Chairperson of the Laboratories Compliance Committee, the Director of Compliance and Privacy Officer will manage the investigatory and disciplinary process, in consultation with the Chief Executive Officer or designee.
- E. When a charge of wrongdoing is directed against any member of the Board of Trustees, the Director of Compliance & Privacy Officer will manage the investigatory process in consultation with the Chief Executive Officer and Management.
- F. Corrective action may include implementation or revision of policies/procedures, associates discipline and education, and computer system modifications. Refunds may be made to affect third-party payors.

**XI. Reevaluation:**

This Plan shall be reviewed by the Corporate Compliance Sub-Committee no earlier than **October 1** and no later than **December 31** of each year. Any Plan changes which are indicated in response to issues raised within OLLHCS, Inc., in response to changes in the regulatory environment, or for any other reason, shall be effected, and the date and text of those revisions shall be noted in the minutes of the Regular Meeting of the Board of Trustees at which the revised Plan is adopted.

**APPROVED BY:** \_\_\_\_\_  
Alexander J. Hatala, President and Chief Executive Officer

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**POLICY NUMBER:** A0019LAB

**NURSING CODE:** \_\_\_\_\_

**PAGE NUMBER:** 16 of 16

**TITLE:** Clinical Laboratories Compliance Plan

**ORIGINAL & REVISION DATE(s):** 07/24/02, 07/14/04

**NEW EFFECTIVE DATE:** 01/17/08

**REQUIRES REAUTHORIZATION IN:** 01/31/11

AS0019LAB  
Clinical Laboratories Compliance Plan

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