Massachusetts General Hospital
Point of Care Testing Program

Program for Addressing
Point-of-Care Testing Compliance with the
Clinical Laboratory Improvement Amendments of 1988

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INTRODUCTION

In 1992, the Department of Health and Human Services (DHHS) issued regulations that established minimal federal standards for laboratory testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). These standards apply to all clinical testing, whether performed in a traditional clinical laboratory, or other sites such as hospital care units or physicians’ offices.

The law consists of four separate sets of regulations:
1) Laboratory standards
2) Application and user fees
3) Enforcement procedures
4) Approval and accreditation programs

To perform laboratory testing, a site must be covered by a CLIA certificate issued by CMS. The Pathology Service has CLIA certificates that cover the Anatomic and Clinical Pathology Laboratories on the MGH Main Campus as well as the Health Center Laboratories. However, these certificates do not cover testing performed at sites that are not part of the Pathology Service and may not be used for billing purposes by other sites.

PROGRAM OBJECTIVES

1. To identify and authorize sites outside the Pathology Service to perform selected laboratory testing. Authorization involves inclusion of the sites under the appropriate CLIA certificate.

2. To ensure that testing sites meet federal regulatory requirements mandated by law under the Clinical Laboratory Improvement Amendments of 1988 and Joint Commission standards required for hospital accreditation.

3. To maintain a single standard of quality throughout the institution.
SCOPE

The MGH POCT program assists MGH sites using POCT technology with CLIA compliance and relevant quality and safety initiatives. These sites include practices, clinics, inpatient units, operating and procedure rooms. Practices with a MGPO component will be assisted to the extent that consistent standards of patient care are maintained. By definition, any MGPO activity is not part of the MGH organization and therefore not subject to the MGH regulatory process. The MGH POCT program will assist MGPO to obtain appropriate CLIA certification. The practice leadership is responsible for meeting all relevant POCT regulations.

PROGRAM SUMMARY

The program expects each site to take responsibility for all aspects of testing performed at their site. In most instances, the director on a certificate (Certificate Director) is a staff pathologist with the Pathology Service. The following administrative personnel must be identified for each department:

- Site Director (Clinical Consultant)
- Site Coordinator 1 (General Supervisor)
- Site Coordinator 2 (General Supervisor)

The Site Director has ultimate responsibility for insuring that all regulatory standards and requirements are met at their site. The Site Director is expected to identify a primary Site Coordinator and back up who will act as contacts for their site and will be responsible for the day-to-day operation of the Point of Care Testing Program. (See Responsibilities of Testing Site on page 7 of POCT Enrollment Form)

Since one certificate may cover multiple testing sites or departments, a site unable to maintain expected compliance can affect other sites sharing that certificate. Sites not in compliance will be expected to develop a remedial action plan to correct deficiencies, be placed on probation, and/or suspend testing if compliance is not maintained.
SITE ENROLLMENT

Prior to implementing a testing program a site must:

1. Notify the Pathology Service’s Associate Director for POCT of their intentions.
2. Complete an MGH POCT Enrollment form and/or HCFA 116 form and agree to the program policies.
3. Work with the Pathology Service to evaluate request for clinical need.
4. Agree to meet the minimal standards of compliance, based on the level of testing desired to be performed.
5. The Pathology Service will process the CLIA application with the State Department of Public Health and relevant regulatory agencies (if required). The site may not begin testing until this process is complete.

If a site is performing testing without a certificate:

1. The Pathology Service will notify the Site Director and Hospital Administration of the site’s non-compliance.
2. If continued testing at the site may place a patient at risk, the site will be expected to discontinue testing while implementing the program.
3. If the test(s) may be discontinued and performed by the laboratory without risk to the patients, the site will be expected to discontinue testing while implementing the program.
4. If the test(s) can be performed at the site without risk to patients, the site will be allowed to continue testing, provided that they submit an acceptable timetable for compliance within 10 business days.

Adding or Removing a Test –

1. To add a test or technology, the site enrollment process is followed.
2. To remove a test:
   a. Reagents, supplies, and devices are removed from the site
   b. The CLIA certificate is modified to reflect the change, and
   c. All relevant documents should be maintained for 4 years.
RESPONSIBILITIES OF THE PATHOLOGY SERVICE

1. Provide Technical Supervisor oversight of POCT at MGH Sites.

2. Ensure that sites enrolled in the program are covered by a CLIA certificate and the appropriate agencies are notified of additions or changes.

3. Perform periodic review of testing sites to assess compliance with regulatory and accreditation standards. Periodic reports will be submitted to the Pathology Division of L&MM leadership and hospital leadership (if needed).

4. Manage the remedial action process for sites that do not meet regulatory standards. The remedial action process will ensure the quality of the tests performed; patient safety and maintain the viability of the CLIA certificates. The remedial action process, if necessary, will include placing a site on probationary status which could lead to the revocation of privileges to perform clinical testing under the certificate.

5. Assist sites in the development and review of policies/procedures that cover test and quality control procedures, quality assurance, training/competency assessment, documentation, results reporting and proficiency testing (if required).

6. Provide consultative services to hospital and individual test sites including:
   - Regulatory requirements associated with point of care testing.
   - Technical issues involving test procedures, method selection/validation and failed device support.
   - Clinical issues concerning test methods/results and clinical implications.

7. Review, standardize, and approve technology.

8. Manage device connectivity set-up between testing site and Information Systems.
RESPONSIBILITIES OF THE TESTING SITE

1. Designate a Point of Care Testing Site Director (or Clinical Consultant) who will be responsible for ensuring compliance with the regulatory requirements and recommendations described in the POCT program document. Including:

- Ensures that staff complies with all regulations, standards and program requirements.
- Reviews and signs policies and procedures annually.
- Reviews, validates, signs and returns the POCT Renewal Form to the Pathology Service annually.
- Develops, reviews approves and implements remedial action plans as needed.
- Ensures that the sites are enrolled in a proficiency testing program, if required.
- Reviews & signs proficiency testing survey, if required to participate.
- Participate in Joint Commission preparation and review.

2. Designate a Point of Care Testing Site Coordinator who is responsible for day-to-day operation of POC Testing and ensuring that the required elements for compliance are performed and documented. This individual will:

- Be the contact person for the MGH POCT Coordinators and Associate Director.
- Read and become knowledgeable with all testing policies/procedures performed at the site.
- Ensure that current test and quality control procedures are available for each test performed and that they are reviewed and signed by the Site Director each year.
- Ensure that there is documented evidence of initial orientation, yearly continued education and competency assessment.
- Ensure that testing personnel adhere to the policies and procedures.
- Ensure that logs and worksheets are periodically reviewed, signed and dated (at least once/month).
- Ensure that staff complete and document remedial action in a timely manner.
- Ensure that required maintenance is performed and troubleshooting problems are addressed and documented.
- Provide the MGH POCT program staff with required information to assess compliance in a timely fashion.
- If required, ensure that proficiency testing is performed as mandated by CLIA.
- Participate in Joint Commission preparation and review.

3. Incorporate the CLIA Standards into the site’s practice and workflow.
   a. Patient Test Management
   b. Quality Control
   c. Proficiency Testing
   d. Test Comparisons
   e. Relate results to clinical data
   f. Personnel
   g. Communications
   h. Complaints
   i. Staff review
   j. Records
4. Meet all applicable CLIA and Joint Commission standards.

**POCT SITE MANAGEMENT**

Once enrolled, the site will participate in a yearly or twice yearly review. Testing may not be authorized without this certification.

Renewal of certification is contingent upon continued compliance with the standards and requirements of the program. Mock unannounced Joint Commission inspections will be conducted by the POCT program.

A findings report will be furnished to the site. A complete remedial action plan is required from non-compliant sites within 7 business days of the report. Two consecutive or two out of three non-compliant notices will result in the site being placed on probation. Hospital leadership will be notified of non-compliant sites.

If a site is placed on probation the medical director will be required to submit a remedial action proposal with a time table for compliance. If the site is not brought into compliance or a remedial action plan is not submitted the Pathology service will work with Hospital leadership to achieve compliance or discontinue testing.

A site may apply to start testing again. Their application for re-entry must include a remedial action plan to ensure future compliance. The application will be reviewed by the POCT Leadership to approve re-entry into the program.

**BILLING**

The POCT program supports billing for point of care tests performed by MGH testing sites that utilize interfaced methods. Manual tests may be billed for by the individual testing sites. The POCT program can assist their billing departments in selecting the correct billing codes.

**SUPPLY MANAGEMENT**

Certain supplies utilized by multiple POCT sites are centrally ordered and available in the POCT offices of GRJ239. These may include i-STAT cartridges, Hemocue reagents and urine dipstick quality control reagents. Approved testing sites are given directions to access the reagents as needed. These reagents are paid for out of the point of care testing cost center. Sites are encouraged to access the central supply to ensure standardized QC and effective inventory management, but participation is optional.