DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

January 31, 2005

Dear Laboratory Director:

The Clinical Laboratory Improvement Amendment of 1988 (CLIA), Public Law 100-578, was promulgated by Congress to address concerns about incorrectly read Pap smears, lack of workload limits for individuals who screen them and the proliferation of unregulated laboratories. The CLIA Law specifically provides for the… "periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions." Final CLIA regulations, published in 1992, implemented the law and established quality standards to ensure the accuracy and reliability of laboratory testing.

The CLIA statute and the Centers for Medicare & Medicaid Services (CMS) recognize the importance of cytology proficiency testing as an additional means to assure high quality women's health care and the overall enhancement of the public health.

With two CMS-approved testing programs and the recent nation-wide availability of testing, the requirement for proficiency testing is in effect for calendar year 2005. We look forward to working with you in the fulfillment of the final phase of the CLIA program for gynecological cytology proficiency testing. This letter contains information about the law and reference material that will be useful to you.

The two CMS-approved Cytology Proficiency Testing (PT) Programs for calendar year 2005 are (a) the State of Maryland Cytology PT Program and (b) the Midwest Institute for Medical Education (MIME) programs. Both programs have met the requirements of Subparts H and I of the CLIA regulations. We look forward to additional applications for CMS-approved proficiency testing. Regulations at 42 CFR 493.901 permit us to approve for calendar year 2006 any additional applications that meet the regulatory requirements so long as they are submitted by July 1, 2005.

The CLIA regulations at §493.855(a) state: "The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS . . ." Effective in 2005, all CLIA certified laboratories (accredited, non-accredited, and CLIA-exempt) that perform gynecologic cytology testing must ensure that each individual (cytotechnologists and pathologists) enrolls in a CMS-approved cytology PT program for 2005, no later than June 30, 2005 and annually thereafter. Following enrollment, you will be notified of the scheduled PT test date at least 30 days prior to the administration of the test. Every individual subject to Cytology PT is required to have completed their initial test no later than December 31, 2005.

The CMS will closely monitor progress in enrollment and test completion during calendar year 2005. We have taken steps in the survey process to ensure that this year (2005) is as educational as possible for those individuals that enroll and test in a timely manner. Please contact the Cytology PT programs listed in the attachment for specific fee, enrollment and testing information. A brief overview of the cytology requirements is also included.

The particular scheduling and logistical arrangements are matters to be worked out between you and the pertinent testing program. However, if you encounter significant difficulties that seem to defy resolution, please contact us. We will do our utmost to seek resolution.

Since the inception of the CLIA program, we have achieved significant progress in improving laboratory performance through collaboration with physicians, laboratories, laboratory professional and accrediting organizations. We will be working throughout the year to continue such progress and ensure that this final aspect of the CLIA implementation can occur as effectively as possible.

If my staff and I may be of assistance, please call 1-410-786-3531, or you may call the State Agency (SA) in the State where your laboratory is located as listed below.

Sincerely,

Judith A. Yost
Director,
Division of Laboratory Services
Center for Medicare & Medicaid Services

Attachment

2005 CMS-Approved Cytology Proficiency Testing Programs

State of Maryland Cytology Proficiency Testing Program
Maryland Department of Health and Mental Hygiene
Office of Health Care Quality – Laboratory Care
Spring Grove Hospital – Bland Bryant Building
55 Wade Avenue
Catonsville, Maryland 21228
Phone Number: (410)402-8028

Midwest Institute for Medical Education, Inc.
9550 Zionsville Road
Suite 110
Indianapolis, Indiana 46268
Phone Numbers: (317)876-4169, (800)575-2342
www.mimeonline.com, www.cytoquest.com, or **www.mimeinc.org**

Brief Overview of Cytology PT Requirements

The laboratory's cytology PT program of choice will ensure a sufficient number of 10-glass Test Slide Boxes to test each individual who examines Pap smears. The Test Slide Boxes consist of gynecologic cytology cases referenced by 100% agreement of at least three pathologists certified in anatomic pathology. Slides exhibiting premalignant (i.e., dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) and malignant lesions have documented tissue biopsy confirmation.

The response categories for the test are outlined in the CLIA regulations at §493.945(b)(3)(ii)(A). Both the State of Maryland and MIME's PT program include at least one case from each of the following diagnostic categories required in the regulations: "A" unsatisfactory, "B" normal or benign changes, "C" low grade squamous intraepithelial lesion and "D" high grade intraepithelial lesions and malignancy.

Pathologists who routinely interpret gynecologic slide preparations only after they have been screened and marked by a cytotechnologist can either be tested using a test set that has been screened and marked by a cytotechnologist in their laboratory or using a test set that has not been previously screened. A pathologist who screens and interprets slide preparations without pre-screening by a cytotechnologist must be tested using a test set that has not been previously screened.

The regulations require all laboratory personnel who examine gynecologic cytology preparations must be present in the laboratory to take the proficiency test on the date that the laboratory has scheduled for them. The precise dates of testing and logistical arrangements are the responsibility of the laboratory and the PT provider. Those individuals not present for the PT test on the scheduled date will need to have an excused absence, verified by the Laboratory Director and must make arrangements to take a make-up test. Participants who miss the scheduled on-site test without an excused absence will receive a failing score of "0". Those individuals working at more than one location must identify the laboratory where they will be tested prior to the first testing event. A passing grade is 90%.

Each individual participating in a CMS-approved Cytology PT Program will be assigned a unique national PT registration number (PTR#) that will remain, regardless of CMS-approved PT program utilized or future places of employment. Identifying information for individuals will be placed in a privacy protected System of Records at CMS and its confidentiality will be maintained.

A complete description of the CLIA regulations may be found at http://www.cms.gov/clia or at http://www.phppo.cdc.gov/clia/regs/toc.aspx. CMS will provide on the above web site a comprehensive set of Questions and Answers.

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Center for Medicaid and State Operations

March 30, 2005

IMPORTANT INFORMATION PLEASE READ

Dear Laboratory Director:

On January 31, 2005, your laboratory was sent an official notification from the Centers for Medicare & Medicaid Services (CMS) containing information on the availability of cytology proficiency testing programs and a brief overview of the cytology proficiency testing requirements under CLIA. The purpose of this letter is to remind laboratories examining gynecologic specimens of the necessity to enroll and participate in one of the two CMS-approved cytology proficiency testing (PT) programs for calendar year 2005.

The two CMS-approved cytology PT programs for calendar year 2005 are the State of Maryland Cytology PT Program and the Midwest Institute for Medical Education (MIME) program. Both programs have received CMS approval for testing in 2005 under the requirements for cytology PT under Subparts H and I of the CLIA regulations. *See* 42 CFR Part 493. While we expect to receive application materials from additional programs that could then be approved for cytology PT testing for 2006, the application window has closed for approving additional programs for testing in 2005. Therefore, every laboratory performing the examination of gynecologic specimens must enroll in one of the two programs listed above.

In our previous letter, CMS reminded you that all CLIA certified laboratories (accredited and non-accredited) and CLIA-exempt laboratories that perform gynecologic cytology testing must ensure that each individual (cytotechnologists and pathologists) is enrolled in a CMS-approved cytology PT program for 2005. To avoid potential enforcement actions, such individuals should enroll as soon as possible in order to complete their initial testing by December 31, 2005 and annually thereafter. Following enrollment, you will be notified of the scheduled PT test date at least 30 days prior to the administration of the test. Every individual subject to Cytology PT is required to have completed their initial test no later than December 31, 2005.

The CMS is closely monitoring the enrollment and testing process during calendar year 2005. We recognize the fact that individuals need time to enroll in a Cytology PT program and the programs and laboratories need time to make the logistical arrangements necessary for testing. Numerous laboratories have enrolled and participated in Cytology PT, thereby ensuring compliance with this statutory and regulatory requirement. However, CMS is also aware of a number of laboratories that have thus far failed to enroll in an approved cytology PT program. This letter serves as a strong reminder to laboratories that have not yet enrolled and participated in a CMS-approved PT program that they should do so. Enforcement provisions will have to be applied against laboratories that disregard the cytology PT requirements. The CMS regional office will initiate alternative sanctions or limit the laboratory's CLIA certificate for cytology, and if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of the CLIA regulations if the laboratory:

- Fails to enroll in a CMS-approved cytology PT program;
- Fails to ensure that all individuals examining gynecologic cytology slides are enrolled in and successfully completed a CMS-approved cytology PT program;

- Fails to ensure that an individual who fails a cytology PT test is retested in accordance with the regulatory requirements for retesting, if such individual continues to examine gynecologic slides for the laboratory; or
- Fails to take the required remedial actions (including retesting, documented remedial training in the area of failure, reexamination of gynecologic slides, cessation of the examination of gynecologic slides, and 35 hours of documented formally structured continuing education in diagnostic cytopathology) specified in the CLIA requirements.

Newly hired individuals who are entering the profession from college or a school of cytotechnology will be granted a 6 month grace period in which they must be enrolled with a CMS-approved program and tested.

If you have additional questions, please refer to the Cytology PT information on the CLIA website at www.cms.hhs.gov/clia/ or you may call the State Agency (SA) in the State where your laboratory is located as listed below.

Sincerely,

Judith A. Yost
Director,
Division of Laboratory Services
Center for Medicare & Medicaid Services