Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CLIA REGULATION OF UNESTABLISHED LABORATORY TESTS

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EXECUTIVE SUMMARY

PURPOSE

To examine how the Centers for Medicare and Medicaid Services (CMS) regulates laboratories conducting Live Blood Cell Analysis and other unestablished laboratory tests.

BACKGROUND

The CMS has become aware that an increasing number of laboratory sites are offering patients Live Blood Cell Analysis and other unestablished laboratory tests. For the purposes of this inspection we have defined unestablished laboratory tests as those laboratory test methods that are not generally accepted by many of the people involved in traditional laboratory practice and oversight.

One such test, Live Blood Cell Analysis, uses a drop of blood from a patient's finger. The blood is placed on a slide and viewed under a specialized microscope connected to a video monitor. Sites where this test is performed are considered laboratories as defined by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and are subject to CLIA regulation. The CMS has encountered problems in trying to regulate Live Blood Cell Analysis and other unestablished laboratory tests such as Biological Terrain Assessment, hair analysis to assess nutritional deficiencies, food allergy testing and other tests.

FINDINGS

Live Blood Cell Analysis Has Not Been Able to Meet CLIA Requirements

To date, laboratories conducting Live Blood Cell Analysis and other unestablished laboratory tests have not been able to meet all CLIA requirements. Many Live Blood Cell Analysis providers are nutritionists, herbologists, naturopaths, chiropractors and others who are unlikely to meet CLIA personnel requirements. All laboratories that offer Live Blood Cell Analysis are unable to meet requirements pertaining to the establishment and verification of test methods.

An unknown, but perhaps significant, number of laboratories that offer unestablished laboratory tests may be operating without CLIA certification. During this study, we identified 200 laboratories that offer unestablished laboratory tests. Eighty percent of these laboratories do not have a CLIA certificate.

CMS Faces Significant Barriers in Enforcing CLIA Regulations for Unestablished Tests

The CMS has difficulty identifying laboratories that perform unestablished laboratory tests and, once identified, CMS has even greater difficulties getting these laboratories into compliance with all CLIA requirements. The program relies on laboratories to voluntarily identify themselves for CLIA enrollment, but laboratories using unestablished test methods have few, if any, incentives to voluntarily enroll in CLIA. Moreover, CMS has inadequate administrative remedies that would permit them to take action against laboratories that refuse to enroll or comply with the Federal law.

Some Laboratories Performing Live Blood Cell Analysis May Have Improperly Obtained CLIA Certificates

The CMS may be unaware that laboratories with waived or provider-performed microscopy CLIA certificates are conducting unestablished laboratory testing. Obtaining these types of certificates is relatively easy. Applications from laboratories do not require disclosure of the use of unestablished test methods, and laboratories seeking waived and provider-performed microscopy certificates are not routinely visited. Consequently, CMS may never discover that these laboratories are performing Live Blood Cell Analysis or other unestablished tests.

Laboratories performing Live Blood Cell Analysis and other unestablished tests that apply for a CLIA Certificate of Compliance to conduct complex testing are more likely to be detected and have their certificate revoked because CLIA surveyors routinely visit them. However, this process is resource intensive and may take up to 3 years to complete. Under current CMS policy, all CLIA laboratories that conduct unestablished tests do so outside the scope of their certificate. These certified laboratories should not be performing Live Blood Cell Analysis or any unestablished test.

State Agencies and Practitioner Respondents Believe Live Blood Cell Analysis Should Be Regulated, but They Differ on How this Should Be Accomplished

Most State agencies believe that CLIA regulation of Live Blood Cell Analysis laboratories would help to ensure the quality of testing and help protect patients from unscrupulous providers. Two-thirds of State agencies believe that CMS should change CLIA policies to better address Live Blood Cell Analysis and other unestablished tests. Most providers of unestablished laboratory tests agree that unestablished tests should be regulated to protect patients, but they feel that CLIA is the wrong program to do this.

Few States Restrict the Use of Unestablished Laboratory Tests; Oversight by Other Federal Agencies Is Limited

The CLIA program plays the primary role in oversight of laboratories. State laws and other Federal regulations may affect laboratories, but CMS is primarily responsible for

overseeing the quality of testing performed at each CLIA certified laboratory. Many States place restrictions on who can order and receive laboratory test results, but only a few have laws that prohibit unestablished laboratory testing. Other Federal agencies enforce regulations that affect the marketing of laboratory equipment, advertising claims, and disposal of biohazardous materials, but these agencies have no direct oversight of laboratory testing practices.

RECOMMENDATIONS

The Clinical Laboratory Improvement Amendments of 1988 were enacted to improve the quality of laboratory testing and to protect the public from harm that might result from poor quality laboratory testing. It recognizes that the risk of harm to patients differs from test to test. The greater the risk of harm, the greater the regulatory requirements.

This report demonstrates that laboratories conducting Live Blood Cell Analysis and other unestablished tests do not fit well into the current CLIA regulatory framework. To help address this situation, we are recommending that CMS take the following actions:

- **Conduct a study to determine whether Live Blood Cell Analysis has value as a diagnostic tool.**

- **Establish procedures for evaluating the usefulness of other unestablished tests.**

- **Seek new administrative authorities that would permit CMS to take specific actions when a laboratory fails to enroll in CLIA.**

- **Require laboratories to disclose on their CLIA application whether they are conducting unestablished tests.**

- **Improve test verification reviews by improving surveyor training and standardizing reviews.**

- **Use the CMS Internet site and other means to provide the public with information on unestablished laboratory tests.**

Implementation of these actions should assist CMS in finding a long-term solution regarding laboratories conducting unestablished tests.

AGENCY COMMENTS

The CMS concurs with all of the recommendations in this report.

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INTRODUCTION

PURPOSE

To examine how the Centers for Medicare and Medicaid Services (CMS) regulates laboratories conducting Live Blood Cell Analysis and other unestablished laboratory tests.

BACKGROUND

In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA). The CLIA law establishes "quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed." The CMS is responsible for implementing CLIA, including laboratory registration, fee collection, onsite surveys and enforcement. The CMS contracts with State agencies and professional organizations to carry out the provisions of the law.

Under current law, all laboratories except those specifically exempted by law, must be CLIA certified to perform testing on human specimens. The CLIA regulations define a laboratory as:

> *[A] facility for the . . . examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.*

The CLIA regulations exempt some laboratories from regulation. Forensic laboratories, drug testing laboratories certified by the Substance Abuse and Mental Health Services Administration and some Federal laboratories are exempt from CLIA regulation. Research laboratories that do not report test results to patients are also exempt from CLIA regulation.

As of July 2000, nearly 170,000 laboratories were registered under CLIA. About 86,500 laboratories have been issued a Certificate of Waiver. These laboratories only perform simple laboratory procedures cleared by the Food and Drug Administration (FDA). Laboratory surveyors do not make routine visits to waived laboratories ensure compliance with CLIA requirements.

Approximately 36,000 laboratories hold Certificates for Provider-Performed Microscopy Procedures. These certificates are issued to physicians and other approved providers who meet CLIA requirements to perform certain moderate level microscopy procedures. In addition to specified microscopy procedures, providers issued this type of certificate can also perform waived tests. As with laboratories issued a Certificate of Waiver, laboratories issued a Certificate for Provider-Performed Microscopy Procedures are not routinely visited by the CLIA program.

The remaining 41,500 laboratories conduct moderate or high complexity testing. They have been issued a Certificate of Compliance or a Certificate of Accreditation. All laboratories conducting moderate and high complexity testing are required to meet specific CLIA requirements. When these laboratories apply for certification they are issued a Certificate of Registration that enables them to participate in the Medicare and Medicaid program until an onsite visit can be conducted to verify compliance with CLIA standards. They are then issued a Certificate of Compliance. State and accrediting agency surveyors revisit these laboratories at least every 2 years to ensure continued compliance with CLIA requirements.

Types of CLIA Certificates

Certificate of Waiver
This certificate is issued to laboratories that only perform tests approved for home use or that employ methodologies that are so simple and accurate the likelihood of erroneous results is negligible or they pose no reasonable risk of harm to the patient if the test is performed incorrectly. These laboratories are not routinely visited.

Certificate for Provider-Performed Microscopy Procedures
This certificate is issued to laboratories where a physician or other qualified provider performs specific microscopy procedures permitted by CLIA. Laboratories with provider-performed microscopy certificates are also permitted to perform waived tests. These laboratories are not routinely visited.

Certificate of Registration
This certificate is issued to laboratories that conduct moderate or high complexity testing or both. This certificate is issued when a laboratory's application is accepted by CLIA and is valid until the laboratory is surveyed.

Certificate of Compliance
Certificate of Accreditation
A Certificate of Compliance or a Certificate of Accreditation is issued after a laboratory is surveyed and found to be in compliance with all applicable CLIA requirements. Routine onsite visits are made to these laboratories to ensure compliance.

Live Blood Cell Analysis

The CMS has identified several unestablished laboratory tests that use blood, urine and saliva.[1] Live Blood Cell Analysis (LBA) uses a drop of blood from a patient's finger.

[1] Information we received from CMS identifies Live Blood Cell Analysis, Biological Terrain Assessment, Thromboelastograph, dental sensitivity testing, food allergy testing and hair analysis to assess nutritional deficiencies as "alternative" tests. These and other tests meet our definition of unestablished testing.

The blood is placed on a slide and viewed while the cells are alive using a specialized microscope connected to a video monitor.[2] The video monitor allows patients to view their blood cells while the provider describes substances found in the blood sample. Some providers use results to assess nutritional deficiencies, to outline a course of treatment or to assess the effects of treatment. Other providers may use Live Blood Cell Analysis for other purposes.

Under current regulations, meeting all CLIA requirements for certification is virtually impossible for a laboratory performing Live Blood Cell Analysis (LBA). Many LBA providers are complementary and alternative medicine providers such as nutritionists, herbologists, naturopaths, chiropractors and others who are unlikely to meet CLIA personnel requirements. The CMS has determined that facilities performing Live Blood Cell Analysis must meet CLIA requirements for high complexity testing including patient test management, proficiency testing, quality control and quality assurance.

Every laboratory must establish and verify every high complexity test method used in the laboratory. Establishing and verifying a test method is usually demonstrated, in part, by 1) comparing the new test results with the results obtained from established methods, 2) testing samples of known value, and 3) testing the same sample multiple times to see if the results are comparable.

Laboratories are required to run quality control samples to ensure that a test is working correctly from day to day. The laboratory must also verify test accuracy by participating in a proficiency testing program. Because LBA is performed on freshly drawn blood samples, it is much more difficult to comply with these CLIA quality assurance requirements.

CMS's Efforts to Address Live Blood Cell Analysis

In 1995, CMS created a work group to address regulation of Live Blood Cell Analysis and other unestablished laboratory tests. The work group asked their Office of General Counsel and the Centers for Disease Control and Prevention (CDC) for assistance in understanding what role, if any, the program should play in regulating laboratories conducting Live Blood Cell Analysis. The Office of General Counsel advised CMS that laboratories conducting LBA are subject to all CLIA requirements. The CDC determined that laboratories performing this test must meet all of the requirements for laboratories

[2] The laboratory method used for LBA is also used in unestablished tests with the following names: Peripheral Blood Assessment, High Resolution Blood Morphology, High Resolution Microscopy, Live Cell Analysis, Live Blood Demonstration, Unchanged Blood Analysis, Vital Hematology, darkfield microscopy and nutritional microscopy.

conducting high complexity testing. The CMS posted the CDC and Office of General Counsel findings in a Special Alert on its website.

The work group developed guidelines for State surveyors to help them when surveying laboratories conducting LBA. The work group has also asked States and their regional offices to provide them with information on laboratories identified as providing LBA and other unestablished tests.

METHODOLOGY

For the purposes of this study, we use the term "unestablished laboratory tests" to mean tests that are not generally accepted by many of the people involved in traditional laboratory practice and oversight.

We collected information about Live Blood Cell Analysis and some information about Biological Terrain Assessment, hair analysis, food allergy testing and other unestablished tests for this study. We focused this report on LBA because it is the unestablished test most often encountered by CLIA personnel, and because CMS has made an effort to address how this test should be regulated by the program. While this report focuses on Live Blood Cell Analysis, the problems in attempting to regulate laboratories doing this test also appear to apply to other laboratory locations that perform unestablished laboratory tests.

This study did not address the validity or accuracy of LBA or any other unestablished laboratory test. Nothing in this report should be construed as an endorsement or condemnation of any laboratory test.

We reviewed CLIA regulations, policies and procedures to determine how they relate to laboratories conducting Live Blood Cell Analysis and other unestablished tests. We interviewed CMS central office staff and regional office staff in five regions. We discussed CLIA enrollment and certification processes, and staff experiences relating to LBA testing and laboratory sites that use unestablished test methods. Similar discussions were held with representatives from the College on Office Laboratory Accreditation, the Joint Commission on Accreditation of Healthcare Organizations and the College of American Pathologists. These accrediting organizations were contacted because they have contracts with CMS to provide survey and certification services for some laboratories.

We contacted the State agencies responsible for carrying out the CLIA provisions in all 50 States, the District of Columbia and Puerto Rico. We conducted in-person interviews with State CLIA staff in the District of Columbia and 11 States: Arizona, California, Delaware, Illinois, Kansas, Maryland, Missouri, New Jersey, New York, Pennsylvania and Wisconsin. We discussed CLIA enrollment and certification processes and obtained

information and opinions about CLIA regulation of laboratories performing unestablished tests. The remaining 39 States and Puerto Rico completed written surveys. Overall, we received responses from 52 State agencies.[3]

To identify facilities offering LBA, we solicited information from CMS central and regional offices, State agencies and the three accrediting organizations. We also used Internet searches to identify manufacturers, instructors, promoters and practitioners of LBA. We were unable to obtain reliable data to determine the total number of laboratory sites performing LBA or other unestablished laboratory tests. From the information we obtained, we compiled a list of laboratory sites conducting LBA and other unestablished tests in the United States.

To obtain the perspective of those providers who use unestablished laboratory test methods, we interviewed people involved in LBA laboratory testing. We contacted industry representatives identified as manufacturing, promoting or offering Live Blood Cell Analysis. Of the 38 potential respondents that we attempted to contact, 18 agreed to participate in this study. Others could not be contacted or were unable to meet with us.

We also interviewed staff at Center for Disease Control and Prevention, National Institutes of Health, the Food and Drug Administration, the Federal Trade Commission, and the Occupational Safety and Health Administration. These agencies were identified by State agencies and CMS staff as playing a role in regulating unestablished laboratory tests. We conducted these interviews to determine what, if any, oversight responsibility each agency has in relation to laboratory testing.

We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

[3] Collectively, the respondents from the 50 States, the District of Columbia and Puerto Rico will be referred to as "State Agencies" or "States" in this inspection report.

FINDINGS

Live Blood Cell Analysis has not been able to meet CLIA requirements

An unknown, but perhaps significant, number of Live Blood Cell Analysis sites operate without CLIA certificates

We identified 200 laboratories in 38 States that purport to offer Live Blood Cell Analysis (LBA) or other unestablished laboratory tests. One hundred fifteen sites were identified using information we received from CMS and State CLIA surveyors. We believe that the remaining 85 sites have not been identified by CMS or State survey staff.

We checked the names and addresses of the 200 laboratory sites offering LBA against CLIA enrollment records and found that nearly 80 percent did not have a CLIA certificate. The remaining sites were certified by the CLIA program. They had been issued Certificates of Waiver, Certificates for Provider-Performed Microscopy Procedures and Certificates of Compliance. Some of these certificates were revoked when CMS discovered that they were doing LBA. Other certificates remain in effect because the laboratory has assured CMS that it has ceased performing LBA.

We asked industry representatives to estimate the number of laboratories offering LBA. One respondent claims to have trained 300 to 400 American physicians to conduct LBA. Another respondent stated that he had trained about 3,000 practitioners. Based on his knowledge of the industry, this respondent estimates that between 10,000 and 15,000 sites may be conducting LBA in the United States.

When a non-certified laboratory is identified, the laboratory is sent a letter advising them to cease testing and to apply for CLIA certification if they wish to resume testing. State agency respondents suspect that some laboratories that offer unestablished testing continue to test despite agreeing to cease and desist. Other laboratories claim they are exempt from CLIA because they are conducting LBA as research. To qualify for this exemption laboratories must agree not to provide test results to patients. Some State agency respondents have expressed concern that these facilities may be providing test results to patients.

Laboratories that perform Live Blood Cell Analysis and other unestablished laboratory tests have difficulty meeting many CLIA requirements

All laboratories that perform LBA must meet regulatory requirements for laboratories performing high complexity testing. To date, no laboratory performing LBA has

successfully met these requirements. Complementary and alternative medicine providers appear most likely to offer their patients LBA and other unestablished laboratory tests. These complementary and alternative medicine providers often do not meet CLIA personnel requirements for high complexity testing. Those laboratories that can meet the personnel requirements cannot meet other CLIA requirements. Meeting the regulatory requirement concerning the establishment and verification of test methods has been particularly problematic for the LBA test method. To meet this requirement, each laboratory must prove that LBA is accurate, precise and an analytically sensitive test. The laboratory must also establish reference ranges to distinguish normal or acceptable results from abnormal or unacceptable results.

CMS faces significant barriers in enforcing CLIA regulations for unestablished tests

CMS cannot take administrative actions against laboratories that refuse to enroll in CLIA and must rely on other agencies to take action

According to CMS staff, CLIA's enforcement provisions work well for CLIA certified laboratories, but are problematic for laboratories not enrolled in the program. When a State agency or CMS discovers that a laboratory is operating without a CLIA certificate, they send the laboratory a letter advising them that they must cease and desist from testing until the laboratory is CLIA certified.

There are no administrative remedies available to CMS when a laboratory refuses to enroll in CLIA and refuses to cease testing. The CMS cannot impose monetary or other administrative penalties on laboratories that defy the law. The only course of action available to CMS is to refer cases to other Federal or State investigative and law enforcement agencies for civil suit or criminal prosecution. There are no intermediate remedies with more proportionate administrative penalties. Consequently, laboratories may be subject to criminal prosecution or civil action that may result in fines or imprisonment. A criminal conviction can result in a fine of up to $10,000 and up to 1 year in prison or both.

As with other laboratory tests that obtain a blood sample using a finger prick, obtaining blood for an LBA test, in itself, appears to pose little risk of harm to patients. Harm to patients is more likely when providers fail to recognize and take appropriate action based on test results and other non-test related factors. Regulations permit CMS to bring suit in the district court of the United States to enjoin a laboratory if CMS believes that continuation of an activity by a laboratory constitutes a "significant hazard to the public health." It may be difficult for CMS to establish that LBA and other unestablished tests pose a significant hazard to patients or the public. During our in-person interviews, we asked State and Federal respondents whether LBA had harmed any patients. We found no evidence that would suggest that LBA or any other unestablished test has harmed patients.

Getting laboratories that perform unestablished tests to enroll in the CLIA program is difficult

Laboratories conducting LBA have little incentive to enroll in the CLIA program. The main incentive for traditional laboratories to enroll under CLIA is reimbursement by Medicare or Medicaid. Nearly all providers bill patients directly for unestablished laboratory tests. Medicare, Medicaid and most other insurance programs do not cover these laboratory tests.

Most State agencies believe that at least 95 percent of all laboratories in their State voluntarily identify themselves for CLIA enrollment. States report that laboratories operating without CLIA certificates often decide to enroll when Medicare and other insurance payers deny their claims.

The CLIA program's reliance on laboratories to identify themselves for enrollment is problematic when it comes to laboratories conducting LBA and other unestablished tests. Some complementary and alternative medicine providers have heard that CMS forces laboratories conducting Live Blood Cell Analysis to close; consequently, laboratories that perform LBA and other unestablished tests may seek to avoid CMS detection.

Chiropractors, herbologists, naturopaths, nutritionist, therapists, health food store owners and other complementary and alternative medicine providers may be unaware of the CLIA program. These practitioners may not be associated with schools or organizations that offer a laboratory curriculum. Physicians (medical and osteopathic) who perform or offer their patients LBA and other unestablished laboratory tests appear more likely to be aware of CLIA. Traditional medical schools and professional organizations help to keep physicians informed about CLIA and other Federal and State regulations that affect laboratories. Training programs, schools and organizations for complementary and alternative medicine practitioners may not adequately inform their clients about CLIA requirements.

Some laboratories performing unestablished tests may have improperly obtained CLIA certificates

The number of laboratories that perform LBA and other unestablished tests is unknown. We do know that some laboratories doing these tests have been issued CLIA certificates. In some cases, a laboratory applied for a CLIA certificate because they were performing traditional laboratory procedures. They subsequently added LBA or other unestablished tests and did not notify CLIA. Others stopped doing the traditional laboratory tests that they were approved to perform under CLIA and only offer LBA and other unestablished tests.

Laboratories doing unestablished tests can easily obtain a CLIA certificate

Any laboratory, including those operated by complementary and alternative medicine providers, can easily obtain a CLIA Certificate of Waiver or a Certificate for Provider-Performed Microscopy Procedures. Applications from laboratories for these types of certificates may be approved and CLIA numbers issued because the CLIA application does not ask laboratories if they are doing LBA or any other unestablished testing. Since laboratories with waived and provider-performed microscopy certificates are not routinely visited, CMS may never know that they are performing Live Blood Cell Analysis or other unestablished tests and that they have been improperly issued a CLIA certificate.

Laboratories that perform unestablished testing and apply for a CLIA Certificate of Compliance are more likely to be detected and have their certificate revoked. However, the process may take up to 3 years to complete. Despite the inability of laboratories performing LBA to meet CLIA requirements, CMS requires that surveyors complete a full site visit of all laboratories performing LBA that submit correctly completed applications. Surveyors examine and determine which CLIA requirements the laboratory meets. Deficiencies noted during onsite surveys are documented on Statements of Deficiency. Deficiency statements for some laboratories conducting LBA have approached 30 pages in length - significantly more than most laboratories. One LBA laboratory response to CLIA survey findings exceeded 200 pages, and we have seen other complex responses to Statements of Deficiency. The CMS must address the issues raised in a laboratory's response to deficiencies cited during the survey process. After receiving CMS's response the laboratory is given the opportunity to, once again, respond to CMS. Laboratories that meet CLIA requirements and satisfactorily pass their onsite inspection may not be visited for 2 years. Those that have difficulty meeting CLIA requirements are given up to 1 year to correct deficiencies before their CLIA certificate is revoked.

The survey and certification process is a long and arduous process considering that no laboratory conducting Live Blood Cell Analysis (or other unestablished tests) has been able to meet all CLIA requirements. Currently, all CLIA certified laboratories that conduct LBA and other unestablished tests do so outside the scope of their certificate. These CLIA certified laboratories should not be performing LBA or other unestablished tests and may be violating the law.

State agencies and practitioner respondents believe Live Blood Cell Analysis should be regulated, but they differ on how this should be accomplished

More than two-thirds of State agencies believe that laboratories conducting LBA create difficulties for CLIA enrollment and certification. State agencies reported several difficulties including: identifying laboratories conducting LBA, enforcing CLIA

requirements for certification for all laboratories, and fitting Live Blood Cell Analysis and other unestablished tests into CLIA standards. Several States reported that they spend an extensive amount of time and resources when laboratories doing LBA apply for CLIA certification.

Laboratory surveyors and providers who offer their patients LBA disagree on the validity of Live Blood Cell Analysis. They also disagree as to whether CLIA is the appropriate program to regulate LBA and other unestablished laboratory procedures. Most State agency respondents and providers who offer LBA and other unestablished tests do agree that these tests should be regulated.

Most of our State agency respondents believe Live Blood Cell Analysis should be regulated under CLIA to protect the public

Most State agency respondents believe that CLIA regulation of laboratories performing LBA and other unestablished tests is needed to protect the public. State surveyors believe that they help protect the public by verifying that laboratories meet CLIA requirements designed to ensure accurate laboratory testing. However, CLIA surveyors cannot ensure that LBA laboratories conduct quality testing if the laboratory fails to enroll in CLIA.

State surveyors are not convinced that LBA provides quality diagnostic information. Many State surveyors generally believe that LBA tests yield results that are inconsistent with basic principles of biology, chemistry and physics. One State respondent said that the scientific application of LBA is limited to what performance characteristics the laboratory can actually validate. This respondent and others believe that some practitioners may make claims about LBA testing that cannot be supported.

Some State respondents also believe that laboratories performing LBA and other unestablished laboratory tests should be regulated because the public assumes some governmental agency is ensuring that their laboratory tests are reliable and accurate. One State respondent said, "If the public is led to believe that any test, whether standard or alternative, is one on which they could or should base some lifestyle adjustment, then there should be accountability of the testing person and the site. . . ." Another State respondent said that "the general public operates under the assumption that anyone in a laboratory coat is a professional and will operate in a professional manner."

A majority of States believe CMS should change CLIA processes rather than the law to address laboratories performing unestablished tests

Two out of three States believe CLIA regulations, policies and processes should be adapted or changed to better address LBA and other unestablished procedures. Some respondents believe that clarification of processes and better guidelines would help them determine whether laboratories that offer LBA and other unestablished tests can comply with current CLIA requirements. Others believe changes to regulations, policies and

processes are needed to better address laboratories that use unestablished methods and offer unestablished tests.

State agency respondents are divided as to whether the CLIA law needs to be changed to address laboratories that perform unestablished testing. Some State respondents believe that the current law is adequate. Other State respondents believe that any changes would dilute the existing law and encourage exceptions for other procedures. Of the States that would like to see a change in the law, many mentioned stronger enforcement authority. A few would like to see language that would specifically exclude unestablished laboratory tests from CLIA regulation.

Some CLIA surveyors are uncomfortable evaluating Live Blood Cell Analysis test methods

Several State surveyors expressed concern about their ability to evaluate non-traditional tests. Others indicated that CLIA regulations and policies are unclear as to what levels of proof are necessary to meet the regulatory requirements concerning validation of test methods. They mentioned that their training is based on traditional laboratory practices and that they often have no experience with unestablished tests. Some State surveyors and CMS personnel would like another entity to determine whether LBA is a reliable and accurate test method. If this question were resolved, CLIA surveyors felt they would be more comfortable evaluating LBA test validity.

Providers of unestablished laboratory tests with whom we spoke believe Live Blood Cell Analysis should be regulated, but not by the CLIA program

Most providers of unestablished tests with whom we spoke would like to be regulated by their peers and not by the CLIA program. One respondent summarized the sentiments of many LBA providers when he said, "CLIA is not in a position to make definitive statements about LBA technology." They believe that many CLIA surveyors have little or no understanding of LBA. Many providers who use unestablished tests believe that there needs to be some checks and balances to protect the public from unscrupulous providers.

One provider with whom we spoke believes that there should be no regulation of LBA testing when providers do not bill Medicare or other insurance. Some pathologists and other traditional medical practitioners who perform Live Blood Cell Analysis also shared this viewpoint. They believe that LBA falls within the scope of their license to practice medicine and that it should not be regulated under CLIA.

Half of our provider respondents believe that an alternative laboratory division should be established. This new division would be responsible for registration and oversight of unestablished laboratory tests. It would regulate unestablished testing, set standards and enforce requirements. This new division would protect the public from providers who

fail to act in the best interest of their patients while not impeding access to unestablished laboratory tests.

A few laboratory providers want to comply with CLIA requirements but with some modifications

Three physician respondents who perform LBA said that they are not opposed to CLIA regulation. They are willing to comply with CLIA if standards more applicable to providers and the unestablished tests they use are developed by CMS. They believe that the CLIA program needs to provide more guidance on how they can come into compliance. They also believe that CMS needs to be more reasonable in assessing new technologies. One respondent said, "CLIA is going to drive the legitimate people out of LBA, and the illegitimate ones will prevail underground."

These three physicians operate laboratories certified to perform moderate and high complexity testing. They meet most CLIA requirements for LBA testing, but they cannot establish the validity of the LBA test method to meet CMS requirements.

Few States restrict unestablished laboratory testing; oversight by other Federal agencies is limited

The CMS plays the primary role in oversight of laboratories. Little oversight exists outside CLIA. Half the States require that laboratories obtain a State laboratory license, but the requirements for most of these licenses do not differ substantially from CLIA. A few States have laws that may affect laboratories offering LBA or other unestablished tests. Other Federal agencies have limited roles in laboratory oversight. Laboratories, the tests they perform and the equipment they use may also come under the scrutiny of FDA, CDC, the Federal Trade Commission and the Occupational Safety and Health Administration.

Few State laws and regulations restrict laboratories from conducting unestablished laboratory tests

Only three States reported that they had State statutes that they believe prohibit laboratories from performing unestablished testing. These three State laws, while somewhat different, prohibit laboratories from conducting tests that do not have "substantial proof of efficacy," and are not "substantiated by an independently conducted and documented scientifically based clinical trial." The Alabama Administrative Code states that procedures employed in a laboratory ". . . shall be the standard procedures which are generally accepted by leading authorities or are equivalents approved by the Alabama Department of Public Health." Maryland and Pennsylvania have statutes with similar language. These States believe that they have the authority to deny or revoke the State laboratory license of any laboratory doing unestablished testing.

Several States reported that they had State laws restricting who can order or receive laboratory test results. Connecticut, Georgia, Hawaii, Oregon, Pennsylvania and Tennessee require that laboratories examine specimens only when requested by a physician or other person authorized by State law to use the findings of laboratory examinations. These States also require that laboratory test results be provided only to physicians or other persons authorized to receive such tests by State law. Some of these State laws also prohibit the reporting of laboratory test results directly to patients.

Three States believe that complementary and alternative medicine providers may not meet State standards governing laboratory personnel. California, Hawaii and Tennessee respondents mentioned that they had State personnel standards that would affect some laboratories doing unestablished testing. For example, California law prohibits chiropractors from drawing blood and thus affects chiropractors who conduct LBA.

Federal agencies play a limited role in regulating unestablished laboratory practices

The CLIA provisions are intended to ensure the quality of laboratory testing. Poor test quality can lead to misdiagnosis, inappropriate treatment and patient harm. Only CLIA looks at how well laboratories perform tests. However, other Federal agencies play a role in regulating discrete elements of laboratory practice, including manufacturer and provider claims, equipment and employee safety.

The Food and Drug Administration. The FDA's Office of Device Evaluation ensures that medical devices are safe and effective. They ensure that these devices perform as claimed and that valid scientific evidence supports the claims made about a product. New medical devices for use in laboratories must receive FDA approval before manufacturers can market them. The FDA is also responsible for classifying new laboratory tests and kits into the various CLIA regulatory categories.

Manufacturers of laboratory equipment and chemical reagents are not required to seek FDA approval to market products that do not substantially differ from products already approved by FDA. The FDA advised us that the microscopes used to perform LBA testing do not differ substantially from microscopes already approved by the FDA for other diagnostic purposes. They indicated that additional FDA approval would only be required if a manufacturer of the microscopes made new claims about the capabilities and uses for their microscope.

Some LBA practitioners make claims as to how this test can be used to assess nutritional deficiencies, diseases and patient health status. These claims are made by the user and not the manufacturer of LBA equipment; therefore, the FDA has no jurisdiction.

The Centers for Disease Control and Prevention. The mission of the CDC is to promote health and quality of life by preventing and controlling disease, injury and

disability. The CDC conducts research and provides services to meet public needs and to achieve public health goals. The CDC is responsible for CLIA program and policy evaluation. The CDC has provided support and technical advice to CMS, and has helped CMS in the development of CLIA regulations and guidelines. Until the year 2000 (when the FDA assumed this task), CDC was also responsible for classifying new laboratory tests and kits into the various CLIA regulatory categories. It was CDC that first advised CMS that laboratories performing LBA would need to meet CLIA requirements for laboratories doing high complexity testing.

We asked CDC if Live Blood Cell Analysis posed any health risks to the population. They advised us that the risk of infection and disease transmission to patients from a finger prick (such as that used in LBA) is low. Our CDC respondents stressed that while the risk of disease transmission was low, it did not mean that no risk existed. They pointed out that anything contaminated with blood poses a potential biohazard. Such products should be properly handled and disposed of to prevent transmission of disease, particularly hepatitis that can remain virulent longer than most other contagious diseases. As with all patient provider encounters, CDC respondents expressed concern about potential harm that might occur when providers fail to recognize seriously ill patients.

The Federal Trade Commission. The FTC is responsible for enforcing Federal antitrust and consumer protection laws. It has enforcement and administrative responsibilities for statutes relating to business competition and consumer protection. The FTC seeks to protect consumers against unfair, deceptive or fraudulent practices by combating actions that threaten consumers' opportunities to exercise informed choice. The FTC can stop advertisers who make false claims about products.

The FTC's Bureau of Consumer Protection reviews the advertising claims made by sellers of health care products to consumers. They focus their investigation and prosecution efforts on large providers where they can have a greater impact and where national publicity is likely to have the greatest deterrent effect. Infractions by smaller businesses are usually addressed through more cost-effective, non-enforcement activities, such as consumer education. The FTC remains a potential source for CMS to use when they find that a provider makes false or misleading claims in their advertising about an unestablished laboratory test. False or misleading claims that providers make to their patients are not addressed by the FTC.

As part of its oversight responsibility, the FTC monitors the Internet for sites containing "bogus claims for products and treatments touted as cures for various diseases." This campaign, known as "Operation Cure.all" uses the Internet both as a law enforcement tool to identify bogus claims and as a communication tool to give consumers reliable health care information. Operation Cure.all has identified five areas of interest: dietary supplements, products that make therapeutic claims, medical devices, diagnostic tests (including LBA) and fraudulent foreign clinics. It is too early to evaluate the effect Operation Cure.all will have on laboratories performing unestablished tests.

The Occupational Safety and Health Administration. Some State and CMS respondents suggested that OSHA could help protect patients from exposure to potentially harmful laboratory tests including unestablished tests. We discussed this with OSHA and found that its primary mission is to save lives, prevent injuries and protect the health of America's workers. The Agency and its State partners ensure that employers provide safety guidelines and adequate protections for their employees. They ensure that employees are safe and that they are not exposed to hazardous materials or events in the workplace.

The Health Standards Programs Division within OSHA ensures that workers follow universal precautions for drawing blood. They also ensure that laboratories properly equip their staff with the tools to perform their jobs in a safe and sterile environment, and that laboratories properly dispose of blood products and biohazardous wastes. To date, OSHA headquarters is not aware of any laboratories offering LBA that would warrant their intervention. The OSHA would become involved in laboratories that offer unestablished tests if they felt that any of these laboratories exposed their employees to biohazardous wastes or any other potential harm.

RECOMMENDATIONS

The Clinical Laboratory Improvement Amendments of 1988 were enacted to improve the quality of laboratory testing and to protect the public from harm that might result from poor quality laboratory testing. It recognizes that the risk of harm to patients differs from test to test. The greater the risk of harm, the greater the regulatory requirements.

This report demonstrates that laboratories conducting LBA and other unestablished tests do not fit well into the current CLIA regulatory framework. To help address this situation, we are recommending that CMS take the following actions:

- **Conduct a study to determine whether Live Blood Cell Analysis has value as a diagnostic tool.**

- **Establish procedures for evaluating the usefulness of other unestablished tests.**

- **Seek new administrative authorities that would permit CMS to take specific actions when a laboratory fails to enroll in CLIA.**

- **Require laboratories to disclose on their CLIA application whether they are conducting unestablished tests.**

- **Improve test verification reviews by improving surveyor training and standardizing reviews.**

- **Use the CMS Internet site and other means to provide the public with information on unestablished laboratory tests.**

Implementation of these actions should assist CMS in finding a long-term solution regarding laboratories conducting unestablished tests.

AGENCY COMMENTS

The CMS concurs with all of the recommendations in this report. The full text of their comments can be found in Appendix A.

APPENDIX A

Centers for Medicare and Medicaid Services' Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: JUN 28 2001

TO: Michael F. Mangano
Acting Inspector General
Office of Inspector General

FROM: Michael McMullan
Acting Deputy Administrator
Centers for Medicare and Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *CLIA Regulation of Unestablished Laboratory Tests* (OEI-05-00-00250)

Thank you for the opportunity to review and comment on the above-referenced draft report. We believe this report provides significant insight into the problems posed by unestablished tests, such as live blood cell analysis testing (LBA), for which clinical validity and utility have not been established. Moreover, as the report notes, these tests are often performed in laboratories that are unable or unwilling to comply with the personnel and quality standards of the Clinical Laboratory Improvement Amendments (CLIA). We are concerned that unestablished laboratory tests may pose a threat to the public health and safety and look forward to working with the OIG and other interested agencies in developing an effective solution to this problem.

The OIG recommends the following:

OIG Recommendation
CMS should conduct a study to determine whether Live Blood Cell Analysis has value as a diagnostic tool.

CMS Response
We concur. Because of our concerns regarding possible public health implications of live blood cell analysis tests, we have initiated requests for further study by outside agencies. We often work closely with the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health on resolving clinical laboratory issues such as these and will enlist their support in working with us on planning a study for this specific test. Funding and program priorities will impact on our ability to accomplish this recommendation.

OIG Recommendation
CMS should establish procedures for evaluating the usefulness of other unestablished tests.

CMS Response
We concur. This is closely related to recommendation #1. Because CLIA's authority does not extend to evaluating the usefulness or clinical utility of laboratory testing, we will need to enlist the support of other Department of Heath and Human Services' agencies. Therefore, to help identify and address possible public safety concerns, and to the extent feasible given CLIA funding and program priorities, we will work with other agencies to help accomplish this recommendation. The clinical validity and usefulness of these other tests can be determined by agencies for which this is their primary responsibility and area of expertise.

OIG Recommendation
CMS should seek new administrative authorities that would permit CMS to take specific actions when a laboratory fails to enroll in CLIA.

CMS Response
We concur. Although we are not seeking legislative changes in the CLIA program, enforcement mechanisms presently available to assist us in taking action against such labs are cumbersome and have been difficult to implement. More effective and efficient procedures based on our existing enforcement authorities and with closer coordination of existing state authorities and enforcement remedies will be evaluated.

OIG Recommendation
CMS should require laboratories to disclose on their CLIA application whether they are conducting unestablished tests.

CMS Response
We concur. We will explore the feasibility of collecting such information as part of the routine application process. In addition, several states have already begun to require such information under their own laboratory licensure programs, and we will be encouraging all states to do the same.

OIG Recommendation
CMS should improve test verification reviews by improving surveyor training and standardizing reviews.

CMS Response
We concur. The findings of this OIG report, as well as findings from our own "Live Blood Cell Analysis National Workgroup" and the Program Integrity Enhanced Routine Survey Pilot will be used to improve surveyor understanding and action when labs are discovered that are performing unestablished laboratory tests. To accomplish this, we will provide surveyor training on analytical test validation reviews and upgrade our current LBA survey protocol as necessary.

OIG Recommendation
CMS should use the its Internet site and other means to provide the public with information on unestablished laboratory tests.

CMS Response
We concur. We have already begun a review of our CLIA Web pages to determine the best means for implementing this recommendation. As more information becomes available about LBA (through our study, etc.), we will assess other vehicles to improve public awareness.