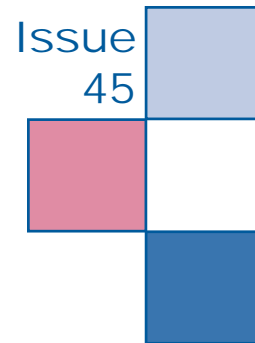
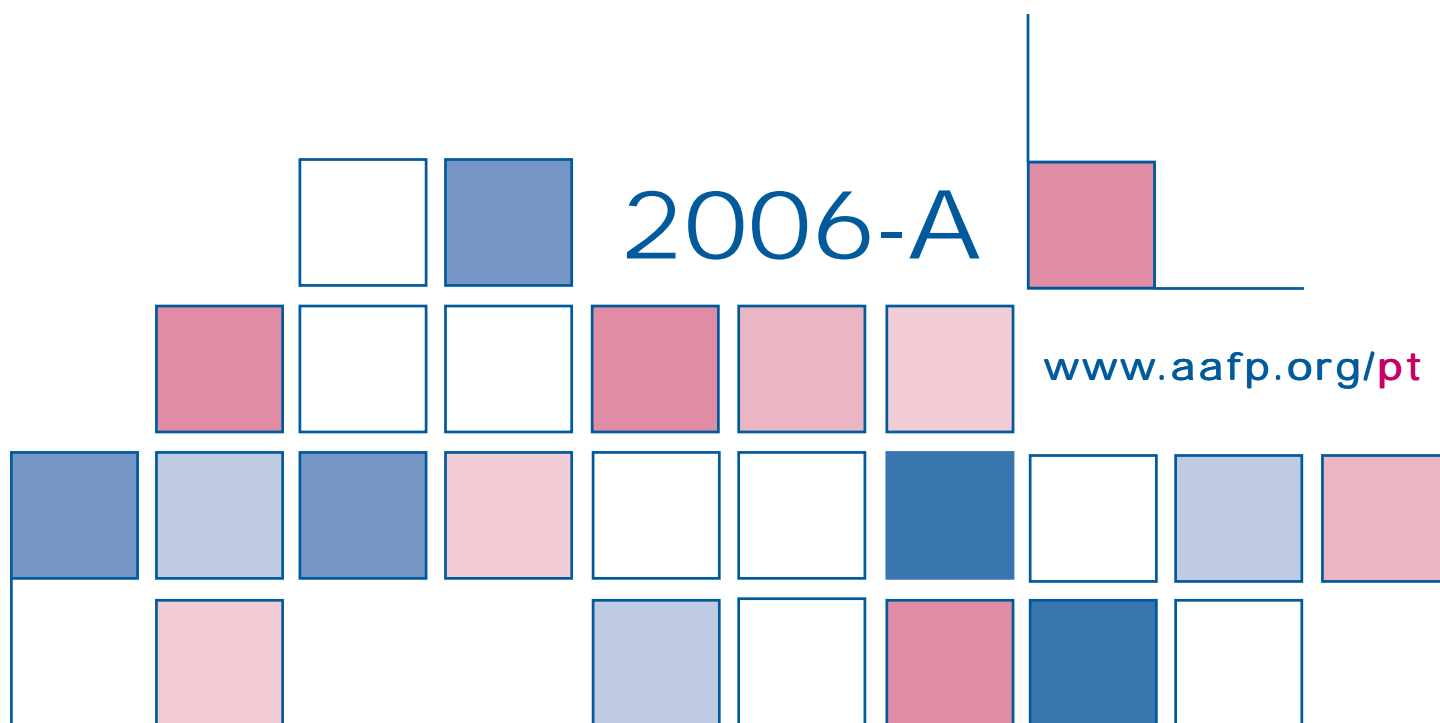


P.O.L.



# Insight

A Continuing Education Publication for the  
Physician Office Laboratory



## In This Issue:

Basics of Quality  
Assessment — Part I

Rapid HIV Testing

Regulatory Update



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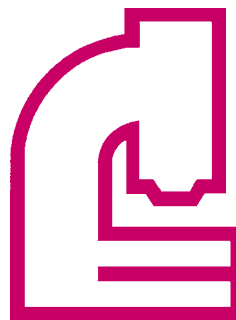
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Following completion of the self-instructional material, the participant will be able to:

1. Describe recent quality assessment changes in CLIA'88, define critical quality concepts, outline the path of workflow in a clinical laboratory, and define each of the recommended quality system essentials.
2. Describe the importance of rapid HIV testing in the POL, discuss the uses for waived HIV testing, understand new CDC trends in counseling and testing, increase willingness to conduct risk assessments with all patients.
3. Describe Good Laboratory Practices for Waived testing sites.

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7.	B	19.	B	31.	B
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Event 2006-A .....	February 28, 2007 .....	254-001-06

## ■ Basics of Quality Assessment

By Toni Clinton, PhD, BCLD (ABB), MT (ASCP)  
Assistant Medical Director American Esoteric Laboratories - Memphis, Assistant Professor, Departments of Pathology and Clinical Laboratory Science; University of Tennessee-Memphis.

Quality and quality indicators have always been an integral part of clinical laboratory operations. Beginning in the 1940's, the focus was primarily on quality control of the testing process. In the 1970's, the CAP proficiency testing program was initiated. A decade later, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) began advancing quality assurance in the healthcare industry, including the clinical laboratory. In the 1990's the FDA, AABB, and ISO 9000 introduced the quality system concept. Efforts began in the blood bank, but they were later transferred to other sections of the laboratory.<sup>1</sup> CLIA '88 quality requirements were revised in 2003 to reflect an emphasis on quality as it related to the flow of a specimen through the clinical laboratory.<sup>2</sup> The revisions relied heavily on the CLSI (NCCLS) quality management system model for health care<sup>3</sup> as well as that organization's laboratory-specific quality guidelines.<sup>4</sup>

This historical progression of quality concepts in the clinical laboratory mimics the hierarchy model of quality<sup>1</sup>, which is outlined in the initial CLSI publication.<sup>3,5</sup> At the base of the model is quality control. Upon that foundation, quality assurance activities are built. Once quality assurance becomes functional, the elements of a quality system may be added. This leads to quality management, and then finally – total quality management. See Figure 1.

*Total quality management (TQM)* is an approach to management that is centered on quality. The objective is long-term success through customer satisfaction. The next level is *quality management (QM)*. This level focuses on the economic aspects of quality, i.e., the "cost of quality." Laboratories successful at quality management will begin to see operating excellence and efficiency. A *quality system*

(QS) is defined as a comprehensive and coordinated effort to meet quality objectives. Successful laboratories should be able to demonstrate the effectiveness of their quality initiatives and business objectives. *Quality assurance (QA)* is a combination of planned and systematic activities which provide confidence that a laboratory fulfills its requirements for quality. QA is done to increase effectiveness, but also to meet both internal and external quality requirements. Finally, *quality control (QC)* are operational techniques designed to fulfill requirements for quality. In the clinical laboratory, this is a not only an operational requirement, but it is also required for regulatory compliance.<sup>1</sup>

In 1999, the Institute of Medicine (IOM) published a report entitled "To Err is Human". The report estimated that medical errors were the 8<sup>th</sup> leading cause of death in the US.<sup>6</sup> The published findings raised the quality standards and expectations of healthcare providers, payors, and patients. Subsequent follow-up reports by the IOM (2001 and 2003), have continued to make patient safety and the reduction of medical errors a key issue in healthcare.<sup>5</sup> As a result, the JCAHO has established new annual patient safety goals for its accredited institutions.<sup>5</sup> That organization has also introduced a new method of laboratory inspection called "tracer methodology," which is designed to better evaluate a laboratory's overall operations as it relates to quality of testing and patient safety.<sup>7</sup> The College of American Pathologists (CAP) has also significantly changed its inspection methods and quality requirements for its accredited laboratories, in part because of a scandal in 2004 concerning quality measures (or the lack thereof) in a Maryland hospital laboratory which had successfully passed several CAP inspections.<sup>8</sup> COLA, which inspects and accredits its primarily physician office laboratories, has recently revised its inspection criteria to include mandatory provisions for a CLSI-compliant quality management system.<sup>9</sup>

This discussion will focus primarily on the quality

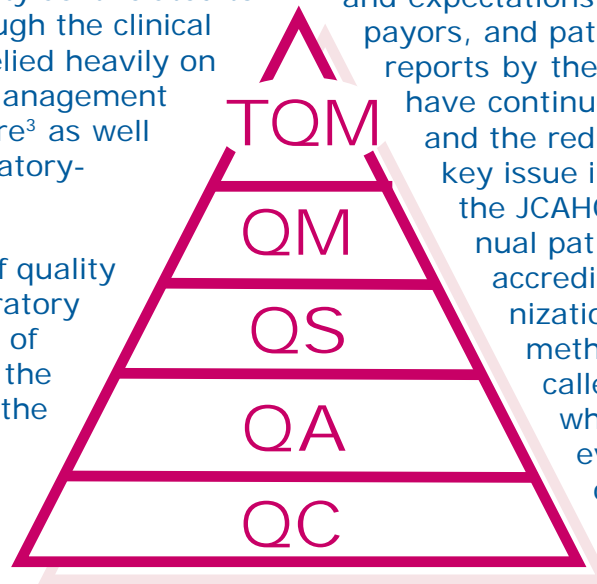


Figure 1



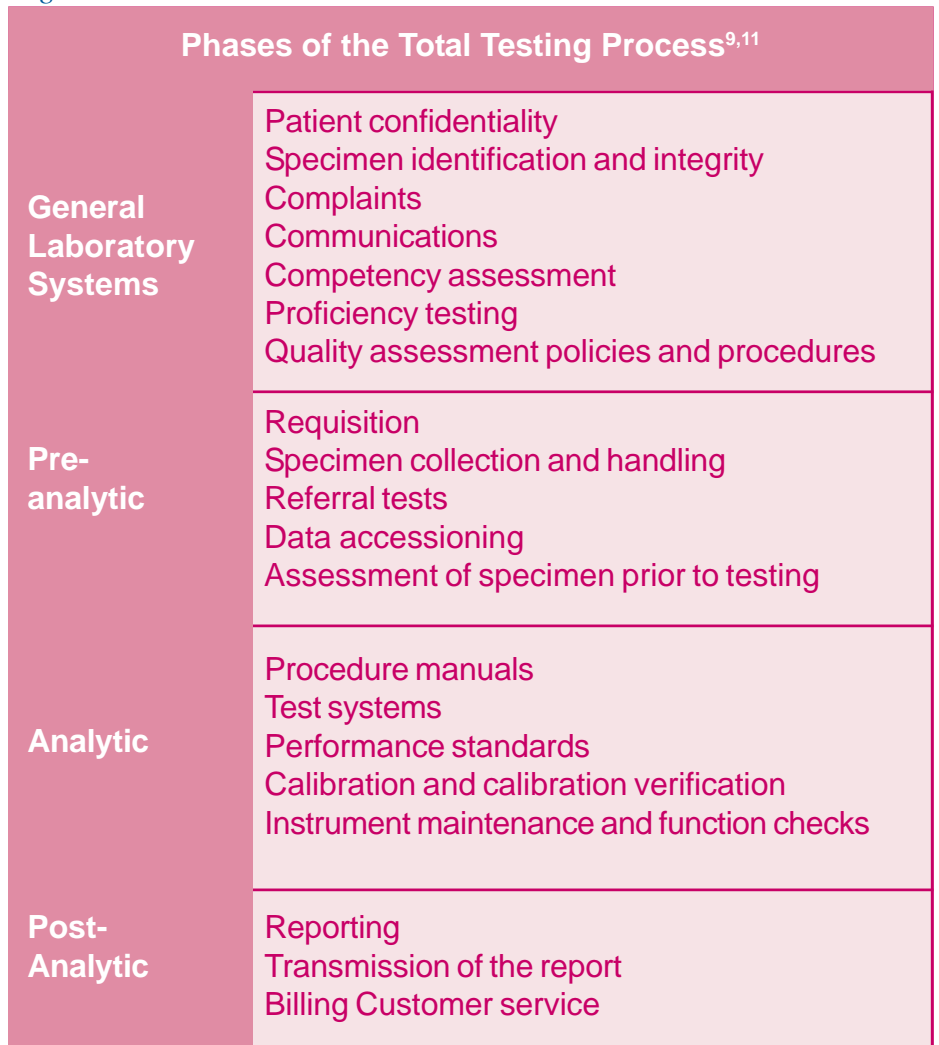
management system (QMS) approach now recommended by CLIA '88 in its final form and referred to most specifically in Subpart K "Quality System for Non-Waived Testing."<sup>2</sup> The term "quality assurance" has been replaced by "quality assessment". The requirements have not changed, but the format reflects an emphasis on assessing quality throughout the total testing process. The latter refers to the pre-analytic, analytic, and post-analytic phases (terms from the original CLIA '88 document), as well as general laboratory systems. "Path of workflow" is a term that is used to refer to the movement of the specimen as it progresses through the clinical laboratory and each phase of the testing process.<sup>10</sup> It is a critical component of the CLSI and CLIA '88 QMS model.

"Quality system" is defined as "all of the laboratory's policies, processes, procedures, and resources needed to achieve quality testing"<sup>11</sup> as specimens move along the path of workflow. The individual phases of the testing process as well as their general requirements are discussed in the following section. *See Figure 2.*

General laboratory systems include the following: confidentiality of patient information, specimen identification and integrity, complaint investigations, communications (internal and external), personnel competency assessment, proficiency testing performance evaluation, and quality assessment policies and procedures.<sup>9,11</sup> All of the items are most commonly covered in a laboratory's "General" procedure manual, which outlines the basic operating principles and procedures of the laboratory. These requirements are not new, but rather moved from various sections of the original CLIA document into a single, consolidated section.

Pre-analytic systems include all those functions associated with the patient and sample *before*

Figure 2



testing begins.<sup>9,11</sup> Those processes comprise the following elements: test requisition, specimen handling (collection, handling, transport), referral of tests not performed on-site, and accessioning (data entry rules and controls including provisions concerning protected health information; "PHI"). Pre-analytic assessment of the quality of the specimen to be tested (hemolysis, lipemia, correct sample, specimen handling, receipt) are also included in this category.

Analytic systems are those processes and procedures that occur during the testing phase.<sup>9,11</sup> Components of this phase consist of procedure manuals, the actual test systems (instruments, reagents, and other supplies), performance standards (linear ranges, normal ranges, quality control parameters), establishment and verification procedures for each test system, calibration and calibration verification policies, maintenance requirements, schedules,



and function checks, test records (including instrument print outs and manual worksheets), corrective action records, and quality control records (validation, recording, review, and corrective actions).

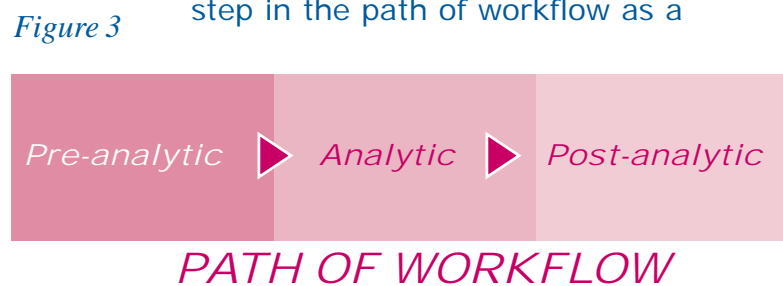
The final phase includes post-analytic systems, which refer to those processes that occur *after* testing is complete.<sup>9,11</sup> Examples include reporting (physical report as well as the reporting process – to whom and by what mechanism), billing, and customer service.

When combined, these phases are the key components of a quality management system (QMS). Together, they describe a planned, systematic review and assessment of each step in the path of workflow as a

specimen is processed through a clinical laboratory. Other important characteristics of QMS is that all activities are *documented, scheduled, communicated, and monitored.*

“Quality System Essentials – QSE’s” are key elements of the CLSI QMS model. They are indicators used to monitor a sample’s progress through the laboratory’s path of workflow.<sup>1,3,4,10</sup> Together, the pre-analytic, analytic, post-analytic, and general laboratory systems as well as their corresponding QSE form the laboratory’s quality management system. Each of the mandated quality requirements may be found in a QSE or as a part of the systems described above.<sup>10</sup> Berte has described the

individual QSE’s as parts of a brick foundation that serve to support the path of workflow in a clinical laboratory’s operation. Any weakness in a QSE can adversely affect the work processes at any point (or multiple points) along the path of workflow.<sup>10</sup> This interdependence is depicted in Figure 3. The Quality System Essentials (QSE’s) are described in Figure 4 and in the following section.



### Organization

- Management review of quality activities
- Oversight and management of quality assessment & corrective actions
- Documented by signatures, active participation

### Personnel

- Regular, periodic review of job descriptions
- Competency assessment
- Training
- Performance review

### Equipment

- Periodic maintenance and records
- Cleanliness
- Regular function checks
- Instrument downtime
- Number and frequency of service calls

### Purchasing and Inventory

- Inventory management
- Supply costs and cost per test calculations and review
- Shipping costs and ordering frequency



Figure 4

Quality System Essential	Description
<b>Organization</b>	Management review of quality activities Oversight of QA and corrective actions
<b>Personnel</b>	Periodic review of job descriptions Competency assessment Training Performance review
<b>Equipment</b>	Periodic maintenance and records Regular function checks Instrument downtime Number & frequency of service calls
<b>Purchasing &amp; Inventory</b>	Inventory management Supply costs and cost per test calculations and review Shipping costs Quality control and calibration costs Repeat run rates
<b>Process Control</b>	Map of complicated laboratory processes Procedure manual review Quality control review process
<b>Documents &amp; Records</b>	Document control processes and procedures Record retention and retrieval
<b>Information Management</b>	HIPAA compliance Laboratory information system (LIS) Flow of information through the laboratory
<b>Occurrence Management</b>	Define and record occurrences along the path of workflow Identify targets for improvement and corrective actions Incident management policies and procedures
<b>Assessments: Internal &amp; External</b>	Internal: TAT, QC failures, instrument downtime, productivity, profitability External: Proficiency testing results and review, inspection outcomes
<b>Process Improvement</b>	Development and initiation of corrective actions required as a result of monitoring activities
<b>Service &amp; Satisfaction</b>	Internal: Performance appraisal, employee satisfaction External: Customer (patient/physician/ clinic)
<b>Facilities &amp; Safety</b>	OSHA compliance Routine maintenance & housekeeping

- Quality control and calibration costs
- Repeat rates

**Process Control**

- Map of complicated laboratory processes
- Procedure manual review
- Quality control review

**Documents and Records**

- Document control processes and procedures
- Record retention and retrieval

**Information Management**

- HIPAA compliance



- Laboratory information system (LIS)
- Flow of information from requisition to report

### Occurrence Management

- Define and record occurrences along the path of workflow
- Identify targets for improvement and corrective actions
- Incident management policies and procedures

### Assessments: External and Internal

- Internal: Turn-around-time, quality control failures, repeat rates, instrument down time, client/employee complaints
- External: Proficiency testing results and follow-up, inspection outcomes

### Process Improvement

- Development and initiation of corrective actions required as a result of monitoring activities
- Problem resolution

### Service and Satisfaction

- Internal: Performance appraisal, employee satisfaction
- External: Customer (patient and physician/clinic) feedback

### Facilities and Safety

- OSHA compliance
- Routine maintenance and housekeeping

The overwhelming message consistent in all applications of quality systems management has been expressed most concisely by Lucia Berte, "Quality needs to be built into each process that contributes to the laboratory's services."<sup>12</sup> If used correctly and appropriately, a quality management system will enable laboratory personnel to incorporate quality and quality initiatives into their daily routine. Careful construction of the laboratory's specific QSE's will lay a strong foundation that will support the laboratory's path of workflow. The use of specific QSE's through out the path of workflow in a POL-specific quality management system will be discussed in Part II of this series.

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## Rapid HIV Tests: The "Waive" of the Future

*By Dr. Donna Sweet, MD, Professor of Internal Medicine, University of Kansas School of Medicine, Director, Kansas AIDS Education & Training Center, Chairman, American College of Physicians Board of Regents, Board Member, COLA.*

HIV Rapid Testing, and specifically waived HIV testing, is making a significant impact on HIV care in the United States. I strongly feel that HIV testing is something that needs to be done as a rapid test. If you do any waived tests in your office, waived rapid HIV testing should be a part of your battery of tests. The CDC is going to be asking every clinician to test people on a regular basis as a part of routine medical care.

The last time any changes were made to the recommendations for how HIV testing is conducted in the US was in 1993. As a result, we are actually behind the rest of the world when it comes to how we approach HIV testing. Necessary changes are currently being considered to bring our guidelines up with what is currently being done in the rest of the world and to de-link testing from counseling. These changes would make HIV testing what it should have always been...a laboratory test that tells patients what they need to know about their health status.

So, why the urgency? Of the approximately 1.2 million people who are infected with HIV there are approximately 300,000 who are unaware of their serostatus and who continue to spread HIV due to this lack of awareness. In addition, about 31% of positive HIV test results in the current counseling and testing system are never reported to the patient because they fail to return for results. That is a huge amount of effort and money expended to test individuals and then not be able to notify them. Doing the rapid test allows you

Proportion of Persons Who do not Return for their HIV Test Results		
	HIV Positive	HIV Negative
1995	25%	33%
1996	26%	33%
1997	33%	42%
1998	38%	44%
1999	43%	48%
2000	42%	47%

Source: CDC Client Record Database, Publicly-funded HIV Testing

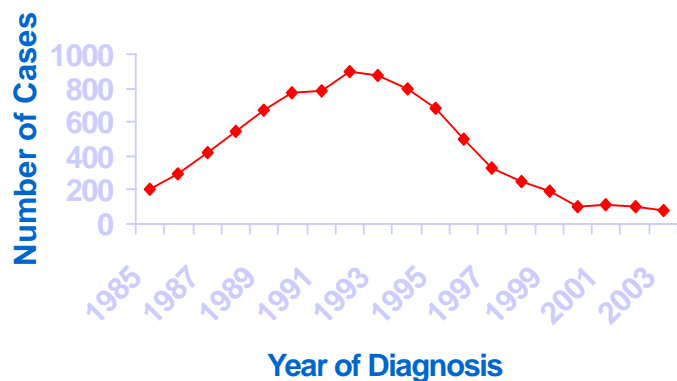
to let these people know their status immediately.

41% of HIV infections progress to full-blown AIDS within 1 year of a positive test. Generally people have been infected 12-15 years before AIDS develops. The whole Ryan White HIV Care system is based on early intervention and treatment. A diagnosis of AIDS within one year means we are failing to detect infections early.

Current testing practices resulted in 29% of patients with HIV infection being unaware of their disease status until their first opportunistic infection, which means they show up in the office or the hospital with Pneumocystis or Cryptococcosis or Histoplasmosis and all those things that are very difficult to treat. Treatment with HAAART works best when started in someone with a CD4 count of 250-350. If you have someone already sick with AIDS that means that their CD4 count is under 200 and you will probably never reconstitute their immune system in the same way that you can reconstitute it in somebody that you can find earlier.

One of the true successes in HIV medicine in the last 10 years is the decrease in perinatal transmission. In 1994, ACT076 results demonstrated that the first protocol that showed that prophylaxis with AZT in pregnant women decreased perinatal transmission by two thirds. This became the standard of care and we became very aggressive, doing triple drug combo during 1995 and 1996 and as a result, in 2005 transmission has decreased to the point that we have few HIV-positive children born to HIV-infected mothers who know their status and are given treatment before and during delivery, and to the baby for 6 weeks after delivery. This shows what HIV testing and medical management can accomplish. This is the model we are going to try to use now to get those other 300,000 people who are unidentified positives tested and to know their status.

Estimated Number of Perinatally Acquired AIDS Cases, by Year of Diagnosis, 1985-2003 -- US



So when is a rapid HIV test indicated? It is indicated in obstetrics for all pregnant women, in PEP work to determine if post-exposure prophylaxis is needed, in urgent care clinics, in public health care settings, in developing countries and, especially, the primary care office. Rapid testing helps prevent transmission to newborns, avoid unnecessary treatment following accidental exposure, reduce hospital stays, and allow for testing of at-risk individuals who may present only to the Emergency Room or STD clinic.

Let's examine conventional vs. rapid testing. The standard EIA is done on plasma, serum, urine or oral fluid with results typically available



within 3-4 days, so you prepare the patient to return for their results after enough time to obtain a confirmatory test, if needed. If negative, it is definitive, unless testing occurs during the window period. The window period is defined as being 6 months from point of infection to a positive test.

Rapid testing is done on plasma, serum, or oral fluid and is comparable to the EIA with results in 10-20 minutes depending on the brand of test utilized. The window period is still there and we still do the Western Blot for confirmation. One caveat, if you get a positive rapid test, do NOT go back and do a standard EIA as you might get a false negative EIA. The rapid test is more sensitive. If you have a positive rapid test you send it for whatever confirmatory test your lab does (IFA or Western Blot.)

Developing countries are probably ahead of us by doing two rapid tests to confirm HIV positivity. The specificity and sensitivity is equal to that of the standard EIA and Western Blot and that is what the World Health Organization now recommends.

Some say that conventional testing has the advantage that by the time you tell someone their results, you can already have the Western Blot. The true disadvantage to this system is that you lose people to care and they don't come back for the test results.

Considerations in selecting a rapid HIV test include cost, ease of use, sensitivity and specificity. We feel that the one we have chosen (OraQuick® Advance™, OraSure Technologies, Bethlehem, PA) provides the easiest format for use, is accurate and available at a reasonable cost. It picks up both HIV-1 (the most predominant strain in the United States) and HIV-2 (from Western Africa and growing in the US due to African immigration). Although the system we use is can be performed with saliva, we continue to do a finger stick as the sensitivity and specificity may be more reliable.\* However, some community based services are unable to handle hazardous waste but are able to do the oral fluid testing. The option of testing with oral fluid has made it possible to take testing into places (health fairs, bars, community programs) that other-

wise would not be able to offer testing due to the inability to handle hazardous waste.

*Editor's Note:* On December 16, 2005, the CDC issued an MMWR Dispatch regarding recent reports of a higher than expected number of false positive test results in certain geographic areas using the oral fluid rapid test for HIV. The CDC, in cooperation with the FDA, reminds users of rapid HIV tests that all preliminary positive test results must be confirmed with additional more specific tests. There was no observed increase in false positives when whole blood specimens were tested. See <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm54d1216a.htm>.

Though the test takes 20 minutes to accurately read, the results almost always start to develop within the first few minutes. Although we cannot deliver the results for the full length of time, we can direct our counseling toward the expected result while we are sitting there talking to the patient. You can do a lot with a captive audience for 20 minutes. My Case Manager sets the

test it so that it faces away from the client and so that she can read the results as they are developing. While she is talking she is then able to direct the conversation so that if it looks like it is going to be positive, she starts the "we will take good care of you if you are positive, it is not a death sentence, there is a lot we can do, the important thing is that you know your status in order to get care and to protect others" speech. If it looks like it is going to be negative, she starts the "if you are negative" approach ("even if you are negative now you need to understand that this does not mean that you cannot get it, there are the things you can do to protect yourself and we will make sure you have information regarding self-protection.")

In my practice, if the testing results are positive, the patient is immediately asked if they want to be in care. The Case Manager takes them around to the front desk, checks them in as a new patient and the first provider available sees them. So they can go from knowing they are positive to an appointment with an experienced HIV provider within about an hour. We provide education, connect them with services, draw blood for confirmatory testing, do a CD4 count, a viral load—all of the standard testing that we need to do. We have very



good luck maintaining our patients in care with this system. It has been shown that the longer a person waits from being told they are positive to getting to see a provider, the less likely they will ever show up for that provider's evaluation.

Any office lab that does strep screens, pregnancy tests and blood glucose levels can do this test just as easily. And though everyone worries about time constraints in all health care settings, the routinizing of HIV testing and the ability to do the rapid, waived test will allow us to identify and care for the 300,000 in our country that are going without care and likely contributing to the spread of this disease. Rapid HIV testing is the "waive" of the future. It is in the best interests of our patients and our communities for all to know their HIV status.

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## Regulatory Update

Both the FDA and CDC have recently published documents which have implications for physician office laboratories performing waived testing.

The first appeared on September 9, 2005 and is entitled *Draft Guidance for Industry & FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) Waiver Applications*. This document, which includes key recommendations from CLIAAC, is designed to ensure that future tests meet the criteria for waiver testing as specified by CLIA'88. The FDA has the authority to determine if a new test meets the conditions for waiver, i.e., "simple" and having "insignificant risk of erroneous results."

Although this publication is directed towards diagnostic test manufacturers, the recommendations it contains may impact the way new waiver tests will be presented to the end-user in the laboratory. The Guidance encourages, but does not require, the manufacturers to:

- Develop training and education programs, including innovative methods such as online courses.
- Provide more precise language regarding frequency and performance of quality control procedures.
- Provide "quick reference" materials for use at the bench in the form of laminated procedure cards or wall charts.
- Use easy-to-understand language in product inserts, technical information, and quick-reference materials.
- Conduct hazard analysis and risk assessment under "real-world" situations when preparing to release a new product.

- Incorporate “fail-safe” mechanisms in their products based on the results of the risk assessment.

The goal of these recommendations is to strengthen and improve the quality of waived testing. This goal is shared by the CDC who released *Good Laboratory Practices for Waived Testing Sites* on November 11, 2005 in *Morbidity & Mortality Weekly Review*. These guidelines were developed in response to a five-year study conducted by CMS and the CDC which raised concerns about the quality of testing in Certificate of Waiver (CW) laboratories. They identified high personnel turnover and inadequate training as the root cause of most quality issues in the CW laboratory.

The MMWR publication summarized the results of this study and presents CLIAC recommendations for Good Laboratory Practices which address these issues.

The new recommendations are designed to follow the flow of testing. Good Laboratory Practice begins with the decision to perform waived testing or to introduce a new waived test. Considerations in this decision include:

- Who will be responsible for testing oversight and are they properly trained?
- Is the lab prepared to meet all state, federal, and local regulations?
- What are the safety issues for both patients and testing personnel?
- Is the physical space adequate?
- What is the cost of offering the test in relation to the benefit in patient care?
- Are there sufficient personnel with adequate training to perform the test? How will it impact current workflow?
- How will records and documentation be recorded and maintained?

The next stage of laboratory practice occurs prior to actual testing in the pre-analytical phase. Good laboratory practice in this area includes:

- Confirmation of test orders
- Patient identification
- Patient preparation and pretest information

- Procedures for specimen collection and handling, including labeling
- Preparation of test area and materials, including temperature checks, instrument calibration, reagent preparation, checking expiration dates, visually examining reagents or test kits for signs of deterioration.

During the testing phase, additional recommendations are given in the document for:

- quality control (frequency and corrective action),
- test performance,
- interpretation,
- results, and
- problem resolution.

Finally, Good Laboratory Practice includes aspects of post-testing. These consist of:

- reporting test results,
- confirmatory testing,
- record keeping, and
- internal/external quality assessment.

Although both the CDC and FDA publications are recommendations without the force of law to support them, the guidelines contained in each are expected to become increasingly incorporated into the procedures of both manufacturers and laboratorians. As a result, the quality of testing results is also expected to continue to improve.

Sources:

1. Lusky, K., *Righting the Waives*, [CAP Today](#), November 2005, pp. 66-74.
2. US Dept. of Health & Human Services, FDA, Center for Devices & Radiological Health, Office of *In Vitro* Diagnostic Device Evaluation & Safety, *Draft Guidance for Industry & FDA Staff: Recommendations for Clinical Laboratory Improvements Amendments of 1988 (CLIA '88) Waiver Applications*, September 5, 2005
3. US Dept. of Health & Human Services, Centers for Disease Control & Prevention, *Good Laboratory Practices for Waived Testing Sites*, [Morbidity & Mortality Weekly Rep.](#), November 11, 2005, Vol.54, No. RR-13.
4. <http://www.fda.gov/cdrh/oivd/guidance/1171.pdf>



## 2006-A CME Questions

The material necessary to review to answer the following questions may be found in this issue of the *P.O.L. Insight* and the *AAFP-PT Handbook* or on the AAFP-PT website (<http://www.aafp.org/pt> and click on Continuing Medical Education). The Test Sheet may be found on page 16 of the *P.O.L. Insight*. The Accreditation information may be found on the inside cover of this issue.

1. True or False: CLIA '88 requirements were revised in 2003 to reflect an emphasis on quality as it related to the flow of the specimen through the laboratory.
  - A. True
  - B. False
2. Total Quality Management consists of:
  - A. Quality Control
  - B. Quality Assessment
  - C. Quality Systems
  - D. All of the above
3. True or False: The objective of TQM is cost savings.
  - A. True
  - B. False
4. True or False: Laboratories successful at quality management will begin to see operating excellence and efficiency.
  - A. True
  - B. False
5. In 1999, medical errors were the \_\_\_\_ leading cause of death in the US.
  - A. 2nd
  - B. 4th
  - C. 8th
  - D. 15th
6. True or False: "Tracer methodology" is designed to evaluate a laboratory's overall operations.
  - A. True
  - B. False
7. True or False: Quality Control and Quality Assessment are the same thing.
  - A. True
  - B. False
8. True or False: "Total testing process" only refers to the analytic phase of laboratory testing.
  - A. True
  - B. False
9. True or False: The progress of a specimen through each phase of testing in the lab is called the "Path of Workflow."
  - A. True
  - B. False
10. Proficiency testing is a component of:
  - A. General Laboratory Systems
  - B. Pre-analytic phase
  - C. Analytic phase
  - D. Post-analytic phase
11. Procedure manuals, test systems, and instrument maintenance are all part of:
  - A. General Laboratory Systems
  - B. Pre-analytic phase
  - C. Analytic phase
  - D. Post-analytic phase

12. True or False: An important characteristic of QMS is that all activities are documented, scheduled, communicated, and monitored.
  - A. True
  - B. False
13. True or False: "Quality System Essentials (QSEs) are indicators used to monitor a sample's progress through the workflow path.
  - A. True
  - B. False
14. Recommendations for HIV testing have not changed in the U.S. since:
  - A. 1986
  - B. 1989
  - C. 1993
  - D. 2002
15. How many individuals with HIV are currently unaware of their positive serostatus?
  - A. 3,000
  - B. 30,000
  - C. 300
  - D. 300,000
16. What percentage of HIV positive results are never reported to the patient?
  - A. 10%
  - B. 31%
  - C. 50%
  - D. 5%
17. True or False: AIDS typically develops in individuals who have been infected with HIV for 12-15 years.
  - A. True
  - B. False
18. Treatment is most effective in individuals whose CD4 count is:
  - A. Under 100
  - B. Under 200
  - C. 250-350
  - D. Does not matter
19. True or False: Treatment of pregnant women and newborns has not been very effective in preventing HIV transmission.
  - A. True
  - B. False
20. Rapid HIV testing is indicated in:
  - A. Obstetrics
  - B. Urgent care
  - C. Primary care
  - D. All of the above
21. Conventional HIV testing provides results in:
  - A. 20 minutes
  - B. 4-6 hours
  - C. 24 hours
  - D. 3-4 days
22. True or False: The "window period" for HIV infection is 6 months.
  - A. True
  - B. False
23. True or False: Rapid HIV testing can be performed on oral fluid only.
  - A. True
  - B. False



24. True or False: Rapid HIV provides results within 10-20 minutes.
  - A. True
  - B. False
25. True or False: You should confirm a positive rapid HIV test using the EIA method.
  - A. True
  - B. False
26. You should confirm a positive rapid HIV test result by:
  - A. IFA
  - B. Western Blot
  - C. Either "a" or "b"
  - D. None of the above
27. True or False: The advantage to conventional HIV testing is that it allows for test confirmation before giving the results to the patient.
  - A. True
  - B. False
28. True or False: Many patients never return to get their results and are lost to care.
  - A. True
  - B. False
29. True or False: The HIV-2 strain is growing in the U.S. due to African immigration.
  - A. True
  - B. False
30. True or False: The 20 minute incubation time is not a good time to begin counseling patients.
  - A. True
  - B. False
31. Who decides if a test meets the criteria for being "waived"?
  - A. CDC
  - B. FDA
  - C. CMS
  - D. The manufacturer
32. The *Draft Guidance* document recommends that test manufacturers:
  - A. Develop training & education programs for users
  - B. Provide more precise instructions regarding quality control frequency and performance
  - C. Incorporate "fail-safe" mechanisms in their products
  - D. All of the above
33. True or False: High personnel turnover and inadequate training are the root causes of most quality issues in the Certificate of Waiver lab.
  - A. True
  - B. False
34. True or False: Good Laboratory Practice begins with the decision to performed waived testing or to introduce a new waived test.
  - A. True
  - B. False
35. True or False: The goal of the FDA and CDC recommendations is to strengthen and improve the quality of waived testing.
  - A. True
  - B. False



# AAFP-PT CME Test Answer Sheet

ALL INFORMATION MUST BE COMPLETED TO OBTAIN CREDIT

**2006-A** (submit by February 28, 2007 to obtain credit)

Fill in the circles for the correct answers:

**Please print:**

**Individual AAFP #:** \_\_\_\_\_

*(All participants in the AAFP-PT are now assigned a 7-digit AAFP number; AAFP-member physicians should use their AAFP-Id number; non-member physicians and laboratory personnel are assigned an Id number the first time CME is submitted)*

**Lab AAFP #:** \_\_\_\_\_

*(All labs enrolled in AAFP-PT are assigned a 7-digit AAFP number. The Lab Id number may be found on the Order Confirmation and on evaluations.)*

\_\_\_\_\_  
Name (Last) (First) (Initial)

\_\_\_\_\_  
Street

\_\_\_\_\_  
City / State/ Zip Code

\_\_\_\_\_  
Fax Number

Address or Fax change       Name change

**Select one if you are a physician:**

- FP                       IM  
 PED                     OB/GYN  
 Other

**Select one if you are laboratory personnel:**

- MT                     MLT                     Nurse Practitioner  
 RN                     LPN                     Physician Assistant  
 Med. Assist.            Laboratory Manager  
 Laboratory Consultant  Other

	<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>
1.	○	○	○	○
2.	○	○	○	○
3.	○	○	○	○
4.	○	○	○	○
5.	○	○	○	○
6.	○	○	○	○
7.	○	○	○	○
8.	○	○	○	○
9.	○	○	○	○
10.	○	○	○	○
11.	○	○	○	○
12.	○	○	○	○
13.	○	○	○	○
14.	○	○	○	○
15.	○	○	○	○
16.	○	○	○	○
17.	○	○	○	○
18.	○	○	○	○
19.	○	○	○	○
20.	○	○	○	○
21.	○	○	○	○
22.	○	○	○	○
23.	○	○	○	○
24.	○	○	○	○
25.	○	○	○	○
26.	○	○	○	○
27.	○	○	○	○
28.	○	○	○	○
29.	○	○	○	○
30.	○	○	○	○
31.	○	○	○	○
32.	○	○	○	○
33.	○	○	○	○
34.	○	○	○	○
35.	○	○	○	○

**Evaluation:** please fill in bubble between 1 & 5 – 1 denotes poor, 5 denotes excellent:

1. To what extent were the objectives achieved?  
*poor*      ①      ②      ③      ④      ⑤      *excellent*
2. To what extent did the AAFP-PT education program *content* relate to the program's objectives?  
*poor*      ①      ②      ③      ④      ⑤      *excellent*
3. Rate your overall degree of satisfaction with this education program.  
*poor*      ①      ②      ③      ④      ⑤      *excellent*
4. In what general area of laboratory practice would you like to receive educational materials? (please mark all that apply).
  - CLIA and/or regulatory. requirements
  - Good laboratory practices
  - Test Procedures
  - Technical Subjects
  - Business/Financial Aspects
  - Other, please specify \_\_\_\_\_



Return to: AAFP-PT Education Program  
 11400 Tomahawk Creek Parkway  
 Leawood, KS 66211-2672  
 or Fax to 913-906-6079

**Important:** Keep a copy of the completed form for your records. Documentation of CME hours earned is mailed to lab personnel in July and January. Allow 7-10 business days for requested transcripts.