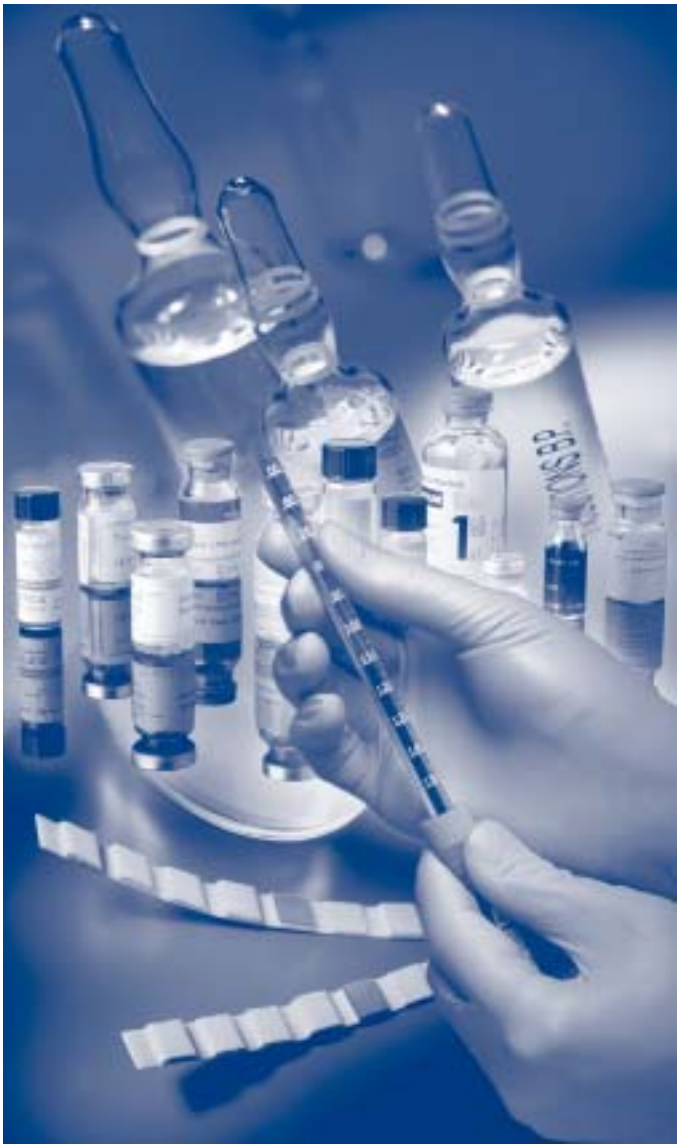
P.O.L. INSIGHT

A Continuing Education Publication for the Physician Office Laboratory

Event 2005-A
Issue 42



Issue Features

AAFPPT
The Physician's Proficiency Testing Program

Accreditation Statements

AAFP Physician's Proficiency Testing Program has been reviewed and is acceptable for up to 12 Prescribed credits by the American Academy of Family Physicians. Term of approval covers three events offered within one year from the beginning distribution date of March 2005. This event has been approved for 4 Prescribed credits. Credit may be claimed for one year from the date of this event.

The American Academy of Family Physicians is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

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The PT Department is staffed from 8:30 AM to 5:00 PM, CST. Please feel free to call us during these hours . . . or use our voice mail system and we will gladly return your call . . . or send one of us an e-mail !

Table Of Contents

2005-A CME Answers

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

CME Learning Objectives

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

1. To implement the CLSI standards for selection of appropriate antimicrobials for urine susceptibility testing.

2. To discuss the process by which a lab's proficiency testing results are evaluated and graded and discuss various related technical issues.

3. To discuss actions or steps labs can take to ensure successful proficiency testing performance.

To earn the CME, answer the questions included with this issue of the *Insight*, using the form included, or submit the test online at **www.aafp.org/pt** – click on Continuing Medical Education

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P.A.C.E.® Due Dates and Course Codes

Event 2004-B ..... May 31, 2005 254-002-04
Event 2004-C ..... September 30, 2005 254-003-04
Event 2005-A ..... February 28, 2006 254-001-05

Urine Susceptibility Antimicrobials

Editor's Note: The Centers for Medicare and Medicaid Services (CMS) has requested all PT programs offering bacteriology susceptibility testing to include educational material discussing antimicrobial agent selection and testing. Further, during 2005, PT programs have been instructed to identify the antimicrobial agents a laboratory tests or reports that are inappropriate by CLSI guidelines, but are not to penalize the laboratory. Beginning in 2006, inappropriate drug choices will be graded as incorrect results.

By Cynthia Kaufman, M.S., MT(ASCP)SM and Linda Marler, M.S., MT(ASCP)SM

Urinary tract infections are among the most common ailments encountered in office practice. Almost fifty percent of women experience a urinary tract infection in their lifetime, most having at least one infection by 24 years of age. Urinary tract infections are caused by a variety of bacteria that cause bacteriuria at levels most often greater than or equal to 10^5 colony-forming units of bacteria/ml of urine. The vast majority of uncomplicated urinary tract infections are caused by the Gram-negative bacillus *Escherichia coli.* Other Gram-negative bacilli causing urinary tract infections include *Klebsiella* species, *Proteus mirabilis* and *Pseudomonas aeruginosa.* Gram-positive bacteria responsible for urinary tract infections include *Staphylococcus saprophyticus, Enterococcus* species and *Staphylococcus aureus.* Treatment of urinary tract infections has been complicated by the ability of these organisms to develop resistance to common first-line antimicrobials. Empirical antimicrobial therapy has changed considerably over the past twenty years due to the increase in various resistance mechanisms by these bacteria. Results from susceptibility tests and surveillance of this data, available on regional, national and global levels and from testing institutions, should be used to guide therapy.

Clinical laboratories have a responsibility to establish standard batteries of antimicrobial agents to be tested on clinical isolates belonging to various organism groups. The choice should not be made based upon the laboratory's perspective alone. Consultations with infectious disease and infection control practitioners, pharmacists and medical therapeutics committee members are suggested to assist the laboratory in determining which agents to test and report. One of the most important principles in the selection process is to test and report antimicrobial agents that physicians prescribe from the institution's formulary, thereby ensuring that drugs tested will be those the physicians most often prescribe to patients. The goal in establishing test batteries is to provide clinically relevant information to aid the selection of the most cost efficient antimicrobial agents. The following resources serve as guides to assist the laboratory in these complex decision making procedures:

- Table 1 in Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) documents M7-A6 and M2-A8 titled *Suggested groupings of U.S. FDA-Approved Antimicrobial Agents That Should Be Considered for Routine Testing and Reporting on Nonfastidious Organisms by Clinical Microbiology Laboratories*
- *The Choice of Antibacterial Drugs* in The Medical Letter
- The Sanford Guide to Antimicrobial Therapy.

After the laboratory has determined the actual drugs on the formulary, they can focus on the resources available to them. The laboratory must select a type of susceptibility test system after taking into consideration the number of drugs available in the system. It must then be established which drugs are to be tested and reported. There is no one test system that accurately detects all the known mechanisms of resistance, as the various susceptibility testing methods (disk diffusion, broth microdilution, antibiotic gradient testing, or automation) all have limitations in their ability to detect resistance in specific organisms. More than one test method may be needed when testing for vancomycin-resistant *Enterococcus* species, methicillin-resistant staphylococci, and extended-spectrum beta-lactamase production in *Enterobacteriaceae*.

Routine testing batteries need to be defined for gram-negative bacilli (*Enterobacteriaceae),* gram-positive cocci (*Staphylococcus* species and *Enterococcus* species), and *Pseudomonas* species, as well as additional testing for very resistant isolates (specifically urine isolates). Table 1 of the CLSI document M100-S15 lists antimicrobial agents in:

- Group A - recommended for primary testing and reporting.
- Group B - reported selectively, such as when an organism is resistant to an agent of the same class in Group A.
- Group C - alternative antimicrobial agents for testing multi-resistant organisms or for treatment of patients with allergies to primary drugs.
- Group O – agents that have clinical indication for the organism group but are generally not

candidates for routine testing and reporting in the United States.

- Group U - agents that are used solely in the treatment of urinary tract infections. Group U agents should not be reported on organisms isolated from sites other than the urinary tract.

Each of the antimicrobial agent groupings is further divided in specific groups of organisms, namely, *Enterobacteriaceae, Pseudomonas aeruginosa, Staphylococcus* species, and *Enterococcus* species.

Selection of antimicrobial agents for routine testing batteries also involves assessing the availability of certain antimicrobial agents for the test method chosen by the laboratory. Disk diffusion methods offer great flexibility, as many agents are available in disk form. A maximum of twelve agents can be tested on a 150 mm Mueller-Hinton agar plate. Commercially prepared microdilution trays can contain up to 29 antimicrobial agents and often use antimicrobial concentrations equivalent to categorical breakpoints recommended in the CLSI interpretive criteria documents. Automated systems typically have various panels available, or a laboratory can have custom panels built for a significant cost.

The following are example antimicrobial batteries that may be used for testing and reporting on the more common urinary tract pathogens. Each selection requires periodic review as new antimicrobial agents are developed. The Infectious Diseases Society of America (IDSA) has recommended that regions establish rates of resistance in urinary tract pathogens and that the standard empiric therapy for treatment of these pathogens be reviewed periodically due to emerging resistance patterns.

Urinary Pathogen	Antimicrobials
Staphylococcus species[2]	**A:** Oxacillin, Penicillin
	B: Clindamycin[1], Trimethoprim-Sulfamethoxazole, Vancomycin
	C: Chloramphenicol[5], Ciprofloxacin or Levofloxacin, Gentamicin, Ofloxacin, Tetracycline[3]
	O: Amikacin, Amoxicillin/Clavulanate, Ampicillin, Cefazolin, Ceftriaxone, Cefuroxime, Cefaclor, Cephalothin[4], Naficillin, Tobramycin, Doxycycline
	U: Lomefloxacin or Norfloxacin, Nitrofurantoin, Sulfisoxazole, Sulfonamides, Trimethoprim

Urinary Pathogen	Antimicrobials
Enterobacteriaceae Note: Many of the beta-lactam drugs have similar activity and the agents cannot be used reliably to predict activity of other beta-lactams. More agents need to be tested in this class of antimicrobials, as there is some overlap in activities; therefore, selection of beta-lactams should be chosen with the help of the aforementioned medical groups.	**A:** Ampicillin, Cefazolin, Cephalothin, Gentamicin
	B: Amikacin, Amoxicillin/Clavulanate, Cefuroxime, Ceftriaxone, Ciprofloxacin or Levofloxacin, Piperacillin and Ticarcillin, Trimethoprim-Sulfamethoxazole
	C: Ceftazidime, Chloramphenicol[5], Tetracycline, Tobramycin
	O: Cefaclor, Cefixime, Doxycycline, Nalidixic acid
	U: Carbenicillin and Lomefloxacin, Fosfomycin, Norfloxacin or Ofloxacin, Nitrofurantoin, Sulfisoxazole, Sulfonimides, Trimethoprim

Source: CLSI 15th Informational Supplement M100-S15.

[1] Clindamycin is a Group B Antimicrobial but is not routinely reported on urinary tract isolates.

[2]Routine testing of urine isolates of *S. saprophyticus* is not advised, because infections respond to concentrations achieved in urine of antimicrobial agents commonly used to treat acute, uncomplicated urinary tract infections (e.g., nitrofurantoin, trimthoprim+sulfamethoxazole or a fluoroquinoline)

[3]Organisms that are susceptible to tetracycline are also considered susceptible to doxycycline and minocycline. However, some organisms that are intermediate or resistant to tetracycline may be susceptible to doxycycline or minocycline or both.

[4]Cephalothin can be used to represent cephalothin, cephradine, cephalexin, cefaclor and cefadroxil. Cefazolin, cefuroxime, cefpodoxime, cefprozil and loracarbef (urinary isolates only) may be tested individually, because some isolates may be susceptible to these agents when resistant to cephalothin.

[5]Not routinely used for urinary tract isolates.

continued next page

Urinary Pathogen	Antimicrobials
Enterococcus species	**A:** Ampicillin or penicillin
	B: Vancomycin
	C: Chloramphenicol[5], Gentamicin, Tetracycline
	O: Doxycycline
	U: Ciprofloxacin/Levofloxacin/Norfloxacin, Fosfomycin, Nitrofurantoin

Urinary Pathogen	Antimicrobials
Pseudomonas aeruginosa Note: Pseudomonas requires a separate battery from other gram-negative organisms.	**A:** Ceftazidime, Gentamicin, Piperacillin and Ticarcillin
	B: Amikacin, Ciprofloxacin or Levofloxacin, Tobramycin
	U: Carbenicillin, Lomefloxacin, Norfloxacin or Ofloxacin

Consultation with infectious disease physicians, pharmacists, infection control practitioners and the pathology medical staff is essential in the routine and selective reporting of specific antimicrobial agents. The use of selective reporting greatly reduces the emergence of multi-resistant organisms by lessening the use of broad-spectrum drugs. Some examples of selective or cascade reporting include reporting a second-generation cephalosporin on *Enterobacteriaceae* if the isolate is resistant to a first-generation cephalosporin, or reporting tobramycin or amikacin on an isolate that is resistant to gentamicin. The laboratory should only report results for agents like nitrofurantoin or norfloxacin on isolates from the urinary tract. There are antimicrobial agents that are not suitable for treatment of infections caused by specific organisms, such as beta-lactams for methicillin-resistant staphylococci and cephalosporins, clindamycin, and trimethoprim-sulfamethoxazole for enterococci.

It is imperative that the microbiology laboratory provides the most accurate antimicrobial susceptibility test data possible by focusing on the detection of bacterial resistance. The selection of antimicrobial agents to test and report for urinary tract pathogens should not be made based upon the laboratory's perspective alone.

The Clinical and Laboratory Standards Institute (CLSI – formerly known as NCCLS) is a globally recognized voluntary consensus standards-developing organization that enhances the value of medical testing within the healthcare community through the development and dissemination of standards, guidelines, and best practices. The American Academy of Family Physicians is a member of CLSI.

For additional information on the Performance Standards for Antimicrobial Susceptibility Testing, 15th Informational Supplement, visit http://www.clsi.org/clsi/M100S15brochure.pdf.

Sources:

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9. http://www.cdc.gov/drugresistance/community (Centers for Disease Control and Prevention.)
10. http://www.cdc.gov/drugresistance/factsheets/index.htm (CDC antimicrobial susceptibility fact sheets)
11. http://cdc.gov/mmwr (Morbidity and Mortality Weekly Report)
12. http://www.idsociety.org/ (Infectious Diseases Society of America.

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Tips

Additional information on urine susceptibility testing may be found in the 2003-A issue of *P.O.L. Insight*.

Don't have access to infectious disease and infection control practitioners, pharmacists and medical therapeutics committee members in your POL? Consider seeking advice from the local hospital as well as reviewing the antimicrobials being prescribed by the physicians in the practice.

PT Evaluation Process

Proficiency testing (PT) events occur three times per year. Each event, AAFP-PT scans the Test Result Booklet pages and uploads online results submitted by participating labs. The data is compiled and peer group, method group and all method statistics are generated based upon:

- The peer (instrument/method), comparative method (like methods/technology) and all method groups (all labs reporting for the specimen and analyte) are formed.
- A data evaluation process (statistical analysis) is performed to calculate the quantitative statistics.
- The mean, median and coefficient of variation (CV) are evaluated and outliers are removed from the data. The mean and median are compared to "closeness" in value; the lower the CV, the more "precise" or less variable the data. As a rule, outliers are data points that are less than or greater than 3 standard deviations from the mean.
- The acceptable range (calculated based on the grading criteria established by the CLIA regulations) and the percent consensus (number of passing labs divided by the total number of labs multiplied by 100) are then calculated.

Quantitative Analytes

If a sufficient number of labs using the same method/instrument have reported results, then these labs are compared.

- If the peer group consensus is 80% or greater, the results are graded by the peer group statistics.
- If the peer group consensus is less than 80%, the results may be graded by either referee labs[1] or by all method statistics – provided that referee or all method statistics achieves 80% or greater consensus.
- If 80% or greater consensus is not achieved with peer, referee nor all method statistics, the results are not graded due to lack of consensus.

If an insufficient number of labs using the same method have reported results, the labs are compared with either comparative method (methods determined to have the same methodology or technology) or all method statistics.

- If the comparative method group consensus is 80% or greater, the results are graded by the comparative method statistics. If comparative method group consensus is less than 80%, the data is reviewed by the all method statistics.
- If the all method group consensus is 80% or greater, the results are graded by the all method statistics unless it is determined that the peer group values vary excessively from the all method values.
- If no comparative method group can be established and the all method group consensus is less than 80% and, the results will not be graded due to lack of consensus.

If there is not a sufficient number of labs reporting at all method, the results are not graded due to no comparison group.

[1]**Referee laboratory** means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty. (42 CFR Part 493)

Qualitative Analytes

- If the total analyte consensus is 80% or greater, the results are evaluated.
- If the total analyte consensus is less than 80%, referee labs are selected. If the referee consensus is 80% or greater, results are evaluated. If the referee consensus is less than 80%, the results will not be graded due to lack of referee consensus.
- Blood bank testing requires a 95% or greater consensus of all participants or 100% of 10 or more referees in order to be graded.

Miscellaneous Grading Situations

Occasionally, the AAFP-PT Advisory Committee determines that a particular specimen or analyte should not be graded following review of the results. Reasons may include documented specimen problems, result variance and invalid results. The evaluation clearly states the reason for not grading a specimen.

Grading Definitions

All Method Statistics – The combined statistics for all labs reporting for the specimen and analyte.

Peer Group Statistics – The combined statistics for labs reporting with the same methodology/ instrument.

Comparative Method (Method Group) Statistics – The combined statistics for labs reporting with like methods/instruments.

Not Graded / Lack of Consensus – Less than 80% of participants in the peer group reporting results for the analyte are within the established acceptable range.

Not Graded / No Comparison Group Found – An insufficient number of laboratories in peer group. Unable to establish a scientifically defensible statistical range for evaluation as defined by CLIA. (Unable to grade by using neither comparative method nor all method statistics).

Not Graded / Lack of Referee Consensus – Less than 80% of referees reporting results for the analyte are within the established acceptable range.

Not Graded / Specimen Problem / Unable to obtain result – Laboratory indicated specimen problem. This typically occurs when the lab is unable to obtain results for the specimen due to specimen performance and no replacement specimens are available.

Not Graded / Excessive Variability Data – The coefficient of variation (CV) is a tool used to express precision of the determination. Precision is a measure of random variability and is defined as the reproducibility of a laboratory determination when it is run repeatedly under similar conditions. An extremely high CV indicates lack of precision and may occur when outliers are included in the statistical calculations. Excessive result variability is also observed when there is a significant difference between the mean and the median indicating no distinct target value. The CV is calculated:

$$\frac{\text{Standard Deviation}}{\text{Mean}} \times 100$$

Not Graded / Exclusion Requested – The lab is unable to report both patient and proficiency testing results during testing period. An exclusion may be granted if the laboratory meets the requirements in 493.823 (b):

1. "Patient testing was suspended during the time frame allotted for testing and reporting PT results, and
2. The laboratory notifies the inspecting agency and the PT program within the time frame for submitting PT results of the suspension of patient testing and the circumstances associated with failure to perform the tests on PT specimens, and
3. The laboratory participated in the previous two PT events."

Referee Grading Used – Grading for a particular specimen is determined by a select group of participating labs (referee labs). The consensus of the referee group must be 80% or higher.

Fail / No Results Received – The laboratory failed to report results for an analyte or module in which they have enrolled.

At Risk Notation on Evaluation - When you are at risk of being unsuccessful, one of the following three warning statements appear on the evaluation under the Comments section of the CMS Performance Summary:

[1] At Risk
The lab is at risk of being unsuccessful for the next testing event. This is listed on the evaluation if the lab's performance is satisfactory on the current testing event, but was unsatisfactory on the previous testing event.

[2] At Risk
The lab is at risk of being unsuccessful for the next two testing events. This is listed on the evaluation if the lab's performance is unsatisfactory for the current testing event. The lab must perform satisfactorily for the next two testing events.

[3] At Risk
The lab's current proficiency testing status is unsuccessful. This is listed on the evaluation if the lab's performance has been unsatisfactory for at least two out of the last three testing events.

Statistics Terminology

Fundamental to the review and analysis of quality control and proficiency testing results is the understanding of the following terminology.

- **Accuracy -** The correctness of a result or the freedom from error. The accuracy of a method may be obtained by comparing the lab's results to results accepted as correct or by comparing them with those from another laboratory. Split specimen testing is based on the comparison of results from two laboratories.
- **Coefficient of Variation (CV) –** A measure of relative precision. The CV is determined by dividing the standard deviation by the mean and multiplying by 100.
- **Linearity –** The measure of the range of concentration of an analyte over which a test produces consistent and accurate results. Many instruments are programmed to contain its linearity information so that out of range results are not reported.
- **Mean –** The arithmetical average of a set of numbers.
- **Median –** a value in an ordered set of values below and above which there is an equal number of values or which is the arithmetic mean of the two middle values if there is no one middle number
- **Outliers –** The extremely abnormal results that are eliminated from the statistical data to eliminate the values from skewing the data.
- **Precision** or **reproducibility –** The measure of the closeness of the results obtained when measuring the same specimen more than once.
- **Sensitivity –** The ability of a test to give a positive result for patients that have the condition for which they are being tested expressed in percent.
- **Specificity –** The ability of a test to give a negative result for patients that do not have the condition for which they are being tested expressed percent.
- **Standard Deviation (SD) –** The difference between an individual value and the arithmetic mean.
- **Standard Deviation Interval (SDI) –** The difference between the result and the group mean. This is expressed as a positive or negative value indicating whether the result is above or below the mean.

Evaluation Criteria - Non-Waived Testing:

Hematology/Coagulation

Erythrocyte count	Target +/-6%
Hematocrit (Excluding spun hematocrits)	Target +/-6%
Hemoglobin	Target +/-7%
Leukocyte (WBC) count	Target +/-15%
Platelet count	Target +/-25%
Prothrombin time	Target +/-15%

Chemistry

Alanine aminotransferase (ALT/SGPT)	Target value ±20%
Albumin	Target value ±10%
Alkaline phosphatase	Target value ±30%
Aspartate aminotransferase (AST/SGOT)	Target value ±20%
Bilirubin, total	Target value ±0.4 mg/dL or ±20% (greater)
Cholesterol, total	Target value ±10%
Cholesterol, high density lipoprotein	Target value ±30%
Creatinine	Target value ±0.3 mg/dL or ±15% (greater)
Glucose	Target value ±6 mg/dl or ±10% (greater)
Total Protein	Target value ±10%
Triglycerides	Target value ±25%
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater)
Uric acid	Target value ±17%

Endocrinology

T3 Uptake	Target value +/-3 SD
Triiodothyronine	Target value +/-3 SD
Thyroidstimulating hormone	Target value +/-3 SD
Thyroxine	Target value +/-20% or 1.0 mcg/dL (greater)

Tips for Successful PT

Using "Other" Method

It is critical that the "Other" instrument/method only be used if the lab's method/instrument is not listed. Personnel should carefully review the list – the methods/instruments are listed in alphabetic order by the manufacturer name and then the kit/instrument name. Methods and instruments commonly used in most laboratories have been included; methods are listed in alphabetic order – by the manufacturer name and then the product name.

Using the "Other" option has impact on the evaluation process. First, it is not possible to include the results within the peer group and/or comparative method statistics; the lab is automatically graded to the all method statistics and, in some cases, it can lead to an insufficient number of labs graded to the peer group or comparative method group. Some modules contain both waived and moderately complex methods (e.g., Rapid Strep and Infectious Mononucleosis); "Other" methods are reported on the CMS Summary and the results are submitted to CMS.

If after reviewing the list and contacting AAFP-PT, the lab's method/instrument is determined to not be on the list, please clearly mark the "Other" option and list the test method next to the "Other" notation. Please complete the "Other Reporting Methods" form found on page 83 of the test result booklet. Please fax this form to AAFP-PT; it is not necessary to send it with your results. AAFP-PT will make every effort to add your method to the next event Test Result Booklet.

Units of Measure

When completing the Test Result Booklet/Web Data Entry System (WDES) form, verify that the recorded result is in the unit of measure provided. A frequent cause of error is recording the absolute number (#) for an automated differential instead of the percentage (%). Not only does this lead to the participant's failure, it can also lead to an insufficient number of labs in the peer group or comparative method group resulting in a "Not Graded" situation for all participants.

The units of measure found in the Test Result Booklet/WDES form are those which are the most common in the clinical laboratory setting. If a result conversion is necessary, a helpful Web site for performing conversions is http://www.onlineconversion.com/weight_all.htm.

Clerical Errors

The most common reason for proficiency testing failures is a clerical error. Examples of clerical errors include:

- Writing one number but filling in a bubble for a different number.
- Writing in the numbers for the results but not filling in the bubble.
- Adding a decimal point where one is not provided in the Test Result Booklet.
- Failing to include a method or kit.
- Reporting absolute numbers on an automated differential instead of the percentage.
- Filling in results in a module in which the lab is not enrolled.

Completing the Test Result Booklet

Carefully review the results recorded in the TRB/WDES form - looking for clerical errors. As an approved proficiency testing provider, AAFP-PT cannot correct clerical errors made by participants.

When all results have been recorded and reviewed, the lab director and testing personnel sign the Attestation Statement on the front page of the TRB. Also include the date the testing was completed. When submitting results through the WDES, it is not necessary to send the Attestation Statement to AAFP-PT; file it with the lab's other proficiency testing records.

Do not make any extraneous marks or notes in the TRB – this can lead to scanning errors. Should you need to include additional information about your results, please complete the "Comment" form on page 84 of the TRB. Please fax this form to AAFP-PT; it is not necessary to send it with your results.

Make copies of all completed pages for your records including the front page. Keep the copies in your proficiency testing files. You should also keep all instrument printouts with your proficiency testing records – do not send printouts to AAFP-PT. Under CLIA, the lab is required to keep the printouts for two years.

Mail your results on or before the results due date that is found on the 2005 shipping calendar. **Late test results cannot be accepted under any circumstances.**

Lab Update

News on Waived Testing

Officials from the Centers for Medicare and Medicaid Services (CMS) provided a status report on CLIA Waived labs at the September 2004 CLIAC meeting. Findings of continued quality problems led CLIAC to establish a workgroup on good laboratory practices for waived testing; the workgroup is to report back at the February 2005 CLIAC meeting. CMS inspected 897 waived labs (45% in POLS and 12% in nursing homes) in 2002 and 1756 in 2003.

The 2002 surveys findings include:

- 44% had new testing personnel
- 8% tested beyond the scope of the waiver certificate
- 14% lacked current manufacturer instructions
- 24% did not perform quality control as required by the manufacturer
- 13% used the wrong units in reporting test results
- 7% did not use the proper expiration data for their storage method
- Two labs put their beneficiaries in immediate jeopardy

The preliminary results of the 2003 survey had similar findings. In December 2004, CMS decided to continue surveying a percentage of waived labs for two more years. CMS conducts the survey which is intended to be educational and information-gathering in nature; CMS does follow-up on any quality problems.

According to CMS, the most commonly performed waived tests include glucose, dipstick urinalysis, fecal occult blood, urine pregnancy and Group A Strep antigen.

See the 2004-B P.O.L. Insight for continuing education on fecal occult blood testing. AAFP-PT will be publishing two articles on dipstick urinalysis testing in 2005.

Sources:
http://www.phppo.cdc.gov/cliac/pdf/addenda/cliac0904/Addendum_F.pdf
National Intelligence Report, October 11, 2004
National Intelligence Report, January 10, 2005

Surveying Agencies to Share Inspection Findings

While details have not yet been made public, representatives from Federal and state agencies that regulate laboratories and representatives from private accrediting agencies have met to discuss sharing information about the labs they survey. This came about when a lack of coordination was discovered in response to allegations of quality issues in a Maryland hospital. In this case, the state was aware of the allegations but did not provide the information to the private accrediting agency.

Source:
National Intelligence Report, December 16, 2004

New Medicare Benefits for Screening Tests

Cardiovascular disease and diabetes screening tests are now covered by Medicare under certain conditions. The cardiovascular disease tests, including total cholesterol, HDL cholesterol and triglycerides, will be covered every five years. Diabetes screening tests include blood glucose, post glucose dose and glucose tolerance. Coverage is limited to once a year for at risk beneficiaries and who either have never been tested for it or were tested and found not to have either diabetes or pre-diabetes. More frequent coverage (twice a year) is allowed for beneficiaries diagnosed with pre-diabetes. CMS defines at risk if the beneficiary has hypertension, dyslipidemia, obesity or previously identified elevated impaired fasting glucose or glucose tolerance. Further, the beneficiary is considered at risk if at least two of the following are present: overweight, a family history of diabetes, age 65 or older or a history of gestational diabetes mellitus or delivering a baby weighing more than nine pounds.

CPT and ICD-9 Codes include:

Cardiovascular Disease
ICD-9 codes: V81.0, V81.1, V81.2
CPT codes: 82465 (Cholesterol, total), 83718 (HDL cholesterol), 84478 (triglycerides) 80061 (Lipid panel)

Diabetes
ICD-9 code: V77.1
CPT codes: 82974 (Glucose, quant., blood (except reagent strip), 82950 (Post glucose dose, includes glucose), 82951 (Glucose; tolerance test GTT, three specimens, includes glucose)

Source:
National Intelligence Report, January 10, 2005

Frequent Technical Support Questions

How are the acceptable ranges established?
Acceptable ranges for regulated analytes are graded according to the criteria established in the CLIA regulations (see page 9 for an abbreviated list; the AAFP-PT Event Summaries include the entire list). AAFP-PT grades all non-regulated quantitative analytes, including Waived tests, at plus or minus three standard deviations from the mean. Non-regulated qualitative analytes are graded based upon either 80 percent consensus or 80 percent referee consensus.

How could the lab fail protime but pass the INR?
It is all in the grading criteria. Protimes, unless using a waived instrument, are a regulated analyte with CLIA established grading criteria – the target value (group mean) plus or minus 15 percent. The INR is non-regulated and is graded at plus or minus 3 standard deviations. Typically, the criteria for the INR allows for a wider range of acceptable results. Participants reporting a waived method for protime are graded at plus or minus 3 standard deviations instead of the plus or minus 15 percent criteria. It is important to remember when reporting proficiency testing results, labs must at minimum report the non-waived protime result and can choose to also report the INR.

What is the appropriate throat culture response when there is no growth on Strep selective media?
Strep selective media (SSM) contains antibiotics to inhibit the growth of most organisms except for the targeted organism. Throat cultures, as well as proficiency testing samples may contain organisms that are inhibited and as such, "No Growth, sterile" (code 141) should not be used. Negative for Group A Strep (code 148) should be used when no growth is observed on SSM.

Please note – SSM does not inhibit the growth of everything except Group A Streptococcus (*Streptococcus pyogenes*). Other organisms that grow on SSM include *Streptococcus sanquis*, *Staphylococcus epidermidis*, *Staphylococcus aureus* (poor growth) and *Enterococcus faecalis*. Of these organisms, only *Staphylococcus aureus* causes beta hemolysis. The colony appearance of Group A Strep is circular, opaque, raised colonies while *Staphylococcus aureus* colonies are circular, white, raised colonies. Further, Group A Streptococcus is Bacitracin sensitive while *S. aureus* is resisitant.

When is a manual differential considered moderate versus high complexity?
According to the July 26, 1993 Federal Register, to perform a moderate level differential, the personnel must have a general knowledge of cellular elements in normal peripheral blood. It also requires identification of common atypical or immature blood cells such as atypical (reactive) lymphs, bands and polychromatic red blood cells and other common red blood cell morphology that can be correlated to RBC indices. Further, the personnel must be able to recognize the presence of uncommon atypical or immature cells (i.e., myelocytes, large or abnormal platelets and extensive abnormal RBC morphology) and to refer them to someone qualified to make the final interpretation and identification (High complexity level testing personnel).

Where can I get a copy of the most current CLIA regulations?
The regulations are posted on the Centers for Disease Control and Prevention at http://www.phppo.cdc.gov/clia/regs/toc.aspx. The surveyor guidelines (Appendix C) are also available at this site. The guidelines give interpretations and direction for conducting a survey.

How do I apply for a CLIA certificate?
Information on how to apply for a certificate may be found at http://www.cms.hhs.gov/clia/cliaapp.asp. CLIA requires all entities that perform even one test, including waived test on ... "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" to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program. The CLIA application collects information about a laboratory's operation, which is necessary to determine the type of certificate to be issued and the fees to be assessed. CMS has made available the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Application for Certification, Form CMS-116 on this site. This form should be mailed to the address of the local State Agency for the State in which your laboratory resides. State agency addresses may be found at http://www.cms.hhs.gov/clia/ssa-map.asp.

2005-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: Beginning in 2006, inappropriate antimicrobial choices for urine susceptibility testing will be graded as incorrect results.
   A. True
   B. False
2. True or False: Urinary tract infections are among the most common ailments encountered in the office practice.
   A. True
   B. False
3. True or False: The majority of uncomplicated urinary tract infections are caused by *Pseudomonas aeruginosa*.
   A. True
   B. False
4. Which of the following organisms are known to cause UTI?
   A. *Escherichia coli*
   B. *Staphylococcus aureus*
   C. *Proteus mirabilis*
   D. All of the above
5. True or False: Treatment of urinary tract infections has been complicated by the ability of organisms to develop resistance to common first-line antimicrobials.
   A. True
   B. False
6. Routine test batteries need to be defined for which of the following organisms?
   A. Enterobacteriaceae
   B. Staphylococcus species
   C. Pseudomonas species
   D. All of the above
7. According to the CLSI guidelines, which of the following antimicrobials are agents used solely for UTI infection with Staphylococcus species?
   A. Norfloxacin
   B. Nitrofurantoin
   C. Sulfisoxazole
   D. All of the above
8. True or False: Clindamycin is a Group B Antimicrobial but is not routinely reported on urinary tract isolates.
   A. True
   B. False
9. True or False: Chloramphenicol is not routinely used for UTI.
   A. True
   B. False
10. True or False: According to the CLSI guideline, Group A antimicrobials are those recommended for primary testing and reporting.
    A. True
    B. False
11. True or False: According to the CLSI guideline, Group O antimicrobials are agents that have clinical indication for the organism group but are generally not candidates for routine testing and reporting in the United States.
    A. True
    B. False

12. Which of the following antimicrobials is Group O for *Enterobacteriaceae*?
    A. Ceftazidime
    B. Chloramphenicol
    C. Cefaclor
    D. Tetracycline
13. True or False: The mean, median and coefficient of variation are calculated as part of the proficiency testing evaluation process.
    A. True
    B. False
14. True or False: In order to be graded at peer group, there must be consensus of 80% or more of the labs.
    A. True
    B. False
15. The combined statistics for all labs reporting for the specimen and analyte are:
    A. Peer group
    B. Comparative group
    C. All method group
    D. Referee group
16. The combined statistics for labs reporting with like methods/instruments are:
    A. Peer group
    B. Comparative group
    C. All method group
    D. Referee group
17. True or False: The coefficient of variation is a tool used to express precision of the determination
    A. True
    B. False
18. The arithmetical average of a set of numbers is the:
    A. Median
    B. Outlier
    C. Mean
    D. CV
19. A value in an ordered set of values below and above which there is an equal number of values is the:
    A. Median
    B. Outlier
    C. Mean
    D. CV
20. True or False: The sensitivity of test is the ability of a test to give a negative result for patients that do not have the condition for which they are being tested, expressed in percent.
    A. True
    B. False
21. True or False: Excessive variability is observed when there is a significant difference between the mean and median.
    A. True
    B. False
22. True or False: Linearity is the range of concentration of an analyte over which a test produces consistent and accurate results.
    A. True
    B. False
23. The difference between an individual value and the arithmetic mean is which of the following?
    A. Mean
    B. Median
    C. Standard Deviation
    D. CV

24. The proficiency testing grading criteria for a non-waived protime is which of the following?
    A. Target +/-25%
    B. Target +/- 15%
    C. Target +/- 2 SD
    D. Target +/- 3 SD
25. Examples of clerical errors include which of the following?
    A. Failing to include a method or kit
    B. Not reporting in the units of measure stated in the result booklet
    C. Not filling in the bubbles corresponding to the numbers written
    D. All of the above
26. True or False: Using “Other” reporting method means the lab will automatically be graded at the all method level.
    A. True
    B. False
27. True or False: AAFP-PT lists methods/instruments by the manufacturer name and then the product name.
    A. True
    B. False
28. True or False: As an approved PT provider, AAFP-PT cannot correct clerical errors made by the participant.
    A. True
    B. False
29. Acceptable range criteria for regulated analytes has been established by:
    A. CLSI
    B. CLIA
    C. AAFP-PT
    D. CDC
30. True or False: AAFP-PT grades non-regulated quantitative analytes at plus or minus three standard deviations.
    A. True
    B. False
31. True or False: When using Strep selective media, a lab should not report “No growth”.
    A. True
    B. False
32. True or False: Only Group A Streptococcus will grow on Strep selective media.
    A. True
    B. False
33. True or False: Under CLIA, a lab must keep it’s instrument printouts for proficiency testing for 2 years.
    A. True
    B. False
34. According to a CMS survey, which of the following waived tests are the most commonly performed?
    A. Glucose
    B. Dipstick urinalysis
    C. Group A Strep antigen
    D. All of the above

AAFP-PT CME Test Answer Sheet

ALL INFORMATION MUST BE COMPLETED TO OBTAIN CREDIT

❒ **2005-A** (submit by February 28, 2006 to obtain credit)

Please print:

Individual AAFP #: ___ ___ ___ ___ ___ ___ ____

(All paticipants 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

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

Fill in the circles for the correct answers:

	A	B	C	D
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.	❍	❍	❍	❍

AAFPPT
The Physician's Proficiency Testing Program

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 in April, July, October and January. Allow 7-10 business days for requested transcripts.