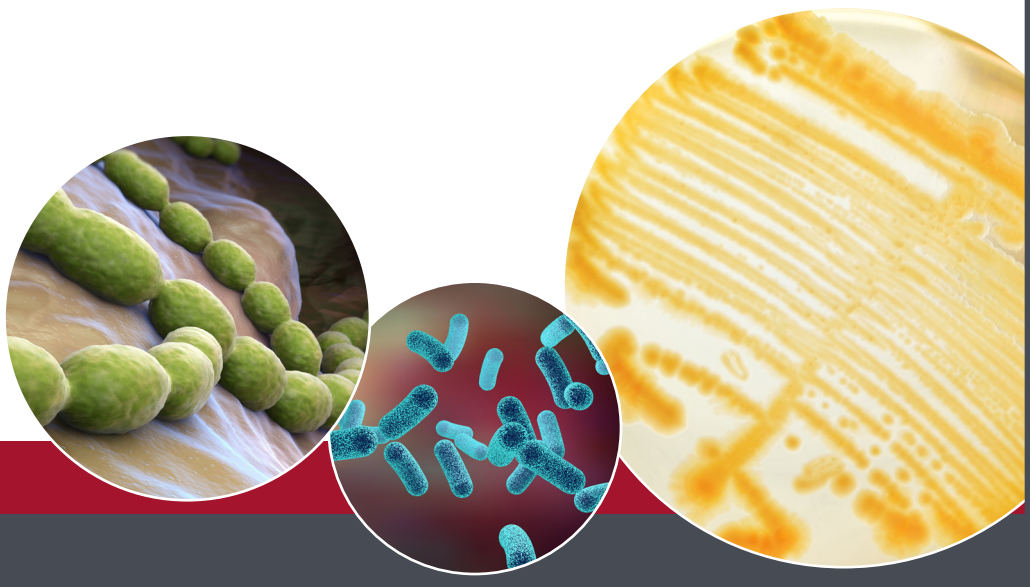
AAFP PROFICIENCY TESTING

2022 Handbook

A PROFICIENCY TESTING PROGRAM FOR OFFICE LABORATORIES



AAFP
AMERICAN ACADEMY OF FAMILY PHYSICIANS

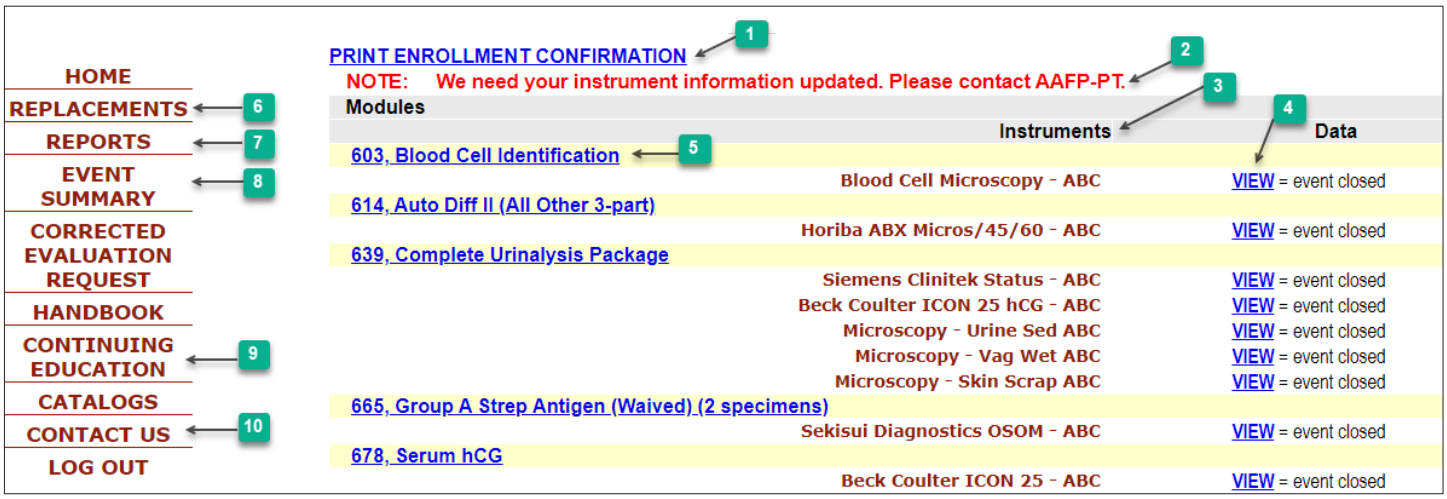
The right choice for proficiency testing

aafp.org/pt

PT Central Quick Start Instructions

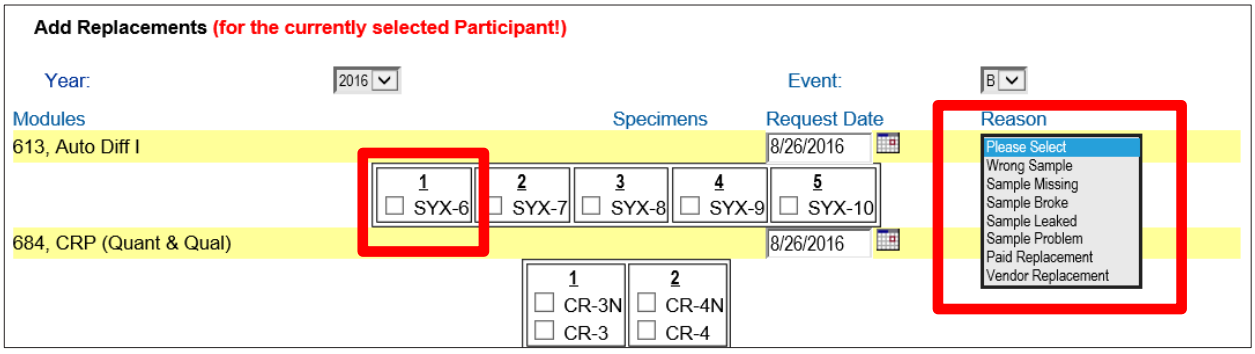
Login at: www.pt-central.com/aafppt/home.asp

Find your login and password on enrollment confirmation or previous evaluation reports.



PT Central offers everything you need – 24/7:

1. Enrollment (setup) Confirmation: Click PRINT ENROLLMENT CONFIRMATION to view your lab's demographic information and current profile of modules and instruments/kits.
2. Note: Find important messages specific to your lab from AAFP-PT Staff.
3. Instruments: Look here to verify your instruments/kits and methods – any changes to your lab's instrument/kit and methods need to be submitted prior to entering results. It's simple – just click on **"CONTACT US"** and send us an email with the changes.
4. VIEW/Enter – Click here to enter and submit **"Final Save"** results.
5. Module Instructions – Click on the module name to find sample handling instructions and, if applicable, the microscopy photos.
6. To request replacement specimens online click on Replacements, then click Add Replacements to view your modules and specimens. Using the drop-down box, ❶select the reason for requesting a replacement and then ❷ to select the specimen ID(s). Last, click the CLOSE link in the bottom right hand corner of the screen.



7. Reports – Click here to create a **data submission report**, retrieve evaluations reports, participation certificate and attestation sheet.
8. Event Summary – Click here to view summary data of each event.
9. Continuing Education (CE) – Access the POL Insight click on the CE link in PT Central. See page 15 of the AAFP-PT Handbook for additional information.

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Ordering Information

AAFP IDENTIFICATION NUMBER

Each laboratory is assigned an AAFP ID number. This number is included on AAFP-PT correspondence with your office. Please have your seven-digit AAFP ID number available when you contact our office—it will allow our staff to access your records.

TEST PROFILE REQUEST

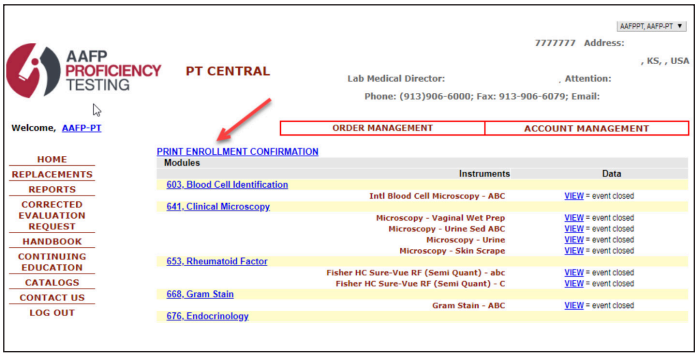
Upon enrollment you should have completed a Proficiency Testing Order Form which required information regarding instrumentation and methods used to test specific analytes. It is critical that this information is accurate to ensure that your results are graded with the correct peer group. If any changes to your test profile or laboratory information is needed, visit our website and complete the Additional Information/Change Request form and email to pt@aafp.org.

WELCOME PACKS

All new enrollees will receive a Welcome Pack via USPS after their setup is complete with all test information specific to the laboratory's instruments and methods. The Welcome Pack will include a handbook, binder materials, instruction letter, and enrollment confirmation.

ENROLLMENT CONFIRMATION

By mid-February, all enrolled participants should log in to PT Central to print and review their Enrollment Confirmation. This form describes your current reporting set up. Please review carefully for an accurate listing of all analytes, units of measure, and testing methods. Indicate any changes to your testing menu (analytes added or deleted) or any changes in instrumentation or kits on the Change Request Form at AAFP.org/PT and email the form to AAFP-PT prior to the next kit shipping date to ensure that the correct test menu is available for result reporting. Changes will not be accepted after the event results deadline and AAFP-PT will not correct any failures that may occur as a result of an incorrect set up.



CERTIFICATES OF PARTICIPATION

All participants may view and print a Certificate of Participation for the current program year in addition to any prior year in which they were enrolled with AAFP-PT. To create a Certificate:

1. Log in to PT Central using your provided user name and password.
2. Choose "Reports" from the menu on the left side of the screen.
3. Select the desired year from the drop-down menu and click "Apply."
4. Click "View" to open the Certificate.
5. Save or print as desired.

CHANGES AND ADDITIONS TO ORDER

All participants will receive a Pre-Shipment Notification approximately six to eight weeks prior to an event. This notice will identify your current module enrollment, instruments, and all reportable analytes. It is the responsibility of each laboratory to inform AAFP-PT of any changes to instruments, kits, methods, or reported analytes prior to reporting proficiency testing results. AAFP-PT is unable to correct any evaluation failures that result from lack of notification of the change. Please review this notice and contact AAFP-PT to make any changes. You will find the Additional Information/Change Request form at AAFP.org/PT. Please complete the form and submit by email to AAFP-PT three weeks prior to an event shipping date. Any module may be added to an existing order depending on the shipping schedule, result due date, and material availability. A $35 shipping charge will be applied if a separate shipment is required. The module cost will be prorated according to the number of shipments remaining in the program year and the financially responsible party will be invoiced.

REFUND/CANCELLATION POLICY

Module cancellations must be received in writing four weeks prior to the event ship date to receive credit for that event. The annual registration fee is not prorated and is non-refundable. Facilities will be issued a credit for deleted modules based on the number of shipments remaining in the program year. Credits will be applied to the following year's proficiency testing order. If no order is being placed for the next year, a refund check will be issued upon request at the end of the current program year.

PT RESULTS RELEASE AUTHORIZATION

AAFP-PT will release information to specified agencies unless otherwise notified in writing. Your surveying agency (CLIA, COLA, State Agency, etc.) identification number must be included with your order.

OFF-SCHEDULE/REINSTATEMENT TESTING

Subject to product availability, proficiency testing specimens are available throughout the program year. Individuals enrolled in AAFP-PT as well as other PT program participants can call AAFP-PT for help with off-schedule/reinstatement or compliance related questions. AAFP-PT provides reinstatement specimens for regulated analytes as required by CLIA regulations. Under normal circumstances, specimens can be shipped the same day or next day, with a seven to 10 day evaluation process once results are received (unless otherwise specified when the order is placed). AAFP-PT will report your reinstatement testing performance to CMS or COLA the same day you receive your evaluation. Price is per specimen. Pre-paid orders only are accepted for off-schedule shipments. AAFP-PT will provide specimen handling instructions and simple-to-use result forms. For more information call (800) 274-7911.

Kit Information

SHIPMENT DUE DATES

It is the participant's responsibility to know when the kits are due to arrive. Shipping dates are published on the back cover of this handbook. A Pre-Shipment Notification email will be sent approximately six to eight weeks prior to the kit shipment. Samples are packaged in white Styrofoam containers and transported by UPS 2-day shipping service. If enrolled in only the Clinical Microscopy modules (Modules 638 and 641), the photo booklets are sent in standard 6x9 envelopes through the U.S. Postal Service. You will receive a courier tracking number to follow the progress of your PT kit. A signature of receipt is required for delivery. Remind the office personnel to watch for the kit and to refrigerate the specimens upon receipt. A cold pack is included in the kit, however, by the time you receive the kit, the cold pack may be thawed and the contents may be warm. **Warm temperatures will not damage the specimens** as they are manufactured specimens and, therefore, more stable.

If you do not receive your kit within **five days** of the shipping date, please call AAFP-PT at (800) 274-7911. Our staff will track your kit and provide you with delivery information if it has been delivered and will re-ship when necessary.

Kits are assumed to have been delivered unless otherwise notified by the participant. Kit shipment dates cannot be changed. If your office will be closed when a kit is due to arrive please call the AAFP-PT office in advance for possible options. Our staff can delay shipment of a kit if the request is made a minimum of two weeks prior to shipment. The results due date will not be changed.

REPLACEMENT SPECIMENS

Laboratory personnel should examine the kit immediately upon arrival to check for missing or broken/leaking specimens. The Packing List/Attestation form and, if applicable, microscopy booklets should be retrieved from the outside of the box before discarding. If any specimens are missing or compromised, please request a replacement sample via your PT Central homepage.

1. Click the "Replacements" link on the left side of your PT Central homepage.
2. Click "Add Replacements."
3. Select the current year and event.
4. Find the relevant module and click the drop-down menu to enter a reason for the replacement request.
5. Click in the box next to each item that needs to be replaced.
6. Click "Close" to complete your request.

A limited amount of replacement specimens are also available for "lab accidents." A "lab accident" is anything that happens to a specimen during testing, such as errors in reconstitution or dropping or spilling specimens while being handled by lab personnel. An invoice will be sent for paid replacement specimens (price per specimen). Replacement specimens are available only as long as quantities last. The last day AAFP-PT can ship replacement specimens is nine days prior to the results deadline.

TESTING THE PT SPECIMENS

AAFP-PT strongly recommends that lab personnel review all materials supplied with the test kit prior to beginning testing. A test kit consists of:

1) **Attestation Statement/Packing List.** Attestation statement includes a signature area for the medical director and testing personnel, as well as the date the testing was performed. The Attestation statement should be kept with your records. It is not necessary to submit the signed copy to AAFP-PT. The packing list will provide a list of the specimens with corresponding modules that are packed in your kit.

2) **Testing/Module Instructions.** Most specimens only need to be brought to room temperature and mixed. Some specimens or test methods require special specimen handling or testing procedures. These instructions can be found by clicking the module name on your PT Central homepage.

3) **PT Specimens.** Your kit will contain various samples for testing. These may be vials/bottles, swabs, page(s) of photographs, or slides. Each sample is labeled with a series of letters which identify the module and a number which is unique for each sample. Verify that you have received the correct samples and notify AAFP-PT if any samples are missing. ***NOTE:*** You may receive samples for tests which are not performed in your laboratory. Disregard these samples. Only test and report results for tests listed in your Set-up Confirmation packet.

Specific time frames are allotted for kit shipment, laboratory testing and results recording, and for returning results for evaluation. AAFP-PT recommends that testing be completed as follows:

- Hematology/Coagulation—within seven days of receipt
- Chemistry—within seven to 10 days of receipt
- Microbiology (non-culture)/Immunology/Urinalysis/Other—within seven to 10 days of receipt
- Microbiology Cultures—within seven days of receipt

COMPARING RESULTS OR REFERRING SPECIMENS

Laboratories are strictly prohibited from sending PT samples to outside laboratories for analysis under any circumstances, and from discussing or comparing results of PT testing with employees of other laboratories prior to submitting results for grading. Violation of this regulation may result in revocation of your CLIA certificate. All laboratory staff must be made aware of this requirement and you should maintain signed documentation of this notification.

BIOHAZARD INFORMATION

All office testing personnel performing proficiency testing should read and understand the following statement:

Laboratory personnel should observe Universal Precautions when handling specimens (including patient, quality control, and proficiency testing specimens). Universal Precautions is an approach to infection control; according to the concept, all human blood and body fluids should be handled as if known to be infectious for HIV, HBV, and other bloodborne pathogens. Some proficiency testing specimens are derived from human blood/body fluids, and while they have tested negative for HBsAG and anti-HIV, they should still be considered potentially infectious. Specimens should be disposed of in biohazard containers.

All AAFP-PT kits are shipped in accordance with regulatory guidelines for shipping infectious material. Damage to packages during shipment should be reported to AAFP-PT with a request for replacement specimens. United States shipping regulations prohibit return shipments of biohazard materials. Unused specimens should be disposed of in biohazard containers. **Please do not ship any of the specimens back to AAFP-PT.**

REPORTING A LAB ACCIDENT WITH A PT SPECIMEN

Personnel exposed to potentially infectious specimens (i.e., cuts and splashes) should be reported to AAFP-PT for evaluation and instructions concerning prophylaxis.

Call (800) 274-7911 for assistance.

LABORATORY ACCIDENT PROTOCOL

"The acute management of skin puncture or mucosal surface contamination should be routine first aid consisting of washing the skin site with soap and water while permitting bleeding, and then, if appropriate, bandaging the site. Contaminated mucosal and conjunctival sites should be washed with large quantities of water. There is no evidence of benefit for application of antiseptics or disinfectants or squeezing (milking) puncture sites in the prevention of infection. Avoid the use of bleach and other agents caustic to skin."[1]

The Lab Accident/Incident Report on www.aafp.org/pt should be completed and emailed, mailed, or faxed to AAFP-PT.

Every physician office should have a procedure for post-exposure evaluation and follow-up including:

- **Who to contact**
  An individual in the physician office (the Safety Officer) should have the responsibility of receiving notice of exposure. Also contact AAFP-PT (800) 274-7911, if the exposure was to a proficiency testing specimen.
- **How to complete a written accident report**
  The physician office should have a format for recording the necessary information about how the accident occurred and the steps taken to reduce the exposure.
- **The employee's rights and the policy for follow-up**
  (i.e., HIV testing as a follow-up to a needle stick.)
- **The process for testing and medical examinations**
- **The record-keeping process for the office**

Personnel should wear gloves at all times when handling specimens.

If a specimen comes in contact with skin or mucous membranes, flush the area immediately with large amounts of water.

References:

1. CLSI. *Clinical laboratory Safety; Approved Guideline – Third Edition.* CLSI document GP17-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.
2. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10106

READ THIS WARNING BEFORE HANDLING PROFICIENCY TESTING MATERIALS

All specimens should be considered infectious and should be handled as though they are capable of transmitting disease.

Specimens are prepared from blood or other source material obtained from human donors or animals.

When working with specimens, precautions should be taken to protect yourself and others from accidental exposure to infectious agents such as HIV, HBV, and HCV.

HIV can be transmitted through accidental parenteral inoculation, mucous membranes, or non-intact skin contact with HIV infected blood or body fluids. HBV and HCV can be transmitted through accidental parenteral inoculation, mucous membranes, non-intact skin contact, aerosolization, or ingestion.

Precautions described in CDC and FDA recommendations and OSHA bloodborne pathogen rules should be followed at all times when handling specimens and reagents. Such precautions include the following:

1. GLOVES should be put on before opening the container and should be kept on, and replaced if contaminated throughout the period specimens are handled.
2. At high altitudes, specimens should be opened in a HOOD OR BIOLOGIC SAFETY CABINET.
3. There should be NO EATING, DRINKING, OR SMOKING in the laboratory.
4. HANDS SHOULD BE WASHED after removing gloves and before leaving the test area.
5. Specimens and reagents should be kept in SEPARATE REFRIGERATORS from those containing blood or blood components for transfusion.
6. Specimens, reagents, and disposable equipment used in testing should be AUTOCLAVED OR INCINERATED and disposed of as hazardous waste.
7. In case of an accident with any proficiency testing samples, contact AAFP-PT at (800) 274-7911 for appropriate exposure protocol.

Reporting Proficiency Testing Results

The results due date, located on the shipping calendar online as well as in the handbook packet, is very important. The testing must be completed and results submitted by the due date for each testing event. Please refer to the calendar to determine your deadline. **This date is strictly enforced!**

As an approved proficiency testing provider, **AAFP-PT cannot accept results submitted after the results due date.**

TEST RESULT REPORTING

All results must be submitted electronically through the PT Central website. **AAFP-PT does not accept results by mail or fax.** Contact AAFP-PT at (800) 274-7911 for assistance logging in or entering your results in PT Central.

SUBMITTING RESULTS FOR MULTIPLE INSTRUMENTS OR METHODS

Under CLIA '88 regulations, laboratories are only permitted to submit results for one instrument or method per analyte per testing event. Laboratories wishing to perform proficiency testing on additional methods or instruments as part of their in-house quality assurance program must notify AAFP-PT in advance. These laboratories must delay testing for the additional methods until the event deadline is past. At that time, the laboratory will receive an email notification indicating a limited time period for performing testing and submitting results from additional instruments. The graded results for the additional instruments/methods will appear on the Evaluation Report, but will not be transmitted to accrediting agencies.

ELECTRONIC RESULT REPORTING (ONLINE)

Access PT Central at www.aafp.org/pt/ptcentral.
Click the "Log in to PT Central" link. A login screen will appear. Your login and password can be found on your Set-up Confirmation or on previous evaluations. If you have questions or need assistance with PT Central you may contact AAFP-PT through the "Contact Us" button located at the left side of the screen.

Once logged in, you will see a listing of all the modules for which your laboratory is enrolled. Verify modules and testing methods (kits/instruments) before continuing and notify AAFP-PT of any discrepancies.

Click the "Enter" button to the right of the instrument name for which you wish to enter results.

- **Qualitative Results:** Choose from a drop-down menu of possible responses for each specimen. Some samples require a double drop-down menu. First, select a series (e.g., cells). A second drop-down menu will appear. Choose an identification response from this menu.
- **Quantitative Results:** Enter the numeric result value in the appropriate box. Use the TAB key to move between fields. ***NOTE:*** You can control the direction of cursor movement by selecting the "horizontal" or "vertical" button located above the data entry area.
- **Exclusions:** If you will not be reporting results for any reason, click the "C" button to the right of the data window. Then select the appropriate exclusion code from the drop-down list. If you wish to include additional comments, click the "Contact Us" button on the left side of the screen to send an email. Please include your AAFP-PT ID number with your comments. ***NOTE:*** you will not be able to report a result for any specimen which has an exclusion.

Modules are reported one at a time; there is no group save. For all results you have the option of "Temporary Save" or "Final Save." Use "Temporary Save" to be able to return to your results for review or additions. Use "Final Save" to submit your results for grading. Be sure to carefully review the results, looking for clerical errors, before selecting "Final Save." As an approved proficiency testing provider, AAFP-PT cannot correct clerical errors made by participants.

Continue reporting results for each module by returning to your home page by clicking on "Home" link. **DO NOT USE YOUR BROWSER'S "BACK" BUTTON.**

Once you have selected "Final Save," a confirmation will be sent electronically to the email address on file at AAFP-PT. Keep this confirmation with your testing records.

Generate a Data Submission Report (see page 8) and retain with your records.

Keep the signed Attestation Statement with your records. Do not fax the Attestation Statement to AAFP-PT

Log out of PT Central by clicking on the "LOG OUT" button on the left side of the screen.

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

REPORTING A ZERO RESULT

If sample testing produces a value of "0" (zero), use the exclusion code drop-down menu and select exclusion code 32 to enter this result. Do not enter "0" in the results field, the system will not recognize this value and will not record this result.

CLINICAL MICROSCOPY AND BLOOD CELL IDENTIFICATION

A complete listing of cells, organisms, and microscopic elements are included with module instructions found on your PT Central homepage.

SAMPLE PROBLEMS/EXCLUSIONS

If you experience a sample problem, first request a replacement specimen from AAFP-PT. If the sample problem is not resolved with a new specimen, check the "C" box on the online reporting screen and select the appropriate exclusion code from the drop-down menu.

If you are unable to perform the proficiency testing AND are also unable to perform patient testing during an event, you may request an exclusion. Reasons for exclusion may include being unable to obtain reagents, a seasonal suspension of testing, an instrument is broken and repairs will not be completed in time, or lab staff is unavailable. To request an exclusion, check the "C" box on the online reporting screen and select the appropriate exclusion code from the drop-down menu. ***NOTE:*** You are required to notify your state agency or private accrediting agency of the request. AAFP-PT must receive your request on or before the results due date.

CREATING AND VIEWING A DATA SUBMISSION REPORT

It is strongly recommended that you create, print, and review a "Data Submission Report." This report will include all the results submitted and will allow you to verify that all results have been entered accurately and completely. Retain a copy of this report with your PT files in case of discrepancy. Note that a Data Submission Report can be generated immediately after submitting results online.

To generate a Data Submission Report:

- Go to www.aafp.org/pt/ptcentral and click "Login to PT Central."
- Enter your laboratory user name and password information.
- Choose "Reports" from the links on the left side of your home page.
- Select the appropriate year and event from the drop-down menu and click "Apply."
- Next to "Data Submission Report," choose "Build." Wait until the report is generated.
- Click "View" to open the report.
- Use the Acrobat Reader print function to print a copy for your records.

SPECIAL INSTRUCTIONS FOR REPORTING MICROBIOLOGY RESULTS

Samples for Microbiology modules may contain more than one organism. For some samples, you may be required to identify only the primary pathogen present. Other samples may require that all organisms present be identified and reported. The requirement for each sample will be indicated on the results reporting page in PT Central. If a sample's reporting page includes result fields for two organisms, you must enter a result in each field. The organism designated as "primary" should be the significant isolate or the isolate present in the higher quantity. Use the "secondary" isolate field to report contaminants/normal flora or the isolate that is present in the smaller quantity.

SPECIAL INSTRUCTIONS FOR REPORTING URINE ANTIMICROBIAL SUSCEPTIBILITIES

If you are performing antimicrobial susceptibility results on urinary isolates, be sure to carefully select the appropriate drugs to test and report based on the identification of the isolate. **Inappropriate drug choices will be graded as incorrect results.** The information will help you select the correct antimicrobials for testing.

SELECTION OF ANTIMICROBIAL AGENTS TO TEST AND REPORT FOR TREATMENT OF URINARY TRACT INFECTIONS

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-S22 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 U - agents that are used solely or primarily 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.

Urinary Pathogen	Antimicrobials
Staphylococcus species	A: Oxacillin (MIC), Cefoxitin, Penicillin, Trimethoprim-sulfamethoxizole
	B: Ceftaroline (S. aureus only), Daptomycin(MIC), Linezolid, Tedizolid, (*S. aureus* only), Doxycycline, Minocycline, Tetracycline, Lefamulin (S. aureus only), Vancomycin (MIC), Rifampin
	C: Ciprofloxacin or Levofloxacin, Moxifloxacin, Gentamicin, Dalbavancin (MIC, *S. aureus* only), Oritavancin (MIC, *S. aureus* only), Telavancin (MIC, *S. aureus* only)
	U: Nitrofurantoin, Sulfisoxazole, Trimethoprim
Enterococcus species	A: Ampicillin or Penicillin
	B: Daptomycin (MIC), Linezolid, Tedizolid (*E. faecalis* only), Vancomycin
	C: Gentamicin (high-level resistance testing only), Streptomycin (high- level resistance testing only), Dalbavancin (MIC, *E. faecalis* only), Oritavancin (MIC, *E. faecalis* only), Telavancin (MIC, *E. faecalis* only)
	U: Ciprofloxacin, Levofloxacin, Nitrofurantoin, Tetracycline, Fosfomycin (*E.coli* and *E. faecalis* only)
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, Gentamicin, Tobramycin
	B: Amikacin, Amoxicillin-clavulanic, Amoxicillin-sulbactam, Azithromycin (*Shigella spp.* and *Salmonella enterica ser. Typhi only*), Ceftazidim-avibactam, Ceftolozane-tazobactam, Imipenem-relebactam, Meropenem-vaborbactam, Pipercillin-tazobactam, Cefuroxime, Cefepime, Cefotetan, Cefoxitin, Cefotaxime, Ceftriaxone, Ciprofloxacin, Levofloxacin, Doripenem, Ertapenem, Imipenem, Meropenem, Trimethoprim-sulfamethoxazole
	C: Aztreonam, Ceftazidime, Ceftaroline, Tetracycline
	U: Cefazolin, Fosfomycin *(E. coli* and *E. faecalis* only), Nitrofurantoin, Sulfisoxazole, Trimethoprim
Pseudomonas aeruginosa Note: *Pseudomonas* requires a separate battery from other gram-negative organisms	A: Ceftazidime, Gentamicin, Tobramycin, Piperacillin-tazobactam
	B: Amikacin, Aztreonam, Cefepime, Ceftazidime-avibactam, Imipenem-relebactam, Ceftolozane-tazabactam, Ciprofloxacin, Levofloxacin, Imipenem, Meropenem, Doripenem
	C:
	U:

Source: CLSI. *Performance Standards for Antimicrobial Susceptibility Testing.* 31st ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2021.

Evaluation Information

WHEN TO EXPECT THE EVALUATION

Evaluations are typically available approximately 30 days after the result due date. This time allows for processing the data. AAFP-PT recommends marking your calendar to remind you when to expect the evaluation. The expected evaluation release date will appear on your PT Central home page shortly after the close of the testing period.

Participants will receive an email with the evaluation attached.

ACCESSING EVALUATIONS

Participants may view and print (if desired) any current or previous evaluation by logging in to their PT Central homepage using their provided login name and password. Once logged in, choose "Reports" from the menu on the left side of the screen. Select the desired year and event from the dropdown menus and click "Apply." Then click "View." This will open the Evaluation as a PDF document which may be saved or printed.

EVALUATION PROCESS

Proficiency testing (PT) events occur three times per year. During each event, AAFP-PT collects data 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 three standard deviations from the mean. See page 14 for definitions of mean, median, and CV.
- 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 there is a sufficient number of labs using the same method/instrument that 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 there is not a sufficient number of labs using the same method that 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%, 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, AAFP-PT in consultation with advising physicians 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 — Less than five 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:

$$\frac{SD \times 100}{Mean}$$

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.

AAFP PROFICIENCY TESTING

American Academy of Family Physicians
11400 Tomahawk Creek Parkway
Leawood, KS 66211-2672
1 (800) 274-7911
www.aafp.org/pt | pt@aafp.org

Proficiency Testing Evaluation

AAFP PT 2022-A 5555555 11D0123456

Evaluation Information

Facility/Contact (1)

Lab Diretor:
Attention:

PT Central: www.aafp.org/pt/ptcentral

Phone: (3)
Fax:
Email: pt@aafp.org
AAFP ID:
CLIA ID:
COLA ID:
STATE ID:

Login Name: (4)
Password:

Copies of this report have been sent to: (5)
1. Centers for medicare and Medicaid Services
2. Certification and Licensing
3. COLA, if applicable

Modules: 614, Auto Diff II; 817, MultiChem 15; 639, Complete Urinalysis Package; 686, Special Chemistry (6)
Specimens: CH-(11-15), CM-(19-27), HD-(11-15), SC-5, UA-3 (7)

Test/Your Method(s)	Spec	Your Result (8)	Target Mean (9)	Group SD (10)	Year SDI (10)	Acceptable Range (11)	Group* (12)	Comments (13)
Module: 614, Auto Diff II Subspecialty: Hematology		CMS Analyte Score: 100%						
White Blood Cell Count in 10^9/L Abbott Cell-Dyn 1400 1								
	HD-11	15.9	17.9	0.56	-3.57	16.2 - 20.6	PG	Pass
	HD-12	8.9	9.5	0.26	-2.31	8.1 - 10.9	PG	Pass
	HD-13	5.5	5.5	0.22	0.00	4.7 - 6.3	PG	Pass
	HD-14	7.2	7.5	0.36	-0.83	6.4 - 8.6	PG	Pass
	HD-15	18.2	21.0	0.57	-4.91	17.9 - 24.1	PG	Pass

*PG - Peer Grou | MG - Method Group | SC - Special Group | AG - All Method Group | GO - Gross Outlier

CMS Performance Summary. Regulated Analytes.

This report summarizes your performance for this current test event and your cumulative performance (current and two previous test events). Pursuant to the CLIA 1988 federal regulations, your performance has been reported to the federal goverment (CMS).

Specialty	Subscepticalty	Analyte	Current Score (14)	Current Performance	2021-C Performance (15)	2021-B Performance (15)	Cumulative Performance (16)
Hematology	**Hematology**		**89%**	**Satisfactory**	**Satisfactory**	**Satisfactory**	**Successful**
	White Blood Cell Count		**100%**	**Satisfactory**	**Satisfactory**	**Unsatisfactory**	**Successful**
	Lymphocyte		**40%**	**Unsatisfactory**	**Satisfactory**	**Unsatisfactory**	**Unsuccessful**
	Granulocyte		**80%**	**Satisfactory**	**Satisfactory**	**Satisfactory**	**Successful**
	Red Blood Cell Count		**100%**	**Satisfactory**	**Unsatisfactory**	**Satisfactory**	**Successful**
	Hemoglobin		**100%**	**Satisfactory**	**Satisfactory**	**Satisfactory**	**Successful**
	Hematocrit		**100%**	**Satisfactory**	**Unsatisfactory**	**Satisfactory**	**Successful**
	Platelet Count		**100%**	**Satisfactory**	**Satisfactory**	**Satisfactory**	**Successful**

Comments:

1. The name of your testing facility
2. PT Event ID
3. Your AAFP-PT ID# and CLIA#
4. Login and Password for PT Central
5. Agencies designated to receive copies of your evaluation
6. Your enrolled modules
7. Specimens shipped for testing
8. The tests for which you submitted results and testing method
9. The results you submitted for each analyte and specimen
10. Your comparison group statistics, including target mean, group standard deviation, and your SDI
11. The acceptable range or response for each specimen
12. Your comparison group
13. A comment area for AAFP-PT to describe any unusual PT circumstances
14. A percentage score representing your current performance for each analyte, specialty, and/or subspecialty in this testing event; to achieve satisfactory performance, your score must be at least 80%
15. A descriptive score representing your performance for each analyte, specialty, and/or subspecialty in the previous two testing events
16. The cumulative results for the current and the two preceding testing events; to achieve successful performance, you must achieve satisfactory scores for two out of three consecutive events

How to Review Your Evaluation

Labs are required to review and evaluate proficiency testing results according to the CLIA Regulations—it is an integral part of performing proficiency testing. A "Pass" in the column labeled "Comments" requires no additional follow-up unless the result has passed because the specimen was "Not Graded." Any analyte (both regulated and non-regulated), specialty, or subspecialty assigned a score that does not reflect the laboratory's performance must be evaluated for accuracy by the laboratory. This includes a review of actual PT results against the PT provider's participant summary results. This requirement is now specified in the regulations. Situations requiring this review include:

- 100% score given due to analyte, specialty, or subspecialty not being graded because of a lack of consensus or other discrepancy.
  - ❯ The CLIA grading criteria are applied to establish the acceptable range for each specimen/analyte. When 80% or greater consensus is not achieved with Peer, Referee, nor All Method statistics, results are not graded due to lack of consensus.
  - ❯ For the various "Not Graded" reasons listed in the "Comment" column of your evaluation, compare your results to the acceptable ranges in the Event Summary. Again, document what you have done and how you would have performed if the specimen had been graded.
- 0% score given due to lab's failure to participate in PT.
- 0% score given due to lab's failure to return results to PT program in required timeframe.

Non-regulated analytes and analytes for which compatible PT samples are not available must also be evaluated for accuracy; this may be accomplished by split or blind testing of materials with known values or other external assessment programs.

Any result preceded by "Fail" always requires follow-up investigation and corrective action.

THE CMS PERFORMANCE SUMMARY

A cumulative report indicating your performance status for all regulated analytes, specialties, and/or subspecialties for which you are enrolled. Federal regulations do not require waived or non-regulated analytes to be included on this summary.

Unsatisfactory performance means failure in a specific event to attain the minimum satisfactory score when compared to the target value or reference mean for the peer group for an analyte, test, subspeciality, or speciality.

Unsuccessful cumulative performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

LABORATORY MEDICAL DIRECTOR RESPONSIBILITIES

The laboratory medical director, as stated on the CLIA license, is responsible for the overall operation of the laboratory. The Laboratory medical director is ultimately responsible even if responsibilities are delegated and must ensure that all the duties are properly performed, staff competencies are met, and applicable CLIA regulations are followed. It is the director's responsibility to ensure that the laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results.

Duties include, but not limited to:

1. Review of quality control measures.
2. Review and adherence of policies and procedures for laboratory testing.
3. Review a sampling of the analytical performance of test systems for acceptability based on your laboratory's criteria.
4. Review of proficiency testing results, failure investigations, and corrective action documentation.

For further information, visit CMS CLIA website at www.cms.hhs.gov/clia under "The Interpretative Guidelines for Laboratories."

INVESTIGATING PT FAILURE

All laboratories, at one time or another, experience a proficiency testing (PT) failure. It is important to promptly investigate all PT failures and initiate corrective action. A systematic approach to PT failure investigation is required and easily adaptable to all laboratory environments. Labs should document completely each step of investigation taken in their effort to uncover the cause of the failure and develop a corrective action plan to prevent reoccurrence. The Investigation Checklist on page 17 of this handbook and on the website to help guide you. The Corrective Action Form on page 20 can be used as your final documentation and filed with your proficiency testing information.

INVESTIGATIONAL DIRECTIVES

- **General**
  - – General errors may indicate Quality Control errors, Calibration errors, Instrument errors, and Reagent/Kit errors.
- **Administrative/Clerical**
  - – Clerical or Administrative errors may indicate a need for additional staff training, review of PT instructions, addition of a second reviewer or investigation of the reporting format provided by the testing instrument. If results reported on the Data Submission Report do not match the results found on the evaluation report, please contact AAFP-PT.
- **Specimen Handling**
  - – Specimen handling errors could indicate a failure to follow the testing/module instructions.

- **Quality Control**
  - Quality Control errors could indicate inappropriate operation of equipment or performance of a method.
- **Calibration**
  - Calibration errors could indicate a failure to follow recommended instrument calibration. A review of the manufacturer guidelines regarding the instrument calibration requirements and performance may be necessary.
- **Instrument**
  - Instrument errors could indicate a failure to follow recommended instrument maintenance. The instrument manufacturer may need to be contacted for assistance.
- **Reagents/Kit**
  - Reagent/Kit errors could indicate a failure to follow the manufacturer instructions regarding the kit or reagents.
- **Testing Personnel**
  - Testing personnel errors may indicate a need for additional staff training and review of PT instructions.
- **Microbiology Specific**
  - These errors are specific to microbiology samples. Refer to section 11 of the Investigation Checklist.

REQUESTING A CORRECTED EVALUATION

Review your evaluation carefully. If the error is not the fault of the participant, your entry will be re-evaluated if AAFP-PT is notified in writing of the problem **within 30 days** of the evaluation release date for the event in question. The correction deadline date is included in the email that accompanies the evaluation for each event. The event is considered closed as of the correction deadline date. Corrected evaluations are returned within approximately four to six weeks after AAFP-PT receives your request.

The corrected evaluation request form can be found on your PT Central Homepage or at www.aafp.org/pt with instructions for making a correction request. Please note that clerical errors made by the laboratory cannot be corrected.

EVENT SUMMARY

A complete Event Summary is available soon after each evaluation online through PT Central at www.aafp.org/pt/ptcentral. The Event Summary contains comprehensive statistics for all the modules offered by AAFP-PT. Please notify AAFP-PT if you are unable to access the information on the website.

Included in the Event Summary information is the Peer Group, Comparative Method, and the All Method statistics (i.e., number of labs, mean, standard deviation, acceptable range, and coefficient of variation) for quantitative results, and the number of labs, responses, and percent consensus for qualitative results. Educational material is provided for some of the qualitative results.

The Event Summary information should be kept as part of the permanent records of proficiency testing performance. The Event Summary contains the information necessary to self-evaluate results when your result is not graded. If you need assistance with your evaluation review, contact the AAFP-PT at (800) 274-7911.

Laboratory Record-Keeping

The CLIA regulations require all laboratories retain certain records for a designated period of time. The following table lists the CLIA record-keeping requirements of laboratory records.

Calibration and Calibration Verification	2 years
Discontinued Procedures	2 years
Equipment Maintenance and Function checks	2 years
Method Performance Validation and Specifications	2 years after discontinuation of method
Proficiency testing Evaluations and Corrective Action	2 years
Proficiency Testing Results (lab worksheets, instrument print outs, data submission reports)	2 years
PT Attestation Statement	2 years
Quality Control Records and Reports (daily QC records)	2 years
Remedial Action- errors in reported patient results (both the original and corrected report)	2 years

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 your 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.

PPM-Provider Performed Microscopy — A subcategory of the Moderately Complex CLIA certificate. Laboratories holding a CLIA PPM certificate may perform waived tests as well as tests using a microscope during the course of the patient visit. These laboratories are subject to additional regulations set forth by CLIA. According to the Final COLA rule, PPM laboratories are to adhere to subparts H (Proficiency Testing), J (Facility Administration for Non-waived testing), K (Quality Systems for Non-waived testing), and M (personnel for Non-waived testing).

Qualitative Test — A test method providing only a positive or negative result. Most qualitative tests have a built in positive ("internal") control and serves as an indicator for proper test performance.

Quantitative Test — A test method providing a result with a definitive value. Most quantitative tests have an acceptable test range (sometimes known as "linearity") for the specific analyte.

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.

Waived Labs — Laboratories holding a CLIA certificate of Waiver may perform only tests classified as waived. The test must be performed as instructed by the manufacturer.

Continuing Education Information

AAFP-PT emphasizes the importance of voluntary laboratory improvement and provides all participants with the educational benefits for total quality assurance. AAFP-PT takes pride in offering educational programs and reference tools for our participants. AAFP-PT is an approved Provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. This is a benefit offered to all participants at no additional cost.

POL Insight, AAFP-PT's continuing education publication is available online three times each year through your **PT Central homepage**. Each issue addresses technical, regulatory, and operational information of interest to the physician office lab (POL). **Credit is earned by reviewing the publication and completing an online quiz from the website above. You must obtain a score of 80% on the quiz to claim credit. Quizzes MUST be completed and submitted online. Quizzes submitted by fax or mail will not be considered for continuing education credit.**

Please follow the instructions below to participate in Continuing Education Online and to obtain documentation:

1. Go to www.aafp.org/pt/ptcentral.
2. Log in using the **laboratory** username and password. (This information is printed on the packing slip that accompanies each kit shipment and also appears on all evaluation reports.)
3. Click the Continuing Education link found on the left side of your PT Central homepage.
4. Follow the instructions on the page to obtain educational material (POL Insight). After reviewing the publication, click where indicated to access the assessment quiz.
5. Enter your **personal** username and password.

   NOTE: First-time participants must:

   a. Click "Create an account?"

   b. Enter personal information.

   c. Choose a user name and password (note this information for future use).

   d. Click "Create My Account."

   e. Click "Continue to what you were doing."

   f. Log in using your new username and password.
6. All currently active quizzes will be listed. Choose the desired test and click "Take the Quiz."

How to Complete Assessment Quiz and Submit Continuing Education Online

1. Review the instructions and click, "continue."
2. Read the questions and click in the circle next to the correct answers. Click "Submit Answer." Review your score. If correct, select "Continue." If incorrect, select "Try Again." Repeat for all questions.
3. When all questions are completed and your score is 80% or better, click "Submit for CME."
4. Complete the post-test evaluation and click "submit answers."
5. Follow the instructions on the "Thank You" screen to obtain documentation of credit.
6. Print out the Certificate of Completion as proof of participation.

How to Obtain a Certificate of Completion for Previous Events

Participants are directed to print a Certificate of Completion at the conclusion of each activity. In addition, a URL link to access certificates will be provided to all participants by email within two weeks of completion of a CE activity. Please contact AAFP-PT at pt@aafp.org if you are unable to print your certificate.

A printed Certificate of Completion is your documentation of completed CE activities. Retain these certificates and submit to your accrediting agency as required.

Accreditation Statement

AAFP-PT is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. AAFP-PT is also an approved provider for California clinical laboratory licensees under the P.A.C.E.® Program. The level of instruction for each event is basic and worth 4 P.A.C.E. contact hours.

AAFP PROFICIENCY TESTING

Additional Information/Change Request

AAFP ID# ____ ____ ____ ____ ____ ____ ____ **Date** _____

Practice Name _____ **State** _____

Information to be added or changed *(mark all that apply)*:

☐ Laboratory Director_____

☐ Practice Name _____

☐ CLIA, COLA, or other Accrediting Agency ID# _____

☐ Addition to Order* (include module #) _____

*What is the full name of the instrument/kit to be used for the new module?

_____

*Please list all tests to be reported in the new module:

_____

☐ Cancellation to Order* (include module #)_____

☐ Lab Contact _____

☐ Phone Number _____ Fax Number _____

☐ Address - Bill To *(Specify Below)* Email_____

☐ Address - Kit Ship To *(Specify Below)*

☐ Other *(Specify Below)*

** If you are adding or canceling a test from the MultiChem modules, you must include the total number of MultiChem tests you will be performing.*

Program Year _____ Event(s): ☐ A ☐ B ☐ C

_____

_____

_____

Authorized Signature ***(required)*** _____

Any changes to your PT order must be submitted in writing.
Email to pt@aafp.org

Cancellations must be received **four weeks** prior to the ship dates to receive credit. Please call customer service at (800) 274-7911 with any additions to an order not received prior to ship date. All additions to an order is subject to specimen availability and a $35 shipping fee.
Registration fees are not refundable.

11400 Tomahawk Creek Parkway | Leawood, KS 66211-2672
(800) 274-7911 | pt@aafp.org | aafp.org/pt

AAFP PROFICIENCY TESTING

Investigation Checklist of Unsatisfactory Proficiency Testing

This form is provided as a reference tool to investigate the possible causes of unsatisfactory proficiency testing results. Not all errors can be identified with one particular tool. Laboratories should consider the unique factors for each test system and expand its investigation when indicated. Complete the Proficiency Testing Corrective Action Form and attach to this checklist along with all records reviewed and other related documentation.

1. General
   - a. Did more than one challenge in this event fail? ☐ Yes ☐ No ☐ NA
   - b. Did more than one analyte fail? ☐ Yes ☐ No ☐ NA
   - c. Are there previous trends/unsatisfactory results for this test? ☐ Yes ☐ No ☐ NA
   - d. Do the SDIs show a bias in the current event? ☐ Yes ☐ No ☐ NA
   - e. Was there low consensus for the analyte? ☐ Yes ☐ No ☐ NA
   - f. Provide the scores for the failed analytes from the three prior events (most recent first):

Year	Event	Score
20___	_____	_____
20___	_____	_____
20___	_____	_____

2. Administrative
   - a. Were results submitted to AAFP-PT by the due date? ☐ Yes ☐ No ☐ NA
   - b. Did you print off the Data Submission Report? ☐ Yes ☐ No ☐ NA

3. Clerical
   - a. Were results transcribed correctly? ☐ Yes ☐ No ☐ NA
   - b. Verify that the decimal point and units of measure are correct. ☐ Yes ☐ No ☐ NA
   - c. Was the correct instrument/reagent kit in PT Central? ☐ Yes ☐ No ☐ NA
   - d. Were calculations performed correctly (even if automated)? ☐ Yes ☐ No ☐ NA
   - e. Do the values on Data Submission Report match the Evaluation report? ☐ Yes ☐ No ☐ NA

4. Specimen Handling
   - a. Was kit refrigerated immediately upon arrival? ☐ Yes ☐ No ☐ NA
   - b. Were contents of kit correct and in good condition? ☐ Yes ☐ No ☐ NA
   - c. Were specimen handling instructions followed? ☐ Yes ☐ No ☐ NA
   - d. Was testing performed within seven to 10 days of receipt? ☐ Yes ☐ No ☐ NA
   - e. Was sample at room temperature when tested? ☐ Yes ☐ No ☐ NA
   - f. Was sample mixed well before testing? ☐ Yes ☐ No ☐ NA
   - g. Was sample diluted properly, if required? ☐ Yes ☐ No ☐ NA

Completed Investigation Checklists and Corrective Action Forms do not need to be sent to AAFP-PT. Keep all documentation with your records. This form is designed to offer assistance in investigation and troubleshooting PT failures. It is the laboratory's responsibility to effectively trougleshoot and resolve all PT failures. Completion of this form does not guarantee future successful performances with proficiency testing.

5. Quality Control
   a. Were quality control materials within the acceptable range on the date of PT testing? ☐ Yes ☐ No ☐ NA
   b. Were there unacceptable QC during the month previous to the day of testing? ☐ Yes ☐ No ☐ NA
   c. Were there unacceptable QC during the month following the day of testing? ☐ Yes ☐ No ☐ NA
   d. Any evidence of trends or shifts in the periods just before and just after PT was tested? ☐ Yes ☐ No ☐ NA
   e. Does QC demonstrate an even distribution (above/below) the mean? ☐ Yes ☐ No ☐ NA

6. Calibration
   a. Does the instrument require calibrations and/or calibration verifications? ☐ Yes ☐ No ☐ NA
      i. Was calibration or calibration verification performed when it was due? ☐ Yes ☐ No ☐ NA
      ii. When was the last calibration performed? _____ /_____ /_____
      iii. When was the last calibration verification performed? _____ /_____ /_____
      iv. Were any calibration problems noted? ☐ Yes ☐ No ☐ NA

7. Instrument
   a. Was daily maintenance performed on the date of PT testing? ☐ Yes ☐ No ☐ NA
   b. Was special maintenance (ex: annual PM) performed just prior to PT testing? ☐ Yes ☐ No ☐ NA
   c. Were instrument problems noted when PT was performed? ☐ Yes ☐ No ☐ NA
   d. Were results within reported linearity for instrument? ☐ Yes ☐ No ☐ NA
   e. Does the sample demonstrate a “matrix effect”? ☐ Yes ☐ No ☐ NA
   f. Have you contacted your instrument manufacturer for assistance? ☐ Yes ☐ No ☐ NA

8. Reagents/Kit
   a. Were new reagents or calibrators recently introduced at or near the time PT was performed? ☐ Yes ☐ No ☐ NA
   b. Are reagents/kit within expiration dates? ☐ Yes ☐ No ☐ NA
   c. Verify that open stability of reagents/kits was not exceeded. ☐ Yes ☐ No ☐ NA
   d. Were reagents/kit components reconstituted properly according to manufacturer package insert? ☐ Yes ☐ No ☐ NA
   e. Were kit components substituted from other kits? ☐ Yes ☐ No ☐ NA
   f. Was reagent/kit log checked for notation of any recent problems? ☐ Yes ☐ No ☐ NA
   g. Has there been changes in manufacturer formulary of reagents/kit? ☐ Yes ☐ No ☐ NA
   h. Were procedure versus manufacturer’s most current package insert reveiwed for any changes or updates? ☐ Yes ☐ No ☐ NA

9. Testing Personnel
   a. Date of last competency assessment for testing personnel. _____ /_____ /_____
   b. Were assay procedure and proficiency sample preparation instructions reviewed to ensure instructions were followed? ☐ Yes ☐ No ☐ NA
   c. Did you review with testing personnel how samples were loaded to rule out misidentification or transposition of samples? ☐ Yes ☐ No ☐ NA
   d. Was retraining of testing personnel required and if so is this completed? ☐ Yes ☐ No ☐ NA

Investigation Form

Completed Investigation Checklists and Corrective Action Forms do not need to be sent to AAFP-PT. Keep all documentation with your records. This form is designed to offer assistance in investigation and troubleshooting PT failures. It is the laboratory's responsibility to effectively trougleshoot and resolve all PT failures. Completion of this form does not guarantee future successful performances with proficiency testing.

10. Repeat Testing
    a. Repeat testing result: _____
    b. Is result now acceptable? ☐ Yes ☐ No ☐ NA

11. Microbiology specific
    a. Was QC acceptable for
        i. The media used? ☐ Yes ☐ No ☐ NA
        ii. The identification system? ☐ Yes ☐ No ☐ NA
        iii. Other biochemical testing? ☐ Yes ☐ No ☐ NA
        iv. Susceptibility testing? ☐ Yes ☐ No ☐ NA
        v. Stains used? ☐ Yes ☐ No ☐ NA
    b. Was the correct culture media selected for inoculation? ☐ Yes ☐ No ☐ NA
    c. Were the growth conditions acceptable (temp, CO2, humidity)? ☐ Yes ☐ No ☐ NA
    d. Were the cultures mixed? ☐ Yes ☐ No ☐ NA
    e. Were adequate isolation techniques used by the personnel? ☐ Yes ☐ No ☐ NA
    f. Was the McFarland standard acceptable? ☐ Yes ☐ No ☐ NA
    g. Did the organism demonstrate a typical biochemical reaction pattern? ☐ Yes ☐ No ☐ NA
    h. Were purity plates OK? ☐ Yes ☐ No ☐ NA
    i. Did the lyophilized organism demonstrate typical characteristics? ☐ Yes ☐ No ☐ NA

Additional Notes

AAFP PROFICIENCY TESTING

Corrective Action Form

Laboratory Name: _____ CLIA #: _____

Testing Event: _____ Year: _____

Proficiency Testing Module: _____ Analyte: _____

Date PT Sample Rcvd: _____ /_____ /_____ Test Date: _____ /_____ /_____ Report Date: _____ /_____ /_____

Sample #: _____ Reported Result: _____ Expected Result/Range: _____

Repeat Analysis Result (if applicable): _____

Sample #: _____ Reported Result: _____ Expected Result/Range: _____

Repeat Analysis Result (if applicable): _____

Sample #: _____ Reported Result: _____ Expected Result/Range: _____

Repeat Analysis Result (if applicable): _____

Sample #: _____ Reported Result: _____ Expected Result/Range: _____

Repeat Analysis Result (if applicable): _____

Sample #: _____ Reported Result: _____ Expected Result/Range: _____

Repeat Analysis Result (if applicable): _____

1. Does this failure represent **unsatisfactory** performance for this analyte, specialty, or subspecialty? ☐ Yes ☐ No
2. Does this failure represent **unsuccessful** performance for this analyte, specialty, or subspecialty? ☐ Yes ☐ No
   (Unsatisfactory performance for two events in a row or two out of three consecutive testing events)

PT Failure Classification:

☐ Clerical Error	☐ Failure to Submit	☐ Equipment Error
☐ Lack of Consensus	☐ Specimen Handling	☐ Quality Control
☐ Training/Competency	☐ Sample Error	☐ Other

Findings:

Corrective Action:

Did this Error Affect Patient Health? ☐ Yes ☐ No If yes, state course of action:

Investigated by: _____ Date: _____ /_____ /_____

Laboratory Director: _____ Date: _____ /_____ /_____

Completed Investigation Checklists and Corrective Action Forms do not need to be sent to AAFP-PT. Keep all documentation with your records. This form is designed to offer assistance in investigation and troubleshooting PT failures. It is the laboratory's responsibility to effectively trougleshoot and resolve all PT failures. Completion of this form does not guarantee future successful performances with proficiency testing.

AAFP PROFICIENCY TESTING

Corrected Evaluation Request

Requests for corrected evaluations must be received by AAFP-PT **within 30 days** of the evaluation being emailed (see the notice included with your evaluation for the specific date). Corrections will only be made if an error occurred in the data evaluation process. AAFP-PT cannot issue corrected evaluations for errors made by the lab.

Please complete the information below and submit this form AND any other testing documentation. Corrected evaluations will be returned within four to six weeks of receipt at AAFP-PT. Denied requests will be returned with an explanation.

Please complete the following information:

AAFP # ____ ____ ____ ____ ____ ____ ____

Practice Name _____

Lab Contact Name _____

Phone Number _____

Email _____

Fax Number _____

Module #	Analyte (i.e., WBC, glucose)	Specimen(s) IDs	Reason for Correction Request

Corrected Evaluation Request

Email to pt@aafp.org

11400 Tomahawk Creek Parkway | Leawood, KS 66211-2672
(800) 274-7911 | pt@aafp.org | aafp.org/pt

CLIA Regulated Analytes

If you are performing testing for any of the analytes or tests listed below, you must be enrolled in Proficiency Testing for those analytes or tests:

Hematology

Cell identification or white blood cell differential

Erythrocyte count

Fibrinogen

Hematocrit (excluding spun microhematocrit)

Hemoglobin (excluding HemaCue)

Leukocyte count

Platelet count

Partial thromboplastin time

Prothrombin time

Diagnostic Immunology

General Immunology

Alpha-1-antitrypsin

Alpha-fetoprotein (tumor marker)

Antinuclear antibody

Antistreptolysin O - quantitative

Anti-human immunodeficiency virus (HIV)

Complement C3

Complement C4

Hepatitis markers (HBsAG,anti-HBc, HBeAg)

IgA

IgG

IgE

IgM

Infectious mononucleosis

Qualitative and quantitative

Rheumatoid factor

Rubella

Syphilis Serology

Chemistry

Routine Chemistry

Alanine aminotransferase (ALT/SGPT)

Albumin

Alkaline phosphatase

Amylase

Aspartate aminotransferase (AST/SGOT)

Bilirubin, total

Blood gas (pH, pO2 and pCO2)

Calcium, total

Chloride

Cholesterol, high density lipoprotein

Cholesterol, total

Creatinine

Creatine kinase, total

Creatinine kinase, isoenzyme (CK-MB)

Glucose (excluding measurements on devices cleared by FDA specifically for home use)

Iron, total

Lactate dehydrogenase (LDH)

LDH isoenzymes

Magnesium

Potassium

Sodium

Total Protein

Triglycerides

Urea Nitrogen (BUN)

Uric Acid

Endocrinology

Cortisol

Free Thyroxine (FT4)

Human chorionic gonadotropin (excluding color comparison tests for urine specimens)

T3 Uptake

Thyroid Stimulating Hormone (TSH)

Thyroxine, total (T4)

Triiodothyronine, total (T3)

Toxicology

Alcohol (blood)

Blood lead

Carbamazepine

Digoxin

Ethosuximide

Gentamicin

Lithium

Phenobarbital

Phenytoin

Primidone

Procainamide (and metabolites)

Quinidine

Theophylline

Tobramycin

Valproic Acid

Immunohematology

ABO group (excluding subgroups)

Antibody identification

Compatibility testing

D(Rho) typing

Unexpected antibody detection

Microbiology

Bacteriology

Mycobacteriology

Mycology

Parasitology

Virology

Note: *you must be enrolled in PT for the full extent of testing being performed, e.g., gram stain, acid fast stain, wet mount, primary inoculation, direct antigen testing, isolation, identification, and susceptibility.*

aafp.org/pt

The right choice for proficiency testing

DPA21120563