The MLE proficiency testing process from the time you receive your catalog through the receipt of your evaluations.

Thank you for participating in the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) Program sponsored by the American College of Physicians. We look forward to working with you.
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Using the Program Guide and Binder

We encourage you to read and become familiar with this Guide in its entirety—before you receive your first proficiency testing (PT) shipment.

This Guide Is Designed To Serve As A:
- Step-by-step procedure manual to explain each process involved in PT—from verification of your order to testing specimens and returning your results to MLE.
- Reference of important agencies and laboratory resources.
- Glossary of terms and formulas necessary for understanding PT.

Understanding the Format of this Guide
- There are 8 sections to this Guide, each designated by the vertical text on each page. This text can easily be seen on the left or right side of the book.
- Terms listed in the glossary section appear in bold-face and italics throughout the Guide.
- Helpful tips can be found in the margins on several pages.

The Professional MLE Binder—for Record keeping and Documentation

Regulatory compliance: Use the preorganized binder to maintain your files for easy access when regulators request this information for their review. Make copies of the following paperwork and place them behind the appropriate tabs:

Enrollment Records Tab:
- Order Form(s)/Renewal Form(s)
- Order Verification(s)
- Invoice(s)
- Change Forms, Letters or other communication with MLE regarding your order.

Test Result Forms and Evaluations Tab:
- Copies of completed Test Result Forms, log sheets and instrument printouts, if applicable
- Copies of notes or letters to MLE regarding your results
- Evaluation report(s)
- Corrective action documentation
What Is Proficiency Testing (PT)?

The MLE Process

- You receive PT specimens at scheduled intervals three (3) times per year.
- You may receive from one to five specimens (challenges) for each test performed in your laboratory, depending upon the regulatory status of the test.
- After you complete the testing, return the results (electronically or via mail) to MLE. MLE grades (evaluates) the results by comparing your laboratory’s results with those of your peers who use similar methodology.
- You will receive an evaluation report analyzing your performance.

CLIA

In all cases, the Clinical Laboratory Improvement Amendments (CLIA) of 1988 require laboratories to participate in PT for all regulated analytes three times per year, testing five challenges each time. CLIA also has requirements for preanalytic, analytic, and postanalytic record keeping and quality systems, and personnel. A discussion of these issues is beyond the scope of this guide; however, the following explains the CLIA proficiency testing enrollment requirements. A laboratory must:

- Notify the Centers for Medicare & Medicaid Services (CMS) of the approved PT program(s) in which it chooses to participate.
- If the laboratory participates in more than one approved PT program, designate the programs used for each specialty, subspecialty, analyte, or test.
- Participate for one year before designating a different program, and notify CMS of the change.
- Authorize the PT program to release testing data required to show compliance.
- Establish and maintain the accuracy and reliability of any test procedure not included in the list of regulated analytes. This means you must have a means of validating your performance for “nonregulated analytes” (This requirement is easily fulfilled by enrolling in proficiency testing for nonregulated analytes.)

Some states, private accreditation organizations, and third-party payers may have PT requirements that differ from those of CLIA—and may be more stringent. For example, some state agencies require PT for waived analytes. You should be familiar with the regulations governing PT in your state. If you need help, contact MLE and we’ll direct you to the appropriate agency.
The MLE Program

The American College of Physicians (ACP) has offered the MLE PT Program for over 40 years. MLE has earned the recognition and approval of CMS, COLA, The Joint Commission (TJC) and College of American Pathologists (CAP) for most analytes, state regulatory agencies, and various international regulatory bodies.

Record MLE ID Number Here:

Customer Service hours: Monday–Friday from 9:00 a.m. to 5:00 p.m. ET
800-338-2746, option 5 mle@acponline.org

Online Tools

- Participant Summary: www.acponline.org/mle/survey.htm
- WDES Login: www.ptresults.org
- CEexpress (FREE and discounted online educational courses): www.acponline.org/mle/ceexpress.htm
- Educational Resources: www.acponline.org/mle/educate.htm
- Download MLE Catalog: www.acponline.org/mle
- Change Form: www.acponline.org/mle/enroll.htm

Event Dates/Adding Modules

- MLE ships 3 times per year. Modules can be added or deleted throughout the year. After the first event, module pricing is prorated. Additional shipping charges may apply for modules added 4 weeks prior to ship date.

Changes to Your Order

Cancellation

Copy the Change Form on page 8 of this Guide (or download the form from MLE’s Website under Enrollment Info) and fax to 202-835-0440.

- Cancelling a module. Cancel in writing up to 4 weeks before the upcoming shipment to avoid charges.
- Cancelling the entire order. We refund charges for unshipped specimens if we receive notification in writing four weeks prior to the next shipping date. Once we have shipped orders for pipettes, we cannot cancel the order or refund the cost. The annual administration fee is non-refundable.
- Cancelling an analyte. Submit a “Test Menu Deletion” form if your laboratory reported tests during the previous event that have since been discontinued, but you are not cancelling the module. Download the form at www.acponline.org/mle/enroll.htm, scroll to “Forms.” Or copy the form on page 33.
Renewal

- Automatically renew your enrollment for the coming year with “auto renewal”. Enroll anytime by written request.
- Renew online or with your renewal form.

**Order Verification**

Approximately 10 days after MLE processes your order, we will send you an Order Verification documenting the order. Please review this information carefully. Reviewing your Order Verification before your first shipment arrives will ensure that you receive the appropriate products for your test methods. Sign and date the Order Verification and fax it to MLE at 202-835-0440. Keep your Order Verification in your Program Binder under the “Your Enrollment Records” tab to document your enrollment.

**Order Verification Instructions**

Thank you for your MLE Proficiency Testing order! We are sending you this Order Verification to confirm the accuracy of your entire MLE order as we have processed it. **Please read and verify each section as described below.**

1. **MLE ID Number**
   - The number assigned exclusively to your laboratory. Please refer to the number when contacting us.

2. **Shipping Address/Contact Info**
   - The address where the kits and evaluation forms will be shipped. If the "Shipment Address" is a P.O. box or APO/AFO address, please indicate box #.

3. **Billing Address/Contact Info**
   - The address where the invoice statement for your proficiency testing order will be sent if there is a balance due on your account.

4. **Lab Director**
   - Be sure you have provided the lab director's name.

5. **CLIA ID Number**
   - Be sure you have provided your CLIA identification number. We need this information to send your results to federal and state regulatory or the private accreditation program you designated on your order form.

6. **Products**
   - The modules you have ordered are listed in numerical order. Also printed are the corresponding ship dates for each item. Please verify that you have ordered all modules necessary for the testing you are performing. Any additions or deletions must be made at least four (4) weeks before the corresponding ship date for that module.

7. **Signature and Date**
   - Please sign and fax the order verification to MLE at 202-835-0440.

8. **Regulatory Agencies**
   - This section indicates the regulatory agencies that have approved all modules for each test method. It will be updated and sent to the Centers for Medicare & Medicaid Service (CMS) or its designee as you have provided your CLIA ID number.

9. **Additional Copies**
   - List any questions and requests from any person you designated to receive copies of your evaluations.

10. **Kit Address**
    - If MLE has been provided a kit shipping address different from the shipping address at the top, this is the address where the kit will be sent. Make this address a P.O. Box.

If you need to make changes to the information printed on your Order Verification, please enter the corrections/additions on the enclosed change form. Use this convenient form now or at any time throughout the year to notify us of important changes. You may return the change form by either faxing it to 202-835-0440 or by attaching postage to the self-mailing form and mailing it to MLE.

Welcome to MLE ... Questions? Contact MLE at 800-338-2746, option 5, or mle@aconline.org.
MLE ID Number

Your MLE ID number is a six-digit number specifically assigned to your facility. Your MLE ID number appears on each form we send you and is always referred to as the “MLE ID number or “Lab ID.” Refer to it when calling, e-mailing, or writing to MLE.
Changing Your Order

For your convenience, you will find a copy of the Change Form at the following locations:

- Included with your Order Verification
- On the next page of this guide
- Online at www.acponline.org/mle/enroll.htm

Use this form to make changes to your order, including additions and cancellations as well as address or name changes.

You may make changes to your PT order throughout the year by notifying us in writing at least four weeks before the next scheduled shipping date. We will make every effort to accommodate your modified order. To receive prorated credits, request cancellations in writing must be received at least four weeks before the scheduled shipping date. After that date, no refunds for the upcoming shipment will be issued. The yearly administration fee is nonrefundable.

Be sure to enter your MLE ID number and provide an authorizing signature in the designated spaces on the Change Form.

Fax it to 202-835-0440, email to mle@acponline.org or mail it to MLE at:

Medical Laboratory Evaluation
Suite 700
25 Massachusetts Avenue, NW
Washington, DC 20001-7401

Make copies of the blank Change Form and use this convenient form any time to notify us of important changes.
2014 Order Change Form

Please Do NOT Send Form Unless You Have Changes. ONLY fill in changes on this form.

(REQUIRED) MLE ID – enter your six-digit MLE ID Number: □ □ □ □ □ □

(REQUIRED) Make these change(s) for the following event[s]: □ M1 □ M2 □ M3 □ Entire year

(REQUIRED)
Signature: ____________________________________________________________
Print Name: ___________________________________________________________
Date: ________________________________________________________________

Fax this form to MLE at 202-835-0440, or return by mail following the instructions on the reverse side (or following page).

NEW Billing Address – Address where the invoice will be sent:
Contact/Facility Name: _________________________________________________
Address: ____________________________________________________________
Phone: ___________________ Fax: ___________________
E-Mail: ___________________

NEW Shipping Address – Address where the kits will be shipped: (This address may NOT be a PO Box).
Contact/Facility Name: _________________________________________________
Address: ____________________________________________________________
Phone: ___________________ Fax: ___________________
E-Mail: ___________________

NEW Laboratory Director: _________________________________

NEW CLIA Number: □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □

☐ Enroll the lab in “Automatic Renewal”

Module Changes – Please list any modules that you wish to add to – or delete from – your order.
List ONLY complete module additions or deletions. Do NOT list analytes. Any additions or deletions must be made at least four weeks before the corresponding ship date for that module.
Module Additions: ___________________________ Module Deletions: ___________________________
_________________________________________ ___________________________
_________________________________________ ___________________________
_________________________________________ ___________________________
_________________________________________ ___________________________
_________________________________________ ___________________________

Please report any individual analytes your laboratory is no longer testing by attaching a note to the Test Result Form pages when sending in results OR by faxing a Test Menu Deletion Form. It is not necessary to send this form and a test menu deletion form; your test menu will be adjusted based upon your order deletions. In most cases, deleting an analyte from your test menu will not affect module orders. Questions? Call MLE Customer Service at 1-800-338-2746, option 5, or e-mail: MLE@acponline.org
Payment Information

An invoice and payment envelope will be mailed approximately two weeks after we process your order or order changes. **Full payment is due within 30 days of your invoice date.**

Please note: If you are enrolled in “automatic renewal” or if you renew earlier than November, as a courtesy, you will not receive an invoice until mid-November.

Payment Options

- VISA or Mastercard
- Check or Money Order (payable to ACP/MLE)
- Purchase Order may be provided upon enrollment

Send the top portion of your invoice with your payment. Keep the bottom portion in your binder for your records.

We will notify you of:

- Overdue balances. **Failure to pay delinquent accounts will result in cancellation of your enrollment.**
- Credit: The credit will remain on your account and be applied to future purchases unless you specifically request a refund or you completely cancel your order.
Test results must be returned by the postmark date listed on your shipping calendar. No extensions are permitted.

If the primary testing person is absent during the PT testing period but patient testing is still being performed by other personnel, PT must still be performed according to CLIA regulations. If someone is qualified to perform patient testing, they must perform PT as well.

A shipping calendar is provided in the yearly binder to help you prepare for the important weeks of the year when your test kits will be shipped. Knowing the dates to expect your test kits is important for successful PT performance. Post the calendar prominently in your laboratory.

MLE has established specific time lines based on the shipping schedule. Keep the following in mind, to best manage each event shipment with MLE:

- Call us if your test kit does not arrive within three days of the ship date.

- Request replacements within three days of receipt of your test kit. Follow the easy steps in “Replacement Specimens” on page 13.

Refer to the shipping calendar when making changes to your PT order. Request changes in writing at least four weeks before the scheduled ship date. See “Changing Your Order” on page 7 for instructions.

- Integrate your office and personal calendars to the shipping calendar.

- Note any ship dates that conflict with scheduled vacations, conferences, or other office closures. If you notify us at least four weeks before the scheduled ship date, we can arrange to send your test kit to an alternate address if your office is closed.

- Post the shipping calendar and tell your co-workers when to expect the test kits.

- Circle the weeks you expect your shipments, as well as the date your results must be postmarked, on your laboratory calendar and personal monthly planner.
Receipt of Shipment

Test kits are shipped by overnight express delivery service. The test kit should arrive the same week it is shipped.

- Refer to the shipping calendar to know when to expect the test kit.
- Be certain all personnel—front office and lab—are aware of the importance of ship dates and that they must refrigerate the kit immediately upon arrival.

If the test kit does not arrive within three days of the ship date—Call MLE

Upon receipt of the test kit:

- Immediately inspect the kit.
- Verify its contents. Follow the instructions outlined on page 12 to verify the kit contents.
- All specimens should be considered infectious and handled as if capable of transmitting disease. Important: Do not handle broken specimens! Read the warning on the Test Result Form (TRF) provided with your test kit before handling specimens.
- Refrigerate specimens. We recommend that you do not test the samples directly after receipt. Let them stabilize in the refrigerator for at least two hours before testing.
- Notify lab testing personnel as soon as the test kit arrives.
- Complete the testing within 10 working days and mail the Test Result Form to MLE or submit the form online to MLE by the postmark date indicated on page 1 of the Test Result Form booklet.

Can’t perform testing right away?

- Open the kit and verify its contents as soon as it arrives. This is important! If you find you need replacement specimens, we will be able to process your request only if we receive the request within three days of receipt of the kit.

Refrigerate your specimens at 2–8°C until you are able to test them.

Note: If you find you need to modify your order, be sure to notify MLE in writing at least four weeks before the next shipment. Review “Changing Your MLE Order” on page 7.
When the Test Kit Arrives

Test Kit Contents

The test kit for each shipment should contain all the proficiency testing specimens you ordered.

As soon as it arrives, make sure the test kit contains:

- **Specimens for the modules you ordered.** Here’s how to verify that you have received all of the specimens for your order:
  - Look at the mailing label on the TRF; notice that the label lists the modules and specimens you have ordered.
  - Find the table of contents on the last pages of the Test Result Form booklet. It lists all of the modules, specimen numbers, and the reporting page numbers (see pages 28-32).
  - Match the specimen numbers from the table of contents with the numbers on the specimens you received in the kit.

- **A cold pack.** The cold pack enclosed in your kit is intended to prevent the specimens from encountering extreme temperatures. *If the cold pack is thawed when your specimens arrive and you have received them within 3 to 4 days of the ship date, the specimens are suitable for testing.* It is important to note that depending on weather conditions, a thawed cold pack will produce condensation within the test kit. This phenomenon is normal, should be expected, and does not adversely affect specimen integrity.

- **Your TRF.** This is a scannable test result form that is bound as a booklet. It is organized into sections that correspond to the modules you have ordered. Specimen handling and reporting instructions are included in the booklet.

- **A return envelope.** MLE provides an oversized envelope to use when you return the appropriate pages from the TRF. This special envelope expedites delivery to us and avoids excessive folding of the scannable form.

**PLEASE NOTE:** Additional postage is required. The envelope will be returned to you by the post office without the required postage and could result in a “failure to participate” being applied to your laboratory.

**Important:**

Do not handle broken specimens!
Read the warning on the TRF provided with your test kit before handling specimens. All specimens should be considered infectious and handled as if capable of transmitting disease.

The return envelope must be postmarked by the postmark due date. CMS prohibits accepting results after the due date. Late results will be given a score of zero.

Important:

Do not handle broken specimens!
Read the warning on the TRF provided with your test kit before handling specimens. All specimens should be considered infectious and handled as if capable of transmitting disease.

The return envelope must be postmarked by the postmark due date. CMS prohibits accepting results after the due date. Late results will be given a score of zero.
When the Test Kit Arrives

**Specimens**

**Specimen Numbering**

All proficiency testing specimens are labeled. In most cases, the specimen number prefix corresponds to the type of specimen contained therein. For example, TC-1 is for Throat Culture, and CH-1 is for Chemistry. This should help to decrease the possibility of specimen mix-ups.

**Replacement Specimens**

MLE is committed to making sure that you have all the materials necessary to successfully perform proficiency testing. We will replace missing or broken specimens if we are notified within three days of receipt of the test kit (limited to specimen availability).

- **Call MLE immediately** if you receive an incomplete test kit or if your kit contains broken specimens.
- **Keep the original Test Result Form** while waiting for your replacement specimens. Enter the results on the original form. Return these result forms to MLE by the postmark date.
- **MLE is unable to give extensions for replacement samples.** The original postmark date must be honored.

If replacement specimens are not available, submit a note with your Test Result Form stating that a replacement was requested, but unavailable. You will not be penalized.
Laboratory Safety

The human source materials used to manufacture MLE proficiency testing specimens have been tested for antibodies to HBsAg, HCV, and HIV. All materials have been found to be nonreactive using FDA-approved testing methods except those in Modules 775, 790 and 791. Because of the incubation period necessary for the formation of antibodies directed toward these pathological agents, nonreactivity does not guarantee nor imply the absence of infectious disease. All specimens of human origin, regardless of whether they are known to contain infectious agents, have the potential to transmit disease and must be handled in strict accordance with universal precautions mandated by the CDC and FDA and described by OSHA rules, regulations, and standards.

While health care workers most commonly are exposed to bloodborne pathogens through needlestick injuries, there are many other ways by which exposure may occur. These include, but are not limited to, contact with the mucous membranes and nonintact skin.

Microbiology Specimens

Microbiology specimens may contain pathogens or potential pathogens and require special handling to ensure the safety of personnel. MLE takes specific steps—adhering to all shipping and packaging regulations and emphasizing the warning statements—to prevent any contamination due to improper handling of microbiology specimens. Hence, we have “Biological Substance Category B” stamped on all microbiology shipping containers. Keep in mind that all specimens of human origin, regardless of whether they are known to contain infectious agents, have the potential to transmit disease and must be handled in strict accordance with the universal precautions mandated by the CDC and FDA, and described by OSHA rules, regulations, and standards.
Laboratory Safety

Laboratory Accidents
Report to MLE immediately if testing personnel are exposed to PT specimens (contamination of the mucous membranes through splashes or aerosolization, cuts from containers or needle sticks). Each laboratory should have a written protocol detailing appropriate measures to take in response to exposure to patient specimens. Follow this protocol in response to proficiency testing specimen exposure as well.

Here is an example of the warning statement included in all MLE Test Result Forms.

WARNING
READ THIS BEFORE PROCEEDING

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.

Extra Precautions for Microbiology Specimens

THESE SPECIMENS MAY CONTAIN DANGEROUS PATHOGENS AND SHOULD BE TREATED WITH EXTREME CARE. They should be handled and disposed of only by personnel trained to work with pathogenic microorganisms following accepted microbiologic methods.

Avoid inhalation, ingestion, or injection of microorganisms. Do not handle the specimens if you have a cut. Do not create aerosols. Dispose of the specimens by autoclaving or by any other method that ensures that microorganisms are killed.

IN CASE OF SPILLS OR CONTAMINATION, CONTACT MLE IMMEDIATELY. FURTHERMORE, EACH LABORATORY SHOULD HAVE A WRITTEN PROTOCOL DETAILING APPROPRIATE MEASURES TO TAKE IN RESPONSE TO EXPOSURE TO PATIENT SPECIMENS. FOLLOW THIS PROTOCOL IN RESPONSE TO PROFICIENCY TESTING SPECIMEN EXPOSURE AS WELL.
General Testing Instructions

The appropriate pages of the TRF must be submitted by the postmark due date printed on the front cover of the TRF. MLE is prohibited by CMS to accept late results.

You have at least 10 working days to test your PT specimens and to return the pages from your TRF that correspond to the modules your laboratory ordered. Begin testing as soon as you can, to allow time to correct any unforeseen problems. Here are some general testing tips; more specific instructions are included with the test kits. Additionally, special testing instructions for certain specialties are discussed in the pages to follow.

- Always test PT specimens as soon as possible. Refrigerate specimens (2–8°C) for at least two hours upon arrival, and keep refrigerated until you are able to test them.

- Verify that you have received the correct specimens. Carefully compare each specimen number to the numbers provided on the Test Result Form—before testing! This process is detailed on page 12.

- Thoroughly read the specimen-specific instructions provided on each test result form before you begin testing. Some samples may require special handling.

- For Microbiology, test only one of the two loops or swabs; we generally give you two for each culture challenge. Store the second loop/swab at 2–8°C for possible use as a backup.

- Read the instructions for submitting results before completing the TRF. Review the master lists of instruments and methods and carefully select the code that represents your test method. This is essential for the correct evaluation of your results.

- Record your observations. You may find it helpful to create a worksheet for recording comments about the testing process for each PT shipment. It may be several weeks from the time you test the specimens until you receive your evaluation. You may not recall any unusual occurrences that may have affected your PT results, so write them down at the time of testing.

- After testing has been completed, store the samples according to the instructions on the TRF until you receive your evaluation.

Call MLE to report any spillage or breakage of specimens.

Discard old PT specimens the same way you discard patient specimens after reviewing the evaluation.

If your laboratory has discontinued testing analytes for which you previously reported results to MLE, you must fill out and return a “Test Menu Deletion” form. The form can be accessed via online, on page 34 of this guide, or by contacting MLE.
Testing Instructions—Hematology

Hematology Specimen Stability
Test whole blood hematology specimens within seven (7) days of receipt. The “shelf-life” stability of the specimen extends throughout the 10-day testing period. However, optimal performance for the whole blood hematology specimens—especially QBC specimens—is obtained by testing the specimens within the first seven (7) days of their receipt.

HemoCue Hemoglobin/Glucose
This module includes two whole blood specimens for hemoglobin and glucose analysis. Although glucose is a “chemistry” analyte, only report HemoCue glucose results on the TRF page designated for the HemoCue listed in the table of contents.

Microhematocrit Methods
The cell “packing” characteristics of PT specimens differ slightly from those of fresh human blood. All laboratories using the microhematocrit centrifugation method for hematocrit testing should spin MLE specimens exactly 5 minutes regardless of the length of time you spin patient specimens to minimize interlaboratory differences.

Hemocytometer Users
Please pay particular attention to these two special PT steps:

The initial dilution should sit for at least 20–30 minutes. This extended time ensures proper lysing of fixed cells in the PT specimens.

The “charged” hemocytometer should sit for at least 10–15 minutes before you perform the count. To allow the cells to settle and to prevent sample evaporation, use a homemade “moisture chamber.”

To make a moisture chamber, follow these steps:

1. Moisten a folded paper towel, gauze, or any other absorbent material with water.

2. Place the moistened material used in Step 1 in the bottom of a Petri dish or any clean, flat-bottomed container with a lid.

3. “Charge” or fill the hemocytometer.

4. Place the filled hemocytometer on top of the moistened material inside of the container and replace the lid.

See next page for manual WBC instructions.

QBC specimens should be tested within 5 days of receipt.
Manual White Blood Cell (WBC)

Due to the artificial nature of these PT samples, you will observe “football-shaped” cells that may appear to be WBCs. Include these cells in your count.

Blood Cell Identification and Automated Differential Reporting

Cell identification and WBC differential are considered one analyte by CLIA regulations. Therefore, when MLE receives results for both blood cell identification and automated differential, we may only send one of these to CMS. Unless you tell us otherwise, we will automatically transmit the results for blood cell identification, not the automated differential. We will, however, grade both sets of results and provide you with comparison information for both.

Here’s how to tell us you prefer that we send the automated differential results to CMS:

- Refer to the notice printed at the bottom of the TRF page on which you report automated differential results.
- Fill in the oval only if MLE should send the automated differential results to CMS instead of the blood cell identification results.
Testing Instructions—Coagulation

The plasma coagulation specimens contain lyophilized powder. You must reconstitute the specimens by adding 1 mL of sterile distilled water to each vial. You will need a volumetric pipette to reconstitute specimens. Contact MLE for information on how to purchase a 1 mL volumetric pipette if your lab does not have one.

The whole-blood coagulation specimens can be reconstituted as directed in the instructions on your TRF. All supplies needed for reconstitution of the whole blood specimens are included in your test kit.

MLE offers a variety of whole blood prothrombin time modules. Please make sure to enroll in the right module for your instrument. Refer to the MLE Catalog, or contact MLE Customer Service for assistance.
Testing Instructions—Urine Sediment and Provider-Performed Microscopy (PPM)

To assess proficiency for microscopic procedures, MLE provides color photographs of microscopic fields. Urine sediment identification photos depict microscopic elements seen in urine sediment, such as cells, casts, crystals, organisms, or artifacts.

PPM photos depict various microscopic slide preparations. Determine the presence or absence of bacteria, fungi, parasites, human cellular elements, pinworms, fecal leukocytes, sperm, nasal eosinophils, and amniotic fluid, as specified on the Test Result Form.
Testing Instructions—Microbiology

Bacteriology Testing

The number and type of microbiology specimens you receive varies with the module(s) ordered. MLE has designed the modules to accommodate most laboratory test menus while ensuring compliance with CLIA regulations. CLIA regulations require laboratories to perform a minimum of five (5) non-waived bacteriology challenges in each test event.

This five-challenge total should cover the test methods performed in your laboratory. The five challenges can include one type of testing on five specimens, or multiple types of testing on one or more specimens. If multiple tests are performed on a single specimen, each test performed counts as one challenge. For example, bacterial identification from culture, Gram stain, and antimicrobial susceptibility testing performed from a single sample would count as three non-waived challenges. Two more challenges would still be needed to meet the five-challenge requirement. If only one non-waived microbiology test is performed in the lab, then five specimens for this test would need to be tested.

Make sure that you have five non-waived challenges in bacteriology each time you receive samples for PT. If you are unsure if you have enrolled for enough challenges, contact MLE Customer Service for assistance.

Challenges performed using waived methods do not count towards the five required for non-waived bacteriology testing. For example, testing for rapid Strep Group A using a waived testing kit would not apply towards the five-challenge non-waived testing requirement.

If you are notified during the year that a previously non-waived test is now waived, you will need to reassess your PT order to ensure that you still have five (5) non-waived challenges.

Culture Specimens

CULTI-LOOPSTM and INOCU-SWAB IT are the trade names for some of the culture specimens provided in the MLE program. We will often refer to these trade names. Here are two quick notes about them.

CULTI-LOOPSTM resemble the bacteriology plating loop you may have in your laboratory. They are plastic loops embedded with the test microorganisms. Each loop comes with a sterile enrichment or diluent broth to rehydrate the microorganisms. The TRF contains easy-to-follow, written instructions for rehydrating and incubating the specimens. Page 26 of this guide provides diagrams illustrating the proper handling techniques for the CULTI-LOOPSTM.

INOCU-SWAB IT resemble a collection swab. It is a cotton-tipped swab that contains lyophilized test microorganism(s). Each swab comes with a rehydration fluid for activation of the organism(s) prior to testing. The TRF contains easy-to-follow written instructions for rehydrating and incubating the specimens. Page 25 of this guide provides diagrams illustrating the proper handling techniques for the INOCU-SWAB IT.

We generally give you two CULTI-LOOPSTM/INOCU-SWAB IT for each specimen and recommend that you only culture one sample. Store the second sample in the refrigerator and culture it when needed. You can use it as a backup specimen or keep it refrigerated until you receive your evaluation; you may need to retest it as a means of troubleshooting PT failures.
Colony Count Specimens

INOCLU-PELLETS™ is a trade name for the colony count specimens provided in the MLE program. We will often refer to this trade name. Each INOCU-PELLETS™ specimen consists of two parts:

A labeled foil pouch containing a lyophilized pellet in a labeled vial.

A 99-mL vial of dilution fluid.

The TRF contains easy-to-follow instructions for rehydrating and incubating the specimens. Page 24 of this guide provides diagrams illustrating the proper handling techniques for the INOCU-PELLETS™ specimens.

Antimicrobial Susceptibility Reporting

Perform antimicrobial susceptibility testing using the antimicrobial agents and techniques used in your laboratory.

In 2006, CMS began requiring PT programs to evaluate whether the drugs reported are appropriate for treatment of the organism tested and for the source of the specimen. The PT program must identify the antimicrobial agents a lab reports that are inappropriate according to the Clinical and Laboratory Standards Institute (CLSI). Inappropriate drug choices must be graded as incorrect results.

If you report susceptibility results for inappropriate drugs, they will be flagged as incorrect, regardless of the actual result reported. The comment “Inappropriate drug for organism and/or source” will appear on your MLE evaluation report.

MLE will determine the appropriateness of each drug using the current edition of CLSI’s “Performance Standards for Antimicrobial Susceptibility Testing.” Each January, an Informational Supplement (document M100) is published, providing updated antimicrobial standards. This document contains tables of suggested antimicrobial agents for routine testing for each organism group, such as Enterobacteriaceae, Staphylococcus species, Enterococcus species, etc. Additional tables list appropriate antimicrobial agents and criteria for interpreting the results of disk diffusion and/or minimum inhibitory concentration (MIC) testing. See Recommended Texts on page 56 for details about CLSI publications.

Respiratory Antigen Detection: Reporting influenza test method and results

There are two kinds of rapid influenza test kits. Some kits differentiate between Influenza Type A and Influenza Type B, and other kits do not.

“The Influenza A & B Combined” refers to methods that cannot distinguish between the 2 types. These kits test for both Type A and Type B in a single test area. There is only one result line, providing a single combined result of either positive or negative. If you use this kind of kit, you will only report one combined result for each
When the Test Kit Arrives

When the Test Kit Arrives

“**Influenza A only and Influenza B only**” refers to methods that can distinguish Type A from Type B. These kits test for Type A and Type B in two separate test areas. They are actually two separate tests in one unit. These kits have two result lines, providing a positive or negative result for each type of influenza virus. If you use this kind of kit, you must enter two results for each specimen: one result (pos. or neg.) for “Influenza A only” and one result (pos. or neg.) for “Influenza B only.”

If you use a kit that distinguishes between Influenza A and Influenza B, use the sample test result form below as a guide to resulting your proficiency test correctly.

<table>
<thead>
<tr>
<th>Antigen Detection</th>
<th>Results V-1</th>
<th>Results V-2</th>
<th>Results V-3</th>
<th>Results V-4</th>
<th>Results V-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
</tr>
</tbody>
</table>

**In the example above:**

Specimen V-1 is negative for both types of Influenza

Specimen V-2 is positive for both types of Influenza

Specimen V-3 is positive for Influenza A only (negative for B)

Specimen V-4 is positive for Influenza B only (negative for A)

Remember, Influenza A and Influenza B are two different tests, and you must include all of your negative results in addition to the positive results.
Virology Testing:
CLIA regulations require laboratories to test a total of five virology specimens in each testing event for the subspecialty of virology.

This requirement does not apply to waived virology testing. However, it is good laboratory practice to perform proficiency testing on ALL tests performed in the laboratory, even if they are waived kits or methods.

Please note: HAV antigen testing, while in our testing booklet in the Immunology section is considered by CMS to be Virology for CLIA purposes.

Instructions for Handling Inocu-Pellets™

Each Inocu-Pellets™ colony count specimen consists of a labeled foil pouch containing a lyophilized pellet in a labeled vial and a labeled 99 mL bottle of dilution fluid.

Be sure to match the specimen with the dilution fluid bottle when testing.

1. Warm an appropriate amount of media, specimen pellet vial and 99 mL bottle of dilution fluid to room temperature (20-25°C) for each specimen tested.

2. Remove the cap from the sample vial and open the flip-top on the dilution fluid bottle.

3. Empty the lyophilized pellet into the dilution fluid and re-cap the bottle securely. Be sure to avoid touching the pellet to avoid contamination.

4. Mix the contents of the bottle vigorously until the entire pellet has dissolved and the suspension is homogenous in appearance.

5. Continue by following the procedures and methods used in your lab to identify the organism(s) present in these specimens and/or perform colony count testing.
Instructions for Handling INOCU-SWAB II™

Each INOCU-SWAB II™ culture consists of 2 swabs containing viable lyophilized microorganisms in a foil pouch and rehydration fluid for activation of the organism(s) prior to use for culture and/or gram staining. Please note: the rehydrating fluid vials are NOT labeled. The rehydrating fluid is not specimen specific; therefore, you may use any of the vials provided to rehydrate your specimens. We recommend you label the rehydrating vial prior to use to avoid confusion.

1. Warm an appropriate amount of media, one specimen swab and one vial of rehydrating fluid to room temperature (20-25°C) for each specimen tested. Store the second swab and extra rehydrating fluid vials in the refrigerator in case repeat testing is necessary.

2. Holding the specimen by the red cap, remove swab from plastic tube.

3. Open a rehydration vial and submerge the swab portion into the fluid. Allow approximately 10 seconds for the lyophilized specimen to liquefy while mixing and swirling the swab gently.

4. Once the swab is saturated, inoculate your media directly with the swab. Return the swab to the rehydration fluid before inoculating each subsequent culture plate.
Special Testing Instructions for Microbiology

Instructions for Handling CULTI-LOOPS™

1. Warm appropriate plated medium to room temperature.
2. Cut open the end of the foil packet as indicated on the label.
3. Remove red sheath from loop while holding tube in hand.
4. Remove tube cap and hold in hand.
5. Break loop shaft off from handle directly into tube containing rehydration fluid. Replace top.
6. Place tube in 35° - 37°C incubator just long enough (10 minutes) for the film to dissolve completely out of the loop.
7. Shake tube gently to suspend the organism.
8. Inoculate appropriate media with a transfer pipette.
9. Streak in the usual manner.
Testing Instructions—Chemistry

Most chemistry specimens are liquid. These specimens have two major benefits—they require no reconstitution and they may be frozen after testing for retesting at a later date. See the TRF for specific storage instructions or, if applicable, reconstitution instructions.

Bilirubin Reporting

MLE has two different specimen types which can be tested for total bilirubin: Chemistry specimens (CH) and neonatal bilirubin specimens (NB). You are only required to test one set of specimens for total bilirubin. If your module order includes both, and you choose to test all 10 specimens, we will grade both sets of results and provide comparison information for both. However, unless you tell us otherwise, we will automatically transmit to CMS the results from the CH specimens, not the NB specimens.

Here’s how to tell us you prefer that we send CMS your total bilirubin results for the neonatal specimens (NB):

- Refer to the printed notice at the bottom of the neonatal bilirubin page of the TRF booklet.
- Fill in the oval only if MLE should send the total bilirubin results for the neonatal specimens (NB) to CMS instead of the results for the chemistry specimens (CH).

Creatinine Reporting

In order to provide appropriate PT grading, MLE has added ovals to the test result form to allow laboratories to indicate which creatinine calibration method is currently in use. Select either “IDMS” for IDMS-traceable calibration method, or “OLD” for traditional calibration method. If you are unsure about the traceability of the calibration for your creatinine method, contact the reagent and/or calibrator manufacturer for assistance.

Background information:
The National Kidney Disease Education Program (NKDEP) launched the Creatinine Standardization Program to address inter-laboratory variation in creatinine assay calibration and provide more accurate estimates of glomerular filtration rate (GFR). Both efforts are part of a larger NKDEP initiative to help health care providers better identify and treat chronic kidney disease in order to prevent or delay kidney failure and improve patient outcomes. The Creatinine Standardization Program encourages in-vitro diagnostics manufacturers to adjust calibrations of routine serum creatinine methods to be traceable to the internationally accepted reference method—isotope dilution mass spectrometry (IDMS)—and to work with clinical laboratories to coordinate this calibration adjustment with the introduction of a revised GFR estimating equation appropriate for use with IDMS-traceable creatinine methods.
When the Test Kit Arrives

REPORTING BY PAPER

The Test Result Form (TRF)

Just as in patient testing, attention to detail is critical to successful PT performance. Properly completing the TRF contributes to your overall success. Be sure to give us the information we need to evaluate your results accurately.

Here is an example of a test result form page:
Your precise recording of instrument codes, reagents, methods, and results will help prevent clerical errors and ensure the accurate comparison of your results with similar methods.

We are committed to evaluating your test results as quickly as possible. That’s why MLE uses optical scanning technology to “read” your results from the TRFs. This technology makes the data entry process fast and accurate.

The TRF is divided into sections corresponding to the modules included in each shipment. Each section has specific instructions to assist you in handling the PT specimens and reporting results. Here are some things you should know about completing the scannable TRF:

**Remove and return the cover page and all** of the pages that correspond to the test modules your laboratory has ordered. Check the table of contents located on the back pages of the TRF to verify which pages are included with each module. Return all pages assigned to each module for which you are enrolled, even if you have not entered results on some of the pages.

- Use a black ink pen to complete the TRF. Avoid using a light pencil or blue ink.

- Fill in your MLE ID number in the boxes provided at the top right corner of EACH page. We will not be able to identify your laboratory’s results without your MLE ID number. MLE will not be responsible for pages returned without identification numbers clearly written on every page.

- Enter all your numbers clearly, block style, as shown here

  1 2 3 4 5 6 7 8 9 0

- Do not write numbers partially in or out of the boxes—the entire number must be within the margins of the box.

- Don’t change the decimal point! The computer only accepts answers that conform to the boxes and decimal points printed on the TRF.

- Note the correct way to place your answers in the boxes, shown below.

  **Example:**

  Glucose 69 mg/dL  

<table>
<thead>
<tr>
<th>Correct</th>
<th>Incorrect</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 9</td>
<td>6 9 0</td>
</tr>
</tbody>
</table>

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If your answer is too large to fit in the boxes provided, you must round-off your result. Follow these guidelines for rounding numbers:

- **If your answer ends in 1, 2, 3, or 4, round down**—decrease your value to the next number. For example, report 13.1 as 13; report 40.32 as 40.3.

- **If your answer ends in 6, 7, 8, or 9, round up**—increase your value to the next number. For example, report 13.8 as 14; report 20.47 as 20.5.

- **If your answer ends in 5, round to make it even.** Here’s how: Look at the digit immediately to the left of the 5. If that digit is even, drop the 5. If that digit is odd, increase your value to the next number. For example, report 13.5 as 14; report 18.45 as 18.5.

Verify that the units of measurement match those printed in the TRF. If they do not match, then your test result MUST BE CONVERTED into the units printed in the TRF.

Indicate correct instrument, method, and/or reagent codes. This allows us to compare your results with those submitted by other users of testing methods that are most similar to yours, i.e., your “peer group.” If you are unsure of the correct code, contact the manufacturer or MLE Customer Service.

Completely fill in the ovals like this:

Do not fill them in like this:

Be sure to report your results in the areas designated for your specific tests and be sure to use the corresponding specimens. Enter the results only in the area reserved for that specimen number. Notes must be submitted on a separate sheet of paper. Do not write across result entry areas. For tests not performed, leave the result area blank.

If you make a mistake using pen, use “white-out” to erase the error. Rewrite your correct answer in the original result boxes. If you make a mistake using pencil, erase your original mark completely. Try not to leave smudges when performing erasures.

If you realize you have made a clerical error after mailing your TRF, contact MLE immediately. We are able to accept corrections up until the postmark due date.

When all testing is finished, review your results carefully. Make sure the testing personnel and lab director, or designee, sign the attestation statement.

Make a copy of all of the pages you are returning to MLE, including the cover page. Also, copy the pages with specimen and reporting instructions for your records. File the copies under the tab “Test Result Forms and Evaluations” in your binder.
Reporting Electronically

The Web Data Entry System (WDES)

MLE has an online reporting system known as WDES. To enroll in online reporting you must send an email to our Web Support: ptwebsupport@acponline.org. Make sure you include your MLE ID when contacting us.

Entering results

- Upon logging into the website, you will find the following sections: General Information, Main, and Additional Links.
- To enter results, click on the link in the Main section for the current test event. This link will give you specific instructions on reporting your results. Please read through carefully before attempting to enter your results. You will also find additional information with tips that will make entering your results easier.

Entering method codes

- If you have not previously reported results with MLE, you will need to enter your method codes using the drop down lists.
- Once you have submitted results with MLE, your methods will be held from event to event. You will only need to change your method codes as you change methods in your laboratory.
- If your method does not appear in the drop down list, choose “other” or O and type in the precise name of the method so that MLE may assign the appropriate code.

Submission of results

- Carefully review the Presubmission Test Receipt before hitting the Final Submit button. You will see any errors at the top of this receipt.
- Click the Final Submit button once all errors have been resolved. You will notice that the Enter Results link now becomes a Test Receipt Link. Print this receipt and retain for your records.
- Sign and retain the Attestation Statement from the front of the TRF booklet that was sent with your test kit. Keep along with your Test Receipt in your binder for future reference.
Before Returning the Results

Be sure to keep a copy of the signed attestation statement with your PT records:

“We the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing materials, have as closely as practical, performed the analyses on these specimens in the same manner as regularly performed on patient specimens.”

Attestation Statement

Surveyors/inspectors review PT records to ensure that laboratory testing personnel and the director, or designee, have signed the attestation statement certifying that PT samples were tested in the same manner as patient specimens.

The lab director or designee and testing personnel must sign the attestation statement prior to returning their PT results to the PT provider. The director may delegate the responsibility for signing the attestation statement to a technical consultant or other designee provided that they meet the CLIA minimum qualifications: A baccalaureate degree in medical technology, biology, chemistry, or one of the physical sciences, plus two years of experience in a clinical setting.

To comply with the federal requirements for PT, your laboratory must do the following:

- Test the PT specimens the same way it tests patient specimens. Specifically, your laboratory must:
  - Assign routine testing personnel to examine or test the PT specimens. The individual who tests the specimens and the laboratory director, or designee, both must attest to the routine integration of the specimens with patient testing.
  - Test the PT specimens the same number of times as done routinely for patient specimens.
  - Refrain from discussing the results of the PT specimens with any other laboratories. This restriction also applies to laboratories with multiple sites.
  - Do not send PT specimens or portions of specimens to another laboratory for analysis. Referral of PT specimens to another laboratory will incur severe penalties if discovered by a regulatory or accreditation agency.
- Document all stages of the testing process for the PT specimens:
  - Copy your completed test result form and the signed attestation statement and maintain the copy in the yearly binder provided by MLE. Make a copy of the instructions for future reference and possible troubleshooting.
  - If you report electronically then print and retain a copy of your Test Receipt, sign the attestation statement from the TRF and retain for your records. Do not mail to MLE.
  - File your instrument printouts in the same binder along with your TRF copy.
  - Maintain these records for two years.
- Only perform PT for the test system, assay, or examination you use as the primary method for patient testing.
Final Checklist

After you have tested your PT specimens and completed the TRF, ask yourself a few questions before sending the results to MLE. If you have inadvertently forgotten to complete any of the following steps, refer to the appropriate page(s) of this guide for instructions. Be sure to correct any errors or omissions before you return your Test Result Form.

Have you:

✓ Confirmed that you have received and tested each specimen for each module ordered? See page 12.

✓ Entered your results in the proper sections, either on the TRF or electronically, matching the specimen numbers as printed on the labels to the corresponding numbers above the result boxes on the TRF?

✓ Tested the PT specimens in the same way you test patient specimens and/or according to the specific instructions on the TRF?

✓ Completed the TRF exactly as directed in the instructions for each section or entered in the Web Data Entry System? If not, your results may not be properly evaluated, leading to unnecessary PT failures. Review pages 28 through 31.

✓ Had the laboratory director, or designee, and testing personnel sign the attestation statement? This is a legal requirement under CLIA. See page 32.

✓ Made a copy of the TRF and testing instructions for your records?

✓ Applied sufficient postage, and mailed it by the postmark due date?

✓ Included a Test Menu Deletion form for any discontinued analytes?

✓ IF YOU SUBMITTED RESULTS ONLINE, DO NOT MAIL THE TRF PAGES TO MLE.

If you can answer “Yes” to each of the questions above, you’re ready to return your TRF pages to MLE using the envelope provided to:

Medical Laboratory Evaluation
Suite 700
25 Massachusetts Ave, NW
Washington, DC 20001-7401
Test Menu Deletion Form
(Fax the Completed Form to: 202-835-0440)

MLE ID NO.: ___________________ TO: MLE Customer Service

DATE: ___________________ NAME: ___________________

FAX #: ___________________ PHONE #: ___________________

This laboratory has discontinued the following tests:
(List each test individually and not by module number)

__________________  ____________________  ____________________

__________________  ____________________  ____________________

__________________  ____________________  ____________________

__________________  ____________________  ____________________

__________________  ____________________  ____________________

__________________  ____________________  ____________________

Signature: ________________________________________________

Name of facility: __________________________________________

By returning this form, you are instructing MLE to remove the above tests from your testing menu. Be sure to also notify your regulatory agency(ies) of these changes.

You may also notify MLE of your test menu deletions by e-mailing us at mle@acponline.org
What Is an Evaluation Report?

Example:

1. The name and address of your testing facility.
2. Your MLE identification number.
3. Your CLIA identification number. We must have a CLIA number for your facility. Without this number, we cannot electronically transmit your PT scores to CMS or its designee.
4. The names of other persons or agencies you designate to receive copies of your evaluations.
5. The test event/shipment description (e.g., 2014 MLE- M1) and the evaluation print date.
6. The modules ordered.
7. The results you submitted for each test (analyte) and specimen.
8. For qualitative results: The acceptable response(s) for each specimen.
9. The comparison group which you were evaluated against.
10. For quantitative results: The comparison group that you were evaluated against and its statistics—including target mean, group standard deviation, and your standard deviation index.
11. For quantitative results: The acceptable range for each specimen.
12. A comment area for MLE to describe any unusual PT circumstances or exceptions.
13. For regulated tests, a score reflecting your current performance for the CMS specialty or subspecialty, as well as your current analyte score.
Understanding the Terms

Familiarity with MLE’s evaluation, statistical, and regulatory terminology will help facilitate interpretation of your PT information and improve the quality of your laboratory services.

CLIA ID Number

The CLIA number, assigned by the CMS, identifies any facility that performs tests on human specimens. MLE needs your 10-digit CLIA number to electronically transmit your PT scores to CMS.

Your Test Method

MLE needs information about the instrument, methodology, reagent, and/or kits used to perform your testing to properly evaluate your results. This information is used to establish the comparison group by which we evaluate your results. Incorrect or incomplete test method information could lead to incorrect evaluation of your PT results. MLE provides lists of codes for common instrument and methods, and provides spaces on each test result form for you to record methods not listed.

Comparison Group

Comparison group, or target group, refers to the tier that MLE uses to compare your results. The target groups used are based on the instruments, methods, reagents, and/or kits reported on your TRF. MLE evaluates all results against one of four possible groups:

- Peer Group
- Method Group
- All Method Group
- Referee Group

In most cases, the comparison group will be your peer group. A peer group includes MLE participants who use identical instruments, reagents, and/or kits and must consist of at least ten laboratories—after the removal of outliers. If fewer than ten laboratories meet the requirement for a peer group, the comparison group will then default to the method group.

A method group consists of labs using a similar method or a similar instrument. For example, there may be fewer than ten MLE labs using an Abbott Cell-Dyn 1400 and fewer than ten MLE labs using an Abbott Cell-Dyn 1600. However, the data from these two groups could be combined because the instruments are similar. Thus, we have formed a method group made up of all Abbott Cell-Dyn instruments. MLE frequently consults with manufacturers to determine appropriate method groups. If fewer than 10 laboratories meet the requirement for a method group, the comparison group will then default to the all method group.
The **all method group** is all MLE participants that reported results for an *analyte*—after the removal of outliers—regardless of instrument or method reported.

A **referee group** is composed of participating laboratories designated by MLE for the purpose of grading a proficiency testing challenge. **Referee laboratories** must be currently in compliance with CLIA requirements, having a record of successful proficiency testing performance. CMS permits results to be evaluated against a referee group provided that there is 80% consensus (agreement) among the referee laboratories, except for blood bank/immunohematology analytes.

**Target Mean**

The *mean*, or average, is a statistical term defined as the sum of all values divided by the number of values. Therefore, the *target means*—which appear on your evaluations and in the Participant Summaries for each specimen—are the averages of all the results for a particular specimen within the comparison group. In most cases, the target mean will be your peer-group mean.

**Group Standard Deviation**

*Standard deviation* (SD) is a statistical term that measures the scatter, or variability, in the distribution of individual results. It is the average difference between an individual result and the mean. SD is a measurement of the degree of *precision* of a test method. The smaller the SD, the more precise the method.

**Your SDI**

*Standard Deviation Index (SDI)* is a calculation that “normalizes” the amount of *bias* in your results so that you can compare the *accuracy* of your results on specimens at varying concentrations. This also allows you to monitor your results across several shipments, or testing events, for *shifts* or *trends*.

**Acceptable Ranges for Quantitative Results**

The *acceptable range* for quantitative results is the upper limit and lower limit of all values that are considered “correct.” MLE prints the acceptable range on your evaluation for every test and specimen evaluated. This range is calculated by applying specific evaluation criteria to the target mean. MLE publishes the evaluation criteria for each analyte in every Participant Summary, immediately following the table of contents.
Acceptable Responses for Qualitative Results

The MLE program generally uses the **consensus method** to grade qualitative results. Acceptable results are established based upon a required consensus, or agreement, of participant responses. In most cases, the required consensus is 80%. This means that at least 80% of participating MLE labs had to have reported the same response. That response or answer then becomes the acceptable response.

There are three ways MLE uses consensus grading techniques: participant consensus by method; overall participant consensus; and referee consensus.

**Participant consensus by method** is used when varying sensitivity or specificity of test methods results in different “correct” answers. It is analogous to grading quantitative results by peer group. Let’s look at urine hCG as an example:

- Suppose the sensitivity of Kit A is 500 mIU/mL and the sensitivity of Kit B is 20 mIU/mL. If the MLE specimen contains 100 mIU/mL hCG, we would expect Kit A to obtain a “negative” result and Kit B to obtain a “positive” result. These are different answers, and they are both correct. Using consensus by method allows us to grade negative and positive as acceptable responses—depending on the test method reported.

**Overall participant consensus** means that all responses are combined to obtain consensus. It is analogous to the all method group for quantitative results.

**Referee consensus** means that a select group of participating laboratories are used to determine the acceptable response. If less than 80% of the participants in a grading group agree, CMS requires that MLE use referee laboratories to try to reach consensus within the group. All participating laboratories are graded against the referee group’s responses. MLE is only permitted to not grade the challenge if less than 80% of referee laboratories agree.

Comment Section

There may be times when you cannot provide complete results, even though you plan ahead and anticipate when your PT specimens will arrive. For example, if you run out of reagent, if your kit is back-ordered, or if your instrument is down for repair. If this happens, you must submit written notification at the time of testing. MLE staff can then enter a special code describing your unusual circumstance(s), and an explanation of your situation will print in the comment section of the evaluation. You should also notify your regulatory agency. MLE cannot grant grading exceptions—we merely note your situation. The final determination of the acceptability of your exception request is always up to CMS or your accreditation agency.

There also may be special times when MLE cannot grade your results. If this happens, we’ll print a note of explanation in the comment section or in the participant summary.
CMS Performance Summary

The *CMS Performance Summary* appears on the last page of your evaluation. This cumulative report indicates your overall performance for all *regulated analytes*, specialties, and/or subspecialties for which you are enrolled. This summary will help you assess your laboratory’s overall regulatory performance.

- The summary page contains the information we electronically transmit to *CMS*.
- Federal regulations do not require the inclusion of waived or nonregulated analytes on this summary; therefore, waived or nonregulated test scores will not appear on the summary page.
- A space is provided on the evaluation for the laboratory director and testing personnel to sign, indicating that they have reviewed the evaluation.
- We encourage the lab director to take an active role in reviewing the entire evaluation report and discussing it with all testing personnel.

The Score

- Carefully review each page of the evaluation to determine how the scores were achieved.
- A score of 100% does not always indicate successful performance. There may be instances when your results are not graded and you receive a score of 100% even though the results were not formally evaluated.
- When results are not graded, compare them with those of other participants to make an assessment of their acceptability. Refer to pages 45 and 46 for steps in self-assessing ungraded results.

An example of a CMS Performance Summary is on the next page.
1. Your MLE identification number.

2. Your **CLIA number**. We must have a **CLIA number** for your facility. Without this number, we cannot electronically transmit your PT scores to CMS or its designee.

3. The test event/shipment description (e.g., 2014 MLE-M1) and the print date.

4. Your percentage score and your **current performance** for each regulated **analyte**, specialty, and/or subspecialty in this specific test event. The score represents the percentage of correct responses. It is calculated using the formula: (# of correct response ÷ total # of challenges) x 100. (Note: See the exceptions for determining bacteriology and parasitology scores on the next page). To achieve satisfactory performance, your score must be at least 80%. For certain blood bank tests you must score 100% to achieve satisfactory performance.

5. Previous event performances.

6. **Cumulative performance** for each regulated **analyte**, specialty, and/or subspecialty—including the current test event and the two preceding test events. To achieve successful performance, you must have achieved satisfactory performance for at least two of the three consecutive test events.

7. Possible comments warning you when you are **at risk** for being unsuccessful (i.e., you have achieved unsatisfactory performance for at least one of three consecutive testing events.) Three warning symbols, [1], [2], and [3], could appear on your CMS Performance Summary. See the next page for explanations of these warning symbols. Note: These comments are for your information only. The only elements of this report transmitted to CMS are the analyte name and percentage score.
CMS Performance Summary

Bacteriology and Parasitology Scoring
Evaluation of bacteriology and parasitology differs from other specialties and subspecialties. The CLIA regulations require these subspecialty scores to be weighted.

Weighting Scores
There is no individual percentage score or performance status for each analyte. A weighted score is given to the entire subspecialty for the current testing event. A current and cumulative performance status (e.g., satisfactory and successful) is given to the entire subspecialty.

At Risk
To remain compliant with CLIA ‘88 regulations, your laboratory must successfully complete 2 out of 3 consecutive proficiency tests. MLE has devised a scoring mechanism to assist you in keeping track of your PT performance. With any unsuccessful PT, one of three “At Risk” codes ([1], [2], and [3]), will appear in the comment section of your Performance Summary. The code will indicate the number of consecutive events you must complete successfully in order to remain compliant with CLIA regulations. These codes are not transmitted to any regulatory agencies. They are intended to alert you to any potential compliance issues a full test event before they come to the attention of regulators. Explanations of these warning symbols are as follows:

At Risk [1] means that your laboratory must successfully complete the next PT event to avoid any regulatory issues.

At Risk [2] means that you must successfully complete the next 2 testing events to remain in compliance.

At Risk [3] means that your laboratory has not successfully complied with the Proficiency Testing requirements of the CLIA regulations. You may receive a letter from CMS or from your accrediting organization regarding your unsuccessful PT, and the letter may require you to cease patient testing for the affected analyte(s).

Note: You must perform and document corrective action when you fail PT. Regulatory agencies use PT as an educational tool, but they have the legal perogative to take punitive action against your laboratory for unsuccessful PT performance. Contact your regulating and/or accrediting agency for more information regarding the possibility of sanctions. See pages 47-53 for information on troubleshooting and corrective action.
Evaluation Report

Reviewing the Evaluation

To benefit from proficiency testing as a means of external quality control, you need to learn how to interpret your evaluation. Don’t just scan the report looking for “flags” marking an incorrect PT result. Go the extra step and take the time to fully understand your evaluation. By doing this, you may identify problem areas that were previously undetected. You may even prevent PT failure on the next testing event.

Follow these helpful hints:

- Read the two preceding sections to learn what information is printed on an evaluation, understand its terms, and know how MLE evaluates your results. This information is necessary for reviewing your evaluation.
- Be thorough and consistent. Review it at a time when you know you will not be interrupted. It may take time to develop a systematic approach, but in the long run, you will save time.
- Review your evaluation within a week of receiving it. If MLE made a data processing error, you must call MLE within two weeks to receive a corrected evaluation.

You might consider developing your own flow chart, or step-by-step process, to review your evaluation, or proceed as follows:

- Be sure the CLIA number is correct. If not, contact MLE immediately to update your file.
- Confirm that we have sent copies to the appropriate agencies and any consultants you designated on your order form.
- Confirm that we have processed all of your test results as you submitted them by comparing the evaluation to your copy of your Test Result Form pages.
- Confirm that all instrument, reagent, and/or kit names are correct. This is important! If you submit incorrect or incomplete information regarding your test methods, you may fail PT challenges due to inappropriate peer- or method-group comparisons. (Unfortunately, incorrect test methods cannot be corrected, per CMS. Make a note so the correct method will be reported during the next testing event).
- Look for any results that are unacceptable. An asterisk (*) will print next to your result if it is out of the acceptable range or if it is an unacceptable response. Remember: CLIA requires documentation and resolution of all PT deficiencies. We’ll help you! Refer to page 47-53.
Review your *SDIs*. They indicate your *accuracy* by showing how far from the *target mean* each result is. SDI values greater than 2, or a predominance of positive or negative values could indicate poor accuracy, a *shift*, or a *trend*. As a general rule, SDI values should be close to zero (within +/- 2.0), with both positive and negative values. This represents normal variation above and below the *mean*.

Look for results that were not graded. The comment section of your *evaluation* provides an explanation for ungraded results. Ungraded results may receive a score of 100% even though they were not formally evaluated. When your results are not graded, compare them with those of other participants to make an assessment of their acceptability. Refer to pages 45 and 46, for steps in self-assessing ungraded results. You must do a “self-evaluation” on any ungraded results and determine if you would have passed, if the results had been graded.

Review your *CMS Performance Summary* to confirm that it includes all the *regulated analytes*, specialties, and subspecialties for which you perform patient testing. Results for waived or nonregulated analytes, not required by CMS, will not be included on this summary.

*Note:* If your *CMS Performance Summary* indicates *unsatisfactory* or *unsuccessful performance*, you must perform and document remedial action. File this documentation with the PT evaluation and hold it for 2 years, just like the PT records.

Review and discuss the PT results and educational critiques in the Participant Summary with the laboratory director and testing personnel.

When you have completed reviewing your evaluation as described above, sign the last page of the CMS Performance Summary and file it in your MLE Binder.
Participant Summary

A Participant Summary is available on-line. You may print the entire document or only those pages pertaining to the analytes your laboratory tested. Hard copies of the participant summaries are available by enrolling in Module 107.

The Participant Summary is a compilation of the collective results of all MLE participants for a specific test event. The results are listed by analyte and grouped by test method provided that at least ten participants submitted results for a particular analyte that was tested by the same method. The Participant Summary should be consulted when reviewing your evaluation. Using the Participant Summary as you review your evaluation provides a complete assessment of your individual performance, as well as a comparison of your performance with that of others testing the same specimens, using identical or similar methods.

At first, the information contained within the Participant Summary may seem overwhelming. However, as you become familiar with it, you will find that the information is not only easy to use, it is also a great help when interpreting your evaluation and your overall PT performance. The Participant Summary includes:

- **Evaluation (grading) criteria.** MLE uses the grading criteria established by the CMS for all regulated analytes. For other analytes, we use scientifically defensible methods to set the evaluation criteria. On the rare occasion that MLE cannot grade a challenge, we provide an explanation in the comment section of your evaluation.

- **Group statistics or comparisons.** For tests with qualitative results, we group all the responses reported by MLE participants and list them in order with the most frequently reported results first. For tests with quantitative results, we calculate the mean, standard deviation (SD), coefficient of variation (CV), median, and acceptable range. These statistics are provided, along with the number of labs included, for all methods combined, method groups composed of similar test methods, and peer groups composed of identical test methods. To validate this information, there must be at least ten laboratories in a group after outliers have been eliminated.

Educational/Technical Critiques

To provide an educational perspective to PT, we often provide extra information in the Participant Summary in the form of technical notes. This is where you will find the answers to our ungraded educational challenges, case history diagnoses, technical tips, information about the composition of specimens, etc. At times, we explain why certain answers are acceptable or not acceptable—sometimes discussing common errors that could lead to erroneous results—and give recommendations for correcting problems. These technical critiques can be used to help determine the cause of PT failures and provides clues for troubleshooting. They can also be used for corrective action and education of testing personnel.
**Data Errors**

**Corrections**

Carefully review your MLE evaluations as soon as you can. Although MLE uses optical imaging technology to minimize chances of data entry error, you may occasionally find an error on your evaluation. We will do all that we can to quickly investigate and resolve these issues.

- Keep copies of your completed test result form pages and Test Receipt and use them to compare the results you submitted to MLE with those printed on your evaluations. Make sure that instruments, methods, reagents, and/or kits listed accurately describe the methods used for patient testing performed in your facility.

- Notify us within two weeks of receiving your evaluation if an error has been made by our data processing department. MLE is unable to make corrections after this two-week period.

MLE can only correct evaluations due to an error made by our data processing department. Clerical errors, such as improperly entered results or method codes on the TRF, cannot be corrected, as transferral to a report form is part of the total testing process. Incorrect coding should be noted in your PT records and a self-evaluation against the correct comparison group should be included in your records for review by your inspector/surveyor. Refer to page 48 for information on how to prevent clerical errors and page 45 on how to self-evaluate your PT results.

**Performing a Self-Assessment**

The following are instances when it is necessary for a laboratory to perform a self-assessment:

- Lack of consensus (participant or referee)/lack of comparison group.
- Unexpected specimen/instrument incompatibility.
- Results submitted after the postmark date.
- No results received.

In the cases of lack of consensus/comparison group, your results will be given a score of 100% even though this may not reflect actual performance.

In the event that you neglected to return results to MLE by the postmark deadline or failed to report results for an analyte which you previously reported, you will receive a “failure to participate.” Any regulated analytes will receive a score of 0%.

Regardless of the reason, any results that were not formally evaluated by MLE will need to be self-evaluated by the laboratory and the results of that assessment documented. Below are the steps on how to use the Participant Summary to perform your self-evaluation for various...
scenarios.

Your results were not graded due to a lack of consensus for qualitative tests: Suppose your evaluation report indicates that MLE did not grade a specimen you reported as “positive”. The Participant Summary says that 700 MLE labs tested the specimen; 450 reported “negative” and 250 reported “positive”. The specimen would not have been graded because there was only a 64.2% overall participant agreement for the correct answer of “negative”; our evaluation criteria require an 80% consensus for the evaluation of the specimen. If the test in question is a regulated analyte and has ten or more laboratories reporting it, MLE must then attempt to grade by referee laboratory consensus. If referee laboratories did not achieve 80% consensus, then the sample would not be evaluated. In either of these instances, you should review the results from others using your same testing kit or method and contact your kit/method manufacturer for guidance.

Your results were not graded due to a lack of comparison group for quantitative tests: Suppose you are one of eight labs reporting the sodium test from our blood gas samples. The Participant Summary will list the median values of these results, since there are less than ten labs needed to establish an “All Method” group. Assume you reported a sodium value of 123 mmol/L, while the median value was 125 mmol/L. How do you know if your result is “acceptable”?

The first step is to locate the Evaluation Criteria. This information is located at the front of the Participant Summary, right after the Table of Contents. For sodium, the grading criteria is ± 4.0 mmol/L of the target mean. Next, you need to calculate the “acceptable range”. Using the median value (125) as the target mean, this is how you would calculate the range:

125 ± 4.0 establishes a range of 121 through 129 mmol/L

As you see, using the data published in the Participant Summary helps you assess your results when they are not evaluated. However, this needs to be used with caution as the median value may not give a true picture if only eight labs report results. Compare how you perform with this range to your usual quality control performance to verify that the median value is not severely skewed. You can also spot check your system’s performance by sending a duplicate patient specimen you tested in house to an outside lab.

You received a Failure to Participate for one or all of your testing results: For most quantitative results, the Participant Summary will list the acceptable range. All you need to do is to determine your comparison group, which is explained in more detail on page 36, find the acceptable range for this group and compare your results to this range. For positive or negative qualitative tests, MLE lists the number of laboratories that reported a positive or negative which indicates the appropriate response. For most other qualitative tests, MLE lists all of the acceptable responses. Simply determine if your response is listed as acceptable.
Troubleshooting and Corrective Action

Successful troubleshooting of Proficiency Testing (PT) is an important tool for identifying errors in your laboratory procedures, subsequently helping to prevent erroneous patient results. To use this tool effectively, it is important to detect and resolve PT failures. In the event that you have a PT failure, you need to determine if the error affected patient test results. Therefore, you should review patient results reported during the same period you performed PT. Document all your corrective action activities, including those related to patient management.

The Process

Follow these basic steps:

- **Review your evaluation reports.** Schedule a time when you know you will not be interrupted. Your time is limited, so use the following information to pinpoint the problem. Identify the error that was made, why it occurred, and whether it affected patient testing. After identifying the error, take steps to resolve it. If it could have affected patient testing, then all potential patient results affected must be reviewed and assessed for possible errors.

- **Take a systematic approach.** Look for patterns (e.g., all results for one specimen are incorrect, or all results for the same analyte are incorrect). Start by checking for common errors (e.g., transcription errors) and proceed to investigating more obscure problems. Consider all five categories of proficiency testing errors: clerical errors, data processing errors, specimen-handling errors, instrument errors, and interpretation errors.

- **Refer to the photocopy of your Test Result Form (TRF) pages.** This will help to determine whether MLE made an error when processing your results, or if you made a clerical error when recording your results on the TRF.

- **Refer to your instrument printouts, worksheets, or recorded observations.** This will help you determine if any unusual occurrences or conditions may have affected your PT results.

- **Contact your instrument or kit manufacturer.** They have the most knowledge about your test method and should be able to assist you in interpreting your quality control and maintenance records to determine if your instrument is producing accurate and precise patient results.

- **Document your corrective action.** MLE has developed a Corrective Action Record for documenting PT deficiencies and corrective action. The form is designed to help you in this process. *(Make a photocopy of the blank master form on pages 52 and 53.)* Keep this documentation in your MLE binder with your evaluation so that it is available when your laboratory is inspected. It is not necessary to send any corrective action records to MLE.
Clerical Errors

Clerical errors are one of the most common PT errors, usually made by laboratory staff when filling out the TRF. We cannot correct this kind of error after the result submission deadline.

To prevent a clerical error, make sure you:

- Follow the detailed instructions on the TRF when completing each section of the form.
- Use the correct TRF page and section to report your results.
- Provide the correct test method information by selecting the correct code from the instrument or reagent list. (Remember: The method code you select determines the comparison group for evaluation of your results).
- Select the correct response from the list of results.
- Transcribe results from the instrument printout, worksheet, or test device onto the TRF or WDES correctly.
- Report results to the decimal place indicated on the TRF.
- Report your results in the proper units of measure. Convert your results if necessary to conform to the units on the Test Result Form.
Data Processing Errors

Data processing errors are easy to detect and to correct. Refer to your copy of your completed TRF and compare the results you submitted with the information printed on your evaluation. If the information doesn’t match, MLE made a data processing error.

If you discover an error, you must contact MLE within two weeks of the evaluation date (see upper right corner of your evaluation) so we can correct the report, otherwise, it cannot be corrected.

Specimen-Handling Errors

Most of the specimens used in the MLE program are liquid. We use liquid specimens to decrease handling and reconstitution errors. However, there are a few lyophilized specimens—primarily, coagulation—that require reconstitution. There is a rule of thumb regarding reconstitution errors: The error will affect all of the tests performed on that specimen, and the magnitude and direction of the error will be the same for all tests.

Hematology specimens are composed of cells suspended in liquid. During storage the cells settle and adhere to the insides of the tubes. If the specimens are not mixed thoroughly before testing, they will not produce accurate results.

Review the specimen-handling instructions on the TRF to ensure these were followed during testing. Specimen-handling errors, once detected, usually do not persist.

As you become more familiar with the PT process, the likelihood of experiencing this kind of error diminishes. Most regulatory inspectors understand and will show leniency if the mistakes are specific to PT and not indicative of patient testing errors and the mistakes are recognized, corrected, and well documented.

Purchasing replacement specimens for repeat testing is a convenient way to determine if specimen-handling errors caused PT failure(s). Results obtained by retesting PT specimens cannot be regraded; however, this can serve to document a handling error. Additional material may be purchased through MLE.

Note: Due to their short shelf life, whole blood specimens may be unavailable for repeat testing. Call MLE Customer Service and we’ll be happy to check on their availability.
Avoid instrument errors by implementing a routine instrument maintenance program.

Instrument Errors

Instrument errors can be random or systematic.

A *random error* usually occurs in one test or one test run and is independent of other parameters at the time of testing. These errors occur in one of the five specimens and maybe resolved by retesting the PT specimen. Examples of random errors are specimen evaporation, pipetting error, temperature fluctuation, or power surges.

*Systematic errors* affect the entire run, and if left uncorrected, may persist from run to run or day to day. These errors are usually proportional, meaning all PT results are uniformly higher or lower than the target mean. Miscalibration is the most common example of a systematic error; however, poor instrument maintenance can also be a factor. Systematic errors may have affected patient testing as well. Review your patient results from that period and decide whether additional action is needed. Keep in mind that your quality control can be in range, while the test system still produces a PT failure because of the different evaluation criteria used.

A good quality assurance and quality control program will minimize the risk for instrument errors. If you suspect instrument error as the cause of your PT deficiency, contact your instrument manufacturer for assistance with identifying and resolving the error.
Interpretation Errors

Interpretation errors occur primarily in identifying blood cells, performing microscopy procedures, and interpreting microbiology cultures or visual urinalysis dipstick readings. PT interpretation errors may occur when laboratory personnel try to identify PT challenges beyond the scope and extent of the testing routinely performed in their lab, or when testing personnel are not proficient in performing the test involved, even though the test is done on patient specimens.

Remember: Don’t report answers for tests that are not performed on patients in your laboratory. If you want to assess your proficiency on a non-patient performed test, write your answer on a worksheet identifying the shipment and specimen numbers, save it in your MLE binder until the test event is graded, then perform a self-assessment.

If you fail a blood cell identification or other microscopy identification challenge, read the technical critique in the Participant Summary thoroughly for an explanation of the key features of the element presented in the photograph. Some helpful textbook references are listed on pages 56 and 57 in the “Laboratory Resources” section.

You might find troubleshooting microbiology PT failures more difficult. Again, refer to the Participant Summary, which lists the microorganism(s) present. Then, review your results and procedures for the test(s) for differentiation.

For example, let’s review results from a throat culture challenge along with the information from a Participant Summary:

246 labs submitted results of “negative for Group A Strep” and 15 labs reported “positive for Group A Strep.” Since the overall consensus was 94%, MLE graded this challenge.

Suppose you were one of the 15 labs that submitted an unacceptable response, resulting in a PT failure that requires corrective action. Review your records for that culture, noting your findings about, for example, the hemolysis pattern, morphologic characteristics, and reaction to the bacitracin disk. If you obtained growth and the participant summary stated that there was no organism present in the specimen, you may have a contamination problem. If your records show that the culture produced growth that you identified as Group A Strep, you need to improve your ability to differentiate organisms correctly.

Interpretation errors may have affected patient testing. Review your patient results from that time period and decide whether additional action is needed.

Avoid interpretation errors by having a continuing education program for all laboratory staff.
MLE Corrective Action Record

MLE Shipment:_________________MLE Specimen #:_________________Analyte:_________________
Your Result: __________Acceptable Range/Correct Answer:__________________________

Data Entry Error

- Clerical error by testing personnel when completing the test result form?   Yes   No

*If yes, attach instrument printouts or other supporting documentation. Describe steps taken to prevent recurrence.*
____________________________________________________________________________
____________________________________________________________________________

- Data processing error by MLE?   Yes   No

*If yes, call MLE immediately upon receipt of your evaluation.*
Describe incident below.
____________________________________________________________________________
____________________________________________________________________________

Specimen-Handling Error

- Did you handle the specimens properly?   Yes   No

*Review the handling instructions on the test result form. If you did not follow the instructions on the test result form, describe the error and the steps you have taken to prevent recurrence.*
____________________________________________________________________________
____________________________________________________________________________

Instrumentation or Test System Error

- Have you identified problems with your instrumentation or test system?   Yes   No

*Describe any problems with your instrumentation or test system that resulted in this PT failure and/or incorrect patient testing. State what you have done to correct the situation and to prevent recurrence.*
____________________________________________________________________________
____________________________________________________________________________
Procedure and Interpretation Error

- Did you follow each step in the MLE Test Result Form specimen instructions?   Yes   No
- Did you follow each step in your procedure manual/package insert?   Yes   No

Review the instructions and your test procedure thoroughly. Make sure that you performed all steps exactly as written. Make sure that there were no special procedures for specimen preparation and handling. Describe any handling, technique, and/or procedural errors.

____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

- Did you incorrectly identify a cell or microorganism?   Yes   No

Review technical critiques in MLE’s Participant Summary, and/or textbooks or other literature. Refer to pages 56-57 of this guide for recommended texts. Describe any educational review or additional training performed.

____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

Quality System Assessment

- Did the reason for the error affect patient results?   Yes   No

If yes, identify volume of patient results affected and follow-up action taken.

____________________________________________________________________________
____________________________________________________________________________

Testing Personnel Signature_______________________________________________________
Date__________________

Laboratory Director  
Signature ____________________________________________________________________
COLA is a nonprofit, physician-directed, national accrediting organization whose purpose is to promote excellence in medicine and patient care through programs of voluntary education, achievement, and accreditation. In the Columbia, Maryland headquarters, COLA’s dedicated staff of administrative and technical personnel interact with surveyors located strategically throughout the country. State-of-the-art technology ensures prompt, quality service for their extensive customer base, which encompasses thousands of facilities nationwide.

Founded in 1988, COLA’s Board of Directors is composed of practicing physicians representing the American Academy of Family Physicians (AAFP), American Medical Association (AMA), American College of Physicians (ACP), and the American Osteopathic Association (AOA).

COLA is accepted by the Centers for Medicare & Medicaid Services (CMS) under CLIA. By earning COLA accreditation, laboratories are in compliance with the Clinical Laboratory Improvement Amendments (CLIA). COLA can also assist those laboratories that are required to meet state requirements. In July 1997, COLA received the recognition of all of its accreditation programs by The Joint Commission (TJC).

**Laboratory Accreditation**

Laboratory professionals throughout the United States have found COLA’s accreditation program to be an excellent quality assurance tool, as well as a convenient way to meet regulations mandated by CLIA. Developed by physicians, the COLA accreditation program is educational in nature. COLA’s goal is to help laboratory professionals operate an accurate and efficient laboratory facility.

For more COLA program information, technical assistance, or questions regarding a variety of other laboratory-related issues:

**Phone:** 800-981-9883

**E-mail:** info@COLA.org

**Web:** www.cola.org; or

**Write:**

COLA
9881 Broken Land Parkway, Suite 200
Columbia, MD 21046
CMS and its Regional Offices

In 1988, Congress passed the Clinical Laboratory Improvement Amendments [CLIA] law to ensure the quality and reliability of medical tests performed in clinical laboratories throughout the nation. Following its passage, the Department of Health and Human Services authorized its federal agencies, namely, CMS and CDC to develop regulations to implement the law. The regulations have evolved over time. CMS released new Quality Systems regulations in January 2003, coordinating quality assessment requirements for moderately and highly complex laboratories. Other parts of the CLIA regulations are being reworked; however, no further changes are anticipated for several years. For more information, please visit our web page for regulatory resources and other related sites at: www.acponline.org/mle/regulate.htm and www.acponline.org/mle/otherweb.htm

CMS or its designees perform biennial inspections of all laboratories, including physician office labs.

We cannot emphasize enough the importance of recognizing your responsibilities as a proficiency testing participant. MLE includes regulatory updates on the website at www.acponline.org/mle/regulate.htm and is willing and prepared to assist you in complying with both state and federal regulations.

A few brief pointers to aid in compliance:

- Report significant changes in laboratory operations to CMS. This includes changes in personnel, instrumentation/methods, test menu/complexity, PT enrollment/participation, and choice of accreditation organizations.

- Report to MLE, in writing, any circumstances leading to the inability to complete all of your PT testing, or if you have discontinued any analyte testing. Regulations require PT providers to assign a score of 0%—“failure to participate”—to any results not received. Attach a note to your Test Result Form and explain the circumstances for not testing before submitting results to MLE. Make a copy of this information to mail to your regional regulatory office.

- The laboratory director and testing personnel must review evaluations carefully to determine the need for any corrective action. Although MLE applies a passing grade to ungraded challenges, labs still must determine the acceptability of each result and recognize whether corrective action is needed.

- Document everything and be prepared to provide documentation as necessary.
**Recommended Texts**

**Bench Manuals for the Office Laboratory**

*Quality Assessment Plan: A Simplified Approach. COLA. Columbia, MD. 2008*


**Comprehensive Reference for Laboratory Testing**


**Microbiology**

Clinical and Laboratory Standards Institute. *M100 Tables 1-A -1C Quick Guide (M100 QG)*. Suggested groupings of antimicrobial agents with FDA clinical indications that should be considered for routine testing and reporting. These laminated guides serve as a useful reference for laboratories seeking to meet requirements for proficiency testing and accreditation. *(Note: New editions are published annually)* Available for purchase at www.clsi.org


*Available through MLE at a discounted rate. See our Educational Resources page online*
OnLine Resource

*COLA Laboratory Director Program

Blood Cell and Urine Sediment Identification

References

- *Morphology of Human Blood Cells* by L.W. Diggs, MD; Dorothy Sturm and Ann Bell, M.S. and published by Abbott Laboratories. Your copy must be prepaid by check or money order (made payable to: ABBOTT LABORATORIES). Send $19.75, which includes shipping and handling, to:

  ADD Distribution Center
  c/o Iron Mountain Fulfillment Services, Inc.
  1521 E Wilson St.
  Batavia, IL 60510
  Telephone: 630-406-1189

  or go online (use Order ID 126272):
  www.abbottpromostore.com

- Reference Materials produced by Siemens Corporation

To order complimentary copies, call 1-800-255-3232.

  *Application of Urine Chemistry and Microscopic Examination in Health and Disease*
  *The Clinical Significance of Urine Test Results*


- *The POL Microscopy Atlas*. A microscopy atlas for the physician office laboratory by the American Academy of Family Physicians (AAFP)*

*Available through MLE at a discounted rate. See our Educational Resources page online.*
Glossary

This glossary defines a number of terms specific to proficiency testing. The glossary does not include cell descriptions and urine sediment descriptions. For guidance in these areas call MLE Customer Service or see the previous pages for appropriate resources.

Acceptable Range. The upper and lower limits of values in which results are considered correct for a quantitative challenge.

Acceptable Response. The correct response for a qualitative challenge.

Accuracy. A measure of how close a result is to the actual or true value.

All Method Group. Target group used to compare results from all methods reported, regardless of instrument or test system. Depending on the analyte, participant results may be graded by comparison to this group when there is neither a peer group nor a method group by which to grade.

Analyte. Substance or constituent for which the laboratory conducts testing.

At Risk. Describes the status of a lab that has achieved unsatisfactory proficiency testing performance. The lab is considered at risk until it achieves satisfactory performance for two consecutive testing events.

Bias. Measure of the departure from accuracy.

Bloodborne Pathogen. Any pathogenic microorganism present in human blood that can infect and cause disease in persons who are exposed to blood or body fluids containing the pathogen.

Calibration. Process of testing and adjusting an instrument or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.

Calibrator. Material or solution with a known amount of an analyte used in performing calibration.

Challenge. In qualitative testing, determination of the presence or absence of an analyte, organism, or substance in a sample; in quantitative testing, assessment of the amount of an analyte or substance present in a sample. Also used to refer to a PT specimen.

Clerical Error. Error in transcribing results from one source to another (i.e., reporting the results of one specimen in the place of another, transposing numbers, improper placement of decimals).

CLIA. The acronym for the federal law, the Clinical Laboratory Improvement Amendments of 1988.
**CLIA Number.** The identification number assigned by the Centers for Medicare & Medicaid Services (CMS) to any facility performing tests on human specimens; must be used by PT providers to transfer proficiency test results electronically to CMS.

**CMS.** Acronym for the Centers for Medicare & Medicaid Services. CMS is the federal agency within the Department of Health and Human Services that is responsible for implementation of CLIA.

**CMS Performance Summary.** A report required by CMS for electronic transmission, also included with evaluations. Indicates a laboratory’s current and cumulative performance status for all regulated analytes and subspecialties.

**Comparison Group.** The participant group your results were compared with or graded against; also called the target group. Possible comparison groups include peer group, method group, all method group, and referee group.

**Consensus, Method.** Evaluation of results based on agreement reached by labs using the same method.

**Consensus, Overall.** Evaluation of results based on agreement reached by labs regardless of method.

**Consensus, Referee.** Evaluation of results based on agreement reached by referee laboratories.

**Corrective Action.** Steps taken to identify and rectify problems that caused errors in testing; required by CLIA following failure of proficiency testing.

**Cumulative Performance.** Describes a laboratory’s overall proficiency achieved for the current test event and previous two events; designated as successful or unsuccessful for regulated analytes and subspecialties.

**Current Performance.** Describes a laboratory’s proficiency achieved for the most recent test event; designated as satisfactory or unsatisfactory for regulated analytes and subspecialties.

**Dilution.** Reduction of the concentration of a specimen using an exact volume of distilled water, saline or other diluent to obtain a reportable result.

**Dilution Factor.** The multiplier used to calculate the correct concentration of an analyte of a diluted specimen; this number is determined by the ratio of specimen to diluent.

**Evaluation.** Individualized report that details a laboratory’s PT performance for a particular test event.

**Interference.** A false increase or decrease in results due to substances in the specimen other than the analyte being tested.

**Instrument Code.** Code entered on MLE Test Result Form that designates the analyzer used to test patient and PT specimens; ensures that PT results are evaluated based on comparison to other laboratories using similar technology.
**Instrument Maintenance.** Steps that are taken as prescribed by an analyzer’s manufacturer to ensure optimal performance of the instrument.

**Laboratory.** Any facility that examines materials derived from the human body for the purpose of providing diagnosis, prevention or treatment of any disease, or assessing the health of human beings.

**Levy-Jennings Chart.** Quality control chart with a graph format, showing horizontal lines for the mean and standard deviations. The vertical y-axis represents the observed control value. The horizontal x-axis represents time.

**Linear Range.** Working range for each procedure that is designed to produce accurate results.

**Lyophilized.** Freeze-dried specimen; requires reconstitution according to instructions on the test result form before testing.

**Manufacturer’s Package Insert.** Information enclosed with reagents and test kits from the manufacturer that includes instructions for use, quality control, principles, storage requirements, and limitations.

**Method Code.** Code entered on MLE Test Result Form that designates the test method used to test patient and PT specimens; ensures that results are evaluated based on comparison to other laboratories using similar technology.

**Method Group.** Target group used when data from all labs using a similar method or a similar instrument are being compared.

**Module.** A term for an MLE proficiency test order that can be purchased; may be composed of several analytes packaged together as one product.

**Outliers.** Extreme results that are eliminated from statistical data to prevent values from adversely skewing the data; these results are usually the product of a lab error.

**Package Insert.** See “Manufacturer’s Package Insert.”

**Participant Summary.** Compilation of the collective results of all MLE participants for a specific test event.

**Peer Group.** For most analytes, a group of ten or more laboratories using the same test method and/or instrument; results within a peer group are used to establish statistical values for grading purposes.

**Performance Summary.** See “CMS Performance Summary.”


**PT Specimen.** The material sent to PT participants for testing; may be called “PT sample” or “challenge.”

**Quality Assurance.** Ongoing process of monitoring and evaluating every step of the laboratory’s testing operations.
**Random Error.** A mistake that usually occurs in one test or one test run; is often independent of other parameters at the time of testing and is seen in one or two of the five PT specimens.

**Reagent Code.** Code entered on Test Result Form that designates the reagent used to test patient and PT specimens; ensures that results are evaluated based on comparison of performance to other laboratories using the same reagent.

**Recalibration.** Repeat performance of calibration procedure after a certain period or when there is an occurrence that may cause a shift in test values.

**Reconstitution.** Process of adding prescribed amount of diluent to lyophilized specimens to make them suitable for testing.

**Referee Group.** A group of laboratories currently in compliance with applicable CLIA requirements, having a record of successful proficiency testing performance, and designated by a proficiency testing program for the purpose of grading a PT challenge.

**Reliability.** Measure of the ability to achieve accuracy and precision over a period.

**Regulated Analyte.** Analyte designated by CMS requiring proficiency testing and quality control at a prescribed frequency.

**Rounding Off.** The process of eliminating a decimal place. May be called “dropping digits.” Leave the last digit of the number you wish to “round” unchanged if the digit that you “drop” is less than five. If greater than five, the last number is increased by one. If the number to be dropped is exactly five, increase the last digit retained by one for odd numbers, leave it the same for even numbers.

**Run.** Interval within which the accuracy and precision of a test system is expected to remain stable; must not exceed 24 hours or be less frequent than the manufacturer’s specifications.

**Satisfactory Performance.** Achieving at least the minimum satisfactory score for an analyte, test, specialty, or subspecialty for one testing event. The minimum satisfactory score is 80%, with the exception of immunohematology. The minimum satisfactory score for the specialty of immunohematology is 80% for antibody detection and identification, and 100% for ABO grouping, D(Rho) typing, and compatibility testing.

**Semiautomated.** Instrument or test system in which some of the steps in the analytical process are mechanized, but others require operator intervention.

**Sensitivity.** The ability of a test to correctly identify individuals who have a given disease or condition. The more sensitive a test, the fewer false-negative results will be produced.
**Specificity.** The degree to which a test method distinguishes the substance being tested from other substances present in the specimen.

**Standard.** Primary reference material of fixed or known composition, that can be used to establish a reference point for all measurements.

**Successful Performance.** Achieving at least the minimum satisfactory score for an analyte, test, or subspecialty for two of three consecutive testing events. The minimum satisfactory score for all analytes, tests, specialties, and subspecialties is 80%, with the exception of immunohematology. The minimum satisfactory score for immunohematology is 80% for antibody detection and identification and 100% for ABO grouping, D(Rho) typing, and compatibility testing.

**Systematic Error.** A determination error that affects the entire run and persists from run to run or day to day. These errors are usually proportional, meaning all PT results are uniformly higher or lower than the target mean.

**Target Group.** MLE term that refers to the group you were compared with or graded against; also called the comparison group. Possible target groups include peer group, method group, all method group and referee group.

**Target Mean.** The average value of results submitted by laboratories in a comparison group.

**Test Kit.** All components of a PT shipment—including PT specimens, test result form with instructions and return envelope for the test result form.

**Test Event.** An occurrence of PT testing; regulations require participation in three events per year for each analyte/specialty/subspecialty.

**Test Result Form (TRF).** The electronically scannable form MLE participants use to submit PT results.

**Troubleshooting.** The process of identifying the source of laboratory problems causing PT failures. Regulations require taking appropriate corrective action and maintaining documentation for two years.

**Unsatisfactory Performance.** Failure to attain the minimum satisfactory score for an analyte, test, or subspecialty for one testing event.

**Unsuccessful Performance.** Failure to attain the minimum satisfactory score for an analyte, test, or subspecialty for two of three consecutive testing events.

**WDES (Web Data Entry System).** MLE’s online result reporting program.
Statistical Terms

This glossary defines statistical terms common to laboratory quality control and necessary to understanding how to use proficiency testing data.

Coefficient of Variation (CV). Standard deviation expressed as a percentage of the mean; derived by dividing the standard deviation by the mean and multiplying by 100.

\[ CV = \frac{SD}{Mean} \times 100 \]

Confidence Limits. Percentiles of the expected distribution of assays. Assuming a Gaussian distribution, 95% of sequentially performed tests on a control specimen will fall within two standard deviations of the mean. Upper and lower control limits—established by applying two standard deviations to the mean—represent a confidence limit of 95%.

Control Sample. May be called “control specimen” or “control.” Specimen with a known concentration for specific analytes used to ensure that test systems are functioning properly. Acceptable ranges for control results may be established by the manufacturer or by individual testing facilities.

Duplicates. A simple check of laboratory precision by dividing a specimen and processing the two portions independently, preferably not in sequence. After completion of a given determination, the two values are compared to see how closely they approximate one another.

Gaussian Distribution Curve. Bell-shaped curve produced as a result of plotting control values from consecutive runs of similar tests on a single control specimen. The values are plotted on the x-axis; the frequency of each value on the y-axis. The narrower the curve, the more precise the test.

Lot. A specific quantity of a control sample and/or reagent that has uniform character and quality within specified limits, produced in batches according to a single order during the same manufacturing cycle. All determinations that make up your quality control statistics should be of the same lot. When it is necessary to change the lot for your controls, establish a new mean value and standard deviation and begin a new quality control graph. Do this while still using the prior control.

Mean, Arithmetic. May be called “average” or “mean.” Value obtained by dividing the sum of several results by the number of results.

\[ \frac{\text{Sum of Results}}{\text{Number of Results}} = \text{Mean} \]

Median Value. The middle value in an ordered set, or list of values, below and above which there are an equal number of values.
Precision. Degree to which repeated analyses of the same material approximate one another.

Shift. Quality control values that fall on the same side of the mean for six or more consecutive days with no tendency toward a consistent rise or fall; usually caused by modifications to procedures, either intentional or unintentional.

Standard Deviation. The difference between an individual value and the arithmetic mean is a deviation. Broadly speaking, the standard deviation represents the average of the individual deviations.

Standard Deviation Index (SDI). Denotes the difference between a test result and the group mean. The calculation of the SDI normalizes the bias of your result and, therefore, allows for a comparison of results from specimens having different concentrations of an analyte.

\[
SDI = \frac{\text{Your Mean} - \text{Group Mean}}{\text{Group SD}}
\]

Trend. Quality control values that continue to increase or decrease over six or more consecutive days; usually caused by deterioration and/or evaporation of reagents, gradual increase in pH, or gradual reagent or instrument contamination.
List of Top 10 Proficiency Test Mistakes
Avoid these common pitfalls that can delay or adversely affect your evaluation!

1. **Failing to report instrument and reagent codes for all tests.**
   Improper or insufficient coding can affect your score by placing you in a different comparison group for grading. Fill in all codes for each test you report.

2. **Using light pencil or blue ink.**
   The form scanner can skip or misread these results. Use only black ballpoint pen to fill out test result forms.

3. **Reporting absolute value (#) for WBC differential, instead of percent (%).**
   This common clerical error will result in an unnecessary failure for the automated diff.

4. **Numbers unclear or written too large.**
   ID numbers and results that are not written neatly or extend outside of the blue boxes may be misread by the form scanner.

5. **Mailing copies instead of original forms.**
   The scanner can only process original test result forms. Keep copies for your records and send the originals.

6. **Writing X’s or notes across the test result areas.**
   The form scanner can interpret this writing as a result. Simply leave blank any tests not performed by your lab. Include a note on a separate sheet of paper if there was a problem, or if the test was recently discontinued.

7. **Entering 0’s for tests not performed.**
   Zero is a number and will be interpreted as a valid test result. See the note above regarding tests not performed.

8. **Failing to return the attestation cover page.**
   This is the page with your address, MLE ID #, list of modules ordered, and signatures of testing personnel and lab director.

9. **Crossing out mistakes.**
   Use correction fluid (“white-out”) to erase mistakes so they will not be misread by the form scanner.

10. **Missing the result deadline.**
    Mark the date when the kit is received on your calendar. Results postmarked after the deadline will not be accepted for evaluation.
Sign Up Now for Automatic Renewal

It’s one important management detail you never have to worry about again! We automatically:

- Renew your enrollment.
- Reorder the modules in which you participated in the previous year.
- Send you an updated catalog to see if you would like to make changes to your order and an order verification for your review.
- Send an MLE order change form should you wish to add or delete modules from your renewed order.

You even have time to cancel your order if you choose by December without penalty!

Enroll by writing your MLE # on the “Change Form” and checking the box next to enroll the lab in “Automatic Renewal.” The Form is located on page 8 of this Guide.

Do You Want to Report or Receive Your Evaluation Electronically?

- Send an email to ptwebsupport@acponline.org and request a password and instructions for accessing your evaluation online.
- You may report electronically or access evaluations for your laboratory back to 2006.
- No additional fee!