Proficiency Testing

Requirements for good laboratory practice and COLA Laboratory Accreditation programs are underlined.

INTRODUCTION

Proficiency testing (PT) is an important aspect of an overall quality assurance program. PT serves as an *external check* to verify the accuracy of a laboratory's results by providing specimens with *unknown values.*

Labs run the PT specimens in the same manner as a patient specimen and report the results to the proficiency testing program. When all of the results are received by the proficiency testing program, they are grouped, analyzed, and then reported back to the participating laboratories.

PT specimen kits are designed to provide a suitable challenge for the testing personnel in the laboratory. Specimen kits are supplied to the participant laboratory with information and instruction sheets, and an attestation test result form. Participants will receive PT specimens for each specialty three times a year. Shipping schedules for PT specimens are available from your PT program. Be sure to note your program's shipping dates. If your specimens do not arrive in a timely manner, contact your provider.

TYPES OF SPECIMENS

Types of specimens provided by PT programs may include:

- Liquid specimens such as urine, plasma, serum, whole blood, and other body fluids.
- Dry loop specimens which are provided for bacteriological identification.
- Lyophilized (freeze-dried) specimens such as urine, plasma, serum, or dried whole blood which require reconstitution. Solutions to be used during reconstitution may be provided.
- 35 mm color transparencies which simulate microscopic specimens.

PREPARATION

It is important to follow the exact step-by-step instructions for the preparation and analysis of the PT specimen. The accuracy of your laboratory's PT results is dependent upon both your instrument and PT specimen reconstitution techniques. Use pipettes of certified accuracy to reconstitute specimens. Class A volumetric pipettes for the reconstitution of PT specimens are available through some PT programs or may be purchased through your laboratory supply distributor. Pipette pumps used to draw up and dispense reconstitution diluents are also available. Refer to your PT program manual for information on pipettes. *Syringes are not acceptable for reconstitution. The hypodermic syringe is not designed for use in the laboratory and is not accurate enough for dispensing, reconstituting, or diluting PT specimens.*

DEFINITIONS

Proficiency testing programs use several different mechanisms to determine the range of acceptable answers. Here are some definitions of the different concepts used in the analyses of the proficiency testing data:

1. **MEAN:** The average of all the results. It is calculated by adding together all of the received results and dividing the total by the number of participants who submitted results.
2. **STANDARD DEVIATION (SD):** A measure of how far the result is from the mean. It is a way of determining how much variation there is in the results. The smaller the SD, the more precise the results.
3. **ACCURACY:** The extent to which a test result is close to the true value of the quantity being measured.
4. **PRECISION:** The reproducibility of a test result in the measurement of an analyte. This occurs when the repeated analysis of an analyte produces test results which approximate one another, but may deviate from the true value.
5. **RELIABILITY:** A test method's capacity to maintain both accuracy and precision.
6. **COEFFICIENT OF VARIATION (CV):** The conversion of the standard deviation into a percentage. It is a measure of precision that is used to compare the amount of error or variation of two or more different sets of results. Good laboratories are able to produce CVs of 5 to 10 percent for most analytes. The smaller the CV, the more precise the results.

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Along with Proficiency Testing Reports, each participant laboratory receives Participant Summary Reports which list results from all participants for each analyte grouped by the methodology used. By comparing the CVs of different instruments from the Participant Summary Reports, it can be determined which instruments provide the most precise results.

7. **PEER GROUPS:** The participants' results are combined into groups of laboratories using comparable methods or instruments called "peer groups." When the peer group is large enough, the results obtained from a participant are evaluated against results obtained by the peer group. When the number of participants using a particular instrument or method is below a cut-off level established by the PT provider, or when a method not listed on the PT program answer sheet is reported, the participant is put into a similar group or is evaluated by a comparative method.

8. **COMPARATIVE METHOD:** A good average or acceptable method that is considered widely compatible with most current methods. It is used to compare the various peer groups with a good historically acceptable method. It is also used as the target value for evaluation of some chemistry analytes and for evaluating participant results for those methods designated by insufficient numbers of participants to generate a separate peer group. If no comparative method has been designated, results will not be evaluated.

9. **FIXED LIMITS:** Used for evaluation of quantitative data. A mean value and SD are calculated for the peer group. Acceptable performance is established based on the target value +/- fixed limits. The target values are determined from either the peer group or comparative method mean.

ENROLLMENT REQUIREMENTS

CLIA regulations and COLA policy state that laboratories must enroll in PT for all regulated analytes and must authorize that their PT results be forwarded to their accrediting agency and/or HCFA (whichever is applicable). Laboratories must also enroll in PT or perform split-sampling (see LabFacts #9) as an external validation of all non-regulated analytes. Proficiency testing for those tests or analytes considered to be waived by federal regulation is highly recommended but not required.

For those regulated analytes which fall under the specialty of Bacteriology, proper enrollment requires a minimum of five challenges per subspecialty for each event. Select modules which offer appropriate challenges for the methods/procedures performed in your laboratory (i.e., gram stain, antigen detection, bacterial identification, susceptibility testing).

CLIA regulations and COLA policy state that laboratories are prohibited from communicating with another laboratory to discuss PT results prior to the cutoff date for submission of test results.

CRITERIA FOR SATISFACTORY PROFICIENCY TEST PERFORMANCE

The criteria used by PT providers to score PT results s definied by HCFA in the *Federal Register.* The following definitions are provided to help you interpret your laboratory's PT performance:

1. **Regulated Analyte:** Those analytes designated by the Federal Government which require PT enrollment. Refer to the Regulated Analyte list included at the end of this LabGuide.

2. **Testing Event:** The time period during which the laboratory receives their PT kit, performs the testing, and returns their results to the PT provider. There are three events, evenly spaced throughout the calendar year, in which the laboratory must participate.

3. **Challenge:** The actual sample provided for PT testing. A minimum of five challenges per test event are required for each regulated analyte.

4. **Unsatisfactory:** A failure to achieve a minimum satisfactory score for an analyte, specialty, or subspecialty for a single test event.

5. **Unsuccessful:** A failure to achieve a minimum satisfactory score for an analyte, specialty, or subspecialty for two consecutive or two of three test events.

6. **Consecutive Unsuccessful:** Unsuccessful PT performance followed by unsatisfactory performance in either of the next two testing events following the initial unsuccessful performance.

7. **Reinstatement of an Analyte:** The corrective action process followed to demonstrate that a laboratory is prepared to successfully begin retesting an analyte, specialty, or subspecialty following a period of cease testing.

A minimum overall testing event score of 80 percent for each regulated analyte, specialty, and subspecialty, except for ABO/Rh which has a minimum score of 100 percent for each testing event, must be achieved for satisfactory PT performance.

TROUBLESHOOTING

Keep in mind that unsuccessful PT performance may be an indication of problems with instrumentation, personnel training, or quality control procedures. It is a good idea to retain and freeze remaining PT samples, except for whole blood, so they may be retested if troubleshooting becomes necessary. Whole blood should be stable refrigerated until results are received.

If your laboratory's result is outside the range of "acceptable values," then there is a problem that must be identified and corrected. Use the following questions as a guide to identifying where the problem lies:

1. What is the scope of this problem?
- Is a single or are several analytes affected?
- Is a single or are several specimens affected?
- Is a single or are several instruments affected?
- Are all ranges or just a certain range of test results affected?

Narrowing the scope of the problem may lead you in the direction of where corrective action is needed.

2. Can you identify any clerical errors?
- Copied onto answer sheet correctly?
- Numbers reversed on answer sheet?
- Was the proper method code used?
- Did the PT program enter your answer correctly?

If clerical errors are the cause of the problems, document your findings and take corrective action to avoid these types of errors in the future. If the PT program made a mistake, contact them immediately to have the error corrected. If this was not the source of the problem, continue:

3. Can you identify any technical processing errors or instrument failures?

- Quality Control acceptable at time of testing event?
- Misidentification of specimens?
- Specimen preparation error?
- Results accepted outside linearity of instrument?
- Are calibrations up to date?
- Has maintenance been performed appropriately?
- Have there been shifts, trends or other changes in the Quality Control results since the testing event?
- Were all reagents, controls, and samples stored properly and not expired?

If any of these questions identifies a possible problem, take corrective action, document and proceed to verify your corrective actions have worked by using frozen PT samples, requesting additional PT samples or using another form of external validation. Remember to document all corrective action and retain this in your laboratory's records.

DOCUMENTATION

It is very important to maintain accurate records of PT data during each testing event. The following items highlight some key points for successful documentation of PT performance.

- Document each step of the handling, preparation, processing, and examination of the PT specimen.

- The individual testing the PT specimen and the laboratory director must sign an attestation statement that PT specimens are tested under the same conditions as patient specimens.

- The laboratory director should review PT results on a regular basis with the laboratory staff and address any unsuccessful PT events.

- Initial and date the PT data to indicate that the results have been reviewed.

- Retain all records of proficiency testing participation for two years, except for immunohematology data which must be retained for five years.

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HELPFUL HINTS FOR PROFICIENCY TESTING

Below are some hints to help you obtain optimal proficiency testing results:

- Enroll in PT for all federally regulated analytes.
- Be sure to indicate to your PT program which analytes you do not perform in your laboratory.
- Give your PT provider your CLIA identification number. If you participate with an accrediting organization, provide the name of the accrediting body and your ID number. If you have a State ID number, give this information as well.
- If your practice has satellite labs, provide the unique CLIA number, and any other ID numbers such as those listed above, for each physical location to your PT provider. This will ensure that PT results from satellite labs are identified correctly by your PT provider and forwarded correctly to HCFA, the State, and your provider.
- If you do not receive your PT specimens, refer to the shipping schedule provided by your PT program to alert them within the allotted time if a shipment has been missed. They will send a replacement shipment promptly if notified in time.
- Contact the PT program promptly if PT specimens are received damaged. You may be able to receive a replacement.
- Strictly follow the PT providers storage or handling requirements prior to testing PT specimens.
- Use a volumetric pipette to reconstitute lyophilized PT specimens. Syringes are not as accurate as a volumetric pipette, and using a syringe will markedly increase your chances of unsatisfactory PT performance.
- Analyze PT specimens within the time frame provided by the PT provider; promptly report results.
- Avoid clerical errors when completing PT answer sheets. Be sure to enter the correct result next to the correct analyte on the answer form. Institute a quality assurance measure of having another staff person double check the answer sheet before sending it to your PT provider.
- Identify the correct instrument or method code so you are graded among your peer group. If you are not sure which method code to use, telephone your PT program's Customer Service area for help.
- If you do not perform a particular analyte listed on the answer form, use the correct code to indicate this (such as Test Not Performed). Answer forms left blank are often counted as a failure to participate and could reflect negatively on your summary score.
- Make and retain copies of all answer forms prior to submitting your results to your PT provider.
- Be sure that the attestation form is signed.
- Carefully review all participant summary reports, follow up on reasons for PT failures, and correct them.
- Document all corrective action in your lab's records.
- If you cannot perform PT for an analyte(s) normally tested in your laboratory due to circumstances beyond your control, notify your PT provider in writing. List the analyte(s) affected and give the reason for lack of performance. Your PT provider can grant an exclusion if they feel the situation warrants it. This will result in your laboratory receiving a passing score for the analyte for that event rather than a failing score. Note: PT providers will not grant multiple requests for exclusions!
- Notify HCFA and/or your accrediting agency of any changes to your test menu and the effective date.

REGULATED ANALYTES

SPECIALTY: MICROBIOLOGY

Subspecialty: Bacteriology
All Cultures (including growth/no growth)/ Susceptibility Testing/Gram Stain/Antigen Detection/Bacterial Identification.

Subspecialty: Mycology
Culture for Yeast or fungal ID at genus or species level.

Subspecialty: Parasitology
Wet mount of stool specimen/Pinworm Prep/Ova and Parasite ID by concentration or permanent stain.

Subspecialty: Virology
Herpes/RSV/CMV/Influenza A/Varicella-Zoster by Antigen Detection or Isolation and IB by Culture.

Subspecialty: Mycobacteriology
Acid Fast Smears/Culture ID, susceptibility testing)

SPECIALTY: DIAGNOSTIC IMMUNOLOGY

Subspecialty: Syphilis Serology

Subspecialty: General Immunology
Alpha-1-Antitrypsin
Antinuclear Antibody
Anti-Streptolysin O
Anti-Human Immunodeficiency Virus (HIV)
Complement C3
Complement C4
Hepatitis marker (Hbs Ag)
Hepatitis marker (Anti-HBc)
Hepatitis marker (Hbe-Ag)
IgA
IgG
IgE
IgM
Infectious Mononucleosis
Rheumatoid Factor
Rubella

SPECIALTY: CHEMISTRY

Subspecialty: Routine Chemistry
Alanine Aminotransferase (ALT)
Albumin
Alkaline Phosphatase
Amylase
Aspartate Aminotransferase (AST)
Bilirubin, Total
Blood Gases ($pH/pO_2/PCO_2$)
Calcium, Total
Chloride
Cholesterol, Total
Cholesterol, HDL
Creatine Kinase
Creatine Kinase, Isoenzyme (CKMB)
Creatinine
Glucose (excluding devices cleared by FDA for home use)
Iron, Total
Lactate Dehydrogenase (LDH)
LDH, Isoenzyme
Magnesium
Potassium
Sodium
Protein, Total
Triglycerides
Urea Nitrogen (BUN)
Uric Acid

Subspecialty: Endocrinology

Cortisol
Free Thryroxine
Human Chorionic Gonadotropin (hCG)
T3 Uptake
Triiodothyronine (T3)
Thyroid Stimulating Hormone (TSH)
Thyroxine (T4)

Subspecialty: Toxicology

Alcohol (Blood)
Lead (Blood)
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Primidone
Procainamide
Quinidine
Theophylline
Vancomycin
Valproic Acid

SPECIALTY: HEMATOLOGY

Cell ID/ White Blood Cell Differential
Erythrocyte Count
Hematocrit (excluding spun Microhematocrits)
Hemoglobin
Leukocyte Count
Platelet Count
Fibrinogen
Partial Thromboplastin Time
Prothrombin Time

SPECIALTY: IMMUNOHEMATOLOGY

Unexpected Antibody Detection ABO/RHO
ABO Group
D(RHO) Typing
Antibody Identification
Compatibility Testing