Association of Public Health Laboratories, Inc.

Informed Consent

Form Approved
OMB No. 0920-XXXX
Exp. Date XX/XX/20XX

Purpose of the Study: This survey is being performed for the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) to understand how laboratories use proficiency testing (PT) and how they perceive its value. This survey will take approximately 20 minutes to complete.

Incentive for Participating: If you wish, by providing your email address, you will be entered in a drawing for a webinar training session on a current laboratory topic. Within 60 days of the closing date of the survey, a random drawing will be held using those email addresses. Winners will be notified via email.

Security Information: All information collected in this survey will be kept in a secure manner. No individual answers will be shared with CDC or APHL. We ask you to include your unique identifier provided in the survey recruitment letter (or your CLIA certificate number) so that we can connect your survey answers to demographic data that are already on file and to ensure that only one response per laboratory is received. Your IP address will NOT be retained.

If you would like to be entered in the drawing to receive free webinar training, at the completion of the survey we will request your email address so that we can notify you if you win. However, your email address will not be linked with data from your survey. The list of email addresses will be stored electronically in a password protected file and will only be used to randomly select the raffle winners. After the drawing, that file will be deleted.

Decision to quit at any time: Participation is voluntary; you are free to withdraw from this survey at any time and you may choose to skip any questions that you do not wish to answer. The number of questions you answer will not affect your chances of winning one of the webinar trainings. If at any point you do not want to continue, you can simply leave this website. If you do not click on the “submit" button at the end of the survey, your answers and participation will not be recorded.

How the findings will be used: The results from the study will be compiled and shared in aggregate as a learning tool, presented at professional conferences, and potentially published in a professional journal in the field of laboratory science.

Contact information: If you have concerns or questions about this study, please contact ptsurvey@aphl.org using the subject line “PT survey.”

Agreement: By clicking the NEXT button and beginning the survey, you acknowledge that you have read this information and agree to participate in this survey, with the knowledge that you are free to withdraw your participation at any time without penalty.

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE , MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).

Welcome

Thank you for taking the time to complete this survey by the Association of Public Health Laboratories (APHL) in collaboration with the Centers for Disease Control and Prevention (CDC). Your feedback is important for guiding APHL and CDC in their efforts to understand how proficiency testing (PT) is used in clinical laboratories. The survey should take approximately 20 minutes of your time. All answers will remain completely anonymous.

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For the purpose of this survey, "proficiency testing" means a Centers for Medicare and Medicaid Services (CMS), approved commercial program that grades your responses and tells you whether you passed or failed each challenge. Click here for a list of PT programs. This list will open in a separate window.

***1. Please enter the 8-digit number that can be found on the address label of the survey announcement OR the 10-digit CLIA number for your laboratory as indicated on the CLIA certificate. Please note: an independent contractor will use these numbers to assure that there is only one response per laboratory and to characterize the demographics of survey respondents. No government agency (local, state or federal) will have the ability to identify any individual laboratory nor have access to responses submitted.**

Please indicate whether you entered the number on the invitation address label or your laboratory's CLIA number.

- ◯ Number on invitation address label
- ◯ CLIA number

Three Phases of Laboratory Testing

Questions 2-9 will relate to the Three Phases of Laboratory Testing:

Pre-analytic (steps taken prior to testing of the specimen)	Analytic (actual testing and analysis)	Post-analytic (steps taken after testing of the specimen)
Test request	Quality control testing	Result reporting
Patient identification and preparation	Test performance	Specimen storage
Specimen collection	Result calculation	Record keeping
Specimen transport	Result recording	
Specimen receipt		
Specimen handling/storage		

2. Which of the following steps are taken in your laboratory to process PT samples from the time they are received until the time results are reported to the PT program? (Check all that apply).

Pre-Analytically, our laboratory:

- [ ] Disguises the PT specimen to appear to be a patient sample
- [ ] Enters the PT specimen into the laboratory information system
- [ ] Examines and evaluates the condition of the specimen when received

Analytically, our laboratory:

- [ ] Performs preventive maintenance on instruments to be used for PT analysis immediately prior to testing, even when not required
- [ ] Recalibrates instruments to be used for PT analysis immediately prior to testing
- [ ] Repeats questionable PT results according to established criteria for repeating patient samples
- [ ] Tests the specimen in more than one run and averages results
- [ ] Tests the specimen multiple times within one run and averages the results
- [ ] Tests the specimen with the same frequency as a patient sample

Post-Analytically, our laboratory

- [ ] Discards PT samples immediately after analysis
- [ ] Discusses PT results with another laboratory for verification before reporting results to the PT program
- [ ] Retains PT samples for future use after reporting results to the PT program
- [ ] Sends PT samples to another laboratory for additional testing to confirm the PT result
- [ ] Sends PT samples to another laboratory for additional testing when our standard operating procedure requires referral for patient testing

3. How does your laboratory determine which staff employee performs PT? (Check all that apply).

- [ ] PT is performed by the staff member performing the patient testing on that day
- [ ] PT is performed by the most experienced staff member
- [ ] PT is systematically rotated among staff on all shifts
- [ ] Other (please specify):

Pre-Analytic Phase

4. Does your laboratory use PT to identify problems that may occur during the pre-analytic phase of laboratory testing?

- ◯ Yes
- ◯ No

Pre-Analytic Phase

5. For the pre-analytic problems listed below, please tell us how important PT is in identifying them.

	Not Important	Potentially Important	Important	Not Applicable
Delayed processing of samples	◯	◯	◯	◯
Determination of insufficient quantity of samples needed for testing	◯	◯	◯	◯
Identification of improperly transported samples	◯	◯	◯	◯
Inappropriate specimen handling, including dispensing	◯	◯	◯	◯
Inappropriate storage of samples	◯	◯	◯	◯
Mislabeled samples	◯	◯	◯	◯
Personnel competency	◯	◯	◯	◯

Other (please specify):

Analytic Phase

6. Does your laboratory use PT to identify problems that may occur during the analytic phase of laboratory testing?

- ◯ Yes
- ◯ No

Analytic Phase

7. For the analytic problems listed below, please tell us how important PT is in identifying them.

	Not Important	Potentially Important	Important	Not Applicable
Calibration errors	◯	◯	◯	◯
Imprecision (result variability)	◯	◯	◯	◯
Incorrect test reagent storage	◯	◯	◯	◯
Instrumentation problems	◯	◯	◯	◯
Specimen dilution errors, if applicable to method	◯	◯	◯	◯
Specimen extraction errors, if applicable to method	◯	◯	◯	◯

Other (please specify):

Post-Analytic Phase

8. Does your laboratory use PT to identify problems that may occur during the post-analytic phase of laboratory testing?

◯ Yes

◯ No

Post-Analytic Phase

9. For the post-analytic problems listed below, please tell us how important PT is in identifying them.

	Not Important	Potentially Important	Important	Not Applicable
Delayed reporting to PT program	◯	◯	◯	◯
Incorrect calculations	◯	◯	◯	◯
Incorrect test result interpretation	◯	◯	◯	◯
Sending tests to the wrong reference laboratory for confirmatory testing	◯	◯	◯	◯
Transcription errors	◯	◯	◯	◯

Other (please specify):

10. To what degree does your laboratory benefit from performing PT for each of the following aspects?

Educational:

	Not Beneficial	Beneficial	Very Beneficial	Not Applicable
Can be used as a means of staff competency assessment	◯	◯	◯	◯
Opportunity to identify educational areas needing improvement	◯	◯	◯	◯
Opportunity to obtain performance feedback from programs that offer PT	◯	◯	◯	◯
Provides a source of continuing education	◯	◯	◯	◯

Technical:

	Not Beneficial	Beneficial	Very Beneficial	Not Applicable
Ability to support confirmation of suspected analytical trends and/or imprecision	◯	◯	◯	◯
Comparison of performance with other participating (peer) sites	◯	◯	◯	◯
Instrument comparison before purchase	◯	◯	◯	◯
Onsite performance evaluation of newly implemented assays	◯	◯	◯	◯
Regular, external check on quality of testing	◯	◯	◯	◯
Troubleshooting assays (identifying and fixing problems)	◯	◯	◯	◯
Use information in PT summary reports to support recommendations to managers for methodology or instrument changes	◯	◯	◯	◯
Verification of assay performance to meet clinical needs	◯	◯	◯	◯

11. How much of a challenge are the following aspects of performing PT to your laboratory?

	Not Challenging	Challenging	Very Challenging	Not Applicable
Cost for panel analytes that are not currently being assayed in your laboratory	◯	◯	◯	◯
Commercially unavailable analytes (analytes for which PT does not exist)	◯	◯	◯	◯
Inability to truly treat PT samples as patient specimens	◯	◯	◯	◯
Large number of ungraded challenges	◯	◯	◯	◯
Matrix problems (interfering substances in sample) prevent comparison across all methods (i.e., limited to method peer groups)	◯	◯	◯	◯
PT program subscription cost	◯	◯	◯	◯
PT programs lag behind advancing technology in laboratory testing	◯	◯	◯	◯
Staff time involved in the PT process (i.e., purchasing, analyzing and/or interpreting)	◯	◯	◯	◯
Time required to receive results from PT programs	◯	◯	◯	◯

12. If your laboratory has multiple analyzers available to conduct testing for a given analyte, how do you choose which analyzer to use for PT?

◯ PT is conducted on the analyzer used for routine patient specimen analysis that day

◯ PT is conducted on an analyzer pre-determined to have the best analytical performance whether routine specimen analysis is performed on that analyzer or not

◯ PT is conducted on the analyzer which is least expensive to operate

◯ PT is rotated among analyzers

◯ Not applicable – Laboratory only has one analyzer for all tests

◯ Other (please specify):

13. CLIA requires PT for only a limited number of tests or analytes. Click here for a list of those analytes.This will open in a separate window. How do you meet the requirements to verify the accuracy of any test or procedure you perform when *PT is not required* by CLIA regulations or your accreditation agency for that analyte or test? (Check all that apply).

- [ ] PT is purchased for at least some non-CLIA analytes
- [ ] Patient specimens are split and analyzed in our laboratory or by a reference or peer laboratory inside our laboratory/hospital laboratory system and results compared
- [ ] Patient specimens are split, a specimen is sent to a reference or peer laboratory outside our laboratory/hospital laboratory system for analysis and results are compared with our results
- [ ] Performance is verified by analysis of quality control materials with established acceptance ranges
- [ ] PT is required by our accreditation organization even if it is not required by CLIA
- [ ] Test results are compared among staff within the laboratory
- [ ] No action taken when commercial PT is unavailable
- [ ] Not applicable to our laboratory
- [ ] Other (please specify):

14. When PT results are not graded by the PT program due to lack of consensus or for some other reason, what steps do you take in your laboratory as a substitute? (Check all that apply).

- [ ] Split patient specimens and analyze them in our laboratory or by a reference or peer laboratory *inside* our laboratory/ hospital laboratory system and compare results
- [ ] Split patient specimens, send a specimen for analysis by a reference or peer laboratory *outside* our laboratory/hospital laboratory system and compare result with our result
- [ ] Reanalyze residual PT material from a previously graded event
- [ ] Compare your result, when possible, with the majority in your peer-group, even if PT was not graded
- [ ] This situation has not occurred in our laboratory
- [ ] Take no action regarding proficiency testing
- [ ] Other (please specify):

15. Do you purchase PT modules for some analytes or tests *even when CLIA does not require it?*

- ◯ No
- ◯ Yes, we purchase for 1 - 5 analytes
- ◯ Yes, we purchase for 6- 10 analytes
- ◯ Yes, we purchase for 11 – 20 analytes
- ◯ Yes, we purchase for >21 analytes

16. How important are the following reasons for purchasing PT that is not required by CLIA?

	Not Important	Potentially Important	Important	Not Applicable
Our accreditation organization requires us to perform PT	◯	◯	◯	◯
Our medical director or laboratory director requires us to perform PT	◯	◯	◯	◯
PT is used to assess instrument performance	◯	◯	◯	◯
PT is used to test competency of testing personnel	◯	◯	◯	◯
PT is used to track accuracy of methodology	◯	◯	◯	◯
PT provides a source of continuing education	◯	◯	◯	◯
PT results are valuable for identifying problems	◯	◯	◯	◯
Used as a marketing tool	◯	◯	◯	◯

Other (please specify):

17. How helpful would the following actions be to improve PT?

	Not Helpful	Helpful	Very Helpful	Not Applicable
Decrease the time allowed to perform PT from receipt of samples to reporting results	◯	◯	◯	◯
Increase the time allowed to perform PT from receipt of samples to reporting results	◯	◯	◯	◯
Increase the use of digital images instead of slides or photographs	◯	◯	◯	◯
Increase the use of slides or photographs instead of digital images	◯	◯	◯	◯
Improve the quality of photographs	◯	◯	◯	◯
Improve PT reporting unit consistency	◯	◯	◯	◯
Standardize the PT reporting format	◯	◯	◯	◯
Improve technical feedback/advice from PT program	◯	◯	◯	◯
Improve PT program customer service	◯	◯	◯	◯
Provide more PT challenges	◯	◯	◯	◯
Provide less PT challenges	◯	◯	◯	◯
Provide more frequent PT events	◯	◯	◯	◯
Provide less frequent PT events	◯	◯	◯	◯
Provide faster return of results from PT programs	◯	◯	◯	◯
Provide more case study oriented challenges	◯	◯	◯	◯
Provide samples that better simulate patient specimens	◯	◯	◯	◯

Other (please specify):

18. How important are the following resources with respect to providing information about PT results, testing, and training?

	Not Important	Potentially Important	Important	Not Applicable	Not aware of this resource
Other laboratory professionals inside the laboratory	◯	◯	◯	◯	◯
Other laboratory professionals outside your laboratory	◯	◯	◯	◯	◯
Centers for Disease Control and Prevention (CDC) publications and online resources	◯	◯	◯	◯	◯
Clinical Laboratory Improvement Amendments (CLIA) Proficiency Testing brochure available from the Centers for Medicare & Medicaid Services (CMS)	◯	◯	◯	◯	◯
CLSI GP27 – "Using Proficiency Testing to Improve the Clinical Laboratory"	◯	◯	◯	◯	◯
CLSI GP29 – "Assessment of Laboratory Tests Where Proficiency Testing is Not Available"	◯	◯	◯	◯	◯
CMS surveyors or Accreditation Organization Inspectors	◯	◯	◯	◯	◯
Educational Modules provided by the PT Program	◯	◯	◯	◯	◯
Professional organization newsletters	◯	◯	◯	◯	◯
Scientific publications	◯	◯	◯	◯	◯
Teleconferences	◯	◯	◯	◯	◯
Web searches	◯	◯	◯	◯	◯

Other (please specify):

19. Does your laboratory perform microbiology testing in your laboratory?

◯ Yes

◯ No

20. Does your laboratory report PT results for microbiology to the same level as reported for your patient testing? For example, if you report patient samples for a particular organism to species level, do you report PT results the same?

- ◯ Yes
- ◯ Yes, but will report to a lower level occasionally
- ◯ Sometimes report PT at a higher level than patient samples
- ◯ No

21. Which of the following elements of the patient demographics or history provided with a PT challenge are needed to process and analyze PT samples appropriately? (Check all that apply).

- ☐ Age
- ☐ Sex
- ☐ Specimen source/type/site
- ☐ Symptom(s)
- ☐ Gram stain reaction

22. According to CLIA regulations microbiology does not have analytes, should changes be made to microbiology PT grading to allow for monitoring performance over time on a particular type of test or examination – for example, culture, or susceptibility testing?

- ◯ Yes, provide scores for each PT test
- ◯ No

23. How important would the following be to improve microbiology PT?

	Not Important	Potentially Important	Important	Not Applicable
Improve the quality of photographs	◯	◯	◯	◯
Improve the quality of stained slides	◯	◯	◯	◯
Include more susceptibility testing challenges	◯	◯	◯	◯
Include less susceptibility testing challenges	◯	◯	◯	◯
Include more emerging or less common organisms	◯	◯	◯	◯
Include fewer emerging or less common organisms	◯	◯	◯	◯
Increase the use of digital images instead of slides or photographs	◯	◯	◯	◯
Increase the use of slides or photographs instead of digital images	◯	◯	◯	◯
Require direct antigen testing in mycology	◯	◯	◯	◯
Require direct antigen testing in parasitology	◯	◯	◯	◯
Require susceptibility testing in mycology	◯	◯	◯	◯
Require susceptibility testing in virology	◯	◯	◯	◯

24. When you consider the benefits of performing proficiency testing as compared to its costs, would you characterize it as...

- ◯ Clearly worth the costs
- ◯ Somewhat worth the costs
- ◯ Neutral
- ◯ Somewhat more costly than its value
- ◯ Clearly more costly than its value
- ◯ No opinion

25. Do you have an opinion or observation about PT that you would like to share that was not addressed in the survey?

26. Please provide your e-mail address so that we can notify you if you win the teleconference training. This is optional, but you cannot be entered in the drawing if an email is not provided.

e-mail: