Abbott

SYSTEM BRIEF

CHOLESTECH LDX™

Achieving Successful Proficiency Testing

Although participation in proficiency testing (PT) is not required for those facilities performing laboratory testing under a CLIA-Waived certificate, performing and passing PT can be an important quality assurance tool. PT is required for those facilities performing most moderate complexity tests under a CLIA nonwaived certificate.

WHAT IS PT AND WHAT ROLE DOES IT PLAY?

PT involves analyzing specimens of unknown concentration provided by a source outside your laboratory, usually a commercial PT program vendor. Your results are then compared to those of participants who tested the same unknown specimens. PT allows participants to verify their diagnostic testing and document performance.

CHOOSING A PT PROGRAM

It is best to enroll in a program that allows you to be compared with other users of the same Abbott™ product. This is called "peer group grading" and means that the same specimen was run and evaluated on the same instrument system, i.e., the same Abbott product, by different users. This eliminates comparison with other instrument systems which may use different methods, calibration and reagents, or that may respond differently to the PT specimens. Some commercial PT program vendors offer both waived and nonwaived modules. A waived module typically contains 2 specimens per shipment vs. the nonwaived modules which typically contain 5 specimens per shipment. It is best to choose a vendor that offers liquid specimens which are easier to handle. It is also a good idea to ask how many other users of the same Abbott product are enrolled in the program to ensure that there are enough users (> 10 labs) for peer group grading.

Once you have chosen a vendor, review the enrollment materials carefully and submit your order. When the PT program vendor confirms your order, check to see that the order is correct. Contact the vendor to make any corrections. Mark your calendar with the shipment dates and expected arrival dates. Read the manual that comes from the PT agency. This contains a wealth of information including how to handle the specimens, complete the forms, and evaluate and interpret the results.

TESTING THE PT SPECIMENS

WHEN THE SPECIMENS ARRIVE:

- **OPEN AND DATE SPECIMENS AND FORMS,** checking for any notices or new instructions. Promptly refrigerate the specimens, if indicated. Notify the vendor and request new specimens if any of the containers are broken or if they are not all cold when received. Document all pertinent information.
- **TEST THE PT SPECIMENS AS SOON AS POSSIBLE,** since they may deteriorate upon storage.
- **TEST THE PT SPECIMENS AS YOU WOULD A PATIENT SAMPLE,** making certain to verify the identity of the specimen as all the vials look the same.
- **CAREFULLY FOLLOW ALL OF THE INSTRUCTIONS FOR HANDLING THE PT SPECIMENS.**
- **MIX EACH PT SPECIMEN BY INVERTING GENTLY, 7-8 TIMES, JUST PRIOR TO TESTING IT.**
- **FOLLOW ALL INSTRUCTIONS FOR USING YOUR ABBOTT PRODUCTS THAT PERTAIN TO PT.** Refer to the package insert that accompanies the product.
- **RECORD YOUR RESULTS.**

AFTER TESTING IS COMPLETE:

- Follow the instructions for reporting results, making sure the numbers and answers are legible as results are usually scanned by machine or entered by data entry personnel.
- Check that you have reported the correct instrument code and/or reagent code. After recording your results, check for errors and be certain all sections of the form are complete. Contact Abbott Product Support if you have questions about which method codes to use.
- Date and sign the attestation section. This is required to confirm that the specimens were tested in the same routine manner as patient samples and that the results have not been shared or discussed with another laboratory. Have the director or technical consultant date and sign the form.
- Copy the form(s) and attach all printouts, labels, or other pertinent data to your copy of the form and file this information. Make certain the original result forms are mailed or faxed within the allowed time frame and with enough postage.
- Label and save (freeze) the PT specimens until the survey results are returned.

REVIEWING THE RESULTS

- Review the results as soon as possible after receipt. Check the results for each analyte, even if your score was 100 percent. Reviewing results for bias (deviation from the expected mean or average) and scores less than 100 percent may avoid future problems. Save all PT reports.
- Take corrective action and document actions if you scored below the minimum satisfactory score for any analyte. If you believe the PT program vendor made a mistake in your scoring, contact them immediately.
- Review the report for clerical errors (i.e., a specimen mix-up). Review quality control results from the period. Review the testing procedure with the personnel who performed the testing.
- Retest the PT specimens, if possible. Compare the retested results with the original survey report. If the survey specimen continues to produce results outside of the acceptable range after retesting, focus your attention on problems involving specimen preparation and storage, survey material and errors such as reagent deterioration. When you determine that these problems were most likely the cause of the error, obtain a new specimen of the survey material from your provider.
- Retest the new PT specimen(s) to verify your conclusion. Carefully review patient reports generated during the same period the PT was done. Take and document all corrective actions. Contact Abbott Product Support if you require any assistance.

NATIONAL PT PROGRAM VENDORS*

- AAFP-PT | 1.800.274.7911 | www.aafp.org
- AAB Proficiency Testing Service | 1.800.234.5315 www.aab-pts.org
- American Proficiency Institute | 1.800.333.0958 www.api-pt.com
- College of American Pathologists | 1.800.323.4040 www.cap.org
- Medical Laboratory Evaluation | 1.800.338.2746 www.acponline.org
- Wisconsin State Laboratory of Hygiene | 1.800.462.5261 www.slh.wisc.edu/proficiency

* May not have PT programs or peer groups for all Abbott products.

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