

Achieving Successful Proficiency Testing

Although participation in proficiency testing (PT) is not required for those facilities performing laboratory testing under a CLIA waived license, performing and passing PT can be an important quality improvement tool. When running PT on the Cholestech LDX® System, remember to **set your analyzer to the serum mode** before you begin testing. If you need assistance with setting the sample mode, contact Cholestech Technical Service (800-733-0404).

What Is Proficiency Testing and What Role Does It Play?

Proficiency testing involves analyzing samples of unknown concentration provided by a source outside your laboratory, usually a commercial vendor. Your results are then compared to those of participants who tested the same unknown samples. Proficiency testing 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 LDX users. This is called “peer group grading” and means that the same sample was run and evaluated on the same instrument system, i.e., the LDX System, by different users. This eliminates comparison with other instrument systems which may use different methods, calibration and reagents. There are several commercial vendors that offer specific LDX modules which allow for peer group grading. Many of these same vendors offer both waived and non-waived modules that are suitable for use on the LDX System. A waived module contains 2 specimens per

shipment vs. the non-waived modules which 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 LDX users are enrolled in the program to ensure that there are enough LDX users (> 10 labs) for peer group grading. Contact Technical Service for assistance in choosing a PT vendor.

Once you have chosen a vendor, review the enrollment materials carefully and submit your order. When the PT 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 samples, complete the forms, and evaluate and interpret the results.

Testing the Samples

When the samples arrive:

- **Open and date samples and forms**, checking for any notices or new instructions. Promptly refrigerate the samples, if indicated. Notify the vendor and request new samples if any of the samples are broken or if they are not all cold when received. Document all pertinent information.
- **Test the samples as soon as possible**, since some samples may deteriorate upon storage.
- **Set your analyzer to the SERUM mode before you begin testing.** Test the samples as you would a patient sample making certain to verify the identity of the sample as all the vials look the same.

- **Allow the samples and test cassettes to come to room temperature for 10 minutes before testing.** Use the gray Cholestech Mini-Pet pipet and tips to deliver the sample to the test cassette. Use a new tip for each sample.
- **Press the RUN button and wait for the tray to open** and the display to read “Load cassette and press Run” prior to pipetting the sample.
- **Mix the sample by inverting gently, 7-8 times, just prior to delivering the sample into the test cassette. Run the test cassette immediately after delivering the sample to the cassette.**
- **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 Cholestech Technical Service (800-733-0404) if you have questions about which method codes to use.
- Date and sign the attestation section. This is required to confirm that the samples were tested in the same routine manner as patient specimens 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 samples until the survey results are returned. **Remember to reset your LDX analyzer to the WHOLE BLOOD mode after you have finished testing your PT samples.**

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 for all scores below 80 percent. If you find the PT agency made a mistake, contact them immediately.
- Review the report for clerical errors (i.e., a sample mix-up?). Review quality control results from the period. Review the testing procedure with the personnel who performed the testing.
- Retest the samples, 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 sample of the survey material from your provider.

- Retest the material to verify your conclusion. Carefully review patient reports generated during the same period the proficiency testing was done. Take and document all corrective actions. Contact Cholestech Technical Service for assistance at 800-733-0404.

Vendors with LDX Proficiency Programs

- American Proficiency Institute
800-333-0958
- College of American Pathologists
800-323-4040
- Wisconsin State Laboratory of Hygiene
800-462-5261

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