Proficiency Testing

The purpose of proficiency testing (PT) is to provide feedback on a laboratory's proficiency among inter-laboratory comparisons. After choosing the PT provider, the laboratory or testing facility will receive "blind" samples. Samples are tested as patients are tested. Results are submitted to the PT provider and evaluated according to specific criteria. Each laboratory or testing facility is then notified of the correctness of their results. Although CLIA waived tests are not required to participate in Proficiency testing programs, some states and accreditation agencies do require or strongly encourage participation. Check all regulations associated with your facility. Even if not required, the value in a proficiency program is the independent assessment of the quality of testing comparing peers using same sample, same test strips. As such, it becomes an important part of an overall quality assessment program.

Recommended Proficiency Provider

American Proficiency Institute (API)   800-333-0958

CardioChek® Proficiency Testing

- API will provide you with a calendar of shipping dates for your testing event samples.

- Mark these dates on your facility calendar to be prepared for testing in a timely manner.

- When samples are received, note the following:
    - Write the date received on the outside of the container
    - Note the condition of the shipping container
    - Note the date required for the return of testing results on your calendar

- Samples must be tested with regular patient workload by personnel routinely performing the test, and using routine testing methods.[1]

- Samples must be tested the same number of times a patient sample is tested.

- The CardioChek analyzer should be properly cleaned prior to testing.

- Quality controls and an optical check should be performed prior to testing.

- When testing is completed, refrigerate the samples and retain test strips until passing results are received.

- All participants should initial all participation records and sign the attestation statement.

- All records should be kept for a minimum of 2 years.

Proficiency Failure

One event failure requires the laboratory to investigate the cause and resolve the problem. A CLIA certificate will not be revoked for an initial failure unless results pose a clear danger to patients.

Investigation should cover the 3 categories of testing:

Pre-Analytical

- Examine the dates on the calendar to ensure timely testing was performed.
- Review storage conditions until testing occurred.
- Review the testing procedure to ensure all instructions were followed, including sampling size and temperature conditions.
- Assess the quality control results at the time of the PT testing.

Analytical

- Bring refrigerated proficiency samples to room temperature and mix well. Retest the samples using the same lot# of test strips to ensure comparable repeat testing. (If re-test fails, refer to PTS troubleshooting for proficiency testing.)

Post-Analytical

- Examine all documents to ensure numbers were not transposed during the reporting phase.
- Document all phases of the investigation and store them with the initial testing file.
- Document the competency of the employee testing the sample. Retraining options and certificate documentation is available on the PTS company website.

Failure for multiple events (i.e.: failing the same analyte in two of three consecutive events) is termed "unsuccessful" by CMS. Facilities and laboratories must have a plan of action that may include investigation and training of personnel. The plan must be followed and documented. Failure for such a plan may include sanctions or even revocation of the CLIA certificate if there is possible danger to the health and safety of a patient. PTS Technical Support will be available to assist the customer with troubleshooting when a proficiency failure has occurred. Contact 877-870-5610 for assistance.

References

1. The New Poor Lab's Guide to the Regulations; Sharon S Ehrmeyer, Ph.D.; Westgard QC, Inc. 2012; p20-21.

   Note: Refer to the CMS Proficiency Brochure at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/CLIAbrochure8.pdf for additional information regarding proficiency testing.