

PTS Diagnostics Proficiency Testing

Proficiency testing (PT) is an important tool a laboratory or facility can use to verify the accuracy and reliability of its testing. PT is the testing of unknown samples sent to a laboratory by a Centers for Medicare & Medicaid Services (CMS) approved PT program (PTS Diagnostics recommends American Proficiency Institute). After testing the PT samples in the same manner as patient specimens, the lab reports the results back to their PT program. The program grades the results using CLIA grading criteria and sends the laboratory scores reflecting the accuracy of the testing. 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, proficiency testing is a valuable independent evaluation of the quality of results reported by a laboratory. As such, it becomes an important part of an overall quality assessment program.

Recommended Proficiency Provider

American Proficiency Institute (API)
800-333-0958 (8am-5pm EST, Monday-Friday)
www.api-pt.com

Suggested API Catalog & Program

Which catalog program should I choose?

Lipid & Glucose (reflectance)

For use with CardioChek[®] PA and CardioChek Plus analyzers

API Catalog #	API Proficiency Testing Program	Number of Samples	Event Frequency	PTS Panels [®] Test Strips
144	Waived Chemistry	2 Samples per Event	3 Events per Year	Cholesterol, HDL, Triglycerides, Glucose

Glucose (electrochemical - eGLU)

For use with CardioChek Plus analyzers

API Catalog #	API Proficiency Testing Program	Number of Samples	Event Frequency	PTS Panels Test Strips
918	Whole Blood Glucose	3 Samples per Event	2 Events per Year	Glucose (eGLU)

Hemoglobin A1C

For use with A1CNow^{®+} system

API Catalog #	API Proficiency Testing Program	Number of Samples	Event Frequency	A1CNow ⁺ System
127	Glycohemoglobin	2 Samples per Event	3 Events per Year	A1CNow ⁺ (HbA1C)

Glucose: Reflectance vs Electrochemical

How do I determine if I have reflectance glucose or electrochemical glucose (eGLU) test strips?

eGLU test strips are offered stand-alone or as part of the Lipid Panel + eGLU test strips smart bundle pack. **ALL eGLU test strips are designated with a lot prefix of X or Q.** If your glucose test strip is not designated with a lot prefix of X or Q, you are using a reflectance test strip.

Method/Reagent Selection:

Analyte	API Catalog #	Method	Reagent Options
Cholesterol, Total	144	PTS Diagnostics CardioChek	PTS single analyte test strip
			PTS dual analyte test strip
			PTS triple analyte test strip
HDL Cholesterol	144	PTS Diagnostics CardioChek	PTS single analyte test strip
			PTS dual analyte test strip
			PTS triple analyte test strip
Triglycerides	144	PTS Diagnostics CardioChek	PTS single analyte test strip
			PTS triple analyte test strip
Glucose	144	PTS Diagnostics CardioChek	PTS single analyte test strip
			PTS dual analyte test strip
			PTS triple analyte test strip
Glucose (eGLU)	918	PTS Diagnostics CardioChek	PTS eGLU test strip
HbA1c	127	PTS Diagnostics A1CNow+ System	PTS A1CNow+ cartridge

API 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:
 - Read and follow storage and testing instructions.
 - Note the date samples are received and condition of the shipping box.
 - Note the date required for the return of testing results on your calendar.
- Samples must be tested using routine testing methods.
- Samples must be incorporated into routine patient workload by personnel who routinely perform the test.
- Samples must be tested the same number of times a routine patient sample is tested.
- When testing is completed, refrigerate the samples and retain test strips of same lot until results are received.
- All participants should initial all participation records and sign the attestation statement.
- Once results are received, review and document any corrective action as needed.
 - Call PTS Diagnostics customer service for assistance with PTS products.
- All records should be kept for a minimum of 2 years.

Questions about Proficiency Testing?

Please call Customer Service at +1-317-870-5610 (direct) or 1-877-870-5610 (toll-free US only) if you have any questions or concerns.

FAQ for API Proficiency Testing

Q: Are the reagent choices the same for the CardioChek PA and the CardioChek Plus analyzers?

A: Yes. The reagent choices are the same for all single, dual, and triple test strips, with the exception of the eGLU test strips which can only be used with the CardioChek Plus analyzer.

Q: Do I need to order proficiency for each site with a CLIA certificate?

A: Yes. If there are multiple testing sites with separate certificates, each site will enroll in PT.

Note: PT testing is not required for a certificate of waiver.

Q: What if I have more than one analyzer?

A: CMS only allows PT for one instrument/method. API offers Verification Programs for convenience of using PT samples and statistics to verify secondary instruments and methods. Scores from verification programs are not reported to regulatory agencies. Please call PTS Diagnostics customer service for specific catalog numbers of specific Verification Programs suggested for CardioChek and A1CNow+ products.

Q: Do I treat PT samples differently than I would treat patient samples?

A: No, the proficiency samples should be tested as a patient sample in accordance with the analyzer user guide and test strip package inserts. For further instructions on testing proficiency samples, log in to API's Paperless Proficiency Testing™ website (www.api-pt.com). Select "Manage Results & Forms." Locate the appropriate test event under the "Enter Results" heading and click on "Instructions." You will be directed to a PDF containing all of the paperwork for the proficiency samples that you have ordered.

Q: How do I report my results?

A: Log in to API's Paperless Proficiency Testing website (www.api-pt.com). Select "Manage Results & Forms." Online result forms are listed under "Enter Results." When you select a result form, you will be taken to a screen that lists all of the programs and sample sets that you have ordered in the test event. When you click on the program name, you will be directed to a list of tests for that program. Proceed to enter and submit your results as directed by the instructions on the screen. Contact API customer service department at 800-333-0958 or PTS Diagnostics customer service for assistance.

Q: How do I report a result that falls outside my instrument linear range?

A: Simply type in the result (for example, a result of <100 mg/dL) using the < or > keys on the keyboard.

Q: Do I need to keep anything after completing my proficiency testing?

A: Yes, print off your submitted results after they are entered and keep them for your records. In addition, keep the proficiency material refrigerated and test strips of the same lot used for testing. After your passing results have been received, you can dispose of the samples. If you receive your results and additional testing is needed, you can use the refrigerated proficiency material and sequestered test strips for re-testing.

Q: I received ungraded results in my survey. Now what?

A: Most important: Ungraded results are not necessarily a proficiency survey failure. The Performance Summary and Participant Data Summary can be used to respond to an ungraded result. If you are unsure how to respond to an ungraded result, please contact PTS Diagnostics customer service for assistance.

Q: I received an unsuccessful survey. Now what?

A: Investigate and identify type of error (ex: clerical, analytical, sample problem, etc.). If possible, retest the samples and document new results. Document corrective action and review applicable information with staff. Please call PTS Diagnostics customer service for assistance.