



Charles River Proficiency Test Program (PTP) Quarterly Audits of LAL Testing Aptitude

User Benefits

- Check and validate analysis techniques
- Verify conformity of procedures to requirements of the Pharmacopoeia and ISO/IEC 17025
- Control and correct possible drift in procedural compliance
- Verify laboratory's ability to recover correct level of contamination
- Compare results to those of other laboratories

The Charles River Proficiency Test Program (PTP) is a quality assurance tool for limulus amebocyte lysate (LAL) users that provides confidential quarterly audits of LAL test proficiency. For almost 20 years, laboratories looking to verify working procedures through an external source have been using the Charles River PTP to ensure internal quality assurance, verify method and report validation, and identify trends and possible training needs.

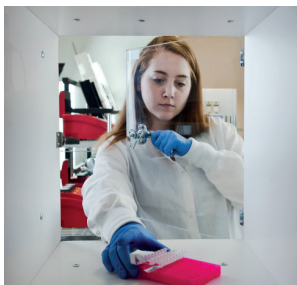
Purpose

The PTP allows users to verify the accuracy of their LAL results by providing a confidential and external quarterly audit of the facility's analysts and to confidentially compare the results to those of other laboratories. It is a mechanism by which a laboratory can demonstrate competence based on practical evaluation of LAL testing and improve procedure and methods when needed.

Process

A blind contaminated sample is sent to all participating LAL analysts. Samples can be sent on a quarterly basis. There is no restriction on method (qualitative or quantitative), reagents, or instruments. This program is open to gel-clot, turbidimetric, chromogenic (classical method or rapid micro method like PTSTM and MCSTM), and endpoint results. The analysts' methodology, results, and report are examined for accuracy in accordance with European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), and United States Pharmacopoeia (USP) regulations. A confidential report with results from all participating analysts is then sent to all laboratories, allowing for comparisons among peers. All the analysts remain identified anonymously.

EVERY STEP OF THE WAY



Industry Benefits

- PTP is helping laboratories progress toward maximum conformity to EP/USP/JP requirements.
- PTP contribute to the improvement of laboratories' LAL testing proficiency such as contamination recovery level.

Participation

The program, which is available at the start of every quarter, is open to any LAL user looking to verify working procedures through an external source with no restrictions on methodology, reagents, or instrumentation. Charles River has worked with more than 388 participating laboratories across 24 countries to improve LAL testing measures.

Online Reporting

Charles River's support staff guides users through the features of our user-friendly, functional, and secure web portal, www.lal-ptp.com, which is available 24 hours a day, 7 days a week. Analysts log their results through this protected interface, ensuring confidentiality of lab data and reducing the risk of lost reports. Once the audit is complete, quantitative and qualitative data can be exported to a spreadsheet for analysis and trending.

Get Started Today

With Charles River's PTP, participants can increase their working knowledge of the LAL assays and ensure LAL test compliance for their laboratory. For more information about the Charles River Proficiency Testing Program, please email ptp.support@crl.com.