

External FAQs

General Questions about Proficiency Testing (PT)

1. Is the program accredited in accordance with ISO/IEC 17043: 2010 as a PT Provider?

Answer: Yes. USP has a strategic alliance with NSI Lab Solution Inc. NSI Lab Solutions, an Antylia Scientific company is the ISO 17043 PT Provider representing the program with multiple accreditations by ANAB, an international accreditation body. See ANAB's website for accreditation information. ANAB is an International Laboratory Accreditation Cooperation (ILAC) recognized body located in the U. S.

2. What is the USP Proficiency Testing Program?

Answer: The USP Proficiency Testing Program is a strategic alliance between USP and NSI Lab Solutions to develop and market proficiency test schemes. NSI is a highly reputable player in the proficiency testing market with multiple accreditations: ISO/IEC 17043, ISO 17034, ISO/IEC 17025, ISO 9001.

3. What is Proficiency Testing (PT)?

Answer: The evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (*defined in ISO/IEC 17043:2010 clause 3.7*).

Proficiency testing uses schemes, also referred to as studies, to evaluate an analyst's competency using a specific material and method.

A scheme is the combination of test item and method evaluated at a specific time.

4. In what language are the schemes available?

Answer: At this time, all schemes/studies are available in English only.

Questions about Schemes

5. How do schemes work?

Answer: Schemes or Studies are identified by the accredited PT providers, subject matter experts and internal committees of the PT organization. PT providers select materials based on validated

methodology, stability, transportability, homogeneity, structure, morphology, safety and fit-for use or purpose. Schemes work by providing participants the required process, and procedure to allow the participants to perform the analysis

6. How are schemes organized?

Answer: The day-to-day operation of each scheme is the responsibility of NSI Lab Solutions. Individual schemes are managed by a team of Scheme Operations Managers, to cover reporting, customer service and technical functions. For some schemes, external advisors may also be used to provide the full range of relevant knowledge and expertise needed to operate the scheme effectively. A small number of schemes are run in collaboration with other organizations.

7. When are routine and express rounds offered?

Answer: Routine schemes are available in rounds 3 times within a calendar year:

- January
- April
- September
- (PT express)
 - PT Express is a study/scheme that can be ordered any time during and after a scheduled round. The final participate report is provided within three business days as compared to the end of a round.
 - <https://www.nsilabsolutions.com/proficiency-testing/pt-express/>

8. Which schemes are now available?

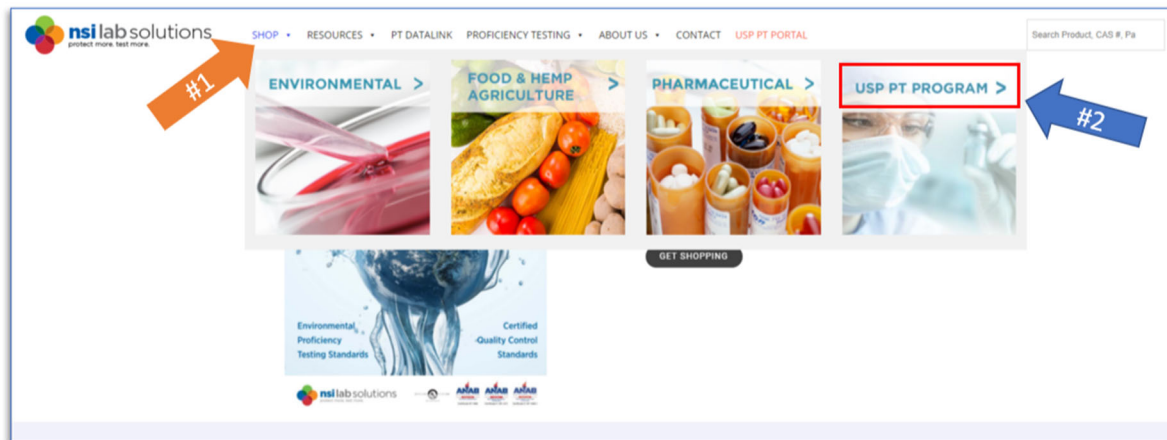
Answer: We are initially launching with pharmaceutical schemes and will be adding more pharmaceutical, microbiological and clinical schemes in 2022-2023.

Please use this link to view the current pricing: https://www.nsilabsolutions.com/wp-content/uploads/2021/10/USP-PT-Sales-Sheet_092121_2021.10.15.pdf

9. What are the steps to purchase or “Shop” a scheme?

Answer: To purchase a scheme, follow the steps below:

- Go to <https://www.nsilabsolutions.com/>
- On the main navigation bar, click on the first tab “Shop”.
- Then click on the “USP PT Program” icon.
- Please see screenshot below:



You can also use a QR code to gain access to purchase schemes.

10. Where do I submit my test performance?

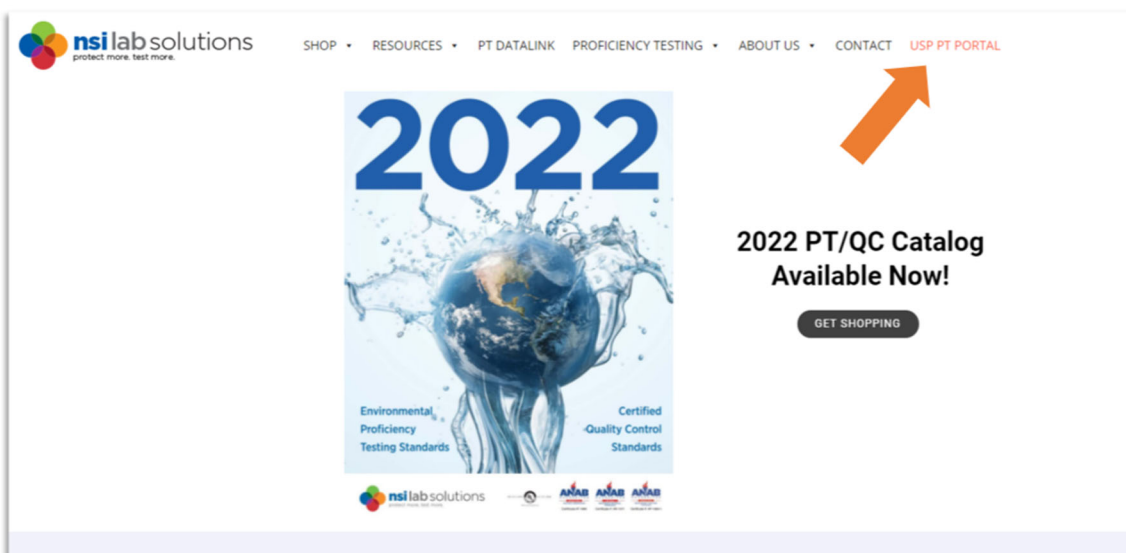
Answer: Testing results should be submitted to the USP PT Portal using the proper login in, Lab codes and passwords.

<https://pharmapt.nsilabsolutions.com/dlSelectStudyView.do;jsessionid=292E66CEE39B3E95EAFD4A0E10495EDB>

11. Is an account needed and how do I create an account with NSI so that I may purchase a scheme?

Answer: Yes, upon purchasing a scheme, the customer creates an account. This is a one-time activity in order to submit test performance and to received results reports.

- a. Once you have purchased a scheme through the NSI website, you will receive an email with your username and password.
- b. Go to: <https://www.nsilabsolutions.com/>
- c. Click on the “USP PT Portal” tab (see screen shot below).



- d. On the USP PT Portal page, enter in your **Participant Lab Code** and password provided by NSI to access the scheme(s) that you have purchased (see screenshot below):

USP PT LOGIN

Please enter your [Participant Lab Code and your password](#).

Your login session will expire after 20 minutes of inactivity.

Participant Lab Code:

Password:

Please contact nsi lab solutions at (800) 234-7837 if you have questions about accessing the PT database.

12. Which payments are accepted for purchasing?

Answer: Payments are accepted by credit card or bank wire transfer. U.S. customers and established customer accounts may pay with a purchase order number. Credit cards are charged, and invoices are sent once the order ships. Nothing is billed until the order ships. Pre-ordering is encouraged but not required.

13. Can I purchase a scheme after a round has started?

Answer: Yes, a participant may purchase a scheme up to two (2) weeks prior to study close. A scheme can be purchased as a PT Express item between rounds based on availability. Schemes that are not offered during certain rounds may also be purchased as PT Express items based on availability.

14. Can orders be returned during and after the study?

Answer: No. Orders that have been delivered to the participants cannot be returned to the manufacturer/ PT provider or USP during or after the round's conclusion.

15. How often can I purchase USP PT schemes?

Answer: A participant may order and pay for as many schemes as desired or needed to meet their internal or external requirements.

16. Is there any discount for purchasing multiple schemes?

Answer: Currently there is not a discount for multiple schemes purchased.

17. How are test materials prepared?

Answer: Materials are prepared according to the requirements of ISO/ IEC 17043.

Questions about Purchasing, Availability and Scheme & Pricing

18. When are the items available to order?

Answer: Items can be ordered by U.S. customers up to 72 hours prior to the study close dates for each PT Study. Study open and close dates are provided on our schedule

webpage: <https://www.nsilabsolutions.com/proficiency-testing/schedules/>

19. Do the online prices include shipping taxes and handling?

Answer: No, the online prices do not include shipping and handling. USP and NSI follow the current domestic and international guidance for additional fees related to shipping and handling.

Questions about PT Results

20. In computing the z score, standard deviation of results among the participants is taken into consideration. Do you have minimum number of participants requirement for the PT?

Answer:

- a. The number of participants for quantitative schemes can range, at a minimum of 5 to greater than
- b. Per the Grubs test and $K=2$ for 95% confidence, it is considered that 21 participants or greater should be in each round.
- c. Z-score is the observed value minus the mean of the sample divided by the standard deviation of the sample.
- d. Laymen's terms: Z-score indicates how much a given value differs from the standard deviation.

21. When is the best time to conduct PT for newly-hired lab analysts?

Answer: After new staff have completed the in-house training and is deemed competent and authorized by management.

22. If a participant does not pass the PT test or has a low Z-score, what is the best next plan of action? If a re-test is to be conducted, what and how should this be conducted?

Answer: If a participant does not meet the requirements of the PT test, there can be an internal investigation, root cause analysis, plan and follow-up to resolve and eliminate the failure or doubtful results. The decision to conduct a retest is based on the policies, practices and procedures of the participant's organization.

- a. Laboratories per their procedures should investigate to determine the root cause of the failure. Laboratories are recommended to develop a plan of resolution, act on the plan and follow-up to ensure the root cause identified as the reason for failure has been eliminated.
- b. A retest should be conducted at the completion of the investigation or risk analysis. The same participant, using the same qualified and calibrated instruments, should be used during the retest.
- c. Once this is completed a participant can repeat the PT either via routine or PT express studies.
- d. If the participant is not successful upon repetition, additional USP education and training is advisable.

23. How often should PT be conducted in QC lab?

Answer:

- a. Each lab should have a policy, procedure or schedule in place to determine how often PT should be conducted and for what purposes. Purposes could include training, risk mitigation, testing scope expansion, corrective action resolution, and internal requirements.
- b. Labs accredited for ISO, WHO-PQ or Regulator, should use PT for all of the methods within the scope of their accreditation or scope expansion according to testing laboratories planned schedule or duration required by the accreditation or regulation body.

24. Does this program meet the requirements for Regulators, ISO or WHO-PQ?

Answer: The USP PT program provides objective evidence verified by an accredited third party that the testing lab participants can perform a specific method or procedure. These results can be used as evidence of performance in on-boarding, training, PT for ISO accreditation, WHO-PQ, corrective and risk actions, and continuous improvement within the laboratory. Each testing lab should check with their regional regulators to ensure compliance.

25. What is the ideal timeline for a PT scheme/study of one method to be completed?

Answer:

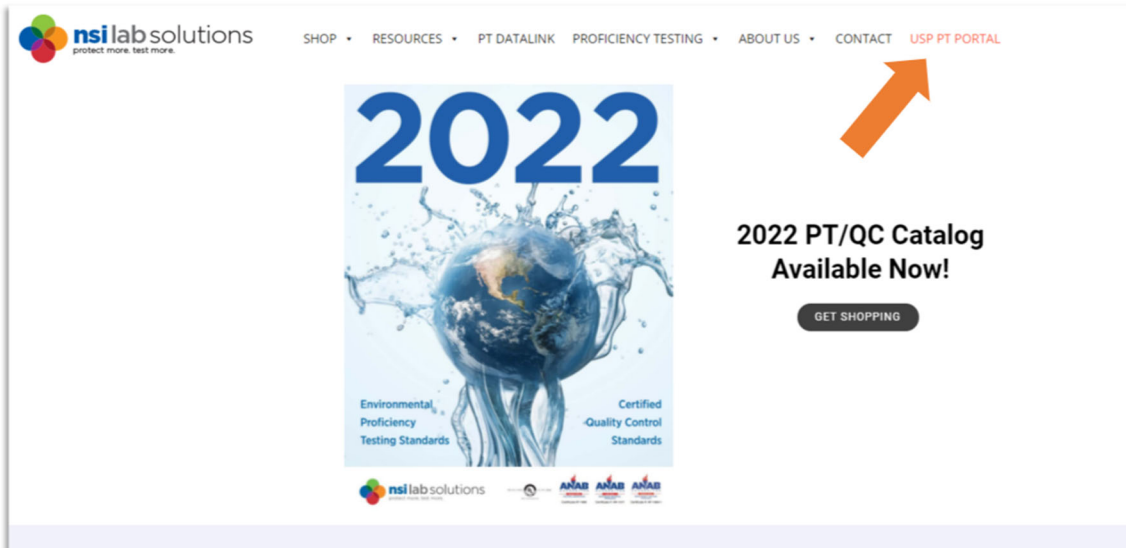
- a. If a scheme is selected, the testing and analysis should be completed in enough time to submit back to the PT provider for review and report generation.

- b. The PT provider indicates the time limit in which a round opens and closes. This time can be a range depending on the complexity of the study and PT provider. See PT Providers website for additional details

26. Where do I submit my test performance?

Answer: Participants must log into the USP PT Portal using username and password.

- Go to <https://www.nsilabsolutions.com/>.
- Click on “USP PT Portal”.
- Enter in your Participant Lab Code and password to then submit your test.



27. Does the study include the same material in every round?

Answer: The selection of microorganisms and materials are re-designed for each PT round.

28. How do I access my test results?

Answer: An email will be sent to the participant showing the results of their proficiency testing.

29. How much material is provided with each order?

Answer: Enough material is provided to perform duplicate analysis.

Distributor Information

30. Can and where do I find information if ordering through authorized distributor?

Answer:

- <https://www.nsilabsolutions.com/resources/distributors/>
<https://www.usp.org/sites/default/files/usp/document/authorized-distrib...>

31. Will authorized distributors be able to carry USP PT Program schemes?

Answer: Yes. Authorized distributors may purchase USP schemes at a discounted price (TBD) and make them available to their customers

Additional Resources

32. Where can I find more information regarding the USP Proficiency Testing Program?

Answer: There are several sources to find out more information or ask questions:

More information: <https://www.usp.org/proficiency-testing>

<https://www.nsilabsolutions.com/product-category/usp-pt-program/>

For questions regarding the program: PTProgram@usp.org

USP.PT@nsilabsolutions.com

33. Are there any USP Education courses available that are related to the USP PT program?

Answer: Yes. USP Educational course are available for a selected number of studies that align with both programs. See the USP Education website for further details.

https://uspharmacopeia.csod.com/LMS/catalog/Welcome.aspx?tab_page_id=-67&tab_id=20000495