How to designate PT providers and products

Last updated December 2024

The proficiency testing (PT) products listed meet the New York State (NYS) PT requirements. The Category Specific Help link provides information on NYS mandated analytes that require PT participation. Please consult the PT provider's website and catalog to determine that you are designating an appropriate product for your methodology and instrumentation, and to find additional important details.

Please contact the PT Administration Group by email at <u>PTAdmin@health.ny.gov</u> with any questions regarding PT product enrollment and/or designation.

Note that you can save your work at any time. The information you entered will still be available if you need to come back to the page, even after logging out.

Login to eCLEP through the Health Commerce System (HCS) home page.



On the HCS home page, under My Applications, select eCLEP.

My Applications	
eCLEP	0
Emergency Contacts	
ServNY	0

On the Welcome to e-CLEP home page, under Proficiency Testing, select PT Designations.



Alternately, on the **Proficiency Testing (PT) – Home** page, select **PT Designations**.

Select Facily Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools PT Home PFI: Name: Proficiency Testing (PT) - Home Proficiency Testing (PT) - Home PT Designations PT Documents Uses the links below to designate BT providers or to view PT related desumants	Wadswor New York State Depa	th Center						eccep electronic Clinical Laboratory Evaluation Program
Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools PT Home PFI: Name: Proficiency Testing (PT) - Home Proficiency Testing (PT) - Home PT Documents Uses the linke below to designate PT providers or to view PT related desuments	home > proficiency testing							Select Facility
PT Home PFI: Name: PT Designations Proficiency Testing (PT) - Home PT Documents Use the linke below to designate PT providers or to view PT related desumants	Permit Materials F	Proficiency Testing	Gross Annual Receipts	LDT Approval	Survey	Blood Resources	Tools	
PT Designations PT Documents Uses the links below to designate BT providers or to view BT related desumants	PT Home	PFI:	Name:					
PT Documents	PT Designations]	Proficienc	<u>:y Testing (PT) - H</u>	lome	
 PT Designations, when open, is used to notify CLEP of both the PT Provider(s) and product(s) the laboratory intends to enroll with for all tests/analytes offered that are either listed in CMS 42 CFR 493 subpart I (CLIA subpart I) OR defined by NYS as requiring PT (collectively, NYS mandated PT analytes). PT Documents include important time-sensitive information for your laboratory including verification of PT enrollment and PT participation issues, and PT performance. 	PT Documents	Use the links b PT Designation offered the PT Document of the performance of the perfor	elow to designate PT provide gnations, when open, is used hat are either listed in CMS 42 uments include important time ance.	rs or to view PT rel to notify CLEP of CFR 493 subpart e-sensitive informa	lated docum both the PT t I (CLIA sub tion for your	ents. Provider(s) and produ part I) OR defined by I laboratory including ve	uct(s) the la NYS as re erification	laboratory intends to enroll with for all tests/analytes equiring PT (collectively, NYS mandated PT analytes). of PT enrollment and PT participation issues, and PT
PT Designations PT Documents				<u>PT Design</u>	<u>ations</u>		PT Docu	<u>uments</u>

Either choice will bring you to the **Proficiency Testing (PT) – Designations** home page.

Wadsworth New York State Departu	tment of Health	_EP lic Clinical Laboratory Evaluation Program
home > proficiency testing > pt de	designations	Select Facility
Permit Materials Pro	roficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools	
PT Home	Brofisionay Testing (BT) Designations	
Instructions	<u>Fronciency resung (F1) - Designations</u>	
Category Specific Help		
FAQs	Use the links at the left to begin or continue the designation process, view instructions, or find additional help regarding specific	PT products.
Browser Issues Designation Steps Step 1 Indicate	Laboratories seeking or holding a New York State (NYS) clinical laboratory permit through the Clinical Laboratory Evaluation Pr proficiency testing (PT) as defined by NYS (NYS mandated PT). NYS mandated PT includes all tests/analytes offered by the la 42 CFR 493 subpart I (CLIA subpart I) OR defined by NYS as requiring PT.	ogram (CLEP) must enroll in boratory that are either listed in CMS
Tests Offered on NYS Specimens	In addition, each laboratory must designate the PT products that will be used to satisfy these PT requirements. Laboratories cu those in applied status for a permit must designate these PT products via this website. This process applies ONLY to your laboratories of the set o	rrently holding a NYS CLEP permit or ratory's PRIMARY test method.
Step 2. Designate PT provider and product	This website lists tests that require PT (a.k.a NYS mandated PT analytes) and prescreened PT products offered by the CMS-ap screened by CLEP to identify those that meet New York State PT requirements for NYS mandated PT analytes. Note that ONL acceptable.	pproved PT Providers that have been Y those PT products listed are
Step 3. View designations Step 4. Submit designations	For each test, your laboratory must indicate whether the test is offered on NYS specimens and, if so, indicate a PT Provider and the left side of the page to progress through the process. You must click "submit" on the final page before the notification period	d product. You must click on the links at I ends.
	 Failure to designate and submit your planned enrollment may result in citation under NYS Clinical Laboratory Standard of Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation. 	of Practice Proficiency Testing
	 Laboratories are required to authorize their PT Providers to submit PT results to NYS. Be sure to provide the PT Provide PT Provider requests a contact name and fax number, please indicate Beverly Rauch at fax number (518) 408-8666. Fai to NYS may result in citation under NYS Clinical Laboratory Standard of Practice Proficiency Testing Standard of Pract of Proficiency Testing Results. 	der with the NYS PFI number. If your lure to authorize release of PT results tice 2 (PT S2): Authorized Release
	 CLEP will compare your planned enrollment to the PT scores we receive from the PT Providers in January. Failure to pa here may result in citation under NYS Clinical Laboratory Standard of Practice Proficiency Testing Standard of Practic Department Notification and Participation. 	rticipate in the PT products selected e 1 (PT S1): Enrollment,
	Laboratories must participate with their chosen provider(s) for the entire calendar year before designating a different program	gram.
	NOTE: The laboratory must comply with Proficiency Testing Standards of Practice 3 (PT S3): Alternative to Proficiency Te PT requirements (e.g., those not indicated as a NYS mandated PT analyte).	esting for all tests not subject to NYS

Step 1. Indicate Tests Offered on NYS Specimens

Click on "Step. 1 Indicate Tests Offered on NYS Specimens"

Only categories your laboratory holds or has requested (is in applied status for) that contain analytes requiring PT participation will appear in the drop-down menu on the page labeled "Indicate tests Offered on NYS Specimens".

Wadsworth New York State Departm	Center nent of Health						eCLEP electronic Clinical Labor	ratory Evaluation	n Program
home > proficiency testing > test s	selection							Selec	t Facility
Permit Materials Prof	ficiency Testing	Gross Annual Receipts	LDT Approval	Survey	Blood Resources	Tools			
PT Home	PFI:	Name:							
Instructions			Indica	te Tests (Offered on NYS	<u>Specimens</u>			
<u>Category Specific</u> <u>Help</u>	PT designation	period is closed.							
FAQs Browser Issues	Laboratories appl proficiency testing CFR 493 subpart	lying for or holding a New York g (PT) as defined by NYS (NYS I (CLIA subpart I) OR defined	State (NYS) clin S mandated PT). by NYS as requi	ical laborato NYS manda ring PT.	ory permit through the ated PT includes all t	e Clinical Labora ests/analytes of	atory Evaluation Program (CLEI fered by the laboratory that are	P) must enroll in either listed in	n CMS 42
Designation Steps Step 1. Indicate Tests Offered on	Laboratories offer calendar year. Fo	ring these tests on NYS specin or a list of NYS-acceptable PT p	nens must design providers and su	nate which F rveys, pleas	PT provider and prod e visit:	uct they will use	to satisfy these requirements f	or the upcoming	9
NYS Specimens	https://www.wads	worth.org/regulatory/clep/pt/pr	ovider-search.						
<u>Step 2. Designate</u> <u>PT provider and</u> <u>product</u>	Categories Requi	iring PT:		~					
Step 3. View designations	Help/Instruction See the Categor	ns	nt. Tox.						
Step 4. Submit designations	Category Specifi	ic Help	ad-Comprehensi	ve					
	·								
	Show 40 v e	ntries					Search:		
	Name				Test Statu	S			$\frac{A}{\Psi}$
					No Data				
	Name				Test Statu	s			
	Showing 0 to 0 of Save Clear	f 0 entries (filtered from 16 tota	l entries)					Previous	Next
		Contact Us	Help FA	0 Acce	ssibility Messa	ae Center			_

For each category in the drop-down menu select "Test Offered" or "Test Not Offered" for each test/analyte in the list.

Select "Test Offered" for a test/analyte even if your laboratory has temporarily suspended testing.

Be sure to save before moving to the next category.

You must save your work for EACH permit category by clicking the 'Save' button at the bottom of the page before choosing a different permit category or clicking a different link. Any unsaved data will be lost.

Wadsworth Center New York State Department of Health electronic Clinical Laboratory Evaluation Progra						
home > proficiency testing > te	> test selection	Select Facility				
Permit Materials P	Proficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools					
PT Home	PFI: Name:					
Instructions	Indicate Tests Offered on NYS Specimens					
Category Specific Help	PT designation period is open from 11/03/2022 08:00 till 11/30/2022 17:00.					
FAQs	Laboratories applying for or holding a New York State (NYS) clinical laboratory permit through the Clinical Laboratory Evalu	ation Program (CLEP) must enroll in				
Browser Issues	CFR 493 subpart I (CLIA subpart I) OR defined by NYS as requiring PT.	le laboratory that are either listed in CMS 42				
Designation Steps	Laboratories offering these tests on NYS specimens must designate which PT provider and product they will use to satisfy	these requirements for the upcoming				
 Step 1. Indicate Tests Offered on 	calendar year. For a list of NYS-acceptable PT providers and surveys, please visit:					
Step 2. Designate	https://www.wadsworth.org/regulatory/clep/pt/provider-search.					
PT provider and product	Categories Requiring PT: Toxicology - Blood Lead-Comprehensive	Categories Requiring PT: Toxicology - Blood Lead-Comprehensive -				
Step 3. View designations	-Help/Instructions-]				
Step 4. Submit	Toxicology - Blood Lead-Comprehensive					
designations	Laboratories are required to enroll in a program(s) that includes:					
	 a minimum of five samples per testing event. 					
	three shipments per year					
	 samples for all CLIA subpart Lanalytes as listed in the Category Specific Help document 					
	Category Specific Help					
		,				
	Show 40 v entries	Search:				
	Name Test Status					
	blood lead Test Offered V					
	Name Test Status					
	Showing 1 to 1 of 1 entries (filtered from 16 total entries)	Previous 1 Next				
	Save Clear					
	Contact US Help FAQ Accessionity Message Center					

Step 2. Designate PT provider and product

Click on "Step 2. Designate PT provider and product"

Wadsworth New York State Departm	ent of Health		eCLEP electronic Clinical Labora	tory Evaluation Program
home > proficiency testing > provi	der product			Select Facility
Permit Materials Prof	iciency Testing Gross Annual Receipts LDT Appro	oval Survey Blood Resources Too	ols	
PT Home	PFI: Name:			
Instructions		Designate PT provider and produ	ict	
Category Specific Help				
FAQs	Next, please choose a PT provider and PT product. Appro	ved PT products must include at least 5 samp	les provided 3 times per year (except for l	Mycobacteriology,
Browser Issues	which is 2 times per year). This requirement also applies to products, please visit https://www.wadsworth.org/regulator	 laboratories offering these tests using waive v/clep/pt/provider-search. 	d kits/devices. For a list of NYS-acceptab	le PT providers and
Designation Steps	Catagorias Requiring PT: Tavisalagy - Blood Load Compr			
Step 1. Indicate	Categories Requiring P1. Toxicology - Blood Lead-Compr	enensive 🗸		
NYS Specimens	Show 40 v entries		Search:	
 Step 2. Designate 	PT Designations - PRIMARY METHOD			
product	Test Name	Provider	Product	÷.
designations	blood lead	WI State Laboratory of Hy	Blood Lead - 01080	~
Step 4. Submit	Test Name		Draduat	
designations	Test Name	American Proficiency Institute	Product	
	Showing 1 to 1 of 1 entries 1 row selected	College of American Pathologists	Prev	vious 1 Next
	*Your PT Provider will not be saved unless you have also	chosen a product.		
	Save Clear			
	Contact Us Help	FAQ Accessibility Message Cer	nter	

Select a category from the drop-down menu.

- The message 'no data' means that your laboratory has selected "Test Not Offered" for all tests that require PT participation in this permit category.
- Select your PT provider from the 'Provider' drop-down menu for each "Test Offered" from Step 1.
- The 'Product' drop-down menu will automatically populate with appropriate product(s) offered by that provider.
- Select the PT product in which you have enrolled or intend to enroll for each "Test Offered".
- Click the 'Save' button for each permit category before selecting another category or leaving this page.

NOTES

- Designate PT ONLY for your primary method. Your laboratory may enroll in additional PT for secondary methods for these tests. Do not designate them here.
- While you may order additional PT samples for certain surveys to assess secondary methods, it is critical that the additional materials and secondary method(s) be tested AFTER the event deadline has passed.
- PT for waived testing performed in a comprehensive clinical laboratory regulated by CLEP must comply with CLIA requirements (generally, five PT samples per event and three events per year). PT products that DO NOT meet these criteria are omitted from the drop-down menus.
- Enrolling in surveys omitted from the drop-down menus will result in citation under New York State Clinical Laboratory Standard **Proficiency Testing Standard of Practice (PT S1): Enrollment, Department Notification and Participation.**

Repeat Steps 1 and 2 for all permit categories

Step 3. View Designations

Click on "Step 3. View designations"

Wadsworth New York State Departme	Center ent of Health		elec	CLEP tronic Clinical Laboratory Evaluation Program
home > proficiency testing > pendir	ng designations			Select Facility
Permit Materials Profi	ciency Testing Gross Annual Receip	ts LDT Approval Survey	Blood Resources Tools	
PT Home	PFI: Name:			
Instructions		View	Designations	
Category Specific Help				
FAQs	A total of 4 record(s) have been modified	Listed below are all the "tests offere	d" and "tests not offered" by your laboratory. T	he "tests offered" include your PT product
Browser Issues	designation(s). The tests with a checkma	rk (💙) were modified since the last s	submission. Tests without a checkmark are per	sistent data from previous designations.
Designation Steps	Tests Offered			
Step 1. Indicate	Category	Test	Provider	Product
NYS Specimens	Toxicology - Blood Lead-Comprehensive	blood lead	WI State Laboratory of Hygiene	Blood Lead - 01080
Step 2. Designate	Category	Test	Provider	Product
PT provider and	Download Tests Offered			
<u>produci</u>	lests Not Offered		-	
 Step 3. View designations 	Category Category		Test	
Step 4. Submit	Download Tests Not Offered			
designations				
	Conta	t Us Help FAQ Acces	sibility Message Center	

This page summarizes the information you designated and any records on PT provider and/or product on file.

- Provider and product designations include both those from previous year(s) and those modified in Step 2. Modified records, both additions (new "Test Offered) and deletions ("Test Not Offered"), are denoted by a '+' in the chart.
- Please review and make any necessary changes before submitting. Changes can be made by returning to Steps 1 and 2.
- Print this page for your records.
- Alternately, use the "Download" buttons to save a csv file to your computer.

Step 4. Submit Designations

Click on "Step 4. Submit Designations"

- If there are tests listed on this page, you either did not select a test status in Step 1 or you did not designate a PT provider and/or product in Step 2, or both. Return to the steps to enter the required information.
- When there are no tests listed on this page, read the **Attestation** statement, and then check the box to indicate your agreement.
- Once you click the 'Submit' button to complete the PT designation process you will no longer be able to make changes.

Wadsworth New York State Departm	ecter nent of Health electronic Clinical Laboratory Evaluation Progra				
home > proficiency testing > pt su	bmission Select Facility				
Permit Materials Prof PT Home Instructions Category Specific Help FAQs Browser Issues Designation Steps	ficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools Submit designations PFI: Name: Name: PT designation period is closed. Additional information is required for all tests listed below. You must complete the information required in order to submit designations. Review steps 1 and 2 to assure that all information is included. Category Test Name				
Step 1. Indicate Tests Offered on NYS Specimens Step 2. Designate PT provider and product Step 3. View designations Step 4. Submit designations	Indicate ffered on secimens Mycology Antigen ID of fungi Culture ID of fungi Culture ID of fungi Molecular ID of fungi Designate rider and Mew fider and Submit stions Attestation Submit affirmation. I understand that signing and submitting this record in this fashion is the legal equivalent of having placed my handwritten signature on the submitted record and this affirmation. I understand and agree that by electronically signing and submitting this record in this fashion I am affirming to the truth of the information contained				
	I, the laboratory director or delegated submitter, attest that my laboratory has enrolled or will enroll in the PT surveys designated here. I understand that these designations are binding for the coming calendar year and that failure to enroll and participate in these surveys for these analytes may result in regulatory sanctions. I further understand that satisfactory PT performance is required to maintain my laboratory's CLEP permit.				
	Contact Us Help FAQ Accessibility Message Center				