



Welcome

# **Important Health Events**



## Select eCLEP





## **Important Health Notifications**

Posted	Priority	Keyword	Source	Audience	Description	Recipients	
12/26/2018	Advisory	Commissioner's Letter	NYSDOH		December 2018 Commissioner's Letter	Recipients	^
12/24/2018	Alert	Infectious Disease	NYSDOH		RB51 BRUCELLA CONTRACTED FROM CONSUMPTION OF RAW MILK	Recipients	
12/21/2018	Advisory	Synthetic Cannabinoids	NYSDOH		Advisory - Synthetic Cannabinoid (SC) - Related Coagulopathies 2018	Recipients	
12/20/2018	Advisory	Influenza	NYSDOH		NYSDOH 2018-19 Influenza Declared Prevalent in the State	Recipients	
12/11/2018	Advisory	Immunization	NYSDOH		Updated Measles Advisory 12-11-2018	Recipients	
12/07/2018	Advisory	NYSDOH Measles Advisory	NYSDOH		Measles Advisory to MDs and Medical Practices	Recipients	~
		Moaclos					
+ New	er		Showing	g notifications	sent in the past 30 days.	Older →	

# Newsroom Highlights...

## Wadsworth Center

eccep electronic Clinical Laboratory Eval

New York State Department of Health

#### home

#### Welcome to e-CLEP

This site contains a collection of tools and resources to assist you in meeting the requirements of the New York State Clinical Laboratory Reference System.

For general information and guidance, please refer to the Wadsworth Center Public Website.

Date Priority Message

Select "PT Designations"

 Permit Materials

 Laboratory Reapplication

 Laboratory Changes

 Proficiency Testing

 PT Designations

 PT Documents

 Gross Annual Receipts

 Reporting



Wadswo New York State De	rth Center						eCLEP electronic Clinical La	boratory Evaluation Progra
home > proficiency testing	> pt designations							Select Facilit
Permit Materials	Proficiency Testing	Gross Annual Receipts	LDT Approval	Survey				
PT Home	PFI: 0000	Name: Internal Test for C	LEP					
<u>Instructions</u> <u>Category Specifi</u> Help	PT designation	period	<u>Profi</u>	ciency Te	esting (PT) - Des	ignations		
FAQs Browser Issues	se the links at	t the left to begin or continue t	he designation pro	cess, view i	instructions, or find ac	dditional help regard	ding specific PT products	
Designation Steps Step 1. Indicate Tests Offered on	Laboratories and must enroll in p listed in CMS 4	oplying for or holding a New Y proficiency testing (PT) as defi 2 CFR 493 subpart I (CLIA su	ork State (NYS) co ned by NYS (NYS lbpart I) OR defined	mprehensiv mandated F d by NYS as	ve clinical laboratory p PT). NYS mandated F s requiring PT.	permit through the ( PT includes all tests	Clinical Laboratory Evalua analytes offered by the l	ation Program (CLEP) aboratory that are either
NYS Specimens Step 2. Designat PT provider and product	In addition, each those in applied status will be co	h laboratory must designate t d status for a permit, must des ontacted by CLEP for PT prov	he PT surveys that signate these PT su vider information as	will be use irveys via th part of the	d to satisfy these PT nis website. Laborator application review. Th	requirements. Labo ries that submitted i his process applies	oratories currently holding initial applications and are ONLY to your laboratory	a NYS CLEP permit, or e not currently in applied 's PRIMARY test method.
Step 3. View designations Step 4. Submit designations	This website lis by CLEP to ide offered on NYS on the links at t	ts tests that require PT as dentify those that meet New You specimens and, if so, indicat the left side of the page to pro	fined by NYS (NYS k State PT requiren e a PT provider and gress through the p	mandated ments for N d survey. Yo process. Las	PT) and PT surveys on YS mandated PT ana ou must click "submit" stly, more detailed ins	offered by the CMS alytes. For each tes " on the final page l structions can be fo	-approved PT providers t t, your laboratory must in before the notification per und <u>here</u> .	hat have been screened dicate whether the test is iod ends. You must click
	CLEP will comp result in citation authorize their different progra	pare your planned enrollment n under NYS Clinical Laborato PT providers to submit PT res im.	to the PT scores w bry Standard Profici sults to NYS. Lastly	e receive fro ency Testin , laboratorie	om the PT providers i ng Sustaining Standar es must participate wi	in January. Failure rd of Practice 1 (PT th their chosen pro	to participate in the PT su S1): Participation. Labor vider(s) for one calendar	urveys selected here may atories are required to year before designating a
	Other surveys o Quality Assess	offered by these providers do ment Sustaining Standard of I	not meet these req Practice (QA S3): C	uirements, Ongoing Ver	but may fulfill require rification of Examinati	ments for other ana ion Accuracy.	alytes under NYS Clinical	Laboratory Standard
Select '	'Step 1"							

Wadsworth New York State Departm	n Center nent of Health electronic Clinical Laboratory Evaluation Program						
<pre>home &gt; proficiency testing &gt; test s</pre>	Selection Select Facility						
Permit Materials Pro	ficiency Testing Gross Annual Receipts LDT Approval Survey						
PT Home	PFI: 0000 Name: Internal Test for CLEP						
Instructions	Indicate Tests Offered on NYS Specimens						
<u>Category Specific</u> <u>Help</u>	PT designation period						
FAQs Browser Issues	Laboratories applying for or holding a New York State (NYS) comprehensive clinical laboratory permit through the Clinical Laboratory Evaluation Program (CLEP) must enroll in proficiency testing (PT) as defined by NYS (NYS mandated PT). NYS mandated PT includes all tests/analytes offered by the laboratory that are either listed in						
Designation Steps	CMS 42 CFR 493 subpart I (CLIA subpart I) OR defined by NYS as requiring PT.						
<ul> <li>Step 1. Indicate Tests Offered on NYS Specimens</li> </ul>	Laboratories offering these tests on NYS specimens must designate which PT provider and survey they will use to satisfy these requirements for the upcoming 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: Bacteriology						
Step 3. View designations	Help/Instructions						
Step 4. Submit designations	Bacteriology Select category						
	<ul> <li>Refer to Category Specific Help for additional information</li> </ul>						
	<ul> <li>Laboratories are required to enroll in a program(s) that includes:</li> </ul>						
	<ul> <li>a minimum of five samples per testing event</li> </ul>						
	<ul> <li>three shipments per year</li> </ul>						
	• samples for bacterial isolation and identification (culture and molecular methods), antigen detection, gram stain, and antimicrobial susceptibility testing						

Categories Requiring PT: Bacteriology	1	-	
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Help/Instructions

Bacteriology

- Refer to Category Specific Help for additional information
- 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 bacterial isolation and identification (culture and molecular methods), antigen detection
- Choose a PT module that best defines the laboratory's level of service for identification. These are de-

#### Category Specific Help

ow 40 ✔ entries	
Name	
lentification of bacterial meningitis pathogens by molecular methods	Test Not Offered V
entification of bacteria by culture	Test Offered V
ntification of blood pathogens (bacterial) by molecular methods	Test Not Offered 🗸
entification of gastrointestinal bacterial pathogens by molecular method	Test Not Offered V

### Select "Test Offered" or "Test Not Offered" for each test listed

Contact Us Help FAQ	Accessibility Message Center
Save Clear	
Showing 1 to 11 of 11 entries (filtered from 116 total entries)	
Name	
Susceptibility (bacterial) testing (AST)	Test Not Offered ✓
	Test Net Offered N
Gram stains	Test Not Offered ✓
Group A Streptococcus direct detection	Test Offered V
Clostridium difficile direct detection	Test Not Offered ✓

# Save!

Wadswo New York State De	p <b>rth C</b>	enter				eCLEP electronic Clinical Laboratory Evaluation Program
home > proficiency testing	>pt designatio	ons				Select Facility
Permit Materials	Proficience	cy Testing	Gross Annual Receipts	LDT Approval	Survey	
PT Home	PFI.	: 0000	Name: Internal Test for C	LEP		
Instructions Category Specif Help FAQs Browser Issues Designation Steps Step 1. Indicate Tests Offered of NYS Specimens Step 2. Designa PT provider and product Step 3. View designations	ic PT of Us Us La the thoustan Thi by offer	designation p e the links at atories app e nroll in pr ed in CMS 42 addition, each ose in applied atus will be con is website lists CLEP to iden ered on NYS	period the left to begin or continue to plying for or holding a New Yo oficiency testing (PT) as define 2 CFR 493 subpart I (CLIA su h laboratory must designate to status for a permit, must des intacted by CLEP for PT prov is tests that require PT as definitify those that meet New Yor specimens and, if so, indicate	Profi he designation prod ork State (NYS) co ned by NYS (NYS i bpart I) OR defined he PT surveys that ignate these PT su ider information as ined by NYS (NYS k State PT requirer e a PT provider and	cess, view instructions, or find addition mprehensive clinical laboratory permit mandated PT). NYS mandated PT inc d by NYS as requiring PT. will be used to satisfy these PT requir inveys via this website. Laboratories th part of the application review. This pr mandated PT) and PT surveys offere ments for NYS mandated PT analytes d survey. You must click "submit" on th	tions hal help regarding specific PT products. through the Clinical Laboratory Evaluation Program (CLEP) ludes all tests/analytes offered by the laboratory that are either ements. Laboratories currently holding a NYS CLEP permit, or at submitted initial applications and are not currently in applied bcess applies ONLY to your laboratory's PRIMARY test method. d by the CMS-approved PT providers that have been screened For each test, your laboratory must indicate whether the test is be final page before the notification period ends. You must click
<u>Step 4. Submit</u> <u>designations</u>	On CL res aut diff Ott Qu	the links at th EP will compa- sult in citation thorize their P ferent program her surveys of iality Assessm	ne left side of the page to prog are your planned enrollment under NYS Clinical Laborato PT providers to submit PT res m. ffered by these providers do nent Sustaining Standard of F	gress through the p to the PT scores w ry Standard Profici ults to NYS. Lastly not meet these req Practice (QA S3): C	process. Lastly, more detailed instructi e receive from the PT providers in Jar ency Testing Sustaining Standard of F , laboratories must participate with the uirements, but may fulfill requirements Ongoing Verification of Examination Ac	ons can be found <u>here</u> . Juary. Failure to participate in the PT surveys selected here may Practice 1 (PT S1): Participation. Laboratories are required to ir chosen provider(s) for one calendar year before designating a for other analytes under NYS Clinical Laboratory Standard couracy.

Select "Step 2..."

Wadsworth New York State Departm	Center						eCLEP electronic Clinical Laboratory Evaluation Program
home > proficiency testing > provid	der product						Select Facility
Permit Materials Prof	iciency Testing	Gross Annual Receipts	LDT Approval	Survey			
PT Home	PFI: 0000	Name: Internal Test for C	LEP				
Instructions			De	signate P	T provider and produc	<u>t</u>	
Category Specific Help	PT designation	period				A	-Select category
FAQs Browser Issues	Next, please cho which is 2 times	ose a PT provider and PT pro per year). This requirement a	oduct. Approved P1 Iso applies to labor	products m atories offer	nust include at least 5 sam ing these tests using	ed 3 devices.	times per year (except for Mycobacteriology, For a list of NYS-acceptable PT providers and
Designation Steps Step 1. Indicate Tests Offered on NYS Specimens	Categories Requ	iring PT: Bacteriology	org/regulatory/clep/	paproviders			
<ul> <li>Step 2. Designate PT provider and product</li> </ul>	Show 40 ∨ en	tries		PT Designa	tions - PRIMARY METHOD		Search:
Step 3. View		Test Nume	×		TIONIGE	V	
Step 4. Submit	Identification of	f bacteria by culture			$\checkmark$		×
designations	Group A Strept	ococcus direct detection			~	[	
	Test Name Provid				Provider		Product
	Showing 1 to 2 o	f 2 entries					Previous 1 Next
	*Your PT Provider will not be saved unless you have also chosen			B - Choose provider			C - Choose product
	Save Clear						
		Contact Us	Help FA(	Acces	ssibility Message Cente	er	

D - Save

# Repeat Steps 1 and 2 for all categories

## Wadsworth Center

New York State Department of Health



eCLEP

electronic Clinical Laboratory Evaluation Program

### **Review changes**

Category

Help

FAQ

Contact Us

#### View Designations

#### PT designation period

A total of 36 test offered records were modified, (+), with 21 tests offered and 15 tests not offered. There are 2 designations in total with 2 modifications. Provider Prodesignations include Provider Product designations made in Step 2 and Provider Product designations on record.

	Tests Offere	d			
Category	Test	Provider	Product		
Bacteriology					
(+)	Group A Streptococcus direct detection				
mmunohematology					
(+)	antibody identification				
Category	Test	Provider	Product		
	Tests Not Offe	ered			
(	Category	Te	est		
Bacteriology					
(+)	Chlam	ydia/Neisseria gonorrhoeae by dire	ct detection		
(+)	Clostri	dium difficile direct detection			
(+)	Gram	stains			
+)	Identif	cation of bacterial meningitis patho	gens by molecular methods		
+)	Identif	cation of blood pathogens (bacteria	<ol> <li>by molecular methods</li> </ol>		
+)	Identif	cation of gastrointestinal bacterial p	athogens by molecular methods		
+)	Identif	cation of genital pathogens (bacter	al) by molecular methods		
+)	Identif	cation of respiratory bacterial patho	gens by molecular methods		
+)	Susce	otibility (bacterial) testing (AST)			
nmunohematology					
+)	ABO g	rouping			
+)	compa	compatibility testing			
+)	Rh gro	Rh group			
+)	unexp	ected antibody detection			
lycology					
(+)	Crypto	coccal antigen detection			
Identification of fungi by molecular methods					

Accessibility

Message Center

Test

Wadswc New York State De	orth Center epartment of Health			electr	LEP onic Clinical Laboratory Evaluation
home > proficiency testing	g > pending designations				Select
Permit Materials	Proficiency Testing	Gross Annual Receipts	LDT Approval Survey		
PT Home	PFI: 0000	Name: Internal Test for C	LEP		
			View De	signations	
Instructions			<u></u>		
Category Speci Help	PT designation	n period			
FAOs	_	-			
Browser Issues	A total of 33 rec	ord(s) have been modified. Li	sted below are all the "tests offered"	and "tests not offered" by your laboratory. Th	he "tests offered" include your PT
Diomoci ibbueb	designation(s).	The tests with a checkmark (	) were modified since the last subm	iission. Tests without a checkmark are persi	stent data from previous designati
Designation Steps	\$		Tests	Offered	
Step 1. Indicate	2	Category	Test	Provider	Product
NYS Specimen:	Bacteriology				
Step 2. Designa	ate Immunohomato	Gro	oup A Streptococcus direct detection		
PT provider and product		logy	ibady identification		
	•	Catagoria		Descrides	Desiduat
<ul> <li>Step 3. View designations</li> </ul>	Download Tests	offered	Test	Provider	Product
Step 4. Submit			Tests N	lot Offered	
designations		Catego	ry	Te	est
	Bacteriology			Chlamudia/Naisaaria gaparrhaasa hu dira	at data atian
				Clostridium difficile direct detection	ci delection
				Gram stains	
	<b>v</b>			Identification of bacterial meningitis patho	gens by molecular methods
	<b>*</b>			Identification of blood pathogens (bacteria	al) by molecular methods
	<b>v</b>			Identification of gastrointestinal bacterial p	oathogens by molecular methods
	×			Identification of genital pathogens (bacter	ial) by molecular methods
	*			Identification of respiratory bacterial patho	gens by molecular methods
	✓	la su:		Susceptibility (bacterial) testing (AST)	
	immunonemato	logy		ABO grouping	
	*			compatibility testing	
	<b>v</b>			Rh group	

Select "Step 4. Submit Designations"

-Attestation-

Please read the following attestation carefully. You must signify agreement by clicking the checkbox below, then click 'Submit'.

I, the laboratory director or delegated submitter, as a representative of the owner and laboratory director, 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 therein.

I attest that my laboratory has enrolled or will enroll in the proficiency test (PT) surveys designated here. I understand that that failure to enroll and participate in these PT surveys for these analytes may result in regulatory sanctions. I understand that satisfactory PT performance is required to obtain and maintain a clinical laboratory permit. I also agree, on the behalf of the laboratory director and owner, to submit to any investigation made by the Department of Health to verify the information provided. If additional information is requested, I agree that it will be provided in a timely manner by the appropriate staff under the direction of the laboratory director and owner.



I have read, and agree with, the above attestation.

-Comment-

If you would like to provide a comment, please do so below: (500 characters max)

Submit Clear



## Check attestation box and click Submit