

**Notification to Add/or
Delete Analyte(s)**

Telephone: (518) 485-5378 Fax: (518) 485-5414
E-mail: CLEPCERT@health.state.ny.us
Web: www.wadsworth.org/labcert/clep/clep.html

Laboratory PFI Number:	Name and Address of Laboratory:

Below are blocks for requesting the addition/deletion of up to three analytes. Please note that review and approval of method validation documentation is required prior to processing patient specimens for in-house developed or "home brew" tests. For commercially distributed kits, provide the FDA labeling as indicated in the package insert (IVD; "For In Vitro Diagnostic Use". RUO; "Research Use Only" IUO; "Investigational Use Only" or ASR "Analyte Specific Reagents"). Laboratories using products labeled RUO, IUO, or ASR must send provide copies of package inserts and sample patient reports. Guidelines for the submission of method validation documentation and other materials are available on our website.

1.	Analyte Name	Request	<input type="checkbox"/> Add <input type="checkbox"/> Delete		
	Permit Category	Indicate FDA Status			
	Method	IVD	RUO	IUO	ASR
	Kit Name				
	If this is a request for an addition, is laboratory ready to process NYS proficiency test specimens immediately if applicable?		<input type="checkbox"/> Yes	<input type="checkbox"/> No (please indicate date you will be ready)	
	Signature of the Assistant Director holding the certificate of qualification for the category, if applicable: _____ CQ Code: _____ Date: _____				
2.	Analyte Name	Request	<input type="checkbox"/> Add <input type="checkbox"/> Delete		
	Permit Category	Indicate FDA Status			
	Method	IVD	RUO	IUO	ASR
	Kit Name				
	If this is a request for an addition, is laboratory ready to process NYS proficiency test specimens immediately if applicable?		<input type="checkbox"/> Yes	<input type="checkbox"/> No (please indicate date you will be ready)	
	Signature of the Assistant Director holding the certificate of qualification for the category, if applicable: _____ CQ Code: _____ Date: _____				
3.	Analyte Name	Request	<input type="checkbox"/> Add <input type="checkbox"/> Delete		
	Permit Category	Indicate FDA Status			
	Method	IVD	RUO	IUO	ASR
	Kit Name				
	If this is a request for an addition, is laboratory ready to process NYS proficiency test specimens immediately if applicable?		<input type="checkbox"/> Yes	<input type="checkbox"/> No (please indicate date you will be ready)	
	Signature of the Assistant Director holding the certificate of qualification for the category, if applicable: _____ CQ Code: _____ Date: _____				

NOTE: All signatures must be original. SIGNATURE STAMPS WILL NOT BE ACCEPTED.

Date

Signature, Laboratory Director

Name, Laboratory Director (Print)