NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
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E-mail: CLEPCERT@health.state.ny.us
Web: www.wadsworth.org/labcert/clep/clep.html

Notification to Add/or Delete Analyte(s)

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	☐ Add ☐ Delete			
	Permit Category		Indicate FDA Status				
	Method		IVD	RUO	IUO	ASR	
	Kit Name						
	If adding a new analyte, is laboratory ready to process NYS proficiency test specimens immediately, if applicable?		☐ Yes	☐ 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	☐ Add ☐ Delete			
	Permit Category		Indicate FDA Status				
	Method		IVD	RUO	IUO	ASR	
	Kit Name						
	If adding a new analyte, is laboratory ready to process NYS proficiency test specimens immediately, if applicable?		☐ Yes	☐ 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	☐ Add ☐ Delete			
	Permit Category		Indicate FDA Status				
	Method		IVD	RUO	IUO	ASR	
	Kit Name						
	If adding a new analyte, is laboratory ready to process NYS proficiency test specimens immediately, if applicable?		☐ Yes	☐ 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)

DOH-3519f (11/08)

For office use only:
Section:_____ **Surveyor**_____ **Compliance**_____ **EPTRS**_____ **CMS** _____