

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-03-CLIA

DATE: October 29, 2010

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Survey and Certification of Chemical Toxicity Public Health Laboratories (CT PHL's) under the Clinical Laboratory Improvement Amendments (CLIA)

Memorandum Summary

- **Certificates:** To facilitate preparedness in the event of a chemical terrorism act, all designated CT PHL's will request and obtain a CLIA certificate at their projected highest level of testing, regardless if testing human samples presently.
- **Surveys:** All CT PHL's will be surveyed by their survey agency immediately to assess compliance using the CLIA Outcome Oriented Survey Process (OOSP) or the accrediting organization's (AO) standard operating procedures by their selected accreditation organization and subsequently, on a routine biennial schedule.
- **Fees:** CLIA fees will be assessed based on actual test volumes, if available; if not, minimum certificate and survey fees will be assessed and adjusted as accurate information becomes available.

Background

The Centers for Disease Control and Prevention (CDC) is working with the Association of Public Health Laboratories (APHL) to establish and prepare the national Laboratory Response Network (LRN) to ensure that there are robust, adequate laboratory testing services available in the event of a chemical terrorism attack. Since these laboratories will be testing human specimens, among other things, they will require the appropriate CLIA certificate.

To avoid the establishment of fraudulent laboratories, current CLIA policy indicates that no CLIA certificate is to be issued to any individual, entity or facility, unless the laboratory is presently testing human samples for health assessment. Because this circumstance represents a reversal or exception to our existing policy, it is being stated here to avoid inconsistent or incomplete implementation. This will facilitate the successful operation of the CT PHL's and avoid confusion and unnecessary angst, if they should be called to use.

Likewise, we typically do not survey laboratories, unless State law contravenes, until they have performed testing and compiled sufficient performance data for CMS to review. In this instance,

we are recommending that the CT PHL's be surveyed prior to testing initiation or as soon as possible following registration and within the surveyors' availability, to expedite the certification process.

Policies for Survey and Certification of CT PHL's

Certificates: All known CT PHL's shall be issued an effective CLIA certificate at their highest level of testing, regardless of whether they are testing human samples or not at this time. This allows the laboratory to operate within the scope of CLIA, ensure quality patient testing and avoid delays should an untoward event occur. These laboratories which have been identified by APHL (see attached list) will have the choice of obtaining a certificate of compliance or a certificate of accreditation, depending on whom they select as their survey agency, as do all other enrolling laboratories. States and regions working with these laboratories should follow the procedures for registering and certifying them as outlined in the State Operations Manual (SOM) at Chapter 6.

Surveys: CT PHL's should be surveyed as soon as possible to check their personnel qualifications and competency, test method establishment/verification, quality control (QC), calibration/calibration verification, proficiency testing (PT) or alternative assessment, operating policies and procedures, and test ordering and reporting mechanisms, at a minimum, when no human testing is being performed and should receive a full survey, if otherwise.

There is an advantage to performing these surveys early, even when no human testing is being conducted, because any problems that exist in key areas can be identified and resolved prior to an actual need for patient testing in an emergent situation.

Surveyors should employ the CLIA OOSP for laboratories requesting a certificate of compliance and the AOs, their standard survey procedure, for laboratories requesting a certificate of accreditation. Subsequent surveys should follow the survey agencies' routine biennial schedule. If any deficiencies are identified, they should be cited and the appropriate follow up per the survey agency's protocol should occur. Following a determination of compliance and receipt of their certificate payment, the CT PHL's will receive the appropriate CLIA certificate.

If a CT PHL has already been surveyed and certified, this policy is not applicable. These laboratories will then fall into a routine biennial survey schedule. If a CT PHL already has a CLIA certificate, but has added chemical terrorism testing to its test menu since its last survey, we encourage the surveyors to visit and review only this testing in the interim until the next biennial survey, as soon as it is feasible.

Fees: For fee determination, we assume the testing will be non-waived and a registration certificate will be issued, following receipt and entry of the CMS-116 form, until the laboratory is surveyed. If the CT PHL is not testing human specimens, then the test volumes should be at the minimum level for certificates and surveys. Specialties and subspecialties should be noted to the best of the laboratory's knowledge about anticipated types of testing and their capabilities to perform it. They can be adjusted at a later date when better information is available. Otherwise, test volumes should be recorded correctly per CMS testing counting instructions that accompany the CMS-116 form.

Data System Instructions: All CT PHL surveys will be entered into the CLIA data system by the CLIA regional office consultants. When entering the survey findings (kits) for these laboratories, please use the “Notes” portion to identify these laboratories in the system, but do not identify them in any fields that could be observed externally.

Complaints: If a complaint is alleged against a CT PHL, follow the procedures outlined in the SOM, Chapter 5.

Scope: **This policy applies to ONLY the CT PHL’s designated by APHL on the attached list.** This list may be updated periodically.

Should you have any questions about the information in this memo, please contact Judy Yost at 410-786-3407 or at Judith.yost@cms.hhs.gov.

Effective Date: Immediately

Training: This policy should be shared with all survey and certification staff, their managers and the State/Regional Office (RO) training coordinator.

/s/
Thomas E. Hamilton

Attachment: List of CT PHL’s.

cc: Survey and Certification Regional Office Management
CLIA RO Consultants

State/Lab	CLIA Certified Y/N?	CLIA #	Other Accred?	Contact
AK PHL	yes	02D0674496	AAALAC	eileen.nickoloff@alaska.gov
AL PHL	No	N/a	No	Sharon.Massingale@adph.state.al.us
AR PHL				
AZ PHL	Yes	03D0641866.	No	jason.mihalic@azdhs.gov
CA PHL				
CO PHL	No	06D0644326	CAP	lpeterso@cdphe.state.co.us
CT PHL				
DC PHL				
DE PHL	Yes	N/A	No	Tara.Lydicke@state.de.us
FL PHL				
FSIS, USDA	No	N/A	ISO 17025 bio and chem	Joseph.Hill@fsis.usda.gov
GA PHL				
HI PHL	Yes	12D0646259	No	alfred.e.asato@doh.hawaii.gov
IA State Hygiene Lab	No	N/A	NELAC, AIHA etc	michael-wichman@uiowa.edu
ID PHL	Yes	13D0646339	No	ballC1@dhw.idaho.gov
Illinois PHL	No	14D0691828	No	Leslie.Chapman@illinois.gov ; george.dizikes@illinois.gov
IN PHL	Yes	15D0662599	No	CGrimes@isdh.IN.gov
KS PHL	yes	17D0648254	No	sgabel@kdheks.gov
KY PHL				
LA County	No	05D1066369	No	avolner@ph.lacounty.gov
LA PHL	Yes	n/a	No	stephen.martin@la.gov
MA PHL	Yes	not shared	CAP (lead program only)	Julianne.Nassif@state.ma.us
MD PHL				
ME PHL	No	n/a	NELAP, AIHA, ASCLAD	James.Curlett@Maine.gov
MI PHL	No	None	No	massey@michigan.gov
MN PHL	Yes	24D0651409	No	paul.swedenborg@state.mn.us
MO PHL	No	26D0667822	CLIA, AIHA, EPA, SA	laura.naught@dhss.mo.gov
MS PHL	Yes	25D1096223	No	Daphne.Ware@msdh.state.ms.us
NC PHL	Yes	34D0692393	No	kaye.flood@dhhs.nc.gov
ND PHL	No	None	None	rolheiser@nd.gov
NE PHL	Not	n/a	Working towards CAP	delhajja@unmc.edu
NH PHL	No	N/A	No	shartman@dhhs.state.nh.us
NJ PHL	Yes	31D0674406	No	Stephen.Jenniss@doh.state.nj.us
NM PHL	Yes	32D0875964	CAP	patrick.dhooge@state.nm.us
NY PHL	Yes	33D0654341	A2LA, NELAP, Clinical Lab Cert	kma01@health.state.ny.us
NYC PHL	No	n/a	no	Jatamian@health.nyc.gov
NV PHL	Yes	29D0652748	CAP	chartman@medicine.nevada.edu
OH PHL	Yes	36D0655844	No	Ram.Chandrasekar@odh.ohio.gov
OK PHL	Yes	N/A	CAP	JohnFM@health.ok.gov
OR PHL	No	N/A	CAP	Teresa.E.McGovern@state.or.us
PA PHL				
RI PHL	Yes	N/A	No	ewa.king@health.ri.gov
SC PHL	Yes	42D0658606	No	reddicje@dhec.sc.gov
SD PHL				
TN PHL	No	N/A	No	walter.whybrew@tn.gov
TX PHL	Yes	45D0660644	CAP	Cathy.Edmonson@dshs.state.tx.us
UT PHL	no	46D0660877	no	schaudhu@utah.gov
VT PHL	No	N/A	no	Stella.Celotti@ahs.state.vt.us
WA PHL	Yes	50D0661453	CAP	blaine.rhodes@doh.wa.gov
WI PHL	No	52D0661989	CAP	nvstox@mail.slh.wisc.edu
WV PH:				
WY PHL	Level 3 lab			