IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

Health/Wellness Events - Collection of Clinical Specimens in the State of Illinois

The state of Illinois requirements for the collection of specimens as described under the **HEALTH FACILITIES AND REGULATION (210 ILCS 25/) Illinois Clinical Laboratory and Blood Bank Act,** Sec. 7-104, mandates that "no person other than a licensed physician or one authorized by law shall manipulate a person for the collection of specimens except that technical personnel of a clinical laboratory may collect blood, or remove stomach contents, or collect material for smears and cultures, under the direction or **upon the written request of a licensed physician or dentist**." (Source: P.A. 87-600.) The request must absolutely be done by no other than one authorized by law.

AGENCY NOTE: Please note one change that affects the previously required class Permit III for laboratories performing health/wellness events. The application for Class III Permits for Laboratories was repealed at 14 Ill. Reg. 2360, effective January 26, 1990 and is no longer required.

Requests to conduct health/wellness events for the collection of clinical samples must be submitted in advance to the Department and must include essential documents.

Specimen collection state law requirement

Direct Access Testing (DAT) is not allowed in the state of Illinois and entities participating in the collection of clinical specimens for referral to CLIA certified laboratory must have on file a written request by a licensed physician or dentist or one authorized by law (http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1221&ChapAct=210).

Training and Education requirements

The collection of the specimens may be done by technical personnel of a clinical laboratory or health professional with proof of completed training in specimen collection OR certified by an Accredited USA Certification Program.

Education: High school diploma, equivalent or higher education.

Training must include:

- Preparation of blood, urine, and other body fluid samples for testing as recommended by the test manufacturer, or as established by a licensed Medical Director following laboratory standards.
- Description of the specimen collection process to the patient.
- Patient evaluation for suitability or ability to withstand venipuncture procedure and explanation to the patient of the procedure.
- Patient care during the process of blood drawing or other body fluid clinical sample.
- Ability to demonstrate proficiency in all aspects of phlebotomy procedures.
- Completion of OSHA blood pathogen training to include vaccination awareness as required.

Reporting and Notification

All entities in state and out of state shall notify the Department of their intent to conduct any initial health/wellness event at least 30 days in advance.

The facility or organization must provide a disclosure of business ownership/state registration, list of planned events (location, date & time), employee names, professions, proof of training and work location.

Changes to preapproved requests must be submitted no later than 7 days before the event(s) and changes in personnel must include an updated participant list with proof of training records.

Once notification is received, the Department will review the required documents and mail or e-mail a confirmation to the requested event. **It is recommended to have on file the required doctor's specimen collection order, copy of CLIA reference laboratory certificate and acknowledgment letter or e-mail from our office printed and ready to be displayed in case one of our surveyors visits the event.**

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All entities interested in conducting health/wellness events for the purpose of collecting clinical samples for referral to CLIA certified laboratory for testing, shall notify the Department of the location and all personnel anticipated to participate. For initial requests the facility or organization must provide a disclosure of business ownership/state registration, list of planned events (location, date & time), employee names, professions, proof of training and work location 30 days in advance.

DISCLOSURE OF BUSINESS/OWNERSHIP

State File Number (Ex: Corp/LLC) _____ to do business in the state of _____
(Illinois entities not familiar with this number, visit **http://www.ilsos.gov/corporatellc/**; other may contact their state business services.)

Federal Tax ID Number _____

Entity/Facility Name_____

Street Address _____

City _____ State _____ Zip Code _____

Type of Entity: □ Sole Proprietorship □ Partnership □ Corporation □ Not for-profit □ For profit

□ Other (specify) _____

_____ _____
Name of facility director or owner (type) Title (type)

_____ _____
Signature of facility director or owner *Date*

Personnel participating in the Health/Wellness event (use a separate page if needed)				
Name	**Job position/profession**	**Proof of training (Y/N)**	**Work location**	**New (Y/N)**

Please provide an answer to each of the listed questions on the next page and sign/date the document.

The following questions must be answered:

Do you have a health/wellness event protocol? If yes, include with this request. If not, include a description on how the event will be conducted on a separate document and add to this request.

Include a description of the training provided to staff members for a safe and successful event

_____
_____
_____
_____
_____

Indicate the type of clinical specimen(s) that will be collected _____
_____

Indicate how confidentiality will be maintained _____
_____
_____

With this request provide the following documents and information:

1. Proof of training of <u>all personnel</u> anticipated to participate in this health/wellness event.
2. Copy of the CLIA certified laboratory(s) certificate(s) where specimens will be referred for testing.
3. Copy of test manufacturers specimen collection instructions as applicable.
4. Copies of educational materials that will be provided to the participant patient/clients.
5. Copies of any forms used in the course of conducting the health/wellness event.
6. Log listing facility name conducting the event, date & time and event location.

Certification and Signature

Before signing this document please carefully read this paragraph. *Under penalty of perjury, I certify the information provided herein is correct. I understand that misrepresentation will be cause to prevent you from participating or conducting any health or wellness events in the state of Illinois, and subject to fines and other penalties allowed by the law.*

Phone _____ Fax _____ E-mail _____

_____ _____
Name of facility director or owner (type) Title (type)

_____ _____
Signature of facility director or owner *Date*

Form can be faxed to: 217-782-0382 or mailed to: IDPH CLIA Program (4th FL) 525 W Jefferson St. Springfield, IL 62761