IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

Requirements for the 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 that a Clinical Laboratory Improvement Amendments (CLIA) certificate is not required for the sole purpose of collecting clinical samples and please make note of 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 The application for Class III Permits for Laboratories was repealed at 14 Ill.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 for testing 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 trained technical personnel or health professional.

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 safety blood pathogen training and other 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.

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, profession and date of training.

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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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/owner/administrator (type) Title (type)

_____ _____
Signature of facility director/owner/administrator *Date*

Personnel participating in the Health/Wellness event (use a separate page if needed)				
Name	**Job position/profession**	**Education**	**Specimen Collection Date of Training**	**Training Coordinator Initials**

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

All questions must be answered:

Do you have a health/wellness event protocol? If yes, include with this request. If not, describe the purpose for collecting clinical samples in the state of Illinois.

_____
_____
_____
_____
_____

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. Copy of clinical specimen collection order. (Standing orders are acceptable).
2. Copy of authorized person professional license.
3. If applicable copy of the CLIA certificate where specimens will be referred for testing.
4. Copy of test manufacturers specimen collection instructions as applicable.
5. Copies of any forms used in the course of conducting the health/wellness event.
6. Schedule listing event date, time and address 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 eee
Date

Completed forms can be submitted via email to ***Dph.Clia@Illinois.gov*** *faxed to 217-782-0382, or mailed to IDPH CLIA Laboratory Certification Program, 525 W. Jefferson St. Fourth Floor, Springfield, IL 62761*