

Health Screening Events in the State of Illinois

The state of Illinois requirements for health screening is specified under title 77 of the Public Health.
<http://www.ilga.gov/commission/jcar/admincode/077/07700450sections.html>.

Please note one change that affects the previously required class Permit III for laboratories performing health screenings for profit. The application for Class III Permits for Laboratories was Repealed at 14 Ill. Reg. 2360, effective January 26, 1990, and is no longer required.

The state of Illinois follows the Federal Clinical Laboratory Improvement Act (CLIA) for laboratory licensing. Facilities operating in our state or receiving specimens from other states to be tested in our state, must have a current CLIA certificate that is appropriate, valid, and in good standing.

All laboratories interested in conducting health screening events in the state of Illinois must have the correct endorsement for temporary testing added to their CLIA certificate. (For questions regarding CLIA certificate temporary testing, out of state laboratories must call their state CLIA program).

Please note that the state of Illinois laboratory requirements, are to follow the active Illinois Clinical Laboratory and Blood Bank Act of the Title 77: Public Health Admin Code Part 450 and failure can lead to penalties or fines.

Under the code, the health screening tests that are allowed are:

1) Blood total cholesterol testing and 2) blood glucose testing. Both tests are to be conducted by the finger stick method.

These two allowed waived tests are exempt from the required (authorized person) state law and can be ordered by any private individual, as long as the tests performed are conducted following an approved protocol by a licensed physician.

AGENCY NOTE: Although there are only two allowed tests at present, the Department accepts requests for additional tests for review. Please note that approval to perform any additional test(s), can be revoked at any time as our current state laws are being reviewed.

Reporting and Notification

All health screening entities shall file a health screening protocol with the Department.

All test performed must be under the category classifies as CLIA waived.

All health screening entities shall notify the Department of all personnel anticipated to conduct any health screening event including name, professions, training background, street address, city, ZIP code at least seven days prior to any health screening event.

All health screening entities are required to notify the Department of all health screening sites including street address, city, ZIP code and any other identifying data that are available at least seven days prior to any health screening event. The notification is to be e-mailed to our office.

Illinois Department of Public Health
CLIA Laboratory Certification Program
525 W. Jefferson St., Fourth Floor
Springfield, IL 62761
Phone: 217-782-6747
Fax: 217-782-0382

Once notification is received, the Department will e-mail a confirmation. It is recommended to have the acknowledgment letter or e-mail from our office printed and ready to be displayed in case one of our surveyors visits the event.

Following is a summarized protocol for conducting health screenings in the state of Illinois. However, we recommend for health screening entities to review the required and detailed protocols that can be found at the website: <http://www.ilga.gov/commission/jcar/admincode/077/07700450sections.html>

SUBPART M: HEALTH SCREENING

- [Section 450.1300 Health Screening and Approved Health Screening Tests](#)
- [Section 450.1310 Protocol for Conducting Health Screening](#)
- [Section 450.1330 Reporting and Notification](#)

AGENCY NOTE: Any entity which performs health screening events shall establish a protocol for health screening activities and submitted the completed document to our office for review and approval.

Protocol for Conducting the Health Screening Events in the State of Illinois

All fields must be answered and protocol signed, dated and approved by a physician licensed to practice medicine in all its branches.

Facilities performing health screening events must have the endorsement for Temporary Testing added to their certificate. **Check this box** if you would like to have the endorsement added to this CLIA certificate.

Facility CLIA ID # _____ Facility Name _____
Address _____ State _____ Zip Code _____

1) Indicate the name of all CLIA Waived test(s) to be conducted. _____

2) Indicate the way in which results shall be reported to the test subject including any available oral counseling and health professional referral program. _____

3) Indicate how confidentiality will be maintained. _____

- 4) Include a written quality control program to assure accurate and precise test values as recommended by the test manufacturer (e.g., explain how you are going to make sure the testing instrument of choice is operating as described by the manufacturer - inferring to make sure that the instrument is operating as expected and patient test results are reliable), and what steps will be taken if the test controls or test values fall outside acceptable limits. _____

- 5) Include a description of the training that will be provided to all employees participating or conducting the listed specific health screening test(s) under question (1). _____

- 6) Indicate how records of test subject results and documentation of quality control items shall be maintained for two years. _____

- 7) Include copy of the test(s) reagent insert(s)/manufacturer's instructions. **(Attach to this document).**
- 8) Include a copy of educational materials for each individual screening test (s) given to each test subject. **(Attach to this document).**
- 9) Include a copy of the document to be given to each test subject that explains the purpose and limitations of each individual CLIA Waived screening test. **(Attach to this document).**
- 10) Include copies of any forms used in the course of conducting this health screening event. **(Attach to this document).**
- 11) Initial and changes in protocol must be sent to the Department at least 30 days prior to event testing date.
- 12) Facilities with preapproved protocols must notify our office of any additional health screening event(s) no later than 7 days.
- 13) Protocols must be signed, dated and approved by a physician licensed to practice medicine in all its branches. **(Attach copy of physician Medical License).**

_____ **Date** _____
Physicians Name (print) *Physicians Signature*

NOTE: Documents missing the required signatures or forms will not be processed.

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