

Clinical Laboratory Program99 Chauncy Street, 2nd Floor, Boston, MA 02111

(617) 753-8439/8438 (617) 753-8240 - Fax

HEALTH PROMOTION SCREENING PROGRAM APPROVAL

Please be advised that section 105 CMR 180.030(D) of the regulations for clinical laboratories requires standards be met before any health screening promotion laboratory testing may be performed. Please submit documentation of the below requirements to the Department for review. Upon determination that all requirements are met, a letter of approval will be issued to the screening program entity.

Testing that may be performed at Health Screening Promotions is limited to:

- § Cholesterol [capillary whole blood]
- § Erythrocyte Protoporphyrin [capillary whole blood]
- § Fecal Occult Blood
- § Hemoglobin [capillary whole blood]
- § Hematocrit [capillary whole blood]
- § HDL Cholesterol [capillary whole blood]
- § Glucose [capillary whole blood]
- § Pregnancy Test, qualitative

In order to demonstrate compliance with these standards, health promotion screening programs must take appropriate measures to assure the accuracy and precision of the testing, as follows:

- (1) The facility must establish a procedure for performing the test. This procedure must include the following information:
 - specimen collection and preparation;
 - materials and equipment required;
 - steps to follow to perform the test;
 - limitations of the procedure;
 - cautions to be observed which may affect the test results;
 - safety precautions to protect patients and testing personnel;
 - normal range of results;
 - results which require follow-up with a physician;
 - quality control procedures to be followed using appropriate reference materials;
 - calibration and maintenance protocol;
 - a plan for remedial or corrective action to be followed in the event that quality control results do not fall within acceptable limits.
- (2) All analytical equipment used for the performance of test (i.e., timers, detectors or meters) must be calibrated or checked as appropriate for the device.
- (3) All test reagents must be properly stored and may not be used beyond their expiration dates.
- (4) Each method must be tested with appropriate reference materials to assure accuracy and precision:

- Each qualitative method must be tested with a positive and negative control on each day of testing.
 - Each quantitative method must be tested with a normal and abnormal or high or low control on each day of testing. In the event that only one control level is available, the control material must be tested after every 20 patient tests during the course of the day.
 - The accuracy of the screening procedure must be verified by sending at least one previously tested specimen to a licensed laboratory on a semi-annual basis.
 - All quality control tests must be performed at the location of (and prior to) each public screening.
 - Remedial or corrective action must be taken in the event that quality control results do not fall within acceptable limits.
- (5) Quality control and calibration measures shall be recorded and documentation shall be maintained for one year.
- (6) All patients must be provided with a confidential written test report that includes pertinent educational materials including, but not limited to, the following information:
- the limitations of the test;
 - the interpretation of the test result(s);
 - associated risk factors;
 - the need for physician follow up; and
 - a telephone number for additional information (if additional information is available)
- (7) All infectious or physically dangerous medical waste including blood saturated materials and sharps must be stored and disposed of in accordance with the requirements set forth in 105 CMR 480.000 of the State Sanitary code, Chapter VIII.
- (8) The entity must maintain records documenting the initial training of any individual who will perform testing. Send documentation of training for each individual who will perform the screening procedures. Ongoing continuing education and retraining shall be provided to such individuals if applicable or as needed. The training program must be taught by health professionals with experience in clinical detection, measurement, and analysis appropriate for the screening services offered. Training programs should reference appropriate national standards as available. The program must include at a minimum:
- a thorough training on proper specimen collection;
 - a thorough training in the content and application of the pertinent test protocols;
 - a means for testing employee technique and proficiency in performing the test including retesting known samples;
 - a thorough training on test limitations and potential errors, interpretation of results, associated risk factors, and appropriate need for physician referral.
- (9) All persons involved with the collection, handling and/or testing of specimens must conform with the:

“Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers”

as issued by the Centers for Disease Control of the Department of Health and Human Services publication dated February, 1989 or as most recently updated. These guidelines require new gloves for the collection and processing of each specimen. Copies can be obtained at the U.S. Department of Labor, Regional Office, Occupational Safety & Health Administration, 133 Portland Street, Boston, MA 02114, (617) 565-7164.

- (10) All puncture wounds resulting from specimen collection must be covered with a sterile gauze adhesive strip (bandaid) following sample collection.
- (11) Please complete the enclosed application for approval which includes a list of health promotion screening sites, dates and period of time (if known). The Department must be notified prior to each health promotion screening event which is to take place in a location other than the location indicated when initial approval is sought. Such notification must be made at least 5 days prior to each event and must include the expected date, location and period of time.
- (12) At every public screening event the Department of Public Health approval letter must be conspicuously displayed.

Send completed application and all required documentation to:

Clinical Laboratory Program
99 Chauncy Street, 2nd Floor
Boston, MA 02111

Clinical Laboratory Program

305 South Street, Jamaica Plain, MA 02130
(617) 983-6739 (617) 983-6740 - Fax

HEALTH SCREENING PROMOTIONS

REQUIRED DOCUMENTS

- Application for Health Screening Promotion - complete, sign, date and return
download from web site

- CLIA [Clinical Laboratory Improvement Amendment] Certificate
copy of current certificate
OR
completed and sign CLIA application
download CMS 116 form from website: <http://www.cms.hhs.gov/forms/>

- Procedures / Forms
 - § Test procedure
 - § Quality control procedure
 - § Patient and testing personnel safety protocols

- Forms
 - § Calibration and Quality Control recording forms [include results if completed at time of application]
 - § Test report form
 - § Educational material that will be provided to the public as part of the health promotion program

- Training Records
 - § Material covered in training
 - § Competency required

Failure to provide this information in a timely manner will result in a delay in the processing of information required for the issuance of a Massachusetts Health Screening Promotion Approval.