

A **Health Fair** or a temporary collecting station is a “one-time, one-site facility, operated by a clinical laboratory under permit, with the prior approval of the department, which collects, draws and/or temporarily stores materials derived from the human body, as part of a health fair, health assessment or health risk reduction program, for the purpose of screening for health risks under a general order (Part 58-1.7 Title 10 NYCRR). Health fairs in New York State may only be operated in conjunction with laboratories that have been approved to hold a New York State Health Fair. There is no fee charged to a clinical laboratory for this approval.

To qualify for approval to operate a Health Fair, a laboratory must hold a New York State Clinical Laboratory permit, and must submit a **Health Fair (Community Screening) Application (CLEP-HF)** form at least two weeks prior to the Health Fair. As indicated on the application, a laboratory procedure manual should be developed for such fairs and must be available for review by the department upon request. This manual must include the name of the authorizing physician who will request the tests for fair participants; who will give permission for results to be given directly to fair participants (if applicable); and who will be responsible for the referral of any abnormal results. Accession and report records for all fair participants are considered patient records and must be retained as required by part 58-1.11 NYCRR.

Tests performed should be those appropriate for a health screen setting, meeting criteria as set forth in Part 58-1.7 NYCRR. The laboratory must either hold a permit in the appropriate category for tests performed on site and/or for tests performed on specimens collected and transported back to the laboratory for analysis or refer the specimens to a laboratory that holds the appropriate New York State permit. Please indicate on the application if and to who these specimens will be referred.

Procedures and documentation of validation and other quality control, as well as justification for offering the test as part of a community screening, may be requested by the department for review before a decision is made concerning the Health Fair Application. If you have any questions, you may contact the Clinical Laboratory Evaluation Program at (518) 485-5378.