SCHOOL WELLNESS PROGRAM POLICY & PROCEDURE ESSENTIAL ELEMENTS: LABORATORY

THIS DOCUMENT IS TO BE USED AS A GUIDANCE TOOL IN DEVELOPING LABORATORY POLICIES AND PROCEDURES FOR SCHOOL WELLNESS PROGRAMS.

Definition: Procedures for "point-of-care" (POC) testing/waived tests and "send out" specimens in the SWP.

Purpose: Ensure the SWP complies with all applicable laws, regulations [such as the Clinical Laboratory Improvement Amendments of 1988 (CLIA)], and standards of care when providing POC testing/waived tests and other laboratory procedures for clients receiving care in the SWP.

The following POC/waived tests are provided in the SWP and the following specimens may be collected for "send out" testing (list "send out" tests).

Procedures Include:

Laboratory Administration:

Laboratory "Director" is identified and responsible for oversight of the SWP laboratory.

Laboratory manual on site that includes at a minimum:

- Manuals for the specific equipment utilized in the laboratory.
- Instructions from the laboratory where any specimens are sent (e.g. MDHHS).
- Specific test policies and procedures and how they are conducted in the laboratory.
- Frequency of control testing.

Required current CLIA license or certification of waiver (if applicable) specific to the SWP is posted in a specific location (e.g. laboratory).

CLIA waiver (if applicable) is renewed and amended for addition or deletion of tests or change of name on waiver.

Process for on-site training of personnel responsible for laboratory procedures and annual competency testing.

Process for training/review of OSHA safety standards for possible occupational exposure and follow-up procedures for personnel performing specimen collection and/or testing.

Identification of person/position type responsible and accountable for maintaining daily laboratory logs, equipment logs, maintenance records, quality control documents, testing records and test results. Length of time for storage of laboratory documentation materials is identified.

Identified process for corrective action when test performance measures and actual POC testing don't meet laboratory standards.

CQI processes to assure test results are followed up and closing of laboratory results are appropriately managed.

Laboratory Environment

Environment testing and storage areas are monitored for temperature per testing materials guidelines and documented. Lab temperature and humidity monitoring logs should be kept on site.

Identified separate clean and dirty areas in the laboratory space.

Equipment maintenance is scheduled and documented per prescribed standards.

Restrictions for "non-lab" materials in laboratory space noted (e.g. food/eating, food stored in specimen refrigerator).

Handwashing facility or antiseptic handwashing solutions on site.

Cleaning process (when, who, what materials used).

PPE, eyewash stand (equivalent), sharps container (s), other medical waste disposal (as needed) in place.

Spaces where specimens are collected are clean, well lit, comfortable and provide confidentiality for the client. Include a process for specimen labeling.

Posting of safety information for clients and staff.

Proper disposal of specimens after testing.

POC Testing Quality Control

Quality control testing process per standard (manufacturer, fiduciary, other) that includes when is the testing completed, who is the person completing the testing and what is the documentation process (patient test logs, control logs for POC, forms, etc.). Corrective action procedures are included.

Process for tracking individual POC tests and specimens "sent out" for testing (electronic, paper logs, other, who is responsible and when tracking occurs, and how closed out).

Process for specimen pick up/transport to outside laboratory.

Specimen Collection/POC Testing

Description of specimen collection/testing initiation (routine/type of client visit, standing order, test order by provider, other).

Process for specimen collection (who, how client is identified, how counseling on/explanation of testing is given, specimen obtained per test instructions).

POC testing process per manufacturer instructions and documentation for tracking requirements.

POC test result "reporting" process (documentation).

Process for sending out specimens to outside laboratories (includes initial tracking documentation and clear procedures for follow-up and closure of laboratory results is specified).

References:

Centers for Disease Control and Prevention Office of Surveillance, Epidemiology and Laboratory Services (2011). Ready? Set? Test? Retrieved from: https://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf

MIOSHA Standard 1209. Retrieved from: http://www.michigan.gov/documents/CIS_WSH_part554_35632_7.pdf

MMR Morbidity and Mortality Weekly Report (2005). Good laboratory practices for waived testing sites. Retrieved from: https://www.cdc.gov/MMWR/PDF/rr/rr5413.pdf

Michigan Department of Health and Human Services (2018). Regional Laboratory Manual. Retrieved from: https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5103_7168-15018--,00.html

Examples of "point-of-care" tests that may be provided in the SWP:

• Influenza • RSV • Cholesterol • Rapid strep testing • STI/HIV testing • Lead • Hg A1C	• Urine dipstick • Urine pregnancy test • Hemoglobin • Blood glucose finger stick • Strep A • Mono