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Clinical Laboratory Onsite Testing Procedure

Effective Date	04/27/2023	DocuSigned by: Dr. Georgina Yoshioka 7DF8077EFA674B2...
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Purpose

To provide direction to designated DBH staff for performing clinical laboratory testing operations including oversight, testing environment, waste disposal, employee training, and quality assurance.

Procedure

Under the direction of a DBH Laboratory Director or designee, trained DBH staff shall perform waived point of care testing at certified, registered, DBH clinics.

Types of POCT Tests

POCT produces rapid, reliable results that aid in identification and monitoring of acute infections or chronic disease. POCT involves screenings and tests ***at or near the point of care*****,** which produce actionable results within minutes.

POCT includes:

- Complete blood count (CBC) with differential;
- Drug and alcohol screening;
- Pregnancy testing;
- Urine testing;
- Hemoglobin diagnostic;
- Cholesterol screening;
- Infectious disease, and
- Fecal occult blood analysis.

For additional information regarding CLIA approved tests and devices visit the FDA website at: https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-waiver-application

Use of Waived Devices and/or Tests

Under the authority and supervision of a DBH Laboratory Director or designee, waived devices and/or tests may be used in DBH clinical laboratories, providing the following conditions are met:

- Training shall be provided to staff **prior** of the use of the device or test.
- Staff shall follow **all of** the manufacturer's instructions for the use of each device or waived test.
- Competency testing shall be included to ensure accuracy.
  - Personnel competency testing shall follow CDPH/CMS guidelines.
- Testing quality issues shall be tracked and managed.
- Staff shall ensure device and/or testing procedures are followed throughout the process.
- Instructions for tests performed at each clinic shall be clearly posted in the laboratory testing area.

Continued on next page

Clinical Laboratory Onsite Testing Procedure, Continued

DBH Staff Training

DBH will provide, at a minimum, the follow training to all DBH staff who perform waived tests:

- Use of personal protective equipment;
- Safe and appropriate handling of non-hazardous and potentially infectious waste;
- Use of and limitations of the test manufacturer's procedures for testing;
- Safe handling and disposal of sharps, when required, and
- Safe storage of reagents when required.

Quality Assurance

DBH clinical laboratories shall maintain an appropriate testing environment that provides the following:

- Compliance with United States Occupational Safety and Health Administration (OSHA) safety standards;
- Appropriate personal protective equipment will be available;
- A clean work area for staff conducting testing;
- Sinks for hand washing or antiseptic hand washing solutions;
- Adequate space for the privacy of clients during routine and directly observed urine testing for urine drug screen sample collection;
- Waste disposal receptacles, including receptacles for sharps or biohazardous waste as required, and
- Reporting of testing irregularities.

Waste Disposal

DBH staff conducting clinical laboratory testing shall adhere to the following:

- All body fluids will be treated as though they may be infectious
- Waste contaminated with blood or other body fluids shall be disposed of in red biohazardous waste receptacles, not with regular trash.

Related Policy or Procedure

DBH Standard Practice Manual:

- Laboratory Services/Physical Assessment Policy (MDS2019)
- Laboratory Services/Physical Assessment Procedure (MDS2019-1)
- Clinical Practice Guidelines for the Management of Substance Use Disorders 2020
- Clinical Laboratory Registration Policy (MDS2033)
- Clinical Laboratory Registration Procedure (MDS2033-1)

Reference(s)

- Standards and Certification: Laboratory Requirements (Code of Federal Regulations Title 42, Section 493)
- Clinical Laboratory Improvement Amendments (U.S. Code Title 42, Section 263a)