Health Care Agency **Mental Health and** **Recovery Services** **Policies and Procedures**	Section Name: Sub Section: Section Number: Policy Status:	Care and Treatment Miscellaneous 01.07.05 ☒New ☐Revised

	SIGNATURE	DATE APPROVED
Director of Operations Mental Health and Recovery Services	Signature on File	2/9/2022

SUBJECT:	Procedures for Conducting CLIA Waived Tests in SUD Programs

PURPOSE:

To establish a standard procedure and outline the regulations and requirements for performing point-of-care laboratory tests under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver for Substance Use Disorder (SUD) Programs.

POLICY:

All laboratory tests performed onsite in an SUD clinic for the purpose of assessing the health status of a client and/or providing information for treatment decision making must be completed under the regulations of a CLIA Certificate of Waiver. These regulations dictate how such tests will be performed and staff training requirements.

SCOPE:

These procedures apply to all staff conducting laboratory tests under a CLIA Waiver in county operated Mental Health and Recovery Services (MHRS) - Substance Use Disorder Programs.

REFERENCES:

42 Code of Federal Regulations, CFR, Chapter IV, part 493 Laboratory Requirements

DEFINITIONS:

Laboratory Test - a test performed for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of a client or to assess the health status of an individual.

CLIA Waived Test - as defined by CLIA, waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.” The Food and Drug Administration (FDA) determines which tests meet these criteria when it reviews manufacturer’s applications for test system waiver.

FORMS:

CLIA Waived Test Staff Training Log (AQIS SUD 22.01.18)

CLIA Waived Lab Test Storage Room Temperature Log (AQIS SUD 22.01.31)

PROCEDURE:

I. In order to perform laboratory tests under a CLIA Waiver, Health Care Agency (HCA) must apply for and maintain an active Certificate of Waiver with the California Department of Public Health, Lab Field Services Branch. A Certificate of Waiver is required of each clinic or program location that will be performing a CLIA Waived Test.

   A. The clinic/program Service Chief I/II or Program Manager shall serve as the 'Lab Owner', and the SUD Medical Director shall serve the role of 'Lab Director' as required for the CLIA Certificate of Waiver registration.

   B. HCA must notify the California Department of Public Health, Lab Field Services Branch within 30 days whenever there is a change in Lab Owner, Lab Director, address or contact information of the clinic/program.

II. HCA staff may only perform tests that are designated as 'CLIA Waived' for the purpose of assessing the health status of a client and/or providing information for treatment decision making.

III. HCA staff should only perform a CLIA Waived Test at the direction of a MHRS Psychiatrist/Physician or Nurse Practitioner.

IV. When performing a CLIA Waived Test, staff must follow the current manufacturer directions for use of that particular test product—directions include intended use and limitations of the test product. Copies of directions for use will be reviewed with staff during training and copies must be made available for reference at all clinic testing locations. Tests can never be performed for any purpose outside of that outlined by the manufacturer. Instructions for a particular test may be changed by the manufacturer over time, so staff should always refer to the instructions that were packaged with each batch of test products.

V. When performing a CLIA Waived Test, staff must follow Personal Protective Equipment (PPE) recommendations as provided through HCA's required safety and Blood Borne Pathogens staff trainings. This applies to PPE and proper handling of any specimen obtained or Other Potential Infectious Materials generated in performing the test.

VI. Results of a CLIA Waived Test must be documented into the client chart of the Electronic Health Record (EHR) by the staff performing the test as soon as possible.

VII. Minimum requirements of clinical staff who are trained to perform a CLIA Waived Test include possessing a High School Diploma or equivalent document.

VIII. All staff performing a CLIA Waived Test must be trained by an HCA medical staff member (MHRS Nurse or MHRS Psychiatrist/Physician or Nurse Practitioner) prior to using that particular test. HCA shall maintain the CLIA Waived Test Training Log that include a record of the date of staff training, products reviewed and names of staff receiving and providing the training. All staff should receive review training on CLIA Waived Tests on an annual basis.

IX. Test product instructions will specify how and under what conditions (such as temperature) that each test should be stored. Temperature of the room in which tests are stored will be checked and logged on the CLIA Waived Lab Test Storage Room Temperature Log every business day. Tests should only be accessible to appropriate HCA staff during the business day and should be stored in a locked cabinet outside of business hours. Additionally, tests should never be directly accessible to clients. Keys to the locked cabinet should be available to trained HCA staff, however, lab tests should never be stored in the same cabinets as medications or medical supplies used by HCA medical staff.

X. Copies of the following documents must be maintained in a binder onsite at each clinic/program location:

A. This Policy

B. The clinic/program Certificate of Waiver.

C. The manufacturer directions and specifications for each CLIA Waived Test in use at HCA MHRS-SUD.

D. A copy of the CLIA Waived Test Training Log for staff at that particular clinic/program.

E. CLIA Waived Lab Test Storage Room Temperature Log.

XI. The following are best practices that staff should follow when performing all CLIA-Waived tests:

A. Ensure that testing area is clean before and after performing any tests.

B. Perform tests only where there is adequate lighting.

C. Check expiration date of test product to be sure it is not expired. Discard if expired and check inventory of tests to ensure that other tests are current.

D. Confirm that copy of manufacturer product instructions is available for reference in testing area. Consult instructions if necessary.

E. Whenever unpacking a new supply of tests, replace product instructions on file in testing area with the updated instructions contained in the shipping box.

F. Always follow the manufacturer instructions without any deviation as to testing indications, sample collection, timing of interpreting results and any other directions for performing the test.

G. Maintain appropriate disinfectant and medical cleaning supplies in immediate area of where tests are performed.

H. Biohazard containers and appropriate disposal supplies must be available whenever performing a test.

I. Ensure that you are aware of manufacturer directions for when to reject a collection sample and test result.

J. Whenever there is a question as to how to perform a test, consult with MHRS Nurse, Physician/Psychiatrist or Medical Director.

K. Confirm identity of client before performing test.

L. Wash hands before and after performing the test for each client—including changing of gloves.

M. Always wear appropriate Personal Protective Equipment (PPE) when performing a test.

N. As soon as practical, document results of test in client's electronic health record (EHR) chart. Document any irregularities that occurred in collection of sample or performing the test.

O. When confirmation of results is needed, follow appropriate process for confirmatory testing by sending sample to contracted laboratory provider.