

JUVENILE COURT HEALTH SERVICES LABORATORY PROCEDURES

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| Subject: LICENSES AND CERTIFICATES | Original Issue Date: 1/31/01 | Policy # A-001 |
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| Departments Consulted: Administration Laboratory | Approved By: (Signature on File) Laboratory Supervisor (Signature on File) Laboratory Director | Approved by: (Signature on File) Health Services Administrator |

PURPOSE

To explain the process for how Juvenile Court Health Services laboratory has the appropriate permits, licenses and accreditation to perform laboratory testing and services.

DEFINITIONS

CLIA: An acronym for Clinical Laboratory Improvement Amendment of 1988, the federal regulations that set forth the conditions that all laboratories must meet to be certified to perform testing on human specimens.

Laboratory Owner: The JCHS administrator acts as the laboratory owner and he or his designee is responsible for reviewing, training, implementing and monitoring employee compliance with the licenses and accreditation policy.

Laboratory Director: Responsible for ensuring that the laboratory is appropriately licensed and accredited. The laboratory director is also responsible for the approval and implementation of laboratory procedure and related compliance policy and for ensuring that all permits, licenses, accreditations and their renewals are submitted and obtained from the appropriate agencies in a timely manner.

Laboratory Supervisor: Laboratory supervisor or other designated party is responsible for ensuring that all referral or Test Send Out (TSO) Laboratories are authorized to perform testing required by JCHS. It is also the laboratory supervisor's or designee's responsibility to ensure that the Testing Personnel and Laboratory Staff pass an annual competency test before they can run POC tests. The laboratory supervisor or designee also acts as POCT coordinator responsible for monitoring all POCT sites compliance to the policy and procedure as per CLIA regulation.

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PROCEDURE

1. Changes to JCHS Licensing

A. Identify the permits, certificates and licenses affected by the change.
Changes in licensure may include, but are not limited to:

- a. Change in the laboratory director
- b. Address change for the testing facility
- c. Closure of the testing facility
- d. Ownership change
- e. Change in testing categories

B. Send notification to the appropriate agency for the affected permit, certificate and/or license. Apply and submit applications and fees if required.

C. Post revised permits, certificates and licenses as appropriate and file a copy in JCHS laboratory.

2. License Renewal

A. Complete the renewal application prior to the expiration date.

Note: If the laboratory has not received a renewal application 30 days prior to the expiration of the current license, the laboratory director and/or designee must contact the licensing agency to request such application.

B. Arrange for payment of any renewal fee required.

C. Upon receipt of the renewal license the original must be maintained and posted at the facility.

D. Provide copies of the renewed permits, certificates and licenses to the administration office.

3. Referral (TSO) Laboratory Licensing

Prior to referring testing to a TSO laboratory, obtain current licenses and accreditations for the TSO Laboratory.

A. If the TSO is appropriately licensed and accredited, then obtain copies of the valid permits, accreditations and licenses to establish that the TSO laboratory can legally perform the testing.

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B. Testing may only be referred to a laboratory that has Federal and State licensure in compliance with state regulations where the patient is located. Any national referral laboratory must be appropriately licensed in any state requiring such licensure.

4. Document Retention

All permits, licenses and accreditations must be retained and filed for 3 years, in accordance with the JCHS policy.

REFERENCES

Clinical Laboratory Improvement Amendment of 1988 at:

[Clinical Laboratory Improvement Amendments \(CLIA\) | CMS](#) or [Clinical Laboratory Improvement Amendments \(CLIA\) | CDC](#)

REVIEW DATES

July 1, 2011; November 2, 2012; February 17, 2019; June 2, 2021