3.1.14 Laboratory Services

(a) Procedure Overview

This procedure describes the structures, processes, and resources that California Correctional Health Care Services (CCHCS) staff shall utilize to ensure patients are provided timely access to laboratory services that are medically necessary.

(b) Responsibility

(1) Statewide

(A) CCHCS and California Department of Corrections and Rehabilitation (CDCR) departmental leadership at all levels of the organization, within the scope of their authority, shall ensure administrative, custodial, and clinical systems are in place and appropriate tools, training, technical assistance, and levels of resources are available to ensure patients have timely access to laboratory services that are medically necessary.

(B) A statewide contract shall be maintained with an outside agency (contract laboratory), or multiple agencies, to provide routine laboratory analysis or testing, including a limited 24-hour STAT laboratory testing menu.

(C) The Statewide Chief of Laboratory Services is responsible for the implementation and maintenance of a safe and effective Laboratory Services program. Specifically, they are responsible for:

1. Developing standard operating procedures for institution adoption into Local Operating Procedures (LOPs).
2. Monitoring and assisting institutions with their maintenance of Clinical Laboratory Improvement Amendments (CLIA) certificate of waivers and Clinical and Public Health Laboratory Licenses, and compliance activities and regulatory agency inspections related to Laboratory Services.
3. Initiating and overseeing statewide Laboratory Services contracts, procurements, policies and procedures, workflows, and forms. This includes coordinating Laboratory Services-related Electronic Health Record System (EHRS) issues with Department technical staff to prioritize corrective measures and maintenance activities.
4. Overseeing and providing quality assurance of the Laboratory Services onsite delivery of services in conjunction with the CCHCS contracted outside agency, or agencies.
5. Providing consultation and advice to health care providers and institution staff regarding their local institution Laboratory Services departments and the Department's Laboratory Services test order menu.
6. Monitoring the performance of the contracted outside agency, or agencies, in collaboration with the medical leadership Laboratory Services staff at the institutions and headquarters.
7. Overseeing and coordinating the competency assessment and related remediation efforts of local, regional and headquarters Laboratory Services staff.

(2) Regional

Regional Health Care Executives are responsible for implementation of this procedure at the subset of institutions within an assigned region.

(3) Institutional

(A) The Chief Executive Officer (CEO) has overall responsibility for administration and ongoing oversight of the laboratory services at the institution. The CEO and all members of the institution leadership team are responsible for establishing an organizational culture that promotes interdisciplinary teamwork and continuous process improvement. The CEO delegates decision-making authority to the Chief Medical Executive (CME), Chief Support Executive (CSE), and Chief Nurse Executive (CNE) for overall management of patients and daily operations to ensure resources are deployed.

(B) The CME is responsible for the overall medical management of patients.

(C) The CNE is responsible for ensuring that the institution has a designated lead scheduling supervisor to monitor scheduling processes on a daily basis and identify and address or elevate barriers to access.

(D) The CSE, and/or designee, is responsible for ensuring the institution has designated specimen collection and processing locations (laboratories) and a clinic administrator responsible for properly functioning lab processing equipment, properly maintained and an adequate amount of lab-related supplies, an adequate number of trained staff, and established lab processing work flows and lab LOPs are adhered to. The CSE, or designee, requires the use of information technology systems to monitor the status of all ordered laboratory studies to ensure the studies are properly processed and documented in the health record.

1. A standardized LOP template shall be developed by the statewide Chief of Laboratory Services.

2. At a minimum, an institution shall adopt a standardized LOP template customized for their site containing the following elements:
   a. General Lab Policy and Staff Roles and Responsibilities.
   b. Laboratory Orders.
   c. Specimen Collection and Processing.
   d. Paternity Testing.
3. Local LOP adoption requires the signature of an institution's Laboratory Director as designated on the CLIA Certificate of Waiver, and the Statewide Chief of Laboratory Services.
4. The LOPs shall be reviewed, updated if required, and resigned at a minimum of every two calendar years.
5. Laboratory Services and non-Laboratory Services staff shall adhere to LOP requirements.
6. Safety Data Sheets (SDS) related to Laboratory Services materials, and equipment inspection logs related to Laboratory Services equipment should be located near Laboratory Services LOP(s) to be readily available for regulatory and compliance inspections.

(E) Health care providers are responsible for ordering medically necessary laboratory studies consistent with community standards and department policy and care guidelines.

(c) Procedure

(1) Routine Laboratory Orders Processing

(A) Routine Laboratory Orders include the following collection priority designations within the EHRS: AM Draw, ASAP, Routine, and Timed Study.

(B) Health care providers shall place orders for all laboratory services in the health record.

(C) Scheduling and ducating procedures shall be followed for the specimen collection of the ordered lab test(s). The ducating and scheduling process may be adjusted to facilitate timely specimen collections on or before the requested collection date.

(D) The laboratory specimen shall be obtained from the patient on or before the requested collection date. The specimen shall not be collected prior to the requested collection date if prohibited by policy or the ordering provider.

1. Staff shall not cancel or discontinue a laboratory study in order to meet compliance deadlines associated with requested collection date timeframes.
2. If there are questions regarding an order, staff shall call or message the ordering health care provider for clarification.
3. Laboratory orders shall be collected by staff during regular business hours.
4. Staff may collect a routine lab test the next business day should the requested collection date fall on a weekend or holiday.

(E) Staff shall record the specimen collection date and time and person collecting the specimen in the EHRS and update the status of the specimen to "collected".

1. Laboratory specimens shall not be labeled prior to collecting the specimen.

(F) For specimens not collected by Laboratory Services staff, e.g., an inpatient collection, the designated staff shall arrange for pick-up or delivery, and final processing at the institution laboratory during regular business hours.

1. The specimen shall remain under surveillance or in a secure storage area with appropriate environmental conditions to maintain the specimen in an adequate state until retrieved by staff or dropped off at the laboratory.
2. Un-retrieved specimens, or specimens collected outside of normal Laboratory Services staff working hours, shall have a designated secure storage area with appropriate environmental conditions to maintain the specimen in an adequate state.

(G) Storage of laboratory specimens awaiting collection by couriers shall be secured in a locked container. Institution health care leadership or a designated health care team member shall coordinate with custody staff to determine the type(s) of locked boxes to be used and their appropriate placement for couriers to readily access and retrieve specimens.

(H) The specimen shall be picked up by the contracted outside agency at a contractually agreed upon time, Monday through Friday (excluding state holidays).

(I) Analysis or testing of the specimen shall be performed within the contracted laboratory's work schedule.

(J) All non-critical results shall be reported to the institution within 24 hours in accordance with the Laboratory Services contract or test schedule.

(2) STAT Laboratory Orders Processing

(A) Health care providers shall place orders for all laboratory services in the EHRS.
1. Unless the ordering provider selects the collection date, the requested collection date will default within the EHRS to an immediate collection on the same calendar day.

(B) Refer to the HCDOM, Section 3.1.5 (c)(3)(C)(4) if a laboratory appointment originated from the order of a psychiatrist.

(C) If there are questions regarding an order, staff shall call or message the ordering health care provider for clarification.

(D) For STAT orders, the patient shall be immediately sent to the appropriate location for collection of the ordered STAT lab test(s).

(E) STAT laboratory orders shall be collected by staff and processed immediately.

(F) Upon notification of a STAT order for laboratory services, the specimen shall be picked up by the contracted laboratory within two hours for non-rural institutions and three hours for rural institutions, 24 hours per day, seven days per week.

(G) Processing of the patient's specimen shall begin immediately upon arrival at the contracted laboratory.

(H) STAT results shall be provided by the contracted laboratory via telephone to the Triage and Treatment Area (TTA), or designated health care team member, within four hours of the telephone request for pick-up for non-rural institutions and five hours for rural institutions.

(I) If the STAT results are received after hours or the ordering provider is unavailable, the TTA staff shall notify the on-call provider within 30 minutes and document the notification in the health record.

(3) Specimens Requiring Special Handling

(A) Staff collecting specimens that require special handling shall follow the specimen requirements provided by the outside agency contracted to provide laboratory analysis and testing.

(B) Clinical Urine Drug Screening for Substance Use Disorder treatment requires special handling and processing (refer to Appendix 1).

(4) Review and Notification of Laboratory Test Results

(A) Laboratory test results shall be electronically interfaced from the contracted laboratory's system to the health record.

(B) Test results that cannot be electronically interfaced shall be faxed and/or printed and provided to the designated location within the institution and scanned into the health record by Health Information Management.

(C) A notification will appear in the ordering health care provider's Message Center informing them of the return of the results.
1. Results or reports that are routed incorrectly to a provider's Message Center may be refused by the reviewing provider within the health record and shall be forwarded to the appropriate health care provider.
2. If the result of a laboratory test is "Test Not Performed," the designated staff may submit a replicate order on behalf of the health care provider unless otherwise directed by the health care provider.
3. If there are questions regarding an order, the ordering health care provider shall be contacted for clarification.

(D) The health care provider shall electronically review and endorse each laboratory result within five calendar days of the date of receipt.

(E) The health care provider shall create a patient notification letter in the health record at the time of review and endorsement of each laboratory result. The patient letters shall include the following:
1. Date of the test/screening to identify the laboratory test/diagnostic screening.
2. Reviewing health care provider's name.
3. Whether the results are within normal limits.
4. Whether a follow-up appointment with the provider is required and will be scheduled.

(F) Patient notification letters shall be printed for collection by the designated staff member to be distributed to the patients.

(G) Patients with clinically significant abnormal test results shall be scheduled for a follow-up appointment with the health care provider, as clinically indicated, after the laboratory results are reviewed.

(H) Any dangerous or life threatening results shall be immediately reported by the contracted laboratory via telephone to the TTA or designated health care team member and requires a read back to be communicated for clarification.

(I) If dangerous or life-threatening results are received after hours or the ordering provider is unavailable, the TTA staff shall notify the on-call provider within 30 minutes and document the notification in the health record.

(5) Patient "No Show" or Failure to Report for Laboratory Services

(A) If the patient does not arrive for a laboratory appointment, the designated staff member scheduled to collect the specimen shall notify custody staff to have the patient escorted to the designated laboratory services area for the laboratory appointment.

(B) If the patient arrives in the laboratory services area and permits specimen collection, the collection shall be performed.

(C) If the patient remains a "no-show" for the laboratory appointment or arrives and refuses specimen collection, the procedure for failure to report for a medical appointment outlined in the Health Care Department Operations Manual, Section 3.1.5, Scheduling and Access to Care, shall be followed.

(D) The ordering provider shall be notified of cancelled orders and of patient refusals.

Appendices

- Appendix 1, Clinical Urine Drug Screen for Substance Use Disorder Treatment

References

- Health Care Department Operations Manual, Chapter 3, Article 1, Section 3.1.5, Scheduling and Access to Care

Revision History

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Appendix 1

Clinical Urine Drug Screening

Urine Drug Screening (UDS) is a urine toxicology study used for therapeutic monitoring purposes, but may be ordered when a patient presents with an altered level of consciousness.

Clinical UDS results, a patient's decision to decline a Clinical UDS, and/or a patient's inability to provide a sample due to paruresis or other reason shall only be available to clinical staff on a need to know basis in order to manage a patient's health care needs, and these results shall not be shared with custody.

CLINICAL UDS ORDERING

1. Health care providers shall place orders for initial clinical UDS studies with an "ASAP" collection priority in the health record.
   a. Unless the ordering provider selects the collection date, the requested collection date for the initial clinical UDS study will default within the Electronic Health Record System to one calendar day from the date of the order.
   b. Staff may collect the initial UDS study on the next business day should the requested collection date fall on a weekend or holiday.
2. Health care providers shall place orders for follow-up UDS studies with a clinically appropriate laboratory order in the health record.
   a. Follow-up UDS studies may be ordered with requested collection dates within one week of one another and should not be considered duplicate orders.
   b. Health care providers should alert Laboratory Services staff of follow-up UDS orders with requested collection dates within one week of one another by placing an order comment in the health record.
   c. The specimen collection for the follow-up clinical UDS study shall occur within the timeframe defined by the laboratory order's requested collection date. Staff may not collect the UDS specimen more than one calendar day prior to the requested collection date.
3. Ordering providers and staff shall follow the procedure for Routine Laboratory Orders Processing as described in Section (c)(1) of the Health Care Department Operations Manual, Section 3.1.14, Laboratory Services, and the Clinical UDS Collection & Handling section below.

CLINICAL UDS COLLECTION & HANDLING

Clinical UDS requires special collection and handling to ensure the specimen is free from tampering.

1. Attempts shall be made to provide patient privacy during UDS specimen collection. This could consist of an enclosed stall in a multi-stall restroom; a single person restroom; a partitioned area allowing for individual privacy; a commode within a single-occupancy inpatient setting; or other acceptable location.
2. Staff shall describe the steps the patient shall adhere to during the collection of the UDS specimen including the following:
   a. The patient shall remove any unnecessary garments, such as a jacket with pockets, or personal property and leave the items outside the collection site.
   b. Following the completion of collection, the patient shall hand the closed container to the staff when instructed to do so.
   c. The patient shall not flush the commode unless instructed to do so by the staff.
   d. The patient shall not wash their hands until informed to do so.
3. Staff are not required to directly observe the patient pass a urine stream during a UDS collection, but are active proctors overseeing the process. Staff shall perform the following actions:
   a. Inspect the collection site before the patient enters the area in order to identify and remove potential specimen adulterants prior to patient entry.
   b. Apply toilet bowl bluing agent to any toilet commode containing water.
   c. Listen for unauthorized commode flushing or handwashing by the patient during the collection process.

d. Ensure the patient provided the clinically adequate specimen volume as defined by the UDS requirements. Immediately discard the specimen if the volume is inadequate and reschedule the collection.
e. Grant access to a handwashing means after the urine specimen collection is complete.
f. Inspect the commode bowl and collection site for unusual paraphernalia that could have been used to alter or substitute a specimen.
g. Flush the commode bowl, or instruct the patient to do so following the completion of the specimen collection and inspection of the commode.
h. Return to the laboratory upon retrieval of the specimen.

4. Staff shall inspect the specimen container for adulteration or substitution by observing the physical characteristics of the specimen such as:
   a. Unusual color (e.g., specimen is blue or green from contact with toilet bowl bluing agent)
   b. Unusual temperature
   c. Presence of foreign objects or material
   d. Unusual odor (e.g., bleach)
   e. Signs of adulteration (e.g., excessive foaming if shaken)
5. Staff shall document the following special handling circumstances in the health record indicating concerns for specimen tampering:
   a. Unauthorized flushing or handwashing occurred by the patient during the collection process.
   b. Unusual paraphernalia that could have been used to alter or substitute a specimen was observed in the collection site or commode, or with the patient.
   c. Observation of the specimen's physical characteristics suggests possible adulteration or substitution.
   d. Staff suspect the integrity of the collected specimen was compromised by any other means.
   e. The patient refuses specimen collection.

   Unless directed by the ordering provider or institution leadership, the corresponding laboratory order exhibiting these circumstances shall be cancelled or discontinued by staff, and the ordering provider shall be notified of the circumstances leading to the cancellation or discontinuation.
6. Staff shall document the following special handling circumstances in the health record indicating inability to collect adequate specimen:
   a) The patient is unable to pass a urine stream, or a clinically adequate specimen volume was not collected by the patient, or both.
   b) The patient fails to report ("no show") for their scheduled UDS collection appointment, and the failure to report was not associated with a specimen collection refusal.

   For laboratory orders exhibiting either of these two circumstances, staff shall attempt to reschedule the patient one-time within one subsequent calendar day for a second specimen collection attempt. Unless directed by the ordering provider or institution leadership, the corresponding laboratory order shall be cancelled or discontinued by staff if there was a failure to obtain a clinically adequate specimen with no suspicion of adulteration within this one calendar day period. The ordering provider shall be notified of the circumstances leading to the cancellation or discontinuation of the order.
7. Specimens with an adequate volume and no reasonable suspicion of adulteration shall have a completed label and security seal placed on the specimen bottle(s).