U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS

LABORATORY SERVICES

IHSC Directive: 10-01
ERO Directive Number: 11819.3
Federal Enterprise Architecture Number: 306-112-002b
Effective: March 11, 2016
Technical Update: December 13, 2021

By Order of the Assistant Director
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Date: 2021.12.13 11:12:00 -05'00'

1. **PURPOSE:** The purpose of this directive is to set forth the policies and procedures for appropriate laboratory services provided by U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) clinics in support of the health care screening, diagnosis, treatment, and management of detained aliens.

2. **APPLICABILITY:** This directive applies to all IHSC personnel, including but not limited to, Public Health Service (PHS) officers, civil service employees and contract personnel. It is applicable to IHSC personnel supporting health care operations in ICE-owned and contracted detention facilities, and to IHSC Headquarters (HQ) staff. Federal contractors are responsible for the management and discipline of its employees supporting IHSC.

3. **AUTHORITIES AND REFERENCES**:

   3-1. Title 8, Code of Federal Regulations, Section 235.3 (8 CFR § 235.3), Inadmissible Aliens and Expedited Removal.

   3-2. Section 232 of the Immigration and Nationality Act, as amended, Title 8, U.S. Code, Section 1222 (8 U.S. Code § 1222), Detention of Aliens for Physical and Mental Examination.

   3-3. Title 8, Code of Federal Regulations, Part 232 (8 CFR 232), Detention of Aliens for Physical and Mental Examination.

   3-4. Section 322 of the Public Health Service Act, as amended, Title 42 U.S. Code, Section 249(a) (42 U.S. Code § 249(a)), Medical Care and Treatment of Quarantined and Detained Persons.

3-5. Title 42, U.S. Code, Section 252 (42 U.S. Code § 252), Medical Examination of Aliens.

4. POLICY: IHSC provides timely laboratory services to detainees/residents (hereafter referred to as "detainees") with a documented need for acute or chronic health services.

4-1. Staffing and organization. The licensed vocational nurse (LVN), licensed practical nurse (LPN), registered nurse (RN), medical assistant or medical technologist (MT) assigned to the laboratory collects and prepares specimens for outside lab work and performs on-site Clinical Laboratory Improvement Amendments (CLIA) waived lab tests under the supervision of the health services administrator (HSA) and guidance of the Clinical Director (CD). Each laboratory obtains a CLIA waiver certificate for on-site testing. The HSA maintains a procedure manual for each service, including protocols for the calibrations of testing devices to ensure accuracy.

4-2. Guidelines for processing lab services.

4-2.1 **Ordering.** Only physicians, dentists, physician assistants, nurse practitioners, and clinical pharmacists can order laboratory tests. The physician or designee should document all laboratory orders in the detainee's health record and schedule a lab review appointment by a provider, as appropriate.

4-2.1.a Completed lab collections, to include date collected, date received, date reviewed, and test(s) performed can be accessed in the 1101 Historical Lab Orders Enterprise Business Optimizer (EBO) Report.

4-2.1.b Each order is sent via the interface between LabCorp and eClinicalWorks (eCW) with a test code, test name, requisition control number and National Provider Identifier (NPI) number.

4-2.2 **Lab Results Reporting.** Within the lab window in the electronic health record (eHR), all laboratory results are assigned to the ordering provider or designee for evaluation. The provider or delegate/surrogate provider should review normal and abnormal labs, via the Lab Jellybean in eCW, within 24 hours.

4-2.2.a If the laboratory results are received on a weekend or holiday, the provider or delegate/surrogate provider should review the results by the next business day. In addition, the provider who reviews the lab result should

ensure a follow-up appointment is scheduled with the detainee to discuss the lab results.

4-2.2.b If the clinic coordinator or designated nursing staff member receives any lab values that fall significantly outside the normal range and/or may represent life-threatening values (e.g., critical lab values) after-hours, the on-call provider should be contacted for further instructions or orders.

4-2.2.c These instructions or orders should be documented in the detainee's eHR via a Telephone Encounter.

4-2.3 **Consent Issues.** The general consent obtained at the intake process includes consent for all laboratories ordered as indicated.

4-2.4 **On-site lab services.** Minimum on-site laboratory services include glucose finger stick, urinalysis dipstick, peak flow meters, urine pregnancy test (for sites with female detainees), rapid strep test, influenza test and fecal occult blood test.

4-2.5 **CLIA waived tests.** CLIA requires that all laboratories that examine materials from the human body for diagnosis, prevention, or treatment purposes are certified by the Secretary of Health and Human Services. The Centers for Medicare and Medicaid Services (CMS) operates the CLIA laboratory certification program for the Secretary of Health and Human Services in conjunction with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). Pursuant to CLIA law (Title 42, Code of Federal Regulations, Part 493), waived laboratories can only perform tests that the CDC and FDA determine as so simple that there is little risk of error.

4-2.5.a IHSC medical facilities may perform certain waived tests on-site. Each facility must maintain current CLIA certification. The HSA, or designee, maintains documentation on-site that diagnostic services are certified or licensed to provide that service.

4-2.5.b All staff members that perform CLIA tests are required to pass an Ishihara Test to assess for color blindness in order to interpret color dependent lab assays.

5. **PROCEDURES:** Each CLIA waived test is performed in accordance with the manufacturer's instructions and local operating procedures. Each test must have

quality control testing performed as instructed by the manufacturer and the value range of the specific test must be documented in a local CLIA lab log. CLIA lab results for detainees are electronically recorded in the detainee's record via the lab window in eCW.

5-1. Off-site lab services. Any outside laboratory facility used must be accredited by the College of American Pathologists (CAP) or licensed by the CDC. Local operational procedures for these services include the following: 1) name, address and telephone number of the clinical laboratory contracted by the agency; 2) how routine and stat results are obtained; 3) bill review process; and 4) inventory and ordering process for laboratory supplies.

5-2. Preparing specimen for transport. All specimens are packaged for transport, with a record of all specimens sent to the reference lab, in accordance with the following: 1) collection tubes are prepared according to the Directory of Services Manual provided by the contractor; and 2) specimens are labeled with the detainee's name, requisition number, date of birth, and date and time of collection as generated by the eHR.

5-3. Specimen collection. For specific instructions on the collection of specimens, refer to the manual of the local laboratory service provider.

5-3.1 All off-site laboratory results are forwarded to the medical provider for further evaluation, as warranted. If paper lab results are received, the medical provider reviews, signs, and dates the original report and forwards the report to Medical Records for inclusion in the detainee's health record. After the provider reviews the paper lab results, the report is scanned into the detainee's eHR. If received electronically via the **(b)(7)(E)**, the provider or delegate/surrogate provider reviews the lab results, via the **(b)(7)(E)** within 24 hours, or if the results are received on a weekend or holiday, by the next business day. The provider who reviews the lab results ensures a follow-up appointment is scheduled with the detainee to discuss the lab results.

6. PROCEDURES: No additional procedures.

7. HISTORICAL NOTES: This document replaces IHSC Directive 10-01: Laboratory Services, effective March 11, 2016. **(b)(7)(E)**

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8. **DEFINITIONS:** See definitions for this policy in the IHSC Glossary located in the IHSC Policy Library.

9. **APPLICABLE STANDARDS**:

9-1. Performance-Based National Detention Standards (PBNDS): PBNDS 2011 Revised 2016:

9-1.1 Part 4: Care; 4.3: Medical Care.

9-2. ICE Family Residential Standards 2020:

9-2.1 Part 4: Care; 4.3: Health Care.

9-3. National Commission on Correctional Health Care (NCCHC): Standards for Health Services in Jails, 2018:

9-3.1 J-D-04: On-Site Diagnostic Services.

10. **PRIVACY AND RECORDKEEPING.** ICE uses detainee health records and information maintained in accordance with the DHS/ICE-013 Alien Health Records System of Records to provide for the care and safety of detainees. IHSC limits access to detainee health records and information to those individuals who need to know the information for the performance of their official duties, and who have appropriate clearances or permissions. IHSC secures paper records in a locked cabinet or room when not under the direct control of an officer or employee with a need for the paper record to perform their duties.

10-1. IHSC staff complete annual training on the protection of patient health information and Sensitive Personally identifiable information.

10-2. IHSC staff reference the Department of Homeland Security Handbook for Safeguarding Sensitive PII (Handbook) at DHS Handbook for Safeguarding Sensitive PII for additional information concerning safeguarding sensitive PII.

10-3. All relevant documents produced or provided in accordance with this Directive must be maintained in accordance with an applicable National Archives and Records Administration (NARA) General Records Schedule (GRS) or a NARA-approved agency-specific records control schedule. If the records are not subject to a records schedule, they must be maintained indefinitely by the agency. In the event the records are subject to a litigation hold, they may not be disposed of under a records schedule until further notification. Prior to the disposition of any records referenced in this directive, ICE Records Officer approval must be obtained.

11. **NO PRIVATE RIGHT STATEMENT.** This directive is an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.

12. **POINT OF CONTACT:** Chief, Medical Services Unit.