

State of California—Health and Human Services Agency California Department of Public Health



GAVIN NEWSOM Governor

TOMÁS J. ARAGÓN, M.D., Dr.P.H. Director and State Public Health Officer

- DATE: June 18, 2024
- TO: LABORATORIES AND PROVIDERS CONDUCTING POINT OF CARE HIV TESTING
- FROM: MARISA RAMOS, Ph.D. Chief, Office of AIDS

RE: REPORTING REQUIREMENTS FOR POINT OF CARE HIV TESTING

As rapid HIV testing continues to expand, California Department of Public Health (CDPH), Office of AIDS (OA) has received multiple questions regarding HIV surveillance reporting requirements as they relate to rapid or point of care tests (POCTs). This document is intended to provide clarification regarding this issue.

The current case definition for HIV (see link below) does not include definitions for suspected or probable cases, only for confirmed cases. However, some California reporting regulations do specify requirements for disease reporting of suspected and/or probable cases.

HIV Surveillance Reporting for Laboratories

Title 17, California Code of Regulations (CCR) Section 2505 requires reporting when a laboratory examination of a human specimen yields evidence suggestive of specified diseases, including HIV. (17 Cal. Code Regs., § 2505, subds. (a), (e)(2).) The laboratory must report initial findings and any subsequent findings as a result of additional laboratory examination. A preliminary positive result on a POCT is considered suggestive of HIV and is therefore reportable under Title 17 CCR Section 2505. Reporting preliminary positive POCT results to the Local Health Officer (LHO) in accordance with Title 17 CCR Section 2505(a) is required regardless of whether confirmatory testing is completed or not. When confirmatory testing is completed, the confirmatory test, consistent with Title 17 CCR Section 2505(a).

Note that Title 17 CCR Section 1230(a)(2) also requires clinical laboratories to confirm all reactive or indeterminate HIV test results by following the HIV diagnostic protocols recommended by the federal Centers for Disease Control and Prevention, the Clinical



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and Laboratory Standards Institute, the Association of Public Health Laboratories or the U.S. Department of Health and Human Services prior to reporting the result as positive.

Preliminary positive POCT results should be confirmed in accordance with Title 17 CCR Section 1230(a)(2).

HIV Surveillance Reporting for Providers

Title 17 CCR Section 2500(b) requires all health care providers knowing of, or in attendance on a case **or suspected case** of HIV, to report to the LHO. A suspected case is defined in relevant part as "A person who the provider believes, after weighing signs, symptoms, and/or lab evidence, to probably have a particular disease or condition." (17 CCR § 2500(a)(25)(A)).

Note that a preliminary positive POCT result with no additional information generally does not meet this definition. However, a preliminary positive result coupled with additional information, such as acute symptoms of seroconversion, symptoms of HIV, or knowledge of behaviors that elevate risk for HIV could meet the definition of a suspected case, based on the judgement of the provider.

How to Report – Laboratories

Laboratories are required to report positive POCT results and any confirmatory lab results to the Local Health Jurisdiction (LHJ) in which the health care provider facility is located (17 CCR 2643.10(a)). Lab reports shall be reported via the same means as other HIV labs: traceable mail, person-to-person transfer, or electronically via Electronic Laboratory Reporting (17 CCR 2643.10(b)).

How to Report – Providers

Health care providers are required to report confirmed or suspected cases of HIV to the LHJ where the health care facility is located. Providers should contact the HIV surveillance program at the LHJ to confirm the preferred method for reporting suspected cases of HIV. Providers can utilize the link below to <u>obtain contact information for each LHJ</u>:

https://www.cdph.ca.gov/Programs/CCLHO/Pages/LHD-Communicable-Disease-Contact-List.aspx

<u>Questions related to HIV surveillance and reporting</u> may be directed to:

Jamie Katayanagi, Chief, Quality Management Unit, Surveillance and Prevention Evaluation and Reporting Branch at Jamie.Katayanagi@cdph.ca.gov.

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Resources

HIV Case Definition: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm 17 CCR 2500 – Reporting to the Local Health Authority 17 CCR 2505 – Notifications by Laboratories 17 CCR 1230 – HIV Screening by Laboratories 17 CCR 1643.5 – HIV Reporting by Providers 17 CCR 2643.10 – HIV Reporting by Laboratories

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