

Guidance for Completing the HIV Antibody Test Laboratory Requisition Forms

This document provides health care providers and laboratory technicians a description of the California Department of Public Health (CDPH), Office of AIDS (OA), *HIV Antibody Test Laboratory Requisition Form for Conventional (LRF-C) and Rapid (LRF-R) testing*, and describes form elements and result recording procedures. Refer to the *OraQuick Rapid HIV Testing Guidelines-Policies, Procedures and Quality Assurance: Supplement to HIV Counseling and Testing Guidelines, Policies, and Recommendations (1997)* and the current product package insert for more detailed information for performing the OraQuick rapid HIV testing and quality assurance procedures.

Whenever questions are unresolved by this LRF guidance contact David Webb at OA at (916) 449-5826. To order additional LRFs contact Denise Humenik at (916) 449-5822. For information regarding OraQuick rapid testing procedures contact Vanessa Lee at (916) 449-5542.

Overview

The LRFs are used by anonymous and confidential publicly-funded counseling and testing (C&T) programs and other programs. The LRF-C is used for conventional (standard) testing and for confirmatory testing after a preliminary positive rapid test result. The LRF-R is used only for rapid HIV tests conducted at point of care.

The LRF is a professional tool to be used **ONLY** by HIV counselors who have completed the OA-sponsored training and by laboratory technicians. Supervised use by new counselors of the LRF-C is permitted as part of their training. This does not apply to performing rapid tests or completing the LRF-R. Only qualified personnel who have successfully completed CDPH/OA OraQuick test kit training and proficiency testing may conduct, read and record the results of a rapid HIV test. Untrained staff must **NEVER** perform client testing or interpret results.

The information captured on the LRFs is critical to the continuous improvement of primary HIV prevention in California. Incomplete or inaccurate recording of this information diminishes the impact of HIV counseling, violates contractual obligations and risks support for effective prevention services. The LRF must be available during counseling sessions when test results are given to clients.

Laboratory Requisition Form – Rapid Testing (LRF-R)

The LRF-R is composed of three copies: **LABORATORY COPY** (copy #1), **TEST SITE COPY** (copy #2), and **DATA ENTRY COPY** (copy #3). The **DATA ENTRY COPY** (copy #3) is double stapled to the CIF or CAQ for entry into the Local Evaluation Online (LEO) data system. The **TEST SITE COPY** (copy #2) is retained by the testing clinic/site. The **LABORATORY COPY** (copy #1) is only used in the event of a preliminary positive rapid test result. In that case, the **LABORATORY COPY** should be attached to the LRF-C used to request follow-up testing and sent to a conventional lab.

The LRF-R is organized into five different areas. Data in the first area is collected for all clients and includes the testing sequence, date of the test and client demographics. The **CONFIDENTIAL TESTING USE ONLY** area is only for clients who elect to test confidentially. The **RAPID TEST** area is used to document the quality assurance elements for the rapid testing procedure. The *CLINIC/SITE NAME, ADDRESS, & PHONE* are recorded in the area provided. The **RESULT** area is used to document the result of the rapid test, to indicate whether a confirmatory specimen was given, to record the Unique Office of AIDS Client Number from a

previous result, when necessary, and to indicate whether the client has ever been in an HIV vaccine trial.

See the paragraphs below for detailed information about how to complete each section.

Form Elements

All information should be completely recorded for each testing procedure. Blanks represent incomplete data and can affect the level of payment for counseling and testing services and reflect the adequacy of the service provided. In this guidance, major headings are the same as the form's label for each area. Topic labels are in bold print. Literal content of an item on the form is presented in italics.

Unique Office of AIDS Client Number

This *Unique Office of AIDS Client Number* is used along with the labels to link the specimen and HIV antibody test, HIV counselor assessment, appointment log, and other record keeping documents.

LAB SLIP NUMBER

Enter the number that indicates the sequence of testing here. If this is the client's first test in the sequence, enter a "1." If this test is a second or follow-up test to a previous result (e.g., a finger stick 'back-up' test to a preliminary positive oral fluid test), enter a "2." This sequencing applies only to a series of related tests performed on a client to get a final result, such as a preliminary positive rapid test followed by a confirmatory test. This sequencing is unrelated to whether the client has tested for HIV previously.

SPECIMEN DATE

Indicate the date of the specimen. (Since this form should be completed as part of the testing procedure, the date entered should be today's date.)

GENDER

Indicate the client's *GENDER* as (1) *MALE*, (2) *FEMALE*, (3) *M-F* (transgender male-to-female) or (4) *F-M* (transgender female-to-male).

DATE OF BIRTH

Record the client's complete *DATE OF BIRTH*: two-digit month, two-digit day and four-digit year (e.g., 03/06/1963 for March 6, 1963).

CONFIDENTIAL TESTING USE ONLY

This area is reserved for confidential testing use ONLY. This information must NEVER be collected for clients electing to test anonymously.

NAME (last, first)

Record the client's *NAME*. Some clients may use two last names or hyphenated names. If this is the case, please enter both last names as one word in this area omitting

hyphens (e.g., Jones-Smith is entered as JonesSmith). We can only be sure of unduplicated reports of HIV cases if the names are recorded consistently and accurately.

RAPID TEST

This area is for documenting the quality assurance elements required for rapid testing procedures.

LOT NUMBER

Record the seven-digit *LOT NUMBER* stamped on the bottom right of the Oraquick rapid test kit packaging.

EXPIRATION DATE

EXPIRATION DATE month and year (*mm/yy*) is stamped below the lot number on the OraQuick rapid test kit packaging. Kit expires at the end of the month and year stamped. Expired tests must be disposed of properly.

COUNSELOR/TECH ID

Enter the LEO system ID of the counselor or technician operating the test kit.

SPECIMEN

Indicate the type of *SPECIMEN* collected for the rapid test. Mark (1) *ORAL* for oral fluid specimens, (2) *FINGER STICK* for blood fingerstick specimens, or (3) *VENIPUNCTURE* for blood specimens collected through venipuncture.

BEGIN TEST

BEGIN TEST is when the absorbent pad is inserted into the vial containing the reagent.

TIME: Record the starting time (e.g., 1:30 for one thirty) and indicate whether it is AM or PM.

TEMPERATURE: Record the current temperature in the testing room in degrees Fahrenheit.

END TEST

END TEST is when the test result is read.

TIME: Record the ending time (e.g., 1:50 for one fifty) and indicate whether it is AM or PM.

TEMPERATURE: Record the current temperature in degrees Fahrenheit.

CLINIC/SITE NAME, ADDRESS, & PHONE

Indicate the name, address, and telephone number of the clinic or site where the testing is being performed.

RESULT

This area is for recording rapid test results.

RESULT

Record the *RESULT* of the rapid test. Mark either (1) *PRELIMINARY POSITIVE*, (2) *NEGATIVE*, or (3) *INVALID*.

If the result is *INVALID*, complete the appropriate section of the Testing Incident Report and staple a copy to the lab slip for data entry. Offer the client the option of retesting with a rapid test or with a conventional lab-based test if the result is *INVALID*. If two invalid test results occur in a row offer clients standard testing.

See **Recording Multiple Tests** at the end of this section for recording procedures for multiple tests. See the *OraQuick Rapid HIV Testing Guidelines-Policies, Procedures and Quality Assurance: Supplement to HIV Counseling and Testing Guidelines, Policies, and Recommendations (1997)* for quality assurance procedures required following two invalid results in a row.

CONFIRMATORY SPECIMEN GIVEN

Indicate whether or not a confirmatory specimen was collected for clients with *PRELIMINARY POSITIVE* results, and attach the lab copy of the preliminary positive result to the LRF-C used to order confirmatory testing.

PREVIOUS LAB SLIP ID

This area is for linking initial testing information and results to the current lab slip. Record the Unique Office of AIDS Client number from the previous lab slip if the *CURRENT* test is a follow-up test for a previous result. For example, a second rapid test might be conducted to follow-up an invalid rapid test, or to follow-up an oral fluid preliminary positive rapid test result. Attach the test site copy of the previous lab slip.

MARK IF CLIENT EVER IN AN HIV VACCINE TRIAL

Mark this box if the client reports having ever been in an HIV vaccine trial. Both rapid and conventional test results can be affected by some vaccine trial drugs.

Laboratory Requisition Form – Conventional Testing (LRF-C)

The LRF-C is composed of five copies. The top three copies – **LABORATORY COPY** (copy #1), **RETURN THIS COPY TO TEST SITE** (copy #2), and **RETURN THIS COPY TO TEST SITE (data entry copy)** (copy #3) – are sent to a clinical laboratory. The **RETURN THIS COPY TO TEST SITE** (copy #2) and **RETURN THIS COPY TO TEST SITE (data entry copy)** (copy #3) are stapled together and sent back to the clinic/site from the laboratory. The **RETURN THIS COPY TO TEST SITE** (copy #2) contains sensitive information and should be filed separately from the Counseling Information Form (CIF). The **RETURN THIS COPY TO TEST SITE (data entry copy)** (copy #3) is double stapled to the CIF for entry into the LEO data system. The **TEST SITE COPY** (copy #4) is retained by the testing clinic/site. The **CLIENT COPY** (copy #5) is given to the client who must bring the slip to the test result disclosure session.

The LRF-C is organized into six different areas. Data in the first area is collected for all clients and includes testing sequence, the date of the specimen, return appointment date and client demographics. The **CONFIDENTIAL TESTING USE ONLY** area is only for clients who elect to test confidentially. The **TESTS REQUESTED & LAB SPECIMEN** area is used to specify type of testing requested for all standard HIV tests and rapid confirmatory & follow-up testing. The *LABORATORY NAME & ADDRESS* and *CLINC/SITE NAME, ADDRESS, & PHONE* are recorded in the area provided. The **PREVIOUS TEST RESULT ID** section is used to record the original Unique Office of AIDS Client Number for clients who received a result that requires additional testing. (For example, a preliminary positive rapid test result or an inconclusive standard test result.)

The *LOCAL LABORATORY NUMBER* area (at the top of the form) and **LABORATORY USE ONLY** areas are for conventional laboratory use only for tracking and recording tests conducted and results.

Form Elements

All information should be completely recorded for each testing procedure. Blanks represent incomplete data and can affect the level of payment for counseling and testing services and reflect the adequacy of the service provided. In this guidance, major headings are the same as the form's label for each area. Topic labels are in bold print. Literal content of an item on the form is presented in italics.

LOCAL LABORATORY NUMBER

The *LOCAL LABORATORY NUMBER* is reserved for a specimen tracking number used by conventional laboratories to identify the laboratory where services are provided and to track specimens.

Unique Office of AIDS Client Number

This *Unique Office of AIDS Client Number* is used along with the labels to track the specimen and HIV antibody test, HIV counselor assessment, appointment log, and other record keeping.

LAB SLIP NUMBER

Enter the number that indicates the sequence of testing here. If this is the client's first test in the sequence, enter a "1." If this test is a second or follow-up test to a previous result (e.g., a confirmatory test following a preliminary positive rapid test), enter a "2." This sequencing applies only to a series of related tests performed on a client to get a final result, such as a preliminary positive rapid test followed by a confirmatory test. This sequencing is unrelated to whether the client has tested for HIV previously.

SPECIMEN DATE

Indicate the date the specimen was collected. This information is used as a quality assurance element as well as to track the volume of testing at each laboratory site.

RETURN APPOINTMENT DATE

Indicate the date the client should return for their test results for standard testing or confirmatory or other follow-up testing. The *RETURN APPOINTMENT DATE* helps labs to schedule

procedures in a timely manner so test results can be sent to testing sites prior to the client's return for their results.

GENDER

Indicate the client's *GENDER* as (1) *MALE*, (2) *FEMALE*, (3) *M-F* (transgender male-to-female) or (4) *F-M* (transgender female-to-male).

DATE OF BIRTH

Record the client's complete *DATE OF BIRTH*: two-digit month, two-digit day and four-digit year (e.g., 03/06/1963 for March 6, 1963).

CONFIDENTIAL TESTING USE ONLY

This area is reserved for confidential testing use ONLY. This information must NEVER be collected for clients electing to test anonymously.

NAME (last, first)

Record the client's *NAME*. Some clients may use two last names or hyphenated names. If this is the case, please enter both last names as one word in this area omitting hyphens (e.g., Jones-Smith is entered as JonesSmith). We can only be sure of unduplicated reports of HIV cases if the names are recorded consistently and accurately.

SSN (last 4 digits)

Record the last four digits of the client's Social Security Number (*SSN*). If the *SSN* is not available, enter four zeroes instead.

TESTS REQUESTED & LAB SPECIMEN

This area is for recording the *TEST(S) REQUESTED* and the *LAB SPECIMEN* for standard tests or confirmatory/follow-up tests for rapid tests.

TRIGGERING EVENT & LAB TESTS REQUESTED

This section is used to indicate to the conventional laboratory what initial testing has already been conducted on the client (triggering event) and what follow-up testing is being requested. Multiple triggering events or tests requested may be indicated if applicable.

Mark the box labeled *NONE* if no initial testing was performed, and request a *STANDARD HIV ANTIBODY* test. (An invalid rapid test result for a reason known to be unrelated to the client [e.g, failure to insert sample, test kit expired, etc.] should be treated as no initial testing in this section.)

Mark *RAPID PRELIMINARY POSITIVE* if a specimen from the client was tested using the OraQuick rapid HIV test, and the result was preliminary positive. Request an *HIV CONFIRMATORY* test.

Mark *DISCORDANT CONFIRMATORY* if the client initially received a preliminary positive rapid test *AND* a confirmatory result which was negative or inconclusive.

Request an HIV CONFIRMATORY test.

Mark INCONCLUSIVE RESULT if additional testing is being requested for a client whose standard test result was inconclusive. Request an HIV CONFIRMATORY test.

Mark SUSPECTED HIV-2 if client presents with risk factors for HIV-2, or belongs to a population at elevated risk for HIV-2. Request an HIV-2 SCREENING test and/or an HIV-2 CONFIRMATORY test according to your agency's protocols.

Mark REACTIVE HIV-2 SCREEN if client has received a reactive result on a test which screens specifically for HIV-2. (E.g., some EIAs screen for HIV-2 only; The MultiSpot HIV-1/HIV-2 test may also produce an HIV-2 specific result.). Request an HIV-2 CONFIRMATORY test.

For any other reason, mark OTHER and specify details in the space provided and/or under NOTE TO LAB. Request tests according to agency protocol, or call the Office of AIDS for technical assistance.

LAB SPECIMEN

Indicate the type of *SPECIMEN* collected. Mark (1) *ORAL* for oral fluid specimens, (2) *FINGER STICK* for blood fingerstick specimens, or (3) *VENIPUNCTURE* for blood specimens collected through venipuncture.

LABORATORY NAME & ADDRESS

List the name, address, and phone number of the conventional laboratory that will receive the specimen and perform the test.

CLINIC/SITE NAME, ADDRESS, & PHONE

Indicate the name, address, and telephone number of the clinic or site where the specimen was obtained. Clinic/site information allows laboratories to identify where test results are to be sent.

PREVIOUS LAB SLIP ID

This area is for linking initial testing information and results to the current lab slip. This section should be completed for all clients who have had an initial rapid test (e.g., preliminary positive) or standard test result (e.g., inconclusive) which requires further follow-up testing.

Record the eight-digit Unique Office of AIDS Client Number of the previous lab slip in the boxes provided and attach the Laboratory Copy of the LRF-R, or the Test Site Copy of the LRF-C if the previous test was a conventional test. (If the conventional lab reports results via some other form, attach a copy of that form.)

MARK IF CLIENT EVER IN AN HIV VACCINE TRIAL

Mark this box if the client reports having ever been in an HIV vaccine trial. Both rapid and conventional test results can be affected by some vaccine trial drugs.

NOTE TO LAB

Use this space to provide any necessary additional information to the conventional laboratory regarding the initial results/triggering event and/or tests requested.

LABORATORY USE ONLY

This area is reserved for use by the conventional laboratory.

EIAs

The enzyme-linked immunosorbent assay (*EIA*) is a test used to check for the presence of antibodies to HIV in blood samples. (1) *REACTIVE* results of EIA indicate the presence of HIV antibodies in the blood and require a supplemental test to confirm results. (2) *NON-REACTIVE* results indicate that no HIV antibodies were found. Results are used in the disclosure session to explain test results to clients and for HIV surveillance and data analysis.

Indicate whether the EIA used screens for HIV-1 only, HIV-2 only, or HIV-1 and HIV-2.

Multispot (HIV-1/HIV-2)

Multispot is an additional screening test that can be useful to distinguish between HIV-1 and HIV-2 in a client who is reactive to the OraQuick Advance (OQA) HIV1/2 test. In some cases, a discordant result (reactive on OQA, but non-reactive on confirmatory testing) may be the result of an HIV-2 infection which was not detected by the confirmatory test.

Four results are possible: (1) HIV-1 REACTIVE, (2) HIV-2 REACTIVE, (3) REACTIVE UNDIFFERENTIATED AND (4) NON-REACTIVE. Any of the first three results require supplemental testing for confirmation.

IFA & WB

A *WESTERN BLOT (WB)* or an immunofluorescent assay (*IFA*) test is used to confirm reactive screening test results including preliminary positive rapid test results. Both tests check for the presence of antibodies to HIV and are used in the disclosure session to explain test results to clients and for HIV surveillance and data analysis. Indicate whether an *IFA* or *WB (HIV-1)* or *WB (HIV-2)* was performed.

(1) *REACTIVE* indicates that HIV antibodies were found; (2) *NON-REACTIVE* indicates that no antibodies were found; (3) *INDETERMINATE* indicates that the results were inconclusive.

Other test, Specify

This section is used to specify other testing not list on the LRF-C.

Other Test Result, Specify

This section is used to specify the results for test specified, above.

SUMMARY INTERPRETATION

SUMMARY INTERPRETATION provides a summary of the interpretation of test results and assists the counselor during the disclosure session in explaining results to clients.

- (1) *HIV ANTIBODY DETECTED* indicates that the client is infected with HIV;
- (2) *HIV-2 ANTIBODY DETECTED* indicates that the client is infected with HIV-2;
- (3) *NO HIV ANTIBODY DETECTED* indicates that the client is not infected with HIV (but see counselor guidelines for an explanation of the window period); and
- (4) *INCONCLUSIVE-SUBMIT ANOTHER SPECIMEN* indicates no conclusion may be drawn regarding the client's HIV-status and another specimen is needed for follow-up testing.

SEE ENCLOSED NOTE: This informs the disclosure counselor that additional notes regarding the results of the test result are included with the form.

LAB NOTES

This area is for laboratory notes to the clinic/site regarding the test results.

DATE RECEIVED

Used by the conventional laboratory to record when the laboratory received the specimen. The date the specimen was received by the lab assists in the scheduling of laboratory procedures.

DATE REPORTED

Indicates the date the laboratory reported the results to the service provider. The date the lab reported the results confirms that results have been sent to the testing site for the disclosure session.

Recording Multiple Tests

Clients who receive preliminary positive rapid test results, invalid rapid test results, or inconclusive standard test results require follow-up testing to determine their HIV-status. Additional LRFs are used to request follow-up testing and to record results. The system needed for linking and accurately recording information from multiple LRFs is described below. It is critical to follow this system accurately in order to document the sequence of tests conducted for each client and ensure that each client receives an accurate result.

Follow these procedures to complete and link multiple LRFs documenting testing for a single client:

1. Fill out a new LRF for the second test. (The new slip is Lab Slip Number "2." The previous lab slip should be labeled Lab Slip Number "1".)
2. Copy the *Unique Office of AIDS Client Number* from Lab Slip Number 1 into the space on Lab Slip Number 2 labeled **PREVIOUS LAB SLIP ID**. Attach a copy of Lab Slip Number 1 to Lab Slip Number 2 prior to sending it to the lab.

3. Place a *Unique Office of AIDS Client Number* label from Lab Slip Number 2 on the CIF at the bottom of page 2 where indicated. Do NOT cover the original/previous number.
4. Double staple the **RETURN THIS COPY TO TEST SITE (data entry copy)** copy of Lab Slip Number 1 to the CIF.
5. Double staple the **RETURN THIS COPY TO TEST SITE (data entry copy)** copy of Lab Slip Number 2 to the CIF when you receive the result.
6. For additional LRFs, repeat the above procedure, adjusting the numbering appropriately.

There may be as many as five LRFs stapled to the CIF in extremely rare cases.