
Releasing Preliminary Positive Results for Standard HIV Testing

Overview of NYS DOH

Regulations 58-8.4

August, 2009

Flow of Standard HIV Testing

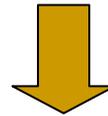
Patient consents to testing and sample is taken



Lab performs ELISA (EIA) screening test

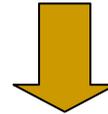


If EIA is -, it is considered a **final test result** and is provided to patient



If EIA is +, a Western Blot is conducted to confirm the result

Preliminary Positive Test Result



If WB is + it is a **final positive test result** and is provided to the patient

Benefits of Releasing Preliminary Positive Test Results

- Eliminates delays in patients learning their HIV test results
 - Even a short delay in learning one's HIV+ status can have serious implications
 - For the patient's health
 - For the patient's sexual or needle sharing partners
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Missed Opportunities

People newly infected with HIV are likely to have a very high viral load which may increase the likelihood of passing HIV to partners

Any time a person is tested and then may not be available to get the result, for example:

- ❑ Scheduled for hospital discharge
- ❑ Inmate scheduled for release from jail or prison
- ❑ Patient is homeless, transient, or difficult to reach
- ❑ Patient has travel plans
- ❑ High risk patient may be difficult to reach for follow-up
- ❑ Occupational exposure cases: result is needed to make treatment decisions

Exceptions

- There are circumstances where these regulations do not allow for release of a preliminary positive result:
 - blood, organ or tissue donors
 - consenting next of kin of a deceased person
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NYS Experience Providing Preliminary HIV+ Test Results

- Patients who test positive on an HIV rapid test are provided a preliminary test result
 - Pregnant women who come to the labor and delivery setting without a documented HIV test during pregnancy are offered HIV testing and provided the preliminary test result if it is positive
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Likelihood of a False Positive

- ELISA is highly sensitive test
 - A very small number of false positives may occur
 - Preliminary positive test results must be confirmed
 - Conducting a risk assessment helps the provider and patient assess the likelihood that the preliminary positive is a true positive
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Process for Requesting or Furnishing Preliminary + HIV Test Result

PROVIDER

Providers should contact the laboratory directly to discuss the process and requirements for obtaining these results.

LABORATORY

Must establish written policies and procedures that address:

1. Storage and retrieval of written authorization to release preliminary positive test results
2. How laboratory staff will be trained to ensure release of results in accordance with the limits of public health law
3. Quality improvement activities to ensure timely release of results

Counseling Messages

- Test result is preliminary and a follow-up test is needed to tell for sure if you have HIV
 - When the confirmatory result will be available and the importance of returning to get result
 - If infected, you could pass HIV to your sexual or needle sharing partners
 - Importance of avoiding behaviors that could pass the virus to others
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Risk Assessment

- Conduct a risk assessment to understand the likelihood that the test result is a true positive
 - Based on the results of the risk assessment, help the client understand the likelihood that the preliminary positive test result is a true positive
 - If the patient has a recent history of high risk behaviors, consider contacting Partner Services and initiating a referral to an HIV specialist for care
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Sample Script

“Because I think it is important for you to have information about your HIV status as soon as possible, I need to tell you that your preliminary HIV test result is positive. This result means that you may be infected with HIV. We won’t know for sure until the result is confirmed with a second test that will be done on the (blood or other fluid) sample that is already in the lab. This second test will be available (indicate when).”

Tailor counseling messages to findings of risk assessment

HIGH RISK

(Hx. multiple sex partners, IDU, partner of IDU)

“Given your risks for HIV, it is likely that the second test will show that the preliminary test result was correct and you do have HIV infection”

LOW RISK

(No hx. unprotected sex or IDU, monogamous with partner known to be HIV-)

“Given your lack of risk for HIV, it is likely that this test result is a false positive and the second test will indicate that you do not have HIV infection.”

Initiating Care and Services

- Use clinical information, patient history and other factors to determine appropriateness of making immediate referrals
 - If high likelihood of HIV+ or acute infection:
 - Consider referral to HIV specialist
 - If recent history of risk behavior:
 - Consider referral to Partner Service
 - NYS - 800-541-2437
 - NYC - 212-693-1419
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Additional Information

- Additional information about HIV testing is available on the DOH website at:

<http://www.nyhealth.gov/diseases/aids/>

- Questions related to laboratory issues may be sent to CLEP@health.state.ny.us
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