

Rapid HIV Testing – a Testing and Interpretation Guide

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This educational article is intended to create awareness in advance of the anticipated availability of rapid Human Immunodeficiency Virus (HIV) antibody testing in Alberta within the next few months. A listing of the sites where this testing will be performed and other operational details will be provided in a Laboratory Bulletin released just prior to implementation.

Key Points

1. The wider availability of rapid HIV testing is intended to improve the timeliness of results for management and/or treatment options in clinical scenarios described below.
2. Important indications for testing are:
 - a) Source of blood or body fluid exposure.
 - b) Pregnant female, near term or in labour with either no previous HIV testing OR tested HIV negative more than four weeks prior to delivery and on-going high risk behaviours for HIV acquisition.
 - c) Acutely ill patient with HIV infection in the differential diagnosis.
 - d) Individual presenting with HIV risk behaviours where testing is highly indicated and there is a low likelihood of a follow-up visit to get results.
3. Testing is performed on serum samples at designated local hospital laboratories using a rapid HIV test kit which:
 - a) Is a single use device for detecting HIV-1&2 antibodies in serum.
 - b) Is a screening assay only – samples testing reactive, invalid or indeterminate will be sent to Provincial Laboratory for Public Health (ProvLab) for HIV confirmatory testing.
 - c) Has a sensitivity of 99.5% and specificity of 99.8%, i.e., although infrequent, both false negative and false-positive results can occur (6). Standard HIV testing at a follow-up visit may be required for a definitive diagnosis.
4. Follow-up standard HIV testing is recommended for a patient with a negative rapid HIV test result, who presents with signs and symptoms suggestive of acute HIV illness with a recent history of high risk behaviours.
5. Rapid HIV test results will be reported electronically or by hardcopy to the healthcare provider requesting the test.

Background

Based upon Alberta surveillance data (1), individuals who are disproportionately represented by new HIV infections are injection drug users, men having sex with men, sex trade workers, those with a history of incarceration, and immigrants from HIV endemic countries (i.e., Africa, Asia, Caribbean, Central & South America and Eastern Europe). New cases of HIV have been identified in individuals perceived to be at “low-risk”, who are more likely to be in the late stages of the disease despite prior encounters with the health system (2).

A rapid HIV test result can be of value in the following four scenarios:

- a) for those individuals who have sustained a needle stick or blood/body fluid exposure, the HIV status of the source individual may influence the appropriate post-exposure prophylaxis for the recipient (3);
- b) in women presenting in labour, their HIV status can be critical in determining the use of anti-retroviral medication to mother and infant to prevent perinatal transmission (4);
- c) for those patients presenting with features compatible with HIV or HIV-associated conditions, a rapid HIV test result can either rule in or rule out HIV, thereby focusing investigations and interventions more appropriately; and
- d) performing rapid HIV testing on individuals with on-going high risk behaviours who are unlikely to return for follow-up will allow them to be connected to appropriate services especially if their HIV status is found to be positive.

Although rapid HIV testing, in specific clinical scenarios, has been provided by Calgary Laboratory Services within the Calgary zone, HIV testing for diagnosis and public health screening for the wider population has only been available through the Provincial Laboratory sites in Edmonton and Calgary. Consequently, results for patients residing outside of these cities have not been timely. Hence, the availability of rapid HIV testing at designated medium size acute care facilities throughout Alberta will move to address this imbalance.

Testing for HIV antibody

Standard HIV testing (performed at the ProvLab): follows the recommended two-tiered algorithm of using a sensitive screening test to identify potential positives followed by confirmatory testing with the Western Blot assay. The latest fourth generation screening HIV test can detect both HIV-1&2 antibodies and HIV-1 core proteins (p24 antigen) (5), whereas the rapid HIV test detects only HIV-1&2 antibodies (7). Hence the ProvLab standard HIV test can detect recently infected patients about five days earlier when they have low or undetectable antibody levels and are viraemic and highly infectious (6). Although these cases are still relatively infrequent, it is important to stress that they can test negative in the rapid HIV test.

Rapid HIV Test (performed at the local laboratory): utilizes a single-use disposable device (INSTI™ HIV-1/HIV-2 Antibody Test Kit, bioLytical Laboratories Inc.) that detects both HIV-1&2 antibodies in serum. The assay takes a few minutes to completion once the serum is added to the device, after which the results are reported as reactive, non-reactive, invalid or indeterminate. A sensitivity of 99.5% and specificity of 99.8% has been reported by the manufacturer from a Canadian clinical trial of 3507 patients (7).

Clinical interpretation of rapid HIV test results:

Rapid HIV result	Sent to ProvLab for confirmatory testing	Clinical Interpretation
Reactive	Yes – automatically	<ul style="list-style-type: none">Patients with a positive rapid HIV result and compatible risk behaviours and/or clinical history can presumptively be considered to be HIV infected
Non-reactive*	See footnote below	<ul style="list-style-type: none">Usually indicates absence of infectionHowever, individuals in the early stages of infection can test negative, although these cases are uncommonRequest standard HIV testing if patient is suspected in early stages of HIV infection
Invalid/Indeterminate	Yes – automatically	<ul style="list-style-type: none">Invalid results are rare and neither rule in nor rule out an HIV infection; risk behaviours and clinical history should guide management

** After the introduction of rapid HIV testing at each site there will be a minimum six month period when all samples with negative results will be sent to ProvLab for standard HIV testing. If the data evaluation indicates that the assay is performing satisfactorily and very few or no patients with very early HIV infections are detected, the automatic referral of negative samples from that site will be discontinued.*

However, the ordering physician will still have the discretion to request standard HIV testing if the clinical picture and/or risk behaviours suggest an early infection after the automatic referral process is discontinued.

Limitations: false negative results can occur in the acute HIV seroconversion window, with agammaglobulinaemia, and with significant immunosuppression; whereas lipid abnormalities and hypergammaglobulinaemia conditions may result in false-positives (7).

When should a rapid HIV test be ordered?

A panel of expert stakeholders considered the following clinical scenarios to be the most appropriate for rapid HIV testing because of its important potential contribution to management or intervention strategies:

- The source patient of a blood or body fluid exposure, usually in the healthcare setting, in order to determine the need for post-exposure prophylaxis for the exposed recipient.
- Any pregnant woman in labour or near term with no prenatal testing OR considered to be at high risk for HIV infection subsequent to her initial prenatal testing, in order to initiate early preventative antiretroviral therapy to reduce the risk of mother to child transmission.
- Any acutely ill patient with HIV infection in the differential diagnosis in order to expedite diagnosis and appropriate treatment.
- Any individual presenting with HIV risk behaviours where testing is strongly indicated and there is a low likelihood of a return follow-up visit to get results, counseling and/or referral as appropriate.

Infrequently, individuals in categories (a) and (b) above could be in the infectious early “seroconversion window” when a negative rapid HIV test result should not be the sole determinant for offering post-exposure prophylaxis to the recipient or treatment for the newborn. Should risk

factors and high risk behaviours indicate otherwise, both an infectious disease consult and standard HIV testing should be considered.

When should a rapid HIV test NOT be ordered?

Rapid HIV testing is ill-advised in the following scenarios, (a) baseline serology of recipient in a blood/body fluid exposure, (b) “routine screening” and (c) where the risk behaviours or clinical picture makes an HIV infection unlikely (low pre-test probability), as testing in these circumstances is more likely to result in false-positives.

Patient Counseling

An approach to pre- and post-test counseling should be tailored to the individual's needs, situation and level of knowledge. Oral informed consent is a minimum requirement together with an explanation of the implications of the test results and follow-up.

Individuals that test as reactive, invalid or indeterminate should be told that the rapid HIV test is a screening test and standard laboratory testing to determine their status will be performed. Patients with a non-reactive rapid test with on-going high risk behaviours should be considered in a “teachable moment”, given individual risk-based counseling, and when appropriate asked to return for follow-up serologic testing.

Reporting of Results

All rapid HIV test results will be reported by the performing site into the respective zone laboratory information system and subsequently into Alberta Netcare.

Standard and confirmatory test results will be reported by ProvLab through existing mechanisms. Confirmed positive results will be reported to public health in accordance with the notifiable diseases guidelines.

References

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