A series of HIV and STD related laws were enacted in December 2018. Below are key facts you should know about these changes

HIV Testing & Reporting

- Pre-HIV-test counseling requirement has been removed
- Before administering an HIV test, requires health care providers to:
  - Inform patients (or their representatives) that an HIV test will be performed;
  - Provide patients (or their representatives) with an opportunity to ask questions;
  - Provide patients (or their representatives) with an opportunity to decline testing.
- Patients can consent to an HIV test verbally or in writing
- If an HIV test is offered but declined, providers must document refusal of test in the patient’s medical record.
- If a patient tests positive for HIV:
  - The health facility must provide post-HIV-test counseling to the patient and referrals to expedite HIV treatment and services.
- Providers must follow the approved test and testing algorithms (see attached) and guidance from the Centers for Disease Control and Prevention or MDHHS.
- The testing facility must report HIV positive test results to Van Buren Cass District Health Department within 24 hours of receipt of results.
- All medical information pertaining to patients are not to be disclosed, only HIV specific information (HIV test results, treatment, diagnosis etc.) may be disclosed in response to a court order, subpoena, to the local health department or other health care provider, for the purposes of protecting the health of the patient, to prevent further transmission of HIV and to diagnose and care for the patient. Only the minimum information necessary to accomplish the intended purpose can be shared. (MCL 333.5131)
  
  (HCB-6016, HCB-6018, HCB-6019, HCB-6023)

Partner Services

- Van Buren Cass District Health Department-approved testing sites must perform partner notification for patients who test positive for HIV.
- The local health department shall maintain individual case files via health departments server or paper files that are encoded to protect the identities of the patient. These records must be destroyed within 365 days after the date received.
  
  (HCB-6017)
Changes to HIV Criminal Laws

A series of laws passed updating Michigan’s HIV felony disclosure laws to require that “intent to infect” must be proven for an individual to be found guilty of a felony. Key areas for attention:

- A person who knows they have HIV:
  - Who has anal or vaginal intercourse with another person WITH THE SPECIFIC INTENT that the uninfected person contract HIV is guilty of a felony;
- Who, without first informing their sexual partner that they have HIV, CAUSES THE UNINFECTED PERSON TO BECOME HIV POSITIVE acts with reckless disregard and is guilty of a felony;
- Who, without informing their sexual partner that they have HIV, and who acts with reckless disregard but DOES NOT TRANSMIT HIV, is guilty of a misdemeanor;
- A person who knows that they have HIV and has been MEDICALLY SUPPRESSED PER ACCEPTED MEDICAL STANDARDS IS NOT ACTING WITH RECKLESS DISREGARD.

(HCB-6019, HCB-6020, HCB-6021)

Perinatal HIV/STD Testing

Michigan’s perinatal HIV and STD testing laws fall in accordance with Centers for Disease Control and Prevention Guidelines.

- Testing for HIV, Syphilis and Hepatitis B shall occur at the time of initial examination, typically in the first trimester of pregnancy.
- Additionally, testing shall occur during the third trimester for syphilis, HIV, and Hepatitis B on an opt out basis.
- Patients can consent to an HIV test verbally or in writing.
- If an HIV test is offered but declined, providers must document refusal of test in the patient’s medical record.

(HCB-6022)
1. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to test for established HIV-1 and HIV-2 infection and for acute HIV-1 infection, respectively. No further testing is required for specimens that are non-reactive on the initial immunoassay. However, if there is a possibility of very early infection leading to a non-reactive initial antigen/antibody immunoassay, such as when recent HIV exposure is suspected or reported, then conduct an HIV-1 nucleic acid test (NAT), or request a new specimen and repeat the algorithm according to CDC guidance (1,4,5,6).

2. Specimens with a reactive antigen/antibody immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved supplemental antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, untypable (undifferentiated).

3. Specimens that are reactive on the initial antigen/antibody immunoassay and non-reactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 NAT.
   - A reactive HIV-1 NAT result and non-reactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence of acute HIV-1 infection.
   - A negative HIV-1 NAT result and non-reactive or HIV-1 indeterminate antibody differentiation immunoassay result indicates an HIV-1 false-positive result on the initial immunoassay.
   - A negative HIV-1 NAT result and repeatedly HIV-2 indeterminate or HIV indeterminate antibody differentiation immunoassay result should be referred for testing with a different validated supplemental HIV-2 test (antibody test or NAT) or repeat the algorithm in 2 to 4 weeks, starting with an antigen/antibody immunoassay (3).

4. Laboratories should use this same testing algorithm, beginning with an antigen/antibody immunoassay on all serum or plasma specimens submitted for testing after a preliminary positive result from any rapid HIV test conducted in a CLIA-waived setting (7).

**The FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody immunoassay can be used as the initial assay in the laboratory HIV testing algorithm for serum or plasma. If any instrumented antigen/antibody test is available, it is preferred due to its superior sensitivity for detecting HIV during acute infection (1,2).**

**This includes specimens reported as HIV-2 positive with HIV-1 cross-reactivity (3).**

**Refer to last bullet, item 3 above.**
<table>
<thead>
<tr>
<th>Test Outcomes</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Sequence</td>
<td></td>
<td>Final Algorithm Interpretation</td>
<td>Interpretation for Provider* (Sample should be reported as:)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
<td>Step 2</td>
<td>Step 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV-1/HIV-2 Ag/Ab IA&lt;sup&gt;a&lt;/sup&gt;</td>
<td>HIV-1/HIV-2 Antibody Differentiation IA&lt;sup&gt;i&lt;/sup&gt;</td>
<td>HIV-1 NAT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonreactive</td>
<td>n/a</td>
<td>n/a</td>
<td>HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.</td>
<td>HIV negative</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-1 Positive</td>
<td>n/a</td>
<td>Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present.</td>
<td>HIV-1 Positive</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-2 Positive</td>
<td>n/a</td>
<td>Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.</td>
<td>HIV-2 Positive</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-2 Positive with HIV-1 Cross reactivity</td>
<td>n/a</td>
<td>Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.</td>
<td>HIV-2 Positive: This result is distinct from HIV positive untypable (undifferentiated).</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV Positive untypable (undifferentiated)</td>
<td>n/a</td>
<td>Positive for HIV-1 and HIV-2 antibodies. Laboratory evidence of HIV-1 and/or HIV-2 infection is present.</td>
<td>HIV Positive</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-1 indeterminate, HIV-2 indeterminate</td>
<td>Detected</td>
<td>Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.</td>
<td>Acute HIV-1 Positive</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-1 indeterminate</td>
<td>Not detected</td>
<td>HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.</td>
<td>HIV Negative</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV-2 indeterminate&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Not detected</td>
<td>HIV antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive.</td>
<td>HIV-1 Negative, HIV-2 inconclusive</td>
</tr>
<tr>
<td>Reactive</td>
<td>HIV Indeterminate</td>
<td>Not detected</td>
<td>HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive.</td>
<td>HIV-1 Negative, HIV-2 inconclusive</td>
</tr>
<tr>
<td>Reactive</td>
<td>Negative</td>
<td>Detected</td>
<td>Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.</td>
<td>Acute HIV-1 Positive</td>
</tr>
<tr>
<td>Reactive</td>
<td>Negative</td>
<td>Not detected</td>
<td>HIV antibodies were not confirmed and HIV-1 RNA was not detected.</td>
<td>HIV Negative</td>
</tr>
<tr>
<td>Reactive</td>
<td>Negative or Indeterminate</td>
<td>Invalid or not performed</td>
<td>Inconclusive</td>
<td>Inconclusive</td>
</tr>
</tbody>
</table>

<sup>a</sup> The tests outlined in this table are not FDA approved for oral fluid or dried blood spots.  
<sup>b</sup> The need for repeating screening IA on an initial reactive test is assay dependent, refer to product package insert.  
<sup>c</sup> This column contains the Final Assay interpretation per the Geenius package insert, the only FDA approved test for this step. We recommend excluding the individual HIV-1 and HIV-2 results on the laboratory report. If they are used, the final assay interpretation or final assay result should also be included.  
<sup>d</sup> This column contains simplified language to be used for the laboratory report and it can be directly used for reporting from LIMS systems.  
<sup>e</sup> This column contains simplified language of the previous column, “Final Algorithm Interpretation,” and is included here for healthcare providers or other non-laboratorians that may also use this table as a reference document. This does not need to be included on the laboratory report.  
<sup>f</sup> Comments under “Further Action” can be included as language in the laboratory report or can be used as guidance for laboratorians to discuss test results with healthcare providers or health department staff.  
<sup>g</sup> Please refer to Centers for Disease Control and Prevention guidance. Available at: https://www.cdc.gov/hiv/testing/laboratorytests.html, https://stacks.cdc.gov/view/cdc/38856 and https://www.cdc.gov/hiv/testing/clinical/index.html  
<sup>h</sup> Please refer to the Centers for Disease Control and Prevention HIV Guidelines and Recommendations to find the most appropriate information by age and risk group for the patient in question. Available at: http://www.cdc.gov/hiv/guidelines/  
<sup>i</sup> Follow Geenius package insert and refer to the CDC Technical Update. Available at: https://stacks.cdc.gov/view/cdc/40790