INSTRUCTIONS FOR COMPLETION OF THE MICHIGAN ADULT CONFIDENTIAL HIV CASE REPORT (DCH-1355)

Michigan Department of Health and Human Services

The Michigan Adult HIV Confidential Case Report Form (ACRF) is Michigan's version of the Centers for Disease Control (CDC) 50.42A/50.42C and, as of the date of its release, replaces all prior HIV and AIDS case report forms for age 13 and over. (A separate form, DCH-1402, is used for reporting HIV/AIDS in persons under age 13.) Instructions for each section of the form are described below. The attached form may be photocopied or downloaded from www.michigan.gov/HIVSTI, specifically at www.michigan.gov/documents/mdhhs/Michigan_Adult_HIV_Confidential_Case_Report_Form_732626_7.pdf.

More copies of the form may be obtained through your local health department or by contacting the Michigan Department of Health and Human Services HIV & STI Surveillance and Epidemiology Section at 313-456-1586.

All patients with evidence of HIV infection, including Stage 3 HIV infection (previously referred to as AIDS), should be reported within 7 days of diagnosis, including a diagnosis made by a clinical care provider based on history and symptoms. HIV Stage 3 (AIDS) cases include all patients with a history of HIV infection who also have documented CD4 levels under 200 cells/ µL or a CD4+ T-lymphocyte percentage of total lymphocytes o f less than 1 4% when a CD4 count is not available, or any of the AIDS indicator diseases referenced in Section XI of these instructions. See December 5, 2008, MMWR supplement No. RR-10, Vol. 57;1-8 for complete HIV and Stage 3 (AIDS) definitions.

Completed forms should be faxed or mailed to the Michigan Department of Health and Human Services (MDHHS). The secure fax to MDHHS Detroit is (**313-456-1580**). The address for forms mailed directly to the state health department is MDHHS HIV Surveillance, PO Box 30727. Lansing, MI 48909. When mailing the form, address the envelope to the HIV Surveillance Unit. To protect patient confidentiality, make sure you either use two envelopes, a security envelope, or wrap a sheet of plain white paper around the case report form (so no confidential information can be seen through the envelope). Finally, to minimize the likelihood that it will be opened inadvertently, mark the envelope **"Confidential"** and **"To Be Opened By Addressee Only."** If you have any questions, call **313-456-1586**.

NOTE: On the case report form, answers of "Y" or "Yes" will be interpreted as if the event in question has occurred. Answers of "N" or "No" will be interpreted as if the event in question did NOT occur. Answers of "U," "Unk," or "Unknown" will be interpreted as if there was no data in the source used to complete the ACRF to allow a determination of "Yes" or "No" to be made. Finally, blank or missing answers will be interpreted as if no source was examined to allow a determination of "Yes" or "No" to be made.

STICKY #: Agencies funded by MDHHS for HIV testing: Complete the 10-digit code from strip of stickers beginning with #26.

SECTION I – State Health Department Surveillance Use Only

Leave this section blank for state health department use.

SECTION II - Patient Identifier Information

For confidential testers, enter the patient's full legal name, alias name, and/or maiden name.

Check one of the boxes next to "Address Type," and complete current address, phone number, alternate phone number, and social security number.

Residence at Diagnosis

If same as current residence, check “Same as current” box; if not, provide full address. For boxes labeled “Residence at HIV diagnosis” or “Residence at Stage 3 (AIDS) diagnosis,” check one or both boxes depending on patient test results. If there are additional addresses or phone numbers, report in Comments section.

SECTION III – Demographic Information

Case Status – Check the appropriate box under Diagnostic Status whether you are reporting adult “HIV Infection” or "Stage 3 (AIDS)."

Indicate if a care provider suspects that this patient is acutely (recently) infected with HIV or is experiencing acute retroviral syndrome. No support documentation is required.

Sex at Birth – Indicate the biological sex the patient was assigned at birth.

Gender Identity – Indicate the gender to which the patient most closely identifies at time ACRF is completed (this may or may not be different than the sex the patient was assigned at birth) and if the patient identifies as a transgender female (Trans to Female) or as a transgender male (Trans to Male). Transgender is an umbrella term used for people whose gender identity and/or gender expression differs from the sex they were assigned at birth. For the purposes of HIV case surveillance this term includes transgender people regardless of whether they have altered their bodies hormonally and/or surgically.

Date of Birth – Indicate month/day/year of birth. Also list any past or current alias dates of birth.

Country of Birth – Check appropriate box and include specific country if other than United States (US) or US Dependencies/Possessions.

Vital Status – Check appropriate box: alive, dead, unknown.

Death Date and the State/Territory of Death – Complete, if known.

Marital Status – Check appropriate status.

SECTION IV – Facility of Diagnosis

For boxes labeled “Site of first + test for HIV diagnosis” or “Site of Stage 3 (AIDS) diagnosis” check one or both boxes depending on patient test results.

Enter the name and specialty of the diagnosing provider along with the facility name, phone number, address, city, state, and zip code of the facility where the patient was **first diagnosed** [as HIV positive or as Stage 3 (AIDS), accordingly].

SECTION V – Current Provider of HIV Care

Enter the name of the provider, facility name, city, state, phone, and medical record number where the patient is currently receiving HIV care. This may or may not be the same provider or facility where the patient was diagnosed.

SECTION VI – Facility Providing Information for this report

If information is the “Same as facility of diagnosis” or “Same as current provider of HIV care,” mark the appropriate box next to the heading.

Provide the date the ACRF was completed, the name, phone number, and facility for the individual who could be reached to answer questions concerning the information provided on the ACRF. This person can be a physician, nurse, physician's assistant or any confidentiality-trained staff member with knowledge to interpret and access the patient's medical information.

SECTION VII – Patient History

Check ALL appropriate risk factor boxes in each column with Yes, No or Unknown. If there is no information for a specific risk factor, check "unknown" rather than leaving it blank. Blanks indicate you did not look for this information.

Mark "Yes" to any of the following only if the patient or the health care provider believes it to be the mode of HIV transmission: clotting factor, transfusion, transplant or health care/laboratory exposure.

If a patient or health care provider believes the mode of transmission includes clotting factor, transfusion, transplant or health care/laboratory exposure, provide details in the comment section. Indicate first and last dates of any blood transfusions, if applicable. Write in specific occupation if patient is, or was a healthcare worker and believes he/she was exposed to HIV in a healthcare setting.

Indicate if patient was having high risk sex – unless another risk has already been noted. This includes exchanging sex for drugs, money, etc., sex with anonymous partners, recurrent STIs, or an unusually high number of sex partners.

Further, if the patient or health care provider believes the mode of transmission includes heterosexual sex with a person with known HIV/AIDS infection and that sex partner is known to have a clotting factor disorder, a transfusion or transplant also indicate this in the comment section.

Indicate if patient was perinatally infected and list name of patient's mother.

SECTION VIII – Treatment/Services Referrals

Complete all Partner Services questions [formerly known as Partner Counseling and Referral Services (PCRS)]. They are: "Has the patient been informed of his/her HIV infection?" and "Who will counsel the patient's partners about their HIV exposure?" Under Michigan law, notifying the known sex or needle-sharing partners of HIV-infected patients is an affirmative duty of the attending physician (clinical care provider). This responsibility may be discharged to local public health by checking the 'Local Health Dept' box.

SECTION IX – Women Only

For women, list all known obstetrical information as requested. Indicate whether the patient is currently pregnant, whether referred to an obstetrician and list their EDC (due date). Provide birth information, if applicable, for their most recent birth: child's date of birth and address of birth hospital. Enter "home birth" if born at home and include the full name of the child.

SECTION X – Documented Laboratory Data

HIV Diagnostic Tests – Enter specimen collection dates and immunoassay (IA) results indicating HIV infection. Call HIV Surveillance with any questions at 313-456-1571. You may attach lab report copies to the case report form, if desired. Examples of typical reporting results are at the end of these instructions.

For each test reported, enter specimen collection date, test results, and manufacturer when indicated. Note if the test is rapid.

X. DOCUMENTED LAB DATA Patient Name: _____

You may add copies of lab results to this form and may fax form to 313-456-1580.

	Type of Test At least 2 Antibody Tests must be indicated for an HIV diagnosis IA = ImmunoAssay	Collection Date	Rapid Test	Positive or Reactive	Reactive for AG	Reactive for AB	HIV 1 Ab Positive	HIV 2 Ab Positive	Indeterminate	Undifferentiated	Negative or Non-Reactive	Manufacturer
1	HIV-1/2 Ag/Ab **Lab** IA Screen (4th Gen Screen)		N	☐					☐		☐	Numerous
2	HIV-1/2 Ag/Ab **Lab** IA (5th Gen Screen)		N		☐		☐	☐		☐	☐	BioPlex
3	HIV-1/2 Ag/Ab **Lab** IA (4th Gen Discriminating Screen)		N		☐	☐					☐	Roche Duo
4	HIV-1/2 Ag/Ab **Rapid** IA (4th Gen Discriminating Screen)		Y		☐	☐					☐	Abbott Determine
5	HIV-1/2 Ab IA (2nd or 3rd Gen Screen)		Y N	☐							☐	
6	HIV-1/HIV-2 Type Differentiating IA (Confirmatory Test)		Y				☐	☐	☐	☐	☐	Geenius or VioOne
7	HIV-1 Western Blot (Confirmatory Test)		N	☐					☐		☐	
8	HIV-1 RNA/DNA Qualitative NAAT		N	☐							☐	Roche, Aptima
9	HIV-2 RNA/DNA Qualitative NAAT		N	☐							☐	Roche
10	Rapid Home Self-Testing HIV Screen		Y	☐							☐	Oraquick
11	HIV-Syphilis Rapid Screen (Report HIV Results Only)		Y				☐	☐			☐	Chembio DPP
12	Last Negative Test (prior to HIV diagnosis)		Y N								☐	

If HIV lab tests were NOT documented, is HIV diagnosis confirmed by a clinical care provider
☐ Yes ☐ No ☐ Unk

If Yes, provide date of documentation by care provider

1 **HIV-1/2 Ag/Ab Lab-Based ImmunoAssay (4th Generation)** – This screening test detects both HIV-1 antigen and antibody to HIV-1 and HIV-2. It is more sensitive than antibody-only tests and can help indicate acute infection. Results are either Reactive or Nonreactive.

2 **HIV-1/2 Ag/Ab Lab-Based ImmunoAssay (5th Generation)** – This screening test detects both HIV-1 antigen and antibody to HIV-1 and HIV-2. It goes further by a.) distinguishing between antigen and antibody reactivity and b.) differentiating between HIV-1 and HIV-2. Example is BioPlex 2200. Results are Antigen reactive, Antibody reactive for HIV-1, Antibody reactive for HIV-2, Undifferentiated (reactive for both HIV-1 and HIV-2 antibodies) or nonreactive. Antigen reactivity may indicate recent infection with accompanying high levels of circulating virus.

3 & 4 **HIV-1/2 Ag/Ab Lab-Based ImmunoAssay OR Rapid ImmunoAssay (4th Generation Discriminating)** – These screening tests detect both HIV-1 antigen and antibody to HIV-1 and HIV-2. Each test goes a step further and distinguishes between antigen and antibody reactivity. Examples are Roche Duo and Abbott Determine. Results are Antigen reactive, Antibody reactive, both or neither. Antigen reactivity may indicate recent infection with accompanying high levels of circulating virus.

5 **HIV-1/2 Ab ImmunoAssay (2nd or 3rd Generation)** – Traditional antibody screening tests or initial immunoassays (IA). Results are either Reactive or Nonreactive. These may be rapid or conventional lab-based tests. Not as sensitive as 4th generation assays. If two IAs are used to diagnose a patient, tests must be different: i.e. test for different virus components or use different methodologies. Using different manufacturers is sufficient; note manufacturer names where indicated.

6 **HIV1/HIV 2 Type Differentiating ImmunoAssay (Confirmatory Test)** – A second or supplemental laboratory test that distinguishes between HIV-1 and HIV-2 antibodies. Examples are the Geenius and VioOne. Multispot is no longer available. The type differentiating test has replaced the Western blot as the confirmatory antibody test in standard laboratory testing sequence. Results are HIV-1, HIV-2, both (Undifferentiated) and Indeterminate. Patients who test reactive on an initial screen and then negative or indeterminate on HIV-1/HIV-2 Antibody Differentiation test should have an HIV-1 nucleic acid test (NAAT) to confirm or rule out infection.

7 **HIV-1 Western Blot (Confirmatory Test)** – Traditionally the second antibody test in standard laboratory sequence, now being replaced by the HIV-1/HIV-2 Type Differentiation test. Results are Positive, Negative or Indeterminate. Patients who test reactive on an initial screen and then negative or indeterminate on HIV-1 Western blot should have an HIV-1 nucleic acid test (NAAT) to confirm or rule out infection.

8 & 9 **HIV-1 or 2 RNA/DNA Qualitative NAAT** – The HIV-1 Nucleic Acid Amplification Test (NAAT or simply, NAT) detects the RNA or DNA of the HIV virus itself and may be either qualitative (HIV detected/not detected) or quantitative (HIV viral load, see below).

Usually, the HIV-1 NAT is run to resolve discordant screen and confirmatory results. Examples are Hologic Aptima or Roche. At this time, most laboratories do not automatically perform a NAAT to sort out conflicting test results, where the initial screen was reactive but the second, supplemental test was negative or indeterminate. The physician must order the follow-up test with a fresh-drawn plasma. A few laboratories will run all 3 tests on the initial specimen when indicated.

The HIV-2 NAT is rarely indicated: only when discordant results or patient risk factors point to possible HIV-2 infection. This NAT is part of the Roche HIV-1/HIV-2 Qualitative Test, may be run on serum or plasma.

10 **Rapid Home Self-Testing HIV Screen** – Rapid test that allows the client to collect the sample, perform the rapid test, and interpret the test results in their own home or other private location. Currently, there is one FDA approved self-test available in the United States: OraQuick IN-HOME HIV test. Results are either positive or negative as reported by the patient.

11 **HIV-Syphilis Rapid Screen** – - Rapid test to detect antibodies to HIV-1, HIV-2 or Treponema pallidum (syphilis). Please report HIV results only here.

Example is Chembio DPP. Results are either Antibody reactive for HIV-1, Antibody reactive for HIV-2, or negative.

12 **Last Negative Test** (prior to HIV diagnosis) – If a prior negative HIV test is documented on an infected patient, indicate collection date of the most recent negative test result. Note test type and manufacturer for the last documented negative test if known: IA, EIA, viral load, NAT, rapid etc. Note that this documented last negative test date is different from the "Date of most recent negative test" in Section XII HIV Testing and Treatment History, which is from the patient's recollection.

HIV Care Tests

HIV-1 RNA Assay Quantitative Viral Load – The viral load detects and quantifies the level of HIV-1 RNA in the bloodstream and is used to monitor disease progression and therapy. It is not meant to be a diagnostic test; however, a detectable level of virus in the blood confirms infection for surveillance purposes.

Record both the earliest and most recent viral load tests. Include date of collection. Enter number of copies per milliliter, plus ">" (greater than) or "<" (less than) if applicable. Log results are no longer collected. If lab report also includes "Detectable" or "Undetectable" result, check appropriate box.

CD4 Count and Percentage – Record the CD4 cell count and percent closest to the current diagnostic status (i.e., HIV or Stage 3 (AIDS) as well as the first CD4 count/percent less than 200/ul or less than 14% of total lymphocytes. The CD4 percentage of less than 14% of total lymphocytes is no longer used to classify infections as Stage 3 (AIDS), unless a CD4 count is not available.

HIV Genotype – Indicate if the patient has received an HIV genotype test, the specimen collection date, and laboratory of collection.

Documentation of Tests – If laboratory documentation of a positive HIV test is unavailable in the medical record, enter the earliest date the clinical care provider documented the patient's HIV infection. A care provider diagnosis is made by clinical and/or laboratory evaluation and should be clearly documented (e.g., in progress notes). Prescription of anti-retroviral drugs is sufficient evidence of a care provider diagnosis of HIV infection.

SECTION XI – Stage 3 (AIDS) Opportunistic Illnesses

For Stage 3 (AIDS) reports, enter name of opportunistic illness from list below along with date of diagnosis.

- Candidiasis, bronchi, trachea, or lungs
- Candidiasis, esophangeal
- Carcinoma, invasive cervical
- Cryptococcosis, extrapulmonary
- Cytomegalovirus retinitis (with loss of vision)
- Cryptosporidosis, chronic intestinal (>1 mo. duration)
- Cytomegalovirus disease (other than in liver, spleen, or nodes)
- Coccidiodomycosis, diseminated or extrapulmonary
- Herpes Simplex: chronic ulcer(s) > (1 mo. duration) or bronchitis, pneumonitis, or esophagitis
- HIV encephalopathy
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (> 1 mo. duration)
- Kaposi's sarcoma
- Lymphoid interstitial pneumonia and/or pulmonary lymphoid
- Lymphoma, Burkitt's (or equivalent)
- Lymphoma, immuonblastic (or equivalent)
- Lymphoma, primary in brain
- Mycobacterium avium complex or M.kansasii disseminated or extrapulmonary

- M. tuberculosis, pulmonary
- M. tuberculosis, disseminated or extrapulmonary
- Mycobacterium, of other/unidentified species, disseminated or extrapulmonary
- Pneumocystis carinii pneumonia
- Pneumonia, recurrent, in 12 mo. Period
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain, onset at >1 mo. of age
- Wasting syndrome due to HIV

SECTION XII – HIV Testing and Treatment History (TTH)

Testing and treatment history information must be completed for all HIV reports in Michigan. Dates are VERY important in this section. Enter patient-reported answers to past testing behaviors and the dates of these tests as reported by the patient. Medical staff can complete this section using information found in the medical record. This information will be used in the calculation of HIV incidence rates (rates of recent infection).

Date questions answered by patient – Enter date of patient interview or date of note in medical record when patient provided most of the HIV testing and treatment history. If information is from more than one date, enter most recent date.

Main Source of TTH Info – Note where testing and treatment history was obtained: interview, medical record, or from medical provider.

First Positive Test Reported by Patient – Do not assume that the current positive HIV test is the first positive for the patient. Ask patient if he/she has ever tested positive for HIV in the past. Enter the month/day/year of the first-ever positive HIV test. Partial dates are acceptable. Note if the first positive HIV test was known to be an anonymous test.

Negative Tests Reported by Patient – Ask patient if he/she ever tested negative for HIV before testing positive. Enter the month/day/year of the of the most recent negative HIV test. Partial dates are acceptable. Enter the total number of negative HIV tests the patient recalls in the 24 months (only) preceding the first positive HIV test.

Antiretroviral Treatment (ARV) Use – Check box if patient NEVER used ARV for any purpose. If patient EVER received medication to treat or prevent HIV, enter at least one medication name, start date and date of last use (if stopped) or most recent use (if still taking ARV). Indicate reason(s) for ARV use, including:

- To treat HIV infection
- To prevent HIV infection via Pre-Exposure Prophylaxis (PrEP)
- To prevent HIV infection following a possible exposure such as a needle stick or unprotected sex. This is Post-Exposure Prophylaxis (PEP)
- To prevent transmission from a pregnant woman to her unborn or newly-born baby

SECTION XIII – Comments

Add any additional laboratory, clinical, partner services, or other relevant information here.