

CONSENT FORM FOR THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) TEST

I have been informed that my blood, obtained by a finger stick, will be tested for antibodies to the Human Immunodeficiency Virus (HIV), the virus that causes AIDS.

I acknowledge that I have been given an explanation of the test, including its uses, benefits, limitations and the meaning of test results.

I acknowledge that I have been offered two testing options. I understand that results using a standard testing procedure may take up to two weeks. Testing using OraQuick will allow me to learn a negative or preliminary positive (reactive) result today. I choose to be tested and learn results today.

I understand that if this test is reactive, a second (confirmatory) test will be performed to confirm these results. I understand that my blood (from a vein) or an oral sample from my mouth will need to be taken for this test.

I understand that I will be considered infected with HIV only if this second test is also positive.

I have been informed that the HIV test results are confidential and shall not be released without my written permission, except to: _____* and as permitted under state law.

I understand that I have a right to have this test done without the use of my name. If my private physician does not provide anonymous testing, I understand that I may obtain anonymous testing at a Michigan Department of Community Health-approved HIV counseling and testing site.

I understand that I have the right to withdraw my consent for the test at any time before the test is complete.

I acknowledge that I have been given a copy of the booklet *Important Health Information*. I have also been given a copy of the brochure "*What You Should Know About HIV and the OraQuick Rapid HIV-1 Antibody Test*". I have been given the opportunity to ask questions concerning the test for HIV antibodies, and I acknowledge that my questions have been answered to my satisfaction.

By my signature below, I consent to be tested for HIV.

Patient/Parent/Guardian Signature Date

Witness Date

AT THIS TIME, I DO NOT WANT TO BE TESTED FOR THE HUMAN IMMUNODEFICIENCY VIRUS

Patient/Parent/Guardian Signature Date

Witness Date

* Please write in the physician or health facility name who will receive the HIV test results.

Consent to Participation in a Study on Rapid HIV Tests

Purpose of the Research: There are two new rapid tests that can tell if someone has been exposed to the Human Immunodeficiency Virus (HIV), the virus that causes AIDS. Because these are new tests, we want to be sure that they can be correctly used before we begin to use them at this clinic. To do this, we are conducting a study and invite you to participate. We will use the results of this study to decide which test(s) will be used in publicly supported testing sites.

Study-related Procedures:

The rapid tests are done using a few drops of blood taken by pricking the tip of your finger. If you agree to participate we will prick one of your fingers and take several drops of blood. We will run two different rapid HIV tests on your blood. If the results from both of these tests are negative, you probably are not infected with HIV.

If the result from one or both of these tests is reactive, we will need to conduct another test to know for sure whether you have HIV. To do this additional test, we will need to take another sample of your blood from a vein in your arm (or from a swab in your mouth). Since results from this additional test will take about two weeks, you will not know for sure today if you are HIV-infected.

You will get a copy of the booklet *Important Health Information*. You will have the opportunity to ask questions about the test before a specimen is collected.

Alternative procedures or courses of treatment (if any): ***If you do not want to be in this study, you can still get an HIV test today. You can get tested with the rapid test already being used in this clinic. If you do not want to be in the study, you will not be penalized in any way. You will not lose the benefit of services offered at this agency.***

Potential risks, discomforts or inconvenience: The potential risks to you are those usually associated with the collection of blood from a finger stick or from a vein in your arm. There may be pain or discomfort at the site of collection. There may also be temporary bruising at that site. Very rarely, the site of blood collection may become infected or need medical treatment.

Potential benefits: There is no direct benefit to you for being in this study. Your being in this study will help decide the benefit of using these new tests in this clinic.

Confidentiality of records: Your HIV test results are confidential. Test results will not be released without your written permission, except as allowed by State law. You have the right to have this test done without the use of your name.

Contact information: For questions about the rights of human research subjects contact Harry McGee 517-241-0806, mcgeeh@michigan.gov, Michigan Department of Community Health, Institutional Review Board, Capitol View Building 7th Floor, 201 Townsend Street, Lansing, MI 48913.

For questions about the research contact Dr Anthony Muyombwe 517-335-8099, muyombwea@michigan.gov, Michigan Department of Community Health, Bureau of Laboratories, 3350 N MLK Jr. Blvd, Lansing, MI 48909.

Voluntary participation & right to withdraw: You have the right to withdraw your consent to participate in this study at any time. If you withdraw your consent to be in this study, you can still get a rapid HIV test today.

This information was reviewed with the participant and they gave oral consent to participate in the research study.

Signature:

Witness

Date

Date of IRB approval of this consent: **9/18/07**

Expiration date of IRB approval of this consent: 12/31/07