

Section 6. Counseling Considerations

The following types of counseling will be provided to all MTN-009 study participants: HIV pre-test, post-test and risk reduction counseling. Participants who are confirmed to be HIV infected will be provided additional post-test result counseling on CD4+, viral load, and standard resistance tests as results become available. Guidance is provided in this section on provision of the types of counseling listed above.

6.1 General Counseling Information

All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, support, skills-building, and/or referrals. The goal of counseling is to allow the participant to talk about her feelings and thoughts concerning HIV in a non-threatening, non-judgmental, environment. The focus should be on the participant, so they feel empowered and not dejected and desperate. To achieve this, effective counseling sessions should include:

- Establishing rapport
- Ensuring privacy and Confidentiality
- Showing respect
- Acknowledging difficult feelings
- Listening to what the participant has to say
- Using an appropriate language level
- Using Open-ended questions

**Table 6-1:
Characteristics of a Counseling Session**

Includes	Does Not Include
♦ Establishing helping relationships with participants	♦ Giving advice
♦ Having conversations that have a purpose	♦ Making decisions on behalf of participants
♦ Listening attentively to participants	♦ Judging participants
♦ Helping participants tell their story	♦ Interrogating participants
♦ Giving participants correct and appropriate information	♦ Blaming participants
♦ Helping participants make informed decisions	♦ Preaching or lecturing to participants
♦ Helping participants recognize and build on their strengths	♦ Making promises that cannot be kept
♦ Helping participants develop a positive attitude to life	♦ Imposing counselor's beliefs on participants

The following are recommendations to ensure a high quality counseling session:

- ♦ **Use written procedures to help counselors conduct effective sessions.** Standard Operating Procedures for HIV counseling can include examples of open-ended questions to help counselors avoid closed-ended questions, and a list of explicit risk-reduction steps to help counselors avoid accepting a participant's suggestion of global risk-reduction steps.
- ♦ **Avoid using counseling sessions for data collection.** Counseling documentation is important and a required study procedure, but counselors should avoid writing chart notes during the counseling session. Rather, wait until the end of a session and then document a summary of the session. If needed, counselors can write short reminders during the session to help them with documentation. Also, standard counseling checklists should be avoided during counseling because they can encourage even skilled counselors to use closed-ended questions, limit eye contact, and miss critical verbal and nonverbal cues.
- ♦ **Avoid providing unnecessary information.** An emphasis on providing information might prompt counselors to miss critical opportunities to provide needed information and cause participants to lose interest. Discussion of theoretical HIV risks (e.g., sex with a person with hemophilia or needle exposures through tattoos) tends to shift the focus away from the participant's actual HIV risk situations to topics that are more "comfortable" or easy to discuss but irrelevant to the participant's risk.
- ♦ **Counselors should prepare for the counseling session.** Preparation for a counseling session is absolutely necessary if you want to conduct an effective counseling session. Counselors must ensure that an appropriate amount of time has been scheduled for each session. Before starting the counseling session, counselors should review any notes from a previous session and have on hand any relevant material that might be useful to the participant. The counselor must also be able to block any personal issues/problems and be fully engaged with the participant during the counseling session. They should also ensure that their state of mind will not interfere with counseling a participant.
- ♦ **Prepare the counseling environment.** HIV counseling must take place in a setting where a private and confidential discussion can be held. Counselors should make sure there is nothing in the room that could lead to a disruption during the counseling session. Whenever possible, disconnect telephones, radios, and computers. Chairs should be arranged so that seating is relaxed and informal. Chairs should not be placed directly facing each other, instead, chairs should be placed at an angle a comfortable distance from each other. Both counselors and participants should feel comfortable.

Example of counseling settings:



Not recommended setting



Recommended setting

6.2 HIV Counseling

HIV pre-test, post-test, and risk reduction counseling is required per protocol for all enrolled study participants. Post-test result counseling is also required per protocol for HIV infected participants when provided their CD4, viral load, and standard resistance test results during follow-up visits. Referrals should also be provided when indicated. The sample HIV Counseling Worksheets provided in Section Appendix 6-1 and 6-2 provides a guide to the minimum requirements for MTN-009 HIV counseling sessions.

All HIV counseling should be provided in accordance with local counseling standards. Study staff who provide HIV counseling should be trained on local practice standards, study-specific HIV testing methods and interpretation of test results (e.g. HIV Drug Resistance). Information on HIV testing during the screening and enrollment visit is provided in Sections 4.2.1 of this manual; further information on interpretation of screening and enrollment and follow-up test results is provided in Table 6-1a and Table 6-1b. These informational resources should be referenced as needed when providing pre-test, risk reduction, and post-test counseling.

Table 6-1a
Interpretation of HIV Tests Performed During SCREENING and ENROLLMENT (Visit 1)
Per Protocol Appendix II

Test Result	Interpretation
Rapid Tests	
Both rapid tests negative	HIV-uninfected; test results indicate that you are not infected with HIV.
Both rapid tests positive	HIV-infected; test results indicate that you are infected with HIV.
Discordant rapid tests (one negative, one positive)	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.
Western blot	
negative	HIV-uninfected; test results indicate that you are not infected with HIV.
positive	HIV-infected; test results indicate that you are infected with HIV.
indeterminate	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.

Table 6-1b
Interpretation of CD4, Viral Load, and Resistance Test Results
PROVIDED During FOLLOW-UP (Visits 2-3)
Per Protocol Appendix III

Test Result	Interpretation
CD4 Count <100 cells/mm ³ 100-200 cells/mm ³ 201-350 cells/mm ³ >350 cells/mm ³	Your CD4 count is very low. You may be eligible for fast track ART initiation (within 2 weeks). Please see your primary care physician as soon as possible. Your CD4 count is very low. You may be eligible to start ART. Please see your primary care physician as soon as possible. You may be eligible to start ART if you are co-infected with TB or if you are pregnant. You should see your primary care physician for further guidance. You do not require ART at this time. Please try to join a wellness program for regular follow up and ask your primary care physician to repeat your CD4+ T cell count in 6 months.
Viral Load < 40 copies/ml 41 – 400 copies/ml >400 copies/ml	Your viral load is undetectable, however you are still infected with HIV. Your viral load is low. Your viral load is high. Please try to see your primary care physician to have your CD4+ T cell counts regularly monitored. You may be eligible for treatment now or in the future.
HIV Resistance None Possible Resistance Resistance	There is no evidence of resistance to this drug There is some evidence of resistance but it may not have been validated or clinically verified. This drug is reduced in effectiveness

When multiple counseling sessions are necessary (e.g. when participants return for their follow-up visits, or when if additional counseling is needed or requested) care should be taken to avoid rote repetition of the same information at each counseling session.

Client-centered approaches should be used to assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results.

Client-centered approaches should also be used when assessing participant risk for HIV infection and providing risk reduction counseling. The counselor should ask open-ended questions, actively listen to participant responses, probe as needed for further information, and guide the participant in identifying her risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

Examples of open-ended question include:

- “How do you think the virus is passed from one person to another?”
- “How much do you know about the risk factors or lifestyles of the people you are having sex with?”
- “What do you understand by the word ‘confidentiality’?”
- “What do you know about HIV infection?”
- “What do you think about using condoms?”
- “Whom have you spoken to about taking an HIV test?”

Supported and facilitated by the counselor, the risk reduction plans identified by the participant should reflect and respond to her current risk assessment and should be practical, yet challenge the participant toward risk reduction. For participants whose risk reduction barriers are significant, risk reduction plans may need to be incremental. Importantly, all risk reduction plans should be agreed upon by the participant and should be documented in the participant’s study records, with a copy made available to the participant if she wishes. The sample HIV Counseling Worksheet in Section Appendix 6-1 incorporates a structure that counselors may find helpful for documenting current risk factors and barriers, experiences with risk reduction since the last session, if applicable, and risk reduction plans until the next session, if required.

At each counseling session, the risk factors, and risk reduction plans identified at the previous sessions should be reviewed and discussed with the participant to determine:

- What was her experience since her last session?
- Was she able to carry out her strategies and plans?
- What were the outcomes?

Risk reduction plans identified and agreed upon with the participant at the current session should then build on experience since the last session:

- Successful strategies should be continued
- Additional strategies may be identified to achieve further risk reduction
- Alternative strategies may be identified if strategies tried since the last session were not successful.

Risk reduction counseling sessions should also offer skills building to the participant when indicated, e.g., on how to use male and female condoms, how to discuss sensitive issues with partners and other influential persons. HIV counseling for partners should always be offered, either as an individual session or as a couples session.

6.2.1 CD4-positive T cell and Viral Load Results

Participants who are confirmed HIV positive per the MTN-009 algorithm will return to the study site for their CD4 and viral load test results. Viral load results may be provided along with the resistant results, depending on when they are available.

When providing CD4+ results, post-test counseling should explain what the test measured, specifically the immune system in patients. Explain WHO and national guidelines for referral for antiretroviral therapy (ART) based on CD4+ count.

When providing viral load test results, post-test counseling should explain what the test measured, specifically the measure of severity of the infection. Study staff should also explain that higher numbers in the viral load test indicate an increased risk of getting sick from opportunistic diseases.

Inform the participant that both tests are important to measure her health and if she consents, the study site will share these results with her doctor.

Please see Section Appendices 6-3 and 6-4 for additional information on CD4 and viral load.

6.2.2 Resistance Test Results

Participants who are confirmed HIV positive per the MTN-009 algorithm will return to the study site within three months for their resistance test results. When providing resistance results, explain what the test measured and what the results signify. If the resistance report shows possible resistance or resistance, explain how someone might acquire a drug resistant virus, keeping in mind that although scientists have an idea how this occurs, it is not always clear how someone may have become infected with a resistant virus. Also explain how the results may impact the effectiveness of certain types of antiretroviral medications. Inform the participant that these test results are important to help determine effective ART and if she consents, the study site will share these results with her doctor.

For additional information on HIV drug resistance, refer to Section Appendix [6-3](#) and 6-4.

6.3 Helpful Hints for Promoting Care and Support Options

One important function of counseling for HIV is linking people who test positive with related services, such as care and support options, skills training, and income-generating mechanisms. HIV-positive participants will be referred to available resources per site's SOP; and, counselors should encourage participants to attend to those referrals, especially, those participants that qualify for ARTs. While ART cannot cure HIV infection, it can significantly reduce the viral load. Counselors should also encourage HIV-positive participants to seek early treatment of any illness, particularly STIs. In addition to referring participants to care and support services, counselors can:

- ♦ Clarify that while traditional herbs and medicines may play a role in boosting the immune system, there is no evidence that they can cure AIDS.
- ♦ Remind participants that prayer may provide some comfort or hope, but there is no evidence that prayer can eliminate HIV from a person's body.
- ♦ Encourage involvement of family and/or friends, where possible.
- ♦ Encourage participants who have tested positive to contact other HIV-positive individuals (through a network/support group or on an individual basis), and share her experiences in a supportive environment.
- ♦ Explore the issue of disclosure with participants and, where appropriate, assist them in disclosing their status to relevant parties. Participants must consider the impact of disclosure and consider who would provide them with unconditional support if their status were revealed.
- ♦ Assist participants to explore creative means of remaining self-sufficient, such as undertaking income-generating activities.

6.4 Documentation

All counseling should be documented in participants study records. The worksheet appended to this section may be adapted for this purpose. In addition to completing the checkbox items on the checklist, notes should be recorded on the checklist and/or on other source documents to document participant responses to the counseling, any concerns raised by the participant, action planned to be taken by the participant, action to be taken by the counselor (or other study staff members, if applicable), and issues to be reviewed or addressed at the next session if applicable.

When referrals are made, study staff should actively follow-up on the referral to determine whether the participant sought the services to which she was referred, determine the outcome of the referral, and determine whether additional referrals are needed. Additional counseling also may be needed to help ensure the participant receives services that may be beneficial to her. All follow-up actions, outcomes, counseling, and plans for next steps should be documented in chart notes.



Section Appendix 6-1: MTN-009 HIV Counseling Worksheet

PTID:	Visit #:
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Pre-Test Counseling

NA Done

- Greet participant and establish rapport
- Explain confidentiality of counseling session
- Assess knowledge of HIV/AIDS; correct misconceptions/misunderstandings
- Review HIV rapid tests to be done today and tests to be done if rapid tests indicate possible infection
- Explain implications and meaning of a positive, indeterminate or negative result, and the window period
- Provide an opportunity for PPTs to ask questions
- Verify readiness for testing

Risk Reduction Counseling

- Use open-ended questions to assess PPTs risk factors
- Provide education on safer sex practices (e.g. condom use, fewer or less risky partners) and healthy lifestyle practices
- Assist the PPT in developing a risk reduction plan including how to overcome challenges to safer sex practices

Post-Test Counseling

- Prepare PPT to receive test results
- Provide and explain test results
- Ensure understanding of test results
- Explain additional testing that may be required per protocol
- Reiterate risk reduction and safer sex strategies including responsibility to protect others
- Provide further information and counseling relevant to client's test results per site SOP

Referrals

NA Done

- If applicable, provide initial or alternative referrals to support groups and/or other psychosocial services.
- If applicable, and in consultation with site medical staff as needed, provide initial or alternative referrals to clinical care services.

Document all referrals per site SOP. Note referrals and other issues requiring follow-up at the next visit (continue on additional sheets if needed).

Staff Initials and Date

Section Appendix 6-3: HIV Resistance, CD4 and Viral Load Fact Sheet

HIV DRUG RESISTANCE, CD4 AND VIRAL LOAD FACT SHEET

Understanding Drug Resistance

HIV is a smart little virus. Although scientists have spent the last 25 years designing medications to fight it, HIV can learn to adapt and avoid medications. When this happens, we say someone has developed “drug resistance.”

How HIV Works

HIV, like all viruses, is a parasite; it needs a human cell in which to reproduce. The first thing HIV does when it enters someone’s body is look for a comfortable place to make its home. Its target is the immune system—in particular, cells known as CD4 or helper T cells. The fact that HIV enters these particular cells is bad news, since CD4 cells are what the body uses to fight off infections.

Key Terms Used in This Fact Sheet

Drug resistance: HIV can mutate (change form), resulting in HIV that cannot be controlled with certain medications.

CD4 count: CD4 cells, also called T cells or CD4+ T cells, are white blood cells that fight infection. HIV destroys CD4 cells, making it harder for the body to fight infections. A CD4 count is the number of CD4 cells in a sample of blood.

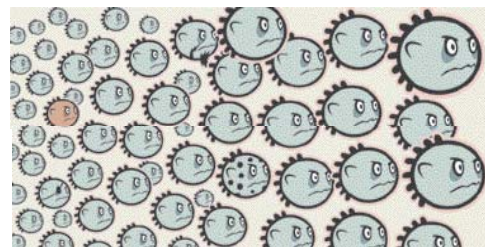
Viral load: the amount of HIV in a sample of blood.

Once HIV gets inside a CD4 cell, it basically takes control of it and transforms the cell from a disease fighter into a factory whose sole mission is to create as many new copies of HIV as it can. These copies then travel to other CD4 cells, infect them and turn them into HIV factories as well. These factories can produce a billion or more copies of HIV per day. The specific number of HIV copies made each day will depend on how many CD4 cells are infected and producing virus. The level of production can be measured by an infected person’s viral load—the lower a person’s viral load number, the less HIV is multiplying. Although the parent HIV dies soon after it makes copies of itself, it produces so many copies before it dies that HIV remains a

continual danger. While HIV is busily creating copies of itself, it’s also destroying the immune system, since soon after it uses CD4 cells to make copies of itself, the CD4 cells die. This explains why, without treatment, someone with HIV may gradually see his or her CD4 count fall. The lower someone’s CD4 count is, the more likely he or she will be to get sick.

HIV Mutations

What does all this have to do with drug resistance? The answer is that HIV isn’t perfect: While HIV is furiously reproducing, there are bound to be errors. Picture infected CD4 cells as poorly run bug factories that are supposed to make two-eyed blue bugs. Because the factories produce more than a billion of these bugs daily, some bugs won’t quite turn out like they’re supposed to. Most have two eyes, but some have three. Some are pink and some have spots. The bugs that are different are called “mutants.” The changes are called “mutations.” HIV mutations occur naturally all the time in everyone with HIV, whether or not they are taking medications. If medications were not needed to treat HIV, mutations wouldn’t matter that much, since mutations generally don’t make the virus more aggressive.



However, mutations matter because eventually almost everyone with HIV needs treatment. Certain mutations can enable HIV to thrive *despite* the presence of medications in a person's body.

HIV Treatment

Successful HIV treatment usually consists of at least three drugs from two different “classes,” or types, of medications. Each class works differently, so that an HIV mutation that makes the virus resistant to one class won't make it resistant to another class. What makes today's HIV treatment so effective is that it is more powerful than ever before, with fewer side effects.

Current treatment combinations can just about stop HIV's ability to reproduce. How will someone know if their HIV is under control? If the medications work well, within about two weeks after starting their first treatment regimen, the amount of HIV in their blood—“viral load”—will decrease dramatically. Within two to six months, they'll probably be told that their HIV is “undetectable.” Undetectable simply means that even though they are still HIV positive and can transmit HIV to others, their viral load is now so low that current viral load tests aren't sensitive enough to detect the HIV in their blood. It's sort of like a needle in a haystack—it's there, but hard to find. HIV can't be totally eliminated because it enters the genetic structure of many cells in a person's body, including “reservoirs,” such as lymph nodes and spinal fluid, where HIV medications may have a hard time reaching. The great thing about being undetectable is that it signifies that a person's HIV is now under control. The number of CD4 cells in a person's body can begin to grow again and their immune system can recover and do its job. With more CD4 cells, the chance of developing opportunistic infections and illnesses is reduced.

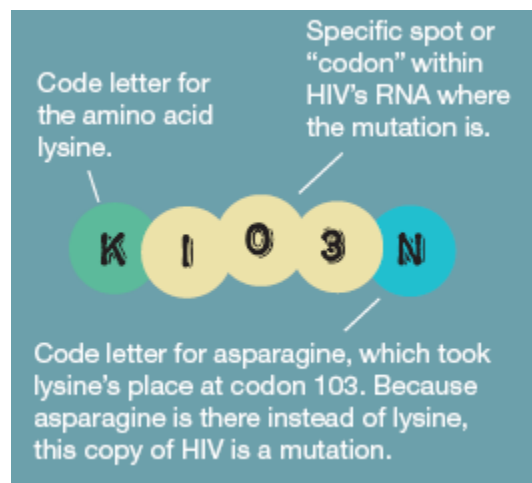
As long as a person keeps taking all their medications on time, their chances of remaining undetectable are excellent. In addition, with HIV's reduced ability to multiply, there are fewer opportunities for HIV mutations to be made. Of course, if someone is on their third, fourth or fifth regimen, and have many drug resistant mutations, reaching an undetectable viral load is sometimes difficult, if not impossible. Fortunately, many recent studies show there's a benefit to keeping a person's viral load as low as possible, even if it's detectable. A low, stable viral load can still allow a person to increase their CD4 count and reduce the chances they will become ill.

How Drug Resistance Occurs

HIV medications are best at fighting the regular — not the mutated—virus. Although most HIV mutations are harmless, sometimes HIV can get lucky: If a mutation differs in just the right way, it can render an HIV medication useless. If this happens, we say that HIV is “resistant” to that medication. Suppose someone frequently misses a dose. HIV will grab this opportunity to start making more copies of itself in their CD4 cells. As the amount of HIV in their body increases while they are not taking their medications consistently, so does the amount of mutated HIV—including mutations that make their virus resistant to their medications.

In other words, if the person misses doses of their medications too often, they're effectively training their mutated, drug-resistant HIV to survive better. The mutated virus may begin to make more and more copies of itself, and could eventually become the most common type of HIV in their body. Once this happens, *no matter how much of that medication they take*, it will no longer have an effect on their HIV. This means they've become resistant to that medication. Once their HIV has developed resistance to a medication, it will stay resistant *forever*, since resistant HIV, like regular HIV, can remain hidden in some of their cells.

What Exactly Is a Mutation? And What Are All Those Numbers About?



To make it easier to work with HIV resistance tests, researchers have a shorthand system for naming HIV mutations.

An HIV "mutation" is actually just a slight change in a specific section of HIV's RNA, the genetic code that provides all the instructions for how HIV works. Mutations occur naturally, not just in HIV, but in other viruses as well—not to mention within the cells of every other living thing, humans included. Every HIV mutation is given a unique name to help researchers identify it.

Let's look at K103N, the most common mutation. The number in the middle is called a "codon"—it identifies the specific position within HIV's RNA where the mutation is

located. The first letter stands for the amino acid that is normally found at that position in wild-type HIV; the last letter stands for the amino acid that's there instead (which is the mutation).

So, in the case of K103N, we have a mutation at codon 103 in HIV's reverse transcriptase gene. In that particular spot, the amino acid K (which stands for lysine) has been replaced by the amino acid N (which stands for asparagine), which makes that particular copy of HIV into a mutation. It just so happens that this particular mutation, K103N, is one of the worst mutations to have, since it makes HIV highly resistant to many of the approved drugs in the NNRTI class. Not all mutations, of course, are so dangerous. Most mutations will have no impact at all on how well someone's medications work.

HIV Monitoring Tests

The CD4 Count Test

This test, also known as a "T-cell count test," gives an indication of the number of CD4 cells in a person's bloodstream. The more CD4 cells a person has, the stronger their immune system is.

A normal CD4 count for someone without HIV is usually between 500 and 1,600. Experts generally agree that when someone's CD4 count goes below 350, they're at a high risk for developing potentially dangerous illnesses.

Healthy	500 - 1,660
Borderline Low	350 - 500
Low	200 - 350
Extremely Dangerous	0 - 200

The Viral Load Test

Viral load tests provide an estimate of how much HIV is circulating in someone's blood. A viral load test measures the amount of HIV in a small amount (milliliter, or mL) of blood. Current viral load tests can detect as few as 50 copies of HIV per milliliter of blood. When a viral load test indicates that someone has fewer than 50 copies/mL of HIV, their health care provider will tell them that their viral load is "below the limit of detection," or "undetectable."

Section Appendix 6-4: FAQs: Resistance, CD4 and Viral Load

FAQS: RESISTANCE, CD4 AND VIRAL LOAD

What is HIV drug resistance?

Answer: Drug resistance is when a drug loses its ability to stop the HIV virus from reproducing.

How does HIV become resistant?

Answer: HIV isn't a perfect virus and thus when replicating itself leads to errors. When the virus reproduces, it makes billions of copies daily. And many of the new copies contain mistakes, or "mutations"—slightly different versions against which medications may fail to work.

How can someone be resistant to HIV medications if they have never taken them?

Answer: The most likely scenario is that the person they got HIV from may have been on HIV treatment and his or her virus may have become resistant to one or more HIV medications. Transmitted along with HIV was resistance to certain drugs.

What are treatment options for people with resistance?

Answer: Resistance to a drug does not automatically mean you can no longer use it. There are different degrees of resistance. Resistance testing can be used to select the HIV medication most likely to be effective against your virus.

How can someone prevent resistance or prevent further HIV resistance?

Answer: To reduce a person's risk of becoming resistant to HIV medications, it is important to take medications exactly as prescribed by their doctor.

What is CD4?

Answer: It's a group of white blood cells that help the body fight infections.

Why is it important to know the CD4 count?

Answer: Keeping track of the number of CD4 in a blood sample helps determine the health of the immune system.

What is viral load?

Answer: Viral load is the amount of HIV in a person's blood.

Why is important to know the Viral Load?

Answer: When used in combination with your CD4 count, viral load is extremely useful in determining when to begin or change HIV treatment.

What does undetectable viral load mean?

Answer: An undetectable viral load means that a person's current HIV medications are effectively treating their HIV and has reduced HIV's ability to reproduce. Having an undetectable viral load, however, does not mean that a person is cured and unable to transmit the virus to someone else. It simply means that the level of viral load in a person's blood is below the threshold needed for detection.

Section Appendix 6-5: Sample ART Drug Resistance Report



ViroSeq™ HIV-1 Antiretroviral Drug Resistance Report

Patient ID: 208-0000xxx Patient Name Last: ----- Patient Name First MI: ----- Accession Number: ----- Patient Gender: Female Patient Birthdate & Age: ----- Report Generated By: admin Report Date & Time: 15 Apr 2010, 03:08:44 PM, EDT Ordering Physician: ----- Institution: Durban Date Drawn: 17 Mar 2010 Assay Operator: Krista Eskay Field1: MTN-009 Field2: -----	Testing Laboratory: MTN Virology CORE Lab 470 Lab Director: Urvi Parikh PhD Assoc Dir Department ID: ----- Mailstop: ----- Street Address1: S804 Scaife Hall Street Address2: 3550 Terrace St City: Pittsburgh State/Province: PA Postal Code: 15216 Country: USA Telephone/Fax: Ph: 412-648-3103 Fax: 412-648-8521 E-mail: ump3@pitt.edu Web Site: www.mtnstopshiv.org
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Drug Class	Drug	Evidence of Resistance
NRTI	EPIVIR® (lamivudine, 3TC)	None
	EMTRIVA® (emtricitabine, FTC)	None
	RETROVIR® (zidovudine, AZT)	None
	VIDEX® (didanosine, ddI)	None
	ZERIT® (stavudine, d4T)	None
	ZIAGEN® (abacavir, ABC)	None
	VIREAD® (tenofovir, TDF)	None
NNRTI	RESCRIPTOR® (delavirdine, DLV)	Resistance
	SUSTIVA® (efavirenz, EFV)	Resistance
	VIRAMUNE® (nevirapine, NVP)	Resistance
PI⁺	INTELENCE™ (etravirine, ETR)	None
	AGENERASE® (amprenavir, APV)	None
	LEXIVA® (fosamprenavir, FOS)	None
	CRIXIVAN® (indinavir, IDV)	None
	FORTOVASE® / INVIRASE® (saquinavir, SQV)	None
	KALETRA® (lopinavir + ritonavir, LPV)	None
	PREZISTA® (darunavir, DRV)	None
	VIRACEPT® (nelfinavir, NFV)	None
	REYATAZ® (atazanavir, ATV)	None
APTIVUS® (tipranavir, TPV)	None	

Drug Class	Drug Resistance Mutations Identified
NRTI	
NNRTI	K103N
PI	

* NOTE: At least one mutation used to determine Evidence of Resistance for this drug has not been fully validated.
 ** NOTE: At least one mutation used to determine Evidence of Resistance for this drug has not been clinically verified.
 *** NOTE: For at least one mutation used to evaluate Evidence of Resistance for this drug, both notes above apply.
 + Evidence of Resistance for Protease Inhibitors estimates response to ritonavir-boosted regimens. Refer to section titled "Notes on Evidence of Resistance".

Review & Release of Results

Signature / Date: _____ Name(Print) / Title: _____
 Notes: _____

FOR IN VITRO DIAGNOSTIC USE

Project ID: C:\Documents and Settings\parikhu\Desktop\009 TRAINING\GEN018DR_05A\GEN018DR_05A