HANDBOOK ON IMPLEMENTING HIV RETESTING FOR VERIFICATION BEFORE/AT ANTIRETROVIRAL THERAPY INITIATION

Among Individuals Age 18 Months and Older

Developed by ICAP at Columbia University.

Disclaimer

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These materials are in the public domain, and we hope that they can play a useful role as part of the ever-expanding "toolbox" of guidelines and manuals being developed to support HIV testing and treatment services globally. This *Handbook* may be freely modified and adapted to country programs' needs and to changes in technology, policy and guidelines.

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TABLE OF CONTENTS

Figures

Tables

ABBREVIATIONS AND ACRONYMS

5Cs	consent, confidentiality, counselling, correct, connection
A1	first-line assay
A2	second-line assay
A3	third-line assay
AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	antiretroviral therapy
CD4	CD4+ T-lymphocyte cell count
CDC	United States Centers for Disease Control and Prevention
DNA	deoxyribonucleic acid
EIA	enzyme immunoassay
ELISA	enzyme-linked immunosorbent assay
EQA	external quality assurance
HIV	human immunodeficiency virus
HIVST	HIV self-testing
HTS	HIV testing services
IEC	information, education, communication
MOH	Ministry of Health
NAT	nucleic acid testing
NABSA	nucleic acid sequence-based amplification
PEPFAR	United States President's Emergency Plan for AIDS Relief
PLHIV	people living with HIV
PMTCT	prevention of mother-to-child transmission (of HIV)
QA	quality assurance
QI	quality improvement
RDT	rapid diagnostic test
RNA	ribonucleic acid
SOP	standard operating procedure
TB	tuberculosis
UCSF	University of California, San Francisco
UVRI	Uganda Virus Research Institute
WHO	World Health Organization

GLOSSARY

Assay: a complete procedure for detecting the presence of or the concentration of an analyte, including all the components of a test kit used to identify HIV-1/2 antibodies. There are usually 3 or 4 assays in a national testing algorithm.

A1, A2, A3: refers to the first assay (A1), the second assay (A2), and the third assay (A3) in a testing algorithm. A1- means that the result of the first assay was HIV negative. A1+ means that the result of the first assay was HIV positive.

Discordant retesting for verification result: a negative or "inconclusive" retesting for verification event result. This result differs from the initial testing event positive result.

External quality assessment (EQA): inter-laboratory comparison to determine if the HIV testing service can provide correct test results and diagnosis.

Generalized epidemic: HIV is firmly established in the general population. Although subpopulations at high risk may contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain the epidemic. Numerical proxy: HIV prevalence is consistently over 1% in pregnant women attending antenatal clinics.

Healthcare provider: a trained professional who provides health-related services to a patient, including but not limited to medical and nursing services as well as psychosocial counselling and support.

Key populations: defined groups who, due to specific higher-risk behaviours, are at increased risk for HIV irrespective of the epidemic type or local context. The WHO (July 2015) *Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection* refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers, and transgender people.

Lay provider: any person who performs functions related to healthcare delivery and has been trained to deliver specific services but has not received a formal professional certificate or tertiary education degree.

Nucleic acid testing (NAT): also referred to as molecular technology; for example, polymerase chain reaction (PCR) or nucleic acid sequence-based amplification (NASBA). This type of testing can detect very small quantities of viral nucleic acid, that is, ribonucleic acid (RNA) (quantitative) or deoxyribonucleic acid (DNA) (qualitative).

Pre-test information: a dialogue and the provision of accurate information by a trained lay provider or healthcare provider and a client before an HIV test is performed.

Post-test counselling: a dialogue between a trained lay provider or healthcare provider and a client tested for HIV after HIV testing is conducted. The content of the post-test counselling session—which includes education, counselling and support—is based on the specific HIV testing procedure conducted (e.g., NAT or RDT) and HIV status reported.

Qualitative PCR: PCR test to detect specific HIV viral DNA (e.g., early infant HIV diagnosis testing).

Quality assurance (QA): a part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality control/process control (QC): a material or mechanism which, when used with or as part of a test system (assay), monitors the analytical performance of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it.

Quality improvement (QI): a part of quality management focused on increasing the ability to fulfil quality requirements.

Quality management system: a system to direct and control an organization with regard to quality.

Quantitative PCR: a test used to detect extracellular viral RNA in the plasma (e.g., viral load test**).**

Rapid diagnostic test (RDT): in vitro diagnostic of immunochromatographic or immunofiltration format for, in the case of HIV diagnosis, the detection of HIV-1/2 antibodies and/or HIV p24 antigen.

Repeat testing: refers to a situation where additional testing is performed for an individual immediately following initial test results, within the same testing visit, using the same assays and, where possible, the same specimen.

Retesting: There are certain situations in which individuals should be retested after a defined period of time: (1) HIV-negative people with recent or ongoing risk of exposure, (2) people with an HIV-inconclusive status and (3) HIV-positive people before they enrol in care or initiate treatment. Reasons for retesting before initiation of care or treatment include ruling out laboratory or transcription error and either ruling in or ruling out seroconversion.

Retesting for verification: testing of a new specimen for newly diagnosed individuals and those previously diagnosed but not yet initiated on antiretroviral therapy (ART), conducted by a different provider using the same testing algorithm, prior to or at the time of initiation of ART.

Self-testing (HIVST): the process by which an individual who wants to know his or her HIV status collects a specimen, performs a test, and interprets the result by him- or herself, often in private. Reactive test results must be followed by additional HIV testing services.

Sensitivity: denotes the probability that an HIV assay will correctly identify all specimens that contain HIV-1/2 antibodies and/or HIV p24 antigen.

Specificity: denotes the probability that the assay will correctly detect specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.

Supplemental assay: an assay that provides additional information for specimens that a first-line assay has found to be reactive but may not be able to definitively confirm that reactivity.

Targeted rollout: when an initiative (such as retesting for verification) is implemented in specific areas or settings, or with specific populations, before full national scale-up to evaluate feasibility, time, cost, staff training requirements, and barriers to implementation in an attempt to improve upon the design prior to full-scale rollout.

Testing algorithm: the combination and sequence of specific assays used within HIV testing strategies.

Testing event or **retesting for verification event:** when a new specimen is tested using the entire 2 or 3-test kit national algorithm.

Testing strategy: a testing sequence for the specific testing objective of diagnosis, taking into consideration the presumed HIV prevalence in the population being tested.

Test and treat: the provision of ART to all clients, or all clients within a specific population (e.g., pregnant women) who test HIV positive without regard for clinical or immunological status. Also referred to as "treat-all approach," "universal ART," or "test and start."

1. ABOUT THIS HANDBOOK

Audience: This *Handbook* was written for professionals working for national Ministries of Health (MOHs) in low- and middle-income countries. It is also designed to be a useful resource for subnational program managers, faith-based organizations, and non-profit organizations, including those with responsibility for planning, rolling out, and monitoring and evaluating HIV testing and antiretroviral therapy (ART) services. This *Handbook* may also be a resource for healthcare and lay providers implementing HIV testing services (HTS) and ART services as well as other organizations who are engaged, formally or informally, in the implementation of these services.

Purpose: The purpose of this *Handbook* is to discuss operational considerations for implementing and/or scaling up retesting for verification prior to/at ART initiation for individuals diagnosed as HIV positive, as recommended by the World Health Organization (WHO) and national guidelines. This *Handbook* also provides guidance on how to take national recommendations from policy into practice, first by targeted rollout, then by national scale-up. This *Handbook* aims to:

- Summarize the evidence in support of retesting for verification
- Offer guidance to countries wishing to include retesting for verification in their national policy documents
- Offer a step-by-step approach to scaling up retesting for verification, whether alone or as part of efforts to roll out universal ART

Context: The recommendation to retest for verification is made with full awareness of many of the barriers to implementation. In late 2016, ICAP at Columbia University had 29 discussions with stakeholders from five of the Rapid Testing Continuous Quality Improvement (RTCQI) (formally known as the Rapid Testing Quality Improvement Initiative) countries. Four of the five countries either already recommended retesting for verification or were in the process of updating their guidelines to recommend retesting for verification. These stakeholders described their HTS, testing external quality assurance (EQA) programs, and general access-related challenges as well as quality assurance challenges. They also provided an overview of retesting for verification procedures (where retesting was already recommended by national policy) and a description of operational challenges faced in implementing retesting for verification, or preconditions for the country to consider adopting retesting for verification. The findings from these discussions informed the breadth and depth of the content of this *Handbook*.

2. BACKGROUND

In late 2014, WHO released an Information Note[i] reminding MOHs and National AIDS Control Programs to retest all persons diagnosed as HIV positive, at the time of, or prior to, ART initiation, to rule out potential misdiagnosis. ***Retesting for verification*** is a quality assurance (QA) activity that refers to the testing of a new specimen for newly diagnosed individuals and those previously diagnosed but not yet initiated on ART, conducted by a different provider using the same testing algorithm. In contrast, ***supplemental testing*** refers to further testing of the same specimen with additional assay(s) to obtain more information.[ii]

Some think that the use of the second or third assay in the algorithm is "retesting for verification." <u>It is not!</u> The second and third assays in the country algorithm are used to confirm the initial

reactivity on the first assay; the result after each of the assays is either reactive or nonreactive. A diagnosis of HIV positive or HIV negative is only made after the algorithm of 1 (if nonreactive), 2 or 3 tests has been completed. Therefore "retesting for verification" is the completion of the entire algorithm of 2 or 3 assays/test kits a second time; a total of 4 (in high prevalence settings) or 6 (in low prevalence settings) test kits should be used to confirm an HIV positive result through the initial HIV testing event and retesting for verification event.

Box 1: HIV Rapid Testing Algorithms

The combination of assays used in a testing algorithm(s) should be validated at the national or subnational level.

- First-line assays (A1) should identify any potential HIV positive specimen and, thus, have superior diagnostic **sensitivity**.
- Second-line (A2) and third-line (A3) assays are used to confirm the initial reactivity observed in the first-line assay, and so they should have superior diagnostic **specificity**, to rule out false reactivity.

It is essential to minimize the potential for shared false reactivity through careful selection of the combination of HIV assays used by validating testing algorithms. The choice of A1, A2, and A3 assays all must be validated. Where possible, assays based on different antigen preparations should be used in combination.[iii] The tiebreaker approach is not recommended. See the testing strategies for HIV diagnosis in high and low prevalence settings in Appendix 1.

Why is retesting for verification being addressed now? HIV retesting for verification has been recommended by WHO since 2012,[iv] but implementation of this policy has been slow. Until recently, CD4 testing was often used to provide guidance on whether an individual testing positive for HIV should start ART. This type of immunological testing indirectly confirmed HIV diagnosis. If the CD4 remained high over several years, it raised a flag about the accuracy of the HIV diagnosis.

In 2012, WHO published a programmatic update that supported ART initiation based solely on diagnosis by RDT for pregnant and breastfeeding women.[v] In 2013, the WHO guidelines also recommended ART initiation based solely on diagnosis by rapid diagnostic test (RDT) (i.e., regardless of CD4 count) for serodiscordant couples, people with active tuberculosis (TB) disease, hepatitis B (HBV) coinfection and severe chronic liver disease, and children less than 5 years of age. The 2016 recommendations went one step further, recommending ART initiation for ***everyone*** living with HIV—adults, adolescents, children, and infants, regardless of WHO clinical stage or CD4 cell count; this is referred to as universal access to ART.[vi] This is also commonly referred to as "test and start" or "test and treat."

The 2016 recommendation to provide universal access to ART is based on evidence that has accumulated since the release of WHO's previously published guidelines in 2013. New research shows that initiating ART earlier reduces acquired immune deficiency syndrome (AIDS)-related and non-AIDS-related conditions and improves survival.[vii,viii,ix] In addition, evidence from a large randomized controlled trial indicated that earlier ART can markedly reduce the risk of sexual transmission to HIV negative sexual partners among heterosexual couples.[x] Other research has shown that earlier ART (i.e., before conception, where possible) clearly reduces rates of mother-to-child HIV transmission (MTCT).[xi]

Where there is universal access to ART or access without immunological testing, there are no laboratory tests that, in effect, provide additional evidence of the presence of HIV infection. CD4 count was previously used to follow HIV infection over time and as CD4 dropped, patients became eligible for treatment. However, without the routine use of CD4 counts to assess ART eligibility, there is no

additional laboratory marker of HIV infection. This underscores the importance of retesting for verification in the era of test and treat to ensure patients are truly positive before starting them on lifelong medications. Many who are eligible for ART initiation under these guidelines will have high CD4 counts, which is why we need to retest for verification before starting patients on ART. As such, it is critical that policy-makers, program managers, and health care providers be aware of and reduce the risk of misdiagnosis of HIV status. Misdiagnosis, irrespective of its scale, is of critical importance. Any incorrect diagnosis, whether a false-positive or a false-negative, has deleterious personal and public health consequences, often with severe repercussions. Retesting for verification helps minimize misdiagnosis.

Box 2: Confirmatory testing

Some countries refer to retesting for verification as "confirmatory testing;" however, in this *Handbook* the term **retesting for verification will be used when referring to the testing of a new specimen from newly diagnosed individuals and those previously diagnosed but not yet initiated on ART, conducted by a different provider using the same national HIV testing algorithm**. Furthermore, some countries refer to the second or third test in the national HIV testing algorithm as "confirmatory testing." Remember that the second and third assays in the national HIV testing algorithm are used to confirm the initial reactivity on the first assay and is **not** retesting for verification.

Who should be retested for verification? *All* newly diagnosed HIV positive individuals and *all* HIV positive individuals who are not yet initiated on ART (e.g., pre-ART clients) should be retested for verification. Retesting for verification is applicable in all settings without regard to ART initiation criteria. This applies to paediatric patients 18 months or older, adolescents, and adults (including pregnant and breastfeeding women).

How does retesting for verification support global targets? HTS as well as universal access to ART are important strategies that underpin country efforts to identify and provide treatment for their citizens with HIV, supporting their ability to meet the Joint United Nations Programme on HIV/AIDS 90-90-90 global HIV targets by 2020:

- 90% of all people living with HIV will know their HIV status
- 90% of all people with diagnosed HIV infection will receive sustained ART
- 90% of all people receiving ART will have viral suppression

Given the importance of early initiation of ART for the benefit of the patient and because it reduces risk of further transmission to partners and from mother to child, more national programs have been scaling up and decentralizing HTS to increase the percentage of people living with HIV who know their HIV status. Even though this has made HTS more accessible to more people, it has also resulted in testing being carried out in some settings without necessary QA measures, thereby increasing the potential risk of error. Retesting for verification addresses this potential risk of error.

Why is it important to verify the diagnosis of HIV positive persons as part of initiating ART? When QA measures are implemented, the performance (sensitivity and specificity) of WHO-prequalified HIV RDTs performed by both laboratory technicians and trained HIV testing providers in resource limited settings is excellent. However, the use of highly sensitive and specific assays is not enough to ensure that an accurate HIV status is always given.[xii] Audits across multiple countries have shown evidence of false-positive diagnoses.[xiii] Although the extent of misdiagnosis is uncertain, the accumulation of evidence

suggests that HIV misdiagnosis occurs. Furthermore, the cost of retesting for verification is minimal in comparison to the cost of lifetime ART for those falsely testing positive.

The aim of retesting for verification is to rule out possible technical or clerical errors, including specimen mix-up through mislabelling and transcription errors, as well as random error either by the provider or the test device. It is important to note that retesting will not exclude misdiagnosis related to poor choice of a testing algorithm. However, this risk should be minimal assuming the testing algorithm is validated.[xiv] Always follow the approved national HIV testing algorithm and ensure adherence to quality testing program with continuous QA.

Isn't retesting for verification wasteful? Just the opposite: retesting for verification actually *prevents* the wasting of resources. Retesting for verification ensures that individuals are not needlessly placed on ART nor needlessly put at risk of the side-effects that can occur with ART. Retesting for verification avoids the psychological impact of an incorrect HIV positive diagnosis.

3. MISDIAGNOSIS AND COST OF RETESTING FOR VERIFICATION

***Why* does HIV misdiagnosis happen?** HIV misdiagnosis can be the result of poor quality HIV testing, which can result from a number of factors including:

- Not following the national HIV testing algorithm
- Poor product performance
- Improper transport or storage of test kits and supplies
- Clerical or transcription errors
- Not following the test kit manufacturer instructions; user errors in performing the test and/or interpreting the test result
- Lack of tester training
- Improper use of the testing strategy and/or algorithm
- Lack of supportive supervision and training
- Lack of standard operating procedures (SOPs)
- Poor documentation and record-keeping practice

Is misdiagnosis of HIV common? Retesting all individuals diagnosed HIV positive in Democratic Republic of Congo with Western Blot found that 10.5% had an initial false-positive result.[xv] In an evaluation of three programs conducted by Médecins Sans Frontières, patients deemed high risk for false-positive diagnosis based on high CD4 count were retested; 10.3 % were found to be misdiagnosed HIV positive in the Democratic Republic of Congo and 4.7% in Ethiopia.[xvi] In Malawi, during a three-month period in 2014, 7% of people previously diagnosed HIV positive who were retested for verification did not have a concordant HIV positive status and may have been misdiagnosed. Following quality improvement (QI) and re-training; during another three-month period in 2014, only 4% of the people

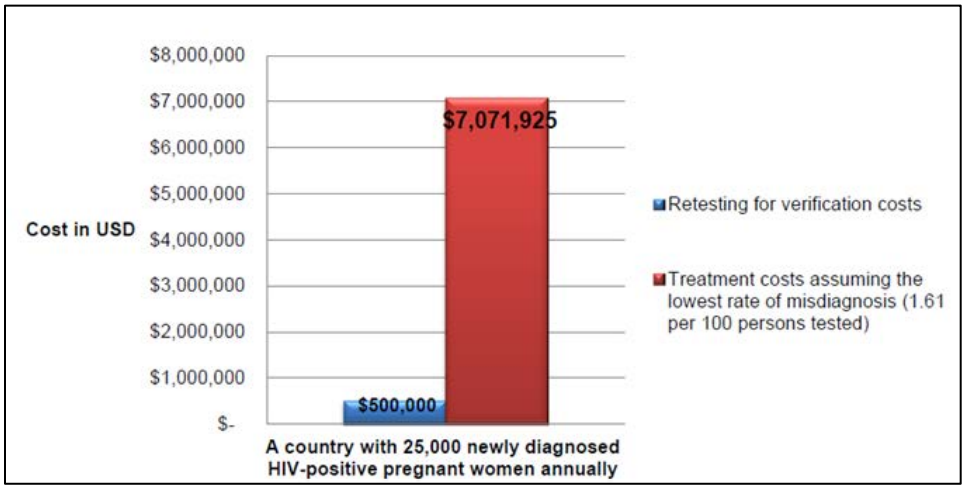
previously diagnosed HIV positive who were retested for verification before ART initiation had discordant results.[xvii] The rate of false-negative HIV results reported (people infected with HIV who are told they are not infected) remains unknown and is difficult to assess, as there is no routine follow-up for people who receive an HIV negative diagnosis.

More information on accuracy of HIV testing programs can be found in Annex 9: Technical guidance update on quality assurance for HIV rapid diagnostic tests in the WHO (July 2015) *Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection*.

Isn't retesting for verification expensive? Programs that have implemented retesting for verification have noted that they were able to do so with minimal costs, which more than paid for itself. In the WHO (July 2015) *Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection*, WHO used the following example of pregnant women to illustrate this point: in resource-constrained settings, total discounted lifetime treatment costs of HIV are estimated at US$17,570 per person given a life expectancy of 30 years from ART initiation and median annual ART costs of $880.[xviii] Assuming a rate of misdiagnosis of 4 per 100 persons tested (mean across all RDTs performed), the per-person cost of retesting would have to be greater than a threshold of (17,570*4/100) = US$703 to outweigh the treatment costs associated with misdiagnosis. Economic evaluations suggest that the cost of testing in healthcare settings using the national validated testing algorithm ranges from US$5–$20 per person; this includes all relevant direct costs such as testing materials, staff time, and administrative overhead. These testing costs are 35- to 140-fold smaller than the aforementioned threshold. Assuming the lowest rate of misdiagnosis, 1.61 per 100 persons tested, the threshold would be US$283, which is 14 times greater than a retesting cost of US$20; or, for every US$20 spent on retesting, a minimum of US$263 is saved in averted treatment costs.

The total cost of retesting for verification all newly diagnosed HIV positive pregnant women will vary based on each country's HIV positivity rate among pregnant women. In adopting a policy of retesting for verification of all newly diagnosed HIV positive pregnant women, under the most conservative assumptions, a country with 25,000 newly diagnosed HIV positive pregnant women annually would spend (25,000*$20) = US$500,000 on retesting for verification and conservatively save (25,000*1.61/100*$17,570) = US$7,071,925 in averted treatment costs, for net medical savings of US$6,571,925.[xix]

Figure 1. Cost of retesting for verification compared to treatment costs of false-positives



These examples indicate that retesting for verification is far less expensive than lifetime ART for those with false-positive HIV status even in settings where false-positive diagnosis rates are low and retesting costs are high. These calculations do not consider the mental and psychological costs that may be associated with HIV diagnosis.

What are the non-financial costs of diagnosing someone with HIV who isn't actually infected? The false HIV positive diagnosis and initiation of ART in a person who is actually HIV negative may result in unnecessary side effects of ART, individual stress due to stigma, and loss of confidence in HIV testing in the community.

What is the cost of implementing HIV retesting for verification? If HIV testing and ART services have already been scaled up, then the cost of HIV retesting for verification includes the following expenses associated with only the incremental cost of retesting for verification:

- Update of HIV testing, HIV treatment, laboratory, and other national guidelines documents
- Update of all monitoring tools, e.g., HTS and ART registers/databases, to include documentation of initial HIV testing and retesting for verification of key quality elements (for more information, see "Section 9: Monitoring and Evaluation of HIV Retesting for Verification" in this *Handbook*)
- Update of QA programs to include retesting for verification
- Revise training curriculum, training of trainers, and training of health care and lay providers and laboratory staff to include retesting for verification
- Establishment of external on-site quality assessment and supervision at all testing sites
- Ensure supply chain reliability by calculating the additional test kits needed for retesting for verification and adjusting forecasting as needed

Variable costs associated with the scale-up and implementation of retesting for verification will include:

- Hire of additional staff to administer the tests, read the result, provide the result to the patient, and record the result in the relevant registers/databases
- Hire of supportive supervision staff for HTS and QA of HIV testing
- Purchase of additional test kits (annual costs are based on the number of HIV positive test results/year as retesting for verification only done for those testing positive)
- Routine quality control (QC) of test kits

However, as previously discussed, this cost should pay for itself under the assumption that fewer people will be tested falsely positive and needlessly initiated on ART.

Who should pay for the test kits for retesting for verification? HIV retesting for verification can be integrated into the budget for HTS as a standard-of-care QA measure, or it can be included in the care and treatment budget.[xx]

4. OPERATIONALIZING GLOBAL RECOMMENDATIONS

What testing algorithm should be used during retesting for verification? The current national HIV rapid testing algorithm should be used on a new specimen, preferably performed by a new tester. Therefore, at the site-level, new types of diagnostic tests will not be needed. However, some countries may want to include a highly specific test for discordant results (see "Section 6: Discordant Results when

Retesting for Verification"), but this testing would be conducted in a laboratory. Also, in certain countries (e.g., West Africa) the retesting for verification algorithm may include a test that differentiates between HIV-1 and HIV-2 since HIV-2 diagnosis requires a different ART regimen; this confirmation is not performed at the site level.

My country's national algorithm uses two tests. If the result of the first testing event is inconclusive, patients are referred to come back after 14 days for a second testing event. Does this count as a retesting for verification event? No, the second testing event does NOT replace retesting for verification. If a patient tests positive at the second testing event, a new provider will need to conduct retesting for verification by repeating the testing algorithm one additional time. However, this can be done on the same day as the second testing event to save time. This can be communicated to the patient as a way to potentially handle challenges around having to conduct additional testing.

Why is a new specimen necessary for retesting for verification? Obtaining a new specimen facilitates identification of errors related to specimen mix up or incorrect specimen collection or processing.

How should my program prepare to ensure we have enough test kits and consumables before implementing retesting for verification? Stock-outs of HIV test kits or essential testing consumables, such as lancets, alcohol swabs, or specimen transfer devices, are one of the biggest sources of poor quality and client dissatisfaction with HTS.[xxi] Ideally, before retesting for verification is implemented, accurate forecasting and supply planning (i.e., quantification) and procurement systems are recommended to be in place and functioning at national, subnational, and local levels to avoid stock-outs. As HTS are generally integrated with other services, so too should be the forecasting, stock management, and procurement of supplies.

Retesting for verification data can be used for post-market surveillance and as an opportunity to revisit supply chain management issues and identify new ideas to resolve problems. Use retesting for verification to improve/refine forecasting systems, supply chain management and storage of supplies.

Can Global Fund monies be used to improve our quantification systems? Yes, Global Fund money can be used to support scale-up of retesting for verification activities, including efforts to prevent stock-outs. In theory, retesting for verification should pay for itself by preventing unnecessary initiation of ART in individuals incorrectly diagnosed with HIV. See "Section 3: Misdiagnosis and Cost of Retesting for Verification".

What is the role of the local HTS or ART services in preventing stock-outs? Clinics providing HIV testing must ensure that an adequate system is in place to:

- Track procurement of test kits, reagents, and consumables: when they are ordered and when received
- Track consumption of all test kits and consumables so that they can inform the central medical stores (or other purchasing body) when they need to replenish stock
- Take note of expiry dates and order ahead, allowing adequate time for the next delivery

In addition, national and subnational authorities as well as local providers will need to:

- Maintain a list of inventory requirements, for example, assays, consumables or additional supplies such as gloves, lancets, alcohol swabs, and disposal containers.
- Ensure adequate physical space to store test kits (including refrigeration if room temperature is above manufacturer's recommended storage conditions) and record storage temperatures.

Further information is available in WHO Manual for Procurement of Diagnostics and Related Laboratory Items and Equipment (http://www.who.int/medical_devices/publications/manual_lab_items/en/).

What should providers do when they do not have all of the rapid HIV test kits in the algorithm (due to, for example, stock-outs or kit expiration)? Deviation from the national HIV testing algorithm due to the unavailability of any of the assays in the algorithm is a common reason for misdiagnosis. Do not give a final HIV *positive* diagnosis based on a single HIV RDT result! In the context of retesting for verification, the provider should inform the client that they do not have all the tests kits required to verify their initial diagnosis. From here, there are two possible scenarios the provider can pursue depending on which kits are available and national/clinic policy:

- If A1 assay is available: In situations where only the first assay in the algorithm is available, where the first assay is reactive (A1) and the second (A2) and/or third assays (A3) are not available, the client should be scheduled to return as soon as all assays are available or immediately referred to another clinic where all assays are available.
- If A1 assay is NOT available: In situations where only A2 or A3 of the testing algorithm is available, do not conduct HIV testing until A1 is available! All clients should be scheduled to return as soon as all assays are available or referred to another site where all assays are available. A2 and A3 assays are selected to be the most specific assays; however, this may be at the expense of sensitivity, thereby increasing the risk of a false negative result.

Which algorithm do I use to verify an individual's initial diagnosis if my country has more than one algorithm? Some countries have two rapid testing algorithms; typically, the second is for use during stock-outs. WHO recommends that the same algorithm be repeated to verify someone's initial diagnosis. If more than one algorithm is approved for use in your country it may not be possible to know which algorithm was conducted on a given individual. Providers should adhere to national guidelines and use the primary algorithm when available. In situations where an individual's retesting for verification result is negative, it will be important for providers to ascertain where the initial testing was conducted and determine if the same algorithm was performed for both the initial and retesting for verification events.

For more information on algorithms, see Annex 7: Diagnostics for HIV Diagnosis in the WHO (July 2015) *Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection*.

Should individuals who test HIV negative be retested for verification? No, retesting for verification is only for individuals with an HIV positive diagnosis. HIV negative individuals who report recent or ongoing risk of exposure should be retested at least annually, or more often depending on client risk behaviours. In generalized epidemics, all HIV negative pregnant women should be retested according to national guidelines, including testing in the 3rd trimester, at labour and delivery, and throughout the breastfeeding period. For most people who test HIV negative, additional retesting to rule out being in the window period is not necessary and may waste resources.

Refer to WHO's *Delivering HIV Test Results and Messages for Re-testing and Counselling in Adults* (http://www.who.int/hiv/pub/vct/hiv_re_testing/en/) for detailed and specific guidance on messages concerning retesting.

Should individuals previously diagnosed with HIV and established on ART be retested for verification? No, once a person is established on ART they should not be retested using RDTs, as RDTs may not accurately reflect their true HIV status. ART suppresses viral replication, and in some individuals, may also suppress the immune response and, thus, antibody production. Therefore, a non-reactive RDT may be possible when conducted on HIV-infected individuals on ART.

Individuals undergoing HIV testing must be made aware of the risk of incorrect diagnosis if they do not disclose that they are on ART. All individuals receiving HIV testing should be asked if they have been tested previously, have previously been told they were HIV-infected, and/or if they are now on ART or have ever received ART.[xxii]

Note: The recommendation to avoid retesting the individual on ART does not refer to retesting for verification in settings where the individual might be started on ART upon receipt of the initial HIV positive diagnosis (e.g., same-day ART initiation for pregnant or breastfeeding women testing HIV antibody positive). In these cases, retesting for verification is conducted when the initial HIV positive test is received. If ART is started that day as well, it will not affect the HIV testing result, as an individual on ART for a few hours will be insufficiently virally suppressed to affect HIV test results.

I have a patient who has been on ART for over a year, but he insists that he was never HIV-infected in the first place and he says that his HIV-antibody test last year was incorrectly positive. What should I do? A patient suspected of having been incorrectly diagnosed with HIV and put on ART, can be retested using laboratory-based diagnostics (e.g., qualitative DNA PCR) to verify their status. Note, viral load testing (quantitative PCR) cannot be used to rule out HIV infection, or confirm a negative HIV diagnosis. Viral load testing is intended as a patient monitoring tool and not as a diagnostic test.

5. WHEN AND WHERE OF RETESTING FOR VERIFICATION

When and where should retesting for verification take place? Ideally, retesting for verification should occur at the site of ART initiation. This helps to ensure that the provider knows the patient's test result has been verified, and reduces the potential for unnecessary repeat retesting (see Figure 2). Actual timing of the retest may depend on the setting and availability of ART at the location where the initial HIV testing event occurred. Possible scenarios for how/when retesting for verification can occur include:

- Integrated HIV testing and ART services: retesting for verification may be done immediately (same day) following the initial diagnosis at service delivery points where ART initiation is available. For example, patients testing HIV positive in antenatal care (ANC) or a TB clinic may be retested for verification immediately. Where possible, retesting for verification should be conducted by a different healthcare provider. Whether conducted by the same or a second healthcare provider, retesting for verification must always be conducted using a new specimen.

Stand-alone HTS and ART sites: retesting for verification may occur on the same day (if the ART site is able to receive the client) or at another point in time. For co-located HTS and ART sites (i.e., the HTS and ART site are conducted by different providers on the same day in proximity to each other, perhaps down the corridor), same-day retesting for verification should be feasible and supported by escorting the patient to the ART site. If the HTS and ART sites are not in proximity, same-day retesting for verification should be supported however possible (e.g., transportation services and/or outreach workers/peer navigators) to avoid loss to follow-up. In both situations (co-located or not), referral and tracking systems need to be in place to ensure that clients are linked to care as soon as possible. For QA purposes HTS providers should verify that newly diagnosed individuals have linked to care, and what the results of their retest for verification are in order to monitor discordant results and use data to inform quality improvement (QI) efforts.

Our national algorithm calls for testing in a series (serial testing), but for retesting for verification, can we use the same tests, in the same order but administer them in parallel? Yes, when conducting retesting for verification, it can be prudent to use a parallel testing algorithm (i.e., where A1 and A2 are run simultaneously) to save time.[xxiii] The decision to adopt parallel testing for retesting for verification should be made at the discretion of the country program. If your program decides to adopt parallel testing during retesting for verification, it is crucial that healthcare workers are properly trained on how to do parallel testing and understand in what circumstances it is appropriate to use this method.

Can the ART site combine retesting for verification with the other routine laboratory testing? Where the ART site has limited staff, retesting for verification might be ordered along with the other recommended laboratory tests for ART initiation (e.g., haemoglobin test, serum creatinine, etc.) using the sample obtained for the other recommended tests. In these instances, the retesting for verification result may not be immediately available, in which case the provider can initiate ART; ART can be later discontinued should the retesting result be HIV negative. If it is not feasible for the site initiating ART to support retesting for verification, another testing site in the vicinity that has a system in place for communicating the retesting for verification result with the ART site may be used.

How might retesting for verification work for clients who test for triage? Test for triage methods, including community testing and HIV self-testing, do not provide a definitive diagnosis. A reactive self-test result always requires additional testing according to a validated national diagnostic testing algorithm. A person who self-refers for HTS or ART after self-testing should be properly tested using the two- or three-test national algorithm. If the HIV testing event yields an HIV positive result, the client should be retested by a different provider, using a new specimen, and following the same algorithm to verify the initial test result. As previously mentioned, retesting for verification should ideally take place where ART will be initiated.

6. DISCORDANT RESULTS WHEN RETESTING FOR VERIFICATION

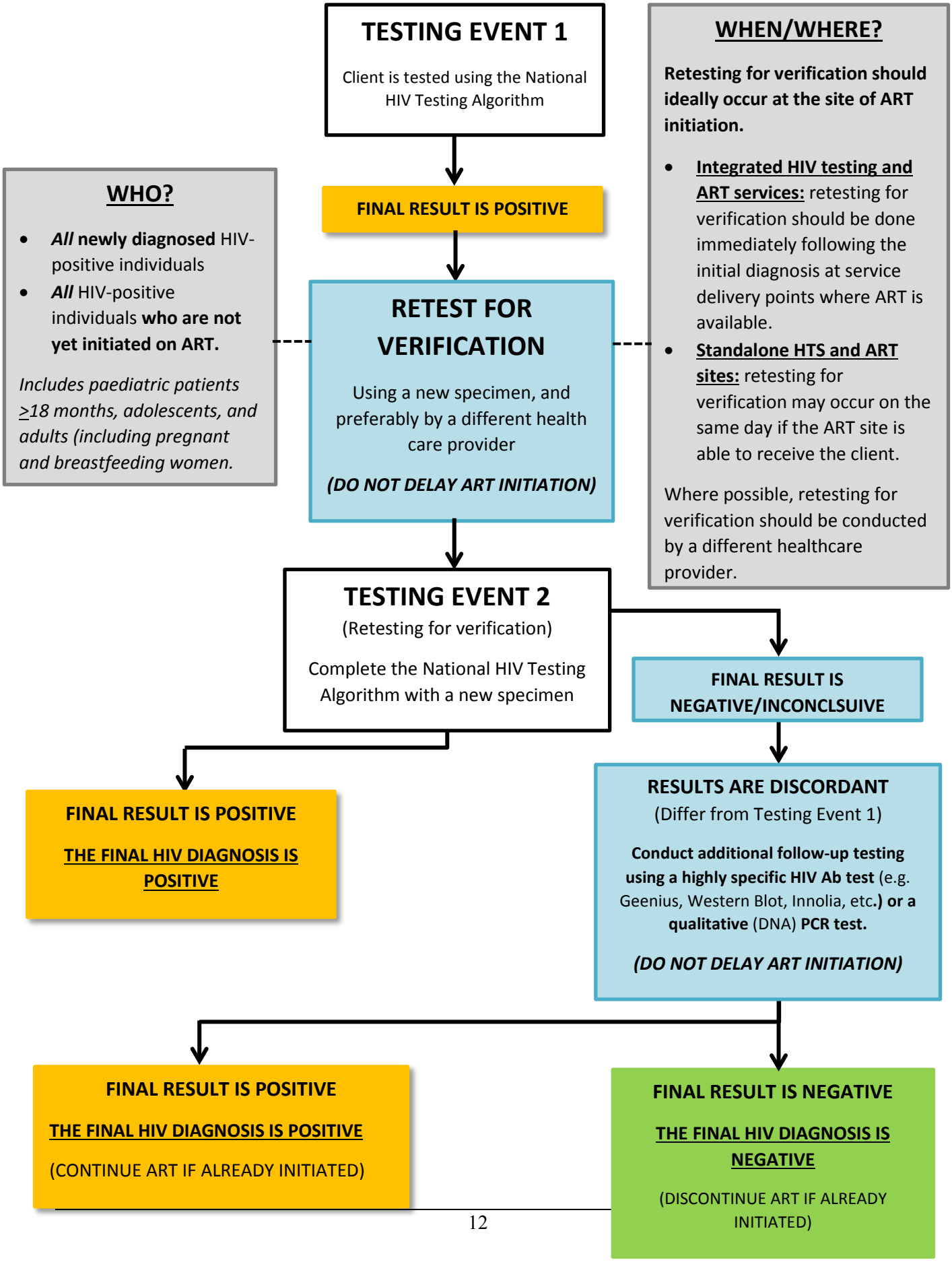
What if, upon retesting for verification, a patient tests HIV negative or inconclusive (i.e., different from the initial HIV testing event result)? If retesting for verification provides an HIV negative or inconclusive result, the results are discordant from the initial testing event (positive). The discordant result should not prevent the individual from being initiated onto ART within the local context and policy guidelines. All individuals (especially pregnant and breastfeeding women, children, and adults with WHO stage III/IV) should be initiated on ART and additional follow-up testing should be conducted by referring the patient to a higher level facility or laboratory for testing with a highly specific HIV antibody test (e.g., Geenius, Western Blot, Innolia, etc.) or with a qualitative DNA PCR test. It is important to use these highly specific tests rather than repeat the national algorithm for a third time because they are more likely to give a correct diagnosis. Based on the final result of the additional follow-up testing, the individual can continue on ART or be discontinued from ART (see Figure 2).

Is it necessary to start ART while waiting for results of additional follow-up testing if the retesting for verification result is discordant? Waiting for return of results should not delay ART initiation within the local context and policy guidelines. Programs should ensure there is a system in place for follow-up with the patient and continuous linkage to care during this timeframe. If the HTS program has a high rate of inconclusive/discordant results, this is indicative of a quality assurance issue that should be resolved before implementing retesting for verification.

Can an enzyme-linked immunosorbent (ELISA) or enzyme immunoassay (EIA) be used when the retesting for verification result is discordant from initial testing event result? Use of ELISA or EIA is NOT recommended as additional follow-up testing when there are discordant results. Although EIA is very sensitive, it is not ideal for confirming HIV infection because of low specificity (i.e., the EIA may yield a false-positive result in circumstances such as this).[xxiv]

Should viral load testing (quantitative RNA PCR) be used to confirm HIV diagnosis as part of the retesting for verification process in place of an RDT-based algorithm? No. Viral load is intended as a patient monitoring tool, not as a diagnostic test. Although detectable viral load can confirm an HIV positive diagnosis, **an undetectable viral load cannot be used to rule out HIV infection (or confirm negative diagnosis**) because some HIV positive individuals will maintain very low viral loads, even in the absence of treatment.

Figure 2: Retesting for Verification prior to/at ART Initiation Flowchart



7. COUNSELLING MESSAGES

Concise HIV pre-test information is provided before an individual is tested for HIV, and HIV post-test counselling when the individual is presented with their result. The messages in the pre- and post-test session will differ depending on context and client need but generally follow the outline provided in the WHO (July 2015) *Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection*.

With the introduction of retesting for verification, the post-test session for those who are HIV negative does not change. However, there will be minor modifications to the pre-test information and the post-test counselling session for those who are HIV positive. The messages around retesting for verification are discussed below for pre-test information and post-test counselling.

Pre-test information and post-test counselling should highlight that those who test positive will be retested for verification. Counsellors should emphasize "the why" of retesting for verification to ensure that trust in the testing process is not compromised, and explain that it is good clinical practice to retest patients to ensure their HIV status before initiating them on ART. It is important that the patient undergo the entire recommended pre- and post-test counselling sessions at the initial testing event. Counselling at the retesting event may be brief since they have had already had a full counselling session at the first testing event and to avoid further delay in the patient receiving their diagnosis. This is an important way to save time when conducting retesting for verification.

Incorporating retesting for verification into pre-test information messages

Should I mention retesting for verification in the pre-test information session? Yes, the routine pre-test session as recommended by national testing protocol, should include the following (these messages will need to be adapted based on setting, local process, the overall pre-test script, and national guidelines):

- *Treatment guidelines have recently changed. The new guidelines state that everyone testing HIV positive is eligible for treatment, so we no longer use CD4 results to determine ART initiation. The best way to verify your result is to retest for verification. This is particularly important since people with HIV may not have any signs or symptoms.*

Depending on the location of the ART site, tailor your message further as follows:

- Integrated HIV testing and ART services*: Should you test HIV positive, we will take another specimen and test you a second time to make sure the first test result was a correct result.*
- Standalone HTS and ART sites*: Should you test HIV positive, another specimen will be taken at the ART clinic to test you for HIV a second time to make sure the first test result was a correct result.*

What do I tell patients who are on pre-ART that are being brought back for retesting for verification? Follow the routine pre-test session as recommended by the national protocol, and include the following (these messages should be adapted based on setting, local process, the overall pre-test script, and national guidelines):

- *Treatment guidelines have recently changed. The new guidelines state that everyone testing HIV positive is eligible for treatment, so we no longer use CD4 results to determine ART initiation. Since you have been previously diagnosed HIV positive but are not yet on ART, we want to verify your diagnosis today before initiating you on lifelong treatment. The best way to verify your diagnosis is to retest for verification. If we verify that you are HIV positive today, we will initiate you on ART.*

Tailor the message as recommended above depending on the location of the ART site.

Retesting for verification, post-test counselling messages:

In the post-test session, what do I tell the individual who tests HIV positive to explain why we have to retest for verification? The healthcare provider should tell the client that (these messages will need to be adapted based on setting, local process, the overall post-test script, and national guidelines):

- Integrated HIV testing and ART services*: When someone tests HIV positive, it is now standard procedure to draw another specimen and retest that specimen to make sure the initial test result was correct. This is considered good clinical practice to verify a test result that has personal and lifelong treatment implications. I will take another specimen now. You should expect the retest for verification result in ___ (fill in timeframe, e.g., minutes, hours, days).*
- Standalone HTS and ART sites*: When someone tests HIV positive, it is now standard procedure to draw another specimen and retest that specimen to make sure the initial test result was correct. This is considered good clinical practice to verify a test result that has personal and lifelong treatment implications. I am going to escort you over to (or make you an appointment at) the ART site where another provider will take another specimen to verify your result and talk to you more about the benefits of treatment.*

See also "Table 1: Patient questions and provider responses related to retesting for verification".

What do I tell the individual who tests HIV positive upon retesting for verification? Keeping in mind the setting, local process, and national guidelines, the healthcare provider should tell the client that:

- *The second specimen that I took to verify the results of the initial testing event has come back HIV positive. This means that you are HIV positive, and that your HIV positive status has been verified.*
- *I know information about what an HIV positive diagnosis means was reviewed with you when you first tested. Do you have any more questions that you want to discuss?*
- **For providers at the ART clinic**, it is important to initiate a detailed discussion about the willingness and readiness of the patient to initiate ART.

What do I tell the individual who has discordant results (HIV negative or inconclusive) upon retesting for verification? Keeping in mind the setting, local process, and national guidelines, the healthcare provider should tell the client that:

- *The second specimen that I took to verify the results of the initial testing even has come back HIV negative (or inconclusive).*
- *Since the first HIV testing event indicated you are HIV positive and the second indicated you are HIV negative (or inconclusive), we will refer to your test results as discordant. You will require additional testing before we know if you are HIV-infected or not.*
- *We don't know the exact reason why the results of the two testing events are different. It may be due to a test kit that is not performing properly or how the test was performed. What we do know is that we need to test you again with a different type of test.*
- The healthcare provided should also ask: *Are you currently on ART? If you are currently on ART this may also affect your HIV antibody test results.*
- The healthcare provider should also describe the next steps (i.e., the individual or their specimen should be referred for additional follow-up testing at a higher-level facility or laboratory) and discuss the timeline for return of test result.
- The healthcare provider should provide counselling on prevention options; for example: *Since your test results were discordant, it is very important that you minimize the chances of transmitting HIV to someone else, such as making sure you use a condom while the HIV testing issue is resolved.*
- The healthcare provider should also ask: *How will you cope during the wait for the next results?*
- The healthcare provider should also ask: *Who can you talk to about this?* Offer to talk to his/her partner or another significant other (parent, adult children if the client is older, etc.).
- Explain that the provider will want to talk with them further about their results and will discuss starting ART while the final result is pending. If the patient has already been started on ART, explain that he/she should continue taking it until the next result is received. Explain that a decision about whether to continue ART will be made after additional testing results return.

Ask: *What questions do you have?* What other questions might clients ask? A listing of frequently asked questions and possible answers follows. Where a particular question is common, healthcare providers may want to incorporate the answer into the pre- or post-test session as a way of pre-empting common misconceptions.

Table 1. Patient questions and provider responses related to retesting for verification

Patient concern	Provider response*
Does retesting for verification mean that the HIV test cannot be trusted?	*Our HIV testing procedure is very good: we follow the national testing protocol carefully. We ensure that our test kits are working properly, our providers are adequately trained, and each test is conducted following the manufacturer's procedure. Despite these best efforts, it is possible that a mistake could be made or the test kit might not perform correctly. Therefore, national protocol recommends that we test you again, using a new blood sample, to make sure the first result was correct.*
Does this mean that you, as my healthcare provider, do not know how to run the HIV test?	*All of our staff who conduct HIV testing have been trained in testing procedures and are certified. In addition, we are regularly tested by our managers and the national laboratory to ensure we are conducting the testing procedure correctly. Please be reassured that that we are well qualified to run the HIV tests.*
I do not have time to wait for my final result, retesting for verification is going to take too long!	***ONLY FOR COUNTRIES WHO WILL CONDUCT PARALLEL TESTING WHEN RETESTING FOR VERIFICATION:***

Patient concern	Provider response*
	Retesting for verification is quicker than the original testing procedure because we can conduct the first two tests in the algorithm at the same time (i.e., in parallel, even if the national algorithm is a serial algorithm)*, rather than one after the other, to save time.* *Retesting for verification is important because it gives us a chance to verify the first HIV diagnosis result. This is important because people with HIV are started on lifelong medicine, even if they don't have any signs or symptoms of HIV. It will only take another _____ minutes to run the test. Can you stay another ____ minutes?* ***ONLY FOR COUNTRIES WHO WILL CONDUCT RETESTING FOR VERIFICATION ON SAMPLES USED FOR OTHER BASELINE TESTING*** *Retesting for verification can be conducted at the same time that other baseline laboratory tests are run and therefore will not take additional time.* Explain that he or she can meet with the ART provider to discuss starting medication even before the result is back so the time will not be wasted.
What happens if my result is different?	*If your retesting for verification result is negative or inconclusive, then we will take another blood specimen and send it to the laboratory for testing using a procedure that we do not have the equipment to conduct here in the clinic. However, we will not delay ART and will adhere to local policy and treatment guidelines.*
Why are you recommending that I start ART while my verification results are still pending?	*We will start ART today because your retest for verification result will likely come back indicating that you are, indeed, HIV positive. The advantage of starting ART now is that it will start making you healthy sooner, and you will be less likely to transmit HIV to your partner (or baby if pregnant or breastfeeding). If the second testing event indicates that the first result was incorrect, we will stop ART immediately.*
What should I tell my partner/family if it turns out my initial results were incorrect?	*You can tell them the same thing that I've told you: that in rare instances the initial testing event can be incorrect and that your case was one of these rare instances. If you would like, you can bring your partner/family to the clinic with you and I can explain it to them. Sometimes it is easier for them to understand and believe if they hear it from a healthcare provider.*
What are my rights as a patient if I've been misdiagnosed?	*You have a right to an accurate and timely diagnosis for HIV, and we will ensure that you have that by retesting you to make sure your test result is accurate.*
*All scripts should be included and adapted depending on national guidelines, clinic testing procedures, services offered at HTS (whether the ART site is integrated or available by referral), and the client's preconceptions and level of understanding.	

8. HEALTHCARE WORKER SENSITIZATION

What is the role of the national program manager in reference to communication and messaging?
The national level—commonly a national-level multi-sector committee that includes representation from key and priority populations—is responsible for:

- Setting national recommendations and policy (to guide program managers and healthcare providers) regarding messaging and the information that these messages should contain.
- Developing communication and messaging materials such as counselling scripts that healthcare providers can use when counselling clients and as part of existing training curricula.

What is the role of the local and subnational program manager in reference to communication and messaging? Program managers at the local level are responsible for adapting already developed messaging from the national level to ensure they are locally relevant. For example, local program managers may need to have nationally developed scripts translated into the local language; local managers and providers might want to adapt the scripts to address local misconceptions or customs.

Program managers based in local or subnational health authorities are also responsible for coordinating communication strategies and messaging between local implementing partners to ensure consistent messaging and to avoid duplication and wastage of resources.

District health officers must talk to staff about the benefits of retesting for verification and share that it is part of a larger, continuous QI process for HIV testing. It is important that retesting for verification is framed in such a way that HTS providers do not feel that they are not being trusted to do their jobs correctly, but rather that retesting for verification is a process that ensures best clinical practice.

9. MONITORING AND EVALUATION OF RETESTING FOR VERIFICATION

Testing registers/logbooks at all sites where retesting for verification is occurring (e.g., HTS, ART site, ANC, laboratories, etc.) and patient-held health cards and care charts will need to be updated to include results from the HIV retesting for verification. **If it is not feasible to develop new registers or update databases**, the existing registers/logbooks can be used to capture key data points; however, it is important to distinguish which one is being used for the retesting for verification (e.g., label it "**Retesting for Verification ONLY"**). HTS delivery sites **should** already be collecting basic information about the initial testing event including information for QA purposes. This information may already be included in the national HTS register/logbook often referred to as the Standardized Rapid Testing Logbook. The national HTS logbook/register should **at a minimum** already be collecting the following information the first (initial) HIV testing event (see Appendix 2):

First HIV testing event

- Site name/identification number and name/identification number of provider conducting the first testing event
- Date of testing event
- Test 1 (Kit name, Lot number, Expiry date)
- Test 2 (Kit name, Lot number, Expiry date)
- Test 3 (Kit name, Lot number, Expiry date)
- Testing result
- Results of regular QC (as per national/program guidelines)

The same variables should also be collected for the retesting for verification event. Sites that use a standardized logbook could use the same logbook and label it specifically for "**Retesting for Verification ONLY**" to distinguish it from the testing results for initial testing events.

- Site name/identification number and name/identification number of provider conducting retesting for verification
- Date of retesting for verification
- Testing algorithm used
- Retest: Test 1 (Kit name, Lot number, Expiry date)
- Retest: Test 2 (Kit name, Lot number, Expiry date)
- Retest: Test 3 (Kit name, Lot number, Expiry date)
- Retesting event final result
- Comments: This section can be used to document if additional follow-up testing was required, i.e., to resolve discordant results between testing event 1 and the retesting for verification testing event
- Final result
- Patient next steps (e.g., referral to care, retesting discordant results, etc.)
- Results of regular QC (as per national/program guidelines)

An example of a register that includes fields for retesting for verification is included as Appendix 2.

In setting up testing monitoring tools, do we want to count patients or tests? Currently, countries may report number of tests conducted as opposed to unique individuals tested. Many of the HTS indicators are more meaningful if they count the number of individuals who have been tested rather than the number of tests performed.

If recording information in an HIV testing register, include a column to collect information about prior testing. Then, repeat testing and retesting can be counted and subtracted from the total number of tests performed for the same individual.

What are the monitoring and evaluation indicators for retesting for verification? Indicators for monitoring retesting for verification may include:

1. Integrated HTS and ART sites: Percentage of those with an initial HIV positive test that were retested for verification
2. Standalone ART sites: Percentage of newly initiated treatment patients that had their HIV status verified
3. Percentage of HIV rapid testing sites using the updated HIV rapid test logbook (or other standard logbook/register) that includes columns for retesting for verification

Information on indicators for HTS can be found in: WHO and CDC. (December 2015). *Improving the Quality of HIV-related Point-of-care Testing: Ensuring the Reliability and accuracy of Test Results.* http://www.who.int/hiv/pub/toolkits/handbook-point-of-care-testing/en/

10. ENSURING THE QUALITY OF CURRENT HIV TESTING PROGRAM

Retesting for verification is one QA measure in the range of testing-related QA and QC measures for point-of-care RDT—from the development of a national testing algorithm that adheres to WHO's standards, to the proper storage and administration of test kits and training of staff. QA activities are required at every facility or testing site offering HTS. The implementation of retesting for verification

provides an ideal opportunity for revising and strengthening current HTS QA processes. Retesting for verification is an important component of a QA system, yet still subject to QC measures.

Retesting for verification provides an important opportunity for programs to use QA data to inform the scale-up strategy. It is critical to use data in order to understand the quality of testing at sites and ensure that sites are prepared to implement retesting for verification. If the HTS program has a high rate of inconclusive/discordant results, this is indicative of a QA issue that should be resolved before implementing retesting for verification.

Likewise, countries should think about their specific laboratory-based systems and what they need to do in order to resolve discordant results on retesting for verification. For example, if turnaround time for early infant diagnosis is already extremely long and/or results are not regularly returned, this would be an indication that there is a need to enhance/support the laboratory infrastructure, especially return of results, in order to prepare for using DNA PCR as an additional follow-up test when retesting for verification results are discordant.

For a discussion of QA for RDT see Adler M, Behel S, Duncan D, et al., Annex 9: Technical guidance update on quality assurance for HIV rapid diagnostic tests in the WHO (July 2015) *Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection*.

If we adopt retesting for verification, will we need to update our national testing algorithm? No. If the national algorithm has been validated, the recommendation is to repeat the entire national HTS algorithm at the time of ART initiation. However, some countries may want to make a note in their algorithm to indicate that retesting for verification is required before ART initiation and indicate how to resolve discordant results.

How is data from the HTS delivery point linked to the ART site and vice versa? National programs will need to think this question through as they scale up retesting for verification and set up their monitoring and evaluation systems. It is important that the site that conducted the initial testing event has access to the result from the second testing event, so that discordant results can be tracked and investigated to identify root causes.

This is where a web-based database is clearly advantageous to the traditional paper-based records. Electronic databases, stored on central servers, facilitate sharing of data between providers. If electronic databases are not available, then systems to share client information might include:

- Patient-held documentation (e.g., referral form): such documentation would be provided at the original testing site and submitted to staff at the site where retesting for verification is conducted. Documentation would require the retesting for verification site to fill in the name of the testing location, HTS provider, date of test, and results, and return this information to the original testing site in monthly batches.
- Unique client identifiers: data on each client identifier can be collated monthly at a subnational level using routine monthly reports from all local providers. This type of system is possible where electronic databases are in use or where the number of clients is relatively small (i.e., in the hundreds

rather than the thousands). This will give a fuller picture of the continuum of care accessed by each patient.

In the absence of a referral form from the initial testing site, the site conducting retesting for verification should try to ascertain enough information about where, when, and who conducted the initial testing event so that feedback can be given to that site (i.e., of the number of clients reported receiving their initial test at your site, number retested, and their results).

How should retesting for verification data be used? Monitoring is used in at least two ways:

- To monitor whether or not staff are conducting retesting for verification: Whether you are at the local, subnational, or national level, staff will want to compare progress against national targets. For example, if the report for the month of January indicates that only 50% of those testing HIV positive are retested (and the target is, for example, 100%), it is obvious that much work needs to be done. Where findings suggest retesting for verification is not being conducted as per national guidelines, local program managers might want to reach out to their providers and ask (in a non-judgmental manner), why retesting for verification is happening only half of the time and what support they need to conduct retesting for verification all of the time. National program managers might want to have similar discussions with subnational managers as well as local managers and providers. Program changes, as well as advocacy for funding, if needed, should be based on these local and subnational needs assessments.
- To monitor the number/percentage of discordant results: Data from retesting for verification can be used to monitor the frequency of misdiagnosis, to identify program or sites where false-positive diagnoses may be occurring relatively frequently, or to suggest ways to improve testing quality.

For supportive supervision visits, what are the key questions to monitor implementation of retesting for verification? Questions that can be added to the Site Improvement through Monitoring System (SIMS) might include:

- Review the 20 most recent entries where both (or all three) RDTs were HIV positive in the HIV testing register/rapid testing logbook. Does a review of these reveal 100% compliance with the national retesting for verification policy and local SOPs on retesting for verification?
- Does the site have written/printed testing protocols or other job aides at every point where HTS are conducted that are in full accordance with the national retesting for verification recommendation?

For more information on SIMS, see PEPFAR. *PEPFAR SIMS Facility Tool.* https://data.pepfar.net/additionalData

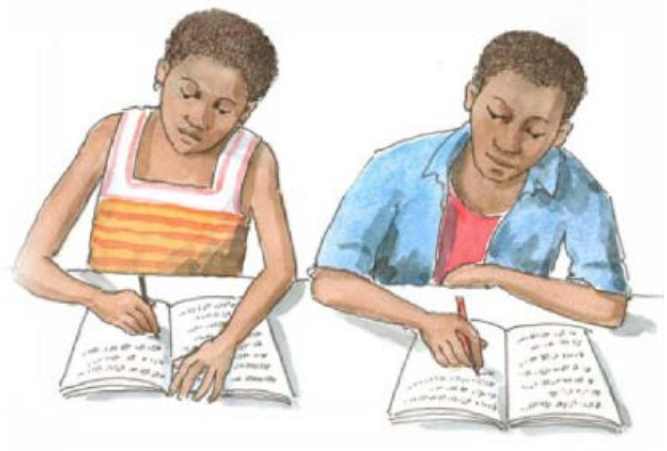
11. HUMAN RESOURCES AND RETESTING TRAINING REQUIREMENTS

The scaling up of retesting for verification requires effective capacity building and periodic supportive supervision to ensure services are of consistently high quality and that they meet the needs of the communities they serve. Capacity building goes beyond training and the attainment of skills. It includes the strengthening of organizations and systems, and establishing and supporting linkages and networks.

Who should be trained to ensure a smooth scale-up of retesting for verification? National policy should indicate who can and cannot provide pre-test information, HIV testing, and post-test counselling. If a provider is conducting HTS, he/she can also provide retesting for verification. Therefore, anyone who conducts HTS should attend the training during which retesting for verification is discussed. As WHO recommends, retesting for verification should ideally be conducted by a different provider than the provider that administered the first testing event.

What topics should be included in the training? The additional components that need to be added to an existing HTC or ART curriculum to support scale-up of retesting for verification include:

- Definition of retesting for verification and how retesting is different from the initial HIV testing event (i.e., the algorithm is completed by a different provider with a different specimen; retesting for verification is NOT supplemental testing)
- Who should be retested and who need not be retested
- Why retesting for verification is important (misdiagnosis, cost/benefits, risks of false-positive result)
- Why retesting for verification is an issue now (in the context of test & treat and universal ART)
- Retesting for verification procedures, when and where retesting should take place; what happens if the patient tests HIV positive, HIV negative, or HIV inconclusive when retested
- QA/QI/QC, including recording retesting for verification activities in testing registers/databases
- What to say to clients about retesting for verification, and the importance of ensuring a uniform message
- Counselling messages: pre-test messages for anyone undergoing HIV testing and post-test counselling specific to those undergoing retesting for verification (see "Section 7: Counselling Messages.")



These topics could feasibly be taught in a six-hour training, including small group discussion and post-test counselling role plays. This *Handbook* may be used to inform the curricula edits.

When does this refresher training need to take place? Training should be held as soon as possible after the retesting for verification policy is approved and ready for implementation. The training will need to take place before rollout out to any site (whether during the targeted rollout phase or national rollout) but within a few weeks of actually initiating retesting for verification.

How often do we need to conduct training? Countries should defer to national guidelines on frequency of refresher trainings for HTS providers. However, according to the WHO, providers should participate in a refresher training that includes a practicum every two years.[xxv]

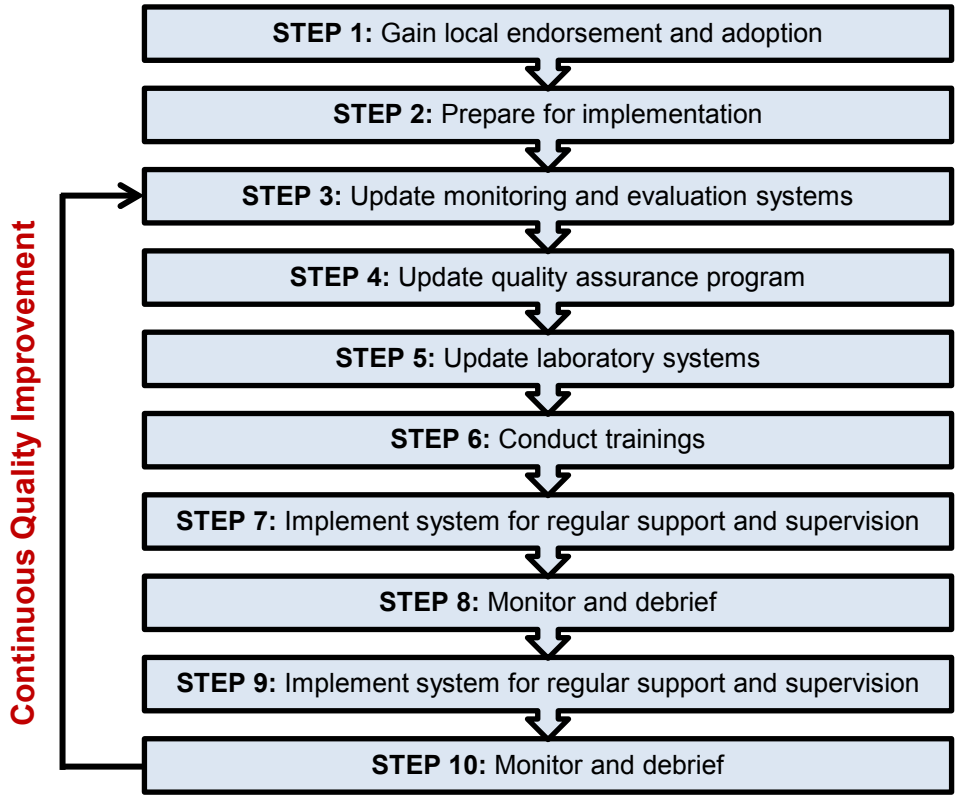
How about training of new employees? The national HTS and ART training curricula should be updated with the topics listed above, and implemented as needed to ensure all new employees are trained within the first few weeks of hire.

What about pre-service training? Like the national in-service HTS and ART training curricula, the pre-service curricula for laboratory and all health-related students (medical, nursing, laboratory, counselling, etc.) will need to be updated to ensure that the curricula in colleges and universities are in line with national policy about retesting for verification.

12. Stepwise Approach to Implementation

A well planned step-by-step process for scaling up any new service—whether it is universal ART, an enhanced QA program, or, in this case, retesting for verification—is important. The ten steps depicted in Figure 3 below should guide the targeted rollout and national scale-up. The National Program Manager and Subnational and Local Implementers Checklists in this section are organized according to these steps. These checklists can be used as tools for planning and implementing targeted rollout and scale-up of retesting for verification at the local, subnational, and national levels. It is important that there is a mechanism established to ensure continuous quality improvement of any process. As such, we have indicated in Figure 3 below how programs should regularly monitor and debrief on the implementation process and incorporate best practices/lessons learned into the system.

Figure 3. Steps for scaling up retesting for verification before/at ART initiation



NATIONAL PROGRAM MANAGER – TO-DO CHECKLIST		
	Person Responsible	**Date Due**
1. NATIONAL ENDORSEMENT AND ADOPTION		
☐ Meet with national stakeholders, committees, task forces and subnational opinion leaders to discuss why retesting for verification is needed from a national and local perspective. * *The presentation should focus on stakeholders (especially healthcare providers and laboratory staff, but also clients and community leaders), and address potential reservations as well as foreseeable barriers.*		
☐ Gain national endorsement from MOH and adoption/endorsement from national stakeholders, committees, and taskforces.		
☐ Develop national communication strategy on retesting for verification. Include discussions regarding whether to include it as part of pre- and post-test counselling messages to individuals receiving HTS.		
2. IMPLEMENTATION PREPARATION		
National Documents		
☐ Update national HTS policy.		
☐ Update national HIV treatment guidelines.		
☐ Update laboratory policies, including RDT quality management and QA.		
☐ Develop model SOP documents.		
Supply Chain Management		
☐ Determine if/how national forecasting, procurement, and tracking of supplies need to be strengthened.		
☐ Determine if/how storage needs to be strengthened.		
☐ Calculate the number of additional test kits that will be needed and adjust forecasting.		
☐ Purchase needed test kits and other testing supplies for scale-up.		
Logistics		
☐ Identify system for transportation of test kits and other supplies.		
☐ Identify system for transportation of trainers and staff conducting supportive supervision.		
3. MONITORING & EVALUATION SYSTEMS		
☐ Determine how to monitor, evaluate, and improve services.		
☐ Define method of how documentation of the retesting event will occur and if it should be reported to the national level or remain within the clinic/district level.		
☐ Update all monitoring tools (e.g., HTS and ART registers/databases) to include documentation of initial HIV testing and retesting key quality elements.		
4. QUALITY ASSURANCE PROGRAM		
☐ Assess sites' QA process and quality of testing.		
☐ Expand the QA program to include retesting for verification.		
☐ Establish external on-site quality assessment and supervision at all testing sites.		
5. LABORATORY		
☐ Work closely with National Reference Laboratory on policy, curriculum, and purchasing of supplies.		
☐ Establish standards for how discordant results between initial and retesting for verification events will be resolved, and for referral of discordant results, including turnaround time.		
6. TARGETED ROLLOUT		
☐ Determine targeted rollout sites based on discussions with national stakeholders. **It is recommended that priority for early scale-up be given to larger facilities in high prevalence areas that provide universal ART based on RDT result, including ANC and postnatal providers.*		
☐ Prepare the targeted rollout sites including training, resource allocation, revised logbooks, and SOP development.		

NATIONAL PROGRAM MANAGER – TO-DO CHECKLIST		
	Person Responsible	**Date Due**
7. MONITOR AND DEBRIEF TARGETED ROLLOUT PROCESS		
☐ Revisit the targeted rollout implementation process, step by step, and make adjustments to implementation plan for national scale-up: • Do policies and training need to be updated with lessons learned? • How did the SOPs have to be changed to best support healthcare providers? Should national SOPs be updated accordingly? • Was the stock forecasting correct? If not, why? • What unanticipated challenges did you meet? • Are the monitoring tools functioning as anticipated? Is additional training required? • Does the training package need updating in light of problems with scale-up? • What is the feedback from the laboratory? • What is the percentage of discordant results? What does that mean in terms of QA at sites and the program as a whole? What monitoring and supervision should the site receive?		
8. NATIONAL TRAINING		
☐ Add retesting for verification to national training package, including monitoring and evaluation of retesting for verification and completion of new registers/databases and medical records.		
☐ Ensure training discusses how discordant results between initial and retesting for verification events will be resolved.		
☐ Provide an updated training module to national trainers for HTS.		
☐ Determine a training schedule for HTS staff in prioritized facilities (e.g., offer a half-day training on-site or within a district).		
☐ Communicate dates of training to sites and/or participants.		
9. SUPPORT AND SUPERVISION		
☐ Develop/update supportive supervision checklist to include retesting for verification.		
☐ Recruit and hire experts to staff teams of multidisciplinary experts for supportive supervision (if not already in existence).		
☐ Meet with supervision teams quarterly to identify key challenges, barriers, and best practices from the rollout.		
☐ Revise the supportive supervision checklists in line with early experience.		
10. MONITOR AND DEBRIEF		
☐ Conduct general monitoring:* • Do policies and training need to be updated with lessons learned? • How did the SOPs have to be changed to best support healthcare providers? Should national SOPs be updated accordingly? • Was the stock forecasting correct? If not, why? • What unanticipated challenges did you meet? • Are the monitoring tools functioning as anticipated? Is additional training required? • Does the training package need updating in light of problems with scale-up? • What is the feedback from the laboratory? • What is the percentage of discordant results? What does that mean in terms of QA at sites and the program as a whole? What monitoring and supervision should the site receive? **Recommended quarterly debriefing during the first year of implementation, and then twice per year thereafter.*		
☐ Meet with training teams annually to find out what issues they've encountered as well as feedback from the field.		

SUBNATIONAL AND LOCAL IMPLEMENTERS – TO-DO CHECKLIST	
Testing Facility Name:	**Testing Facility ID** (if applicable):
Testing Point Name:	**Type of testing point** (circle one) **VCT/HTC** **PITC** **PMTCT** **TB Clinic** **Laboratory** **Treatment Center** **Other** (specify):
Location/Address:	
Level (Circle one and specify name): **Region/Province/Zone:** **District:** **Referral Centre:** **Health Centre:** **Dispensary:** **Health Post:** **Other** (Please specify to reflect country context):	**Affiliation** (circle one): **Government** **Private** **Faith-Based Organization** **Non-Governmental Organization** **Other:**
Number of Testers:	**Average Monthly Tested:**

	Person Responsible	Due Date
1. LOCAL ENDORSEMENT AND ADOPTION		
☐ Meet with subnational and local stakeholders, committees, task forces, and subnational opinion leaders. Discuss how retesting for verification is needed from a national and local perspective. **Focus presentation on stakeholders (especially healthcare providers and laboratory staff, but also clients and community leaders); ensure you address their reservations and the foreseeable barriers.*		
2. IMPLEMENTATION PREPARATION		
National Documents		
☐ Interpret national policy in terms of what needs to happen locally to ensure compliance.		
☐ Support facility managers to adapt national SOPs to their facility. Provide feedback to national team where SOPs need to be edited.		
Supply Chain Management		
☐ As needed, determine how you will improve forecasting, tracking, and re-ordering of supplies.		
☐ Determine if there are any storage issues and how to rectify those issues.		
☐ Calculate the number of additional test kits that will be needed for retesting for verification.		
Logistics		
☐ Provide feedback to national team on resource allocation, specimen transport for additional follow-up testing, etc.		
3. MONITORING AND EVALUATION SYSTEMS		
☐ Ensure revised monitoring tools are in place and that staff are trained to use them.		
☐ Provide frequent supportive supervision to ensure new monitoring tools are completed correctly and in a timely manner.		
4. QUALITY ASSURANCE PROGRAM		
☐ Ensure expansion of enhanced QA program to your site and troubleshoot where problems occur.		
5. LABORATORY		
☐ Ensure your site has an agreement with laboratory for referral of discordant results. Agreement should include standards on turnaround time.		
6. TRAINING		
☐ Prioritize training for staff and organize trainings for local healthcare providers in collaboration with national or subnational training team.		
☐ Ensure staff are trained on how to deal with discordant retesting for verification results.		
7. SUPERVISION AND SUPPORT		
☐ Conduct internal audits to examine retesting for verification at site level.		
☐ Conduct supportive supervision visits.		

8. MONITOR AND DEBRIEF		
☐ Conduct general monitoring:* • How did SOPs have to be changed to best support healthcare providers? • Was the stock forecasting correct? • Were there stock-outs? If so, what could be done to ensure they don't happen again? • What unanticipated challenges were met? • How is turnaround time and return of results for additional follow up testing? • What is the percentage of discordant results? What does that mean in terms of QA at sites and the program as a whole? ☐ Compile results, highlight issues to be addressed and return to subnational AIDS control program or equivalent. **Recommended quarterly debriefing during the first year of implementation, and then twice per year thereafter.*		

13. WHAT TO EXPECT WHEN SCALING UP

What are some of the barriers to implementing a retesting for verification strategy? Implementation issues are outlined in Table 2 below, not to give excuses to avoid retesting for verification, but instead to provide national planners with a roadmap of what they can expect and therefore what to plan for. Although many of these barriers are in reference to HTS generally, they can be exacerbated when additional responsibilities are added to HTS such as with retesting for verification.

Table 2. Recommendations to address common barriers to the scale-up of retesting for verification

Barriers	Recommendations
Public misconceptions about retesting for verification; concerns that there is insufficient evidence to indicate that retesting for verification is necessary	• Ensure that there is support for retesting for verification. It is recommended that national staff take the lead to ensure healthcare providers and stakeholders hear the evidence base and have an opportunity to discuss their reservations. In the early phases, national staff may need to spend time presenting at key meetings and conferences, developing policy documents and briefs that address barriers. A major policy change cannot get off the ground until the stakeholders agree that it is important.
Policy guidelines do not reflect most recent WHO recommendations, or policy guidelines are not properly disseminated and/or adhered to by providers	• Update and disseminate relevant national guidelines. Sample language for updating national policy is provided in Appendix 3. • Ensure that ***sub***national program managers are well-trained on policy, HTS SOPs, supportive supervision, and monitoring and evaluation of HTS and QA. Subnational program managers are crucial to successful implementation: they can take messages from the national program to the sites, address healthcare provider misconceptions, support sites to offer quality services, create a culture of quality, advocate on behalf of sites, and communicate local needs back to the national level.
Human resources (there is insufficient number of staff, inadequately trained staff, and/or high turnover)	• Train and support lay providers to undertake more HTS activities (pre-test counselling, test administration, and post-test counselling) including for retesting for verification (See Section 11: "Human Resources & Retesting Training Requirements"). However, lay providers must be adequately managed, and their manager must be provided with training to do this and released from other duties so that they can prioritize this role. • Where necessary, a single provider can conduct both the initial and the second testing events.

Barriers	Recommendations
	• When conducting the retesting for verification event, administer A1 and A2 in parallel. • Communicate in advance policy regarding trainee per diem and reimbursement for transportation, accommodation or food. • Establish a national testing certification program and annual performance audits for all testers to ensure the quality of testing.
Stock-outs or the fear of stock-outs; transportation of supplies to the peripheral level	• Use retesting for verification as an opportunity to revisit supply chain management issues, forecasting, and storage of supplies, and identify new ideas to resolve these issues. • Use Global Fund money where possible to support scaling up of retesting for verification activities. In theory, retesting for verification should pay for itself by preventing unnecessary initiation of ART in individuals incorrectly diagnosed with HIV. See Section 3: "Misdiagnosis and Cost of Retesting for Verification."
Monitoring of retesting for verification	• Update registers to include retesting for verification, and train staff on the use of registers (See Section 9: "Monitoring and Evaluation of HIV Retesting for Verification). • Update the patient-held medical record (passport to health card) to include a field for HIV testing and HIV retesting for verification. • Expand supportive supervision to ensure registers are completed in a timely manner and completed correctly. • HTS providers are/should be tracking HIV positive clients to ensure linkage to care. In this linkage process, they can also ascertain whether the individual was retested and their test result (See Section 10: "Ensuring the Quality of Current HIV Testing Program). • District Health Management Teams can also develop reporting systems where ART clinics report results (number of concordant, number of discordant, and the sites where discordancy is more prevalent) so that a QA specialist can follow up with sites to assess testing procedures and proficiency of providers. See "Section 9: Monitoring and Evaluation of HIV Retesting for Verification."
QA activities are not routinely undertaken; EQA is undertaken but feedback is not provided to staff in a timely manner	• Create a culture that values QA through training and supportive supervision. Reinforce this culture by ensuring that QA programs are sufficiently funded and QA/supportive supervision staff have access to transportation to get to sites (See Section 10: "Ensuring the Quality of Current HIV Testing Program"). • If the aim is to conduct EQA and supportive supervision quarterly and this goal cannot be met, consider reducing EQA to an achievable level, perhaps twice a year. • Establish a routine whereby EQA and supportive supervision staff provide feedback during a multi-disciplinary team meeting at the end of the visit.

Box 3: Case study – Malawi

In their 2015–2020 National Strategic Plan for HIV and AIDS, Malawi re-confirmed their commitment to routine retesting for verification (referred to locally as confirmatory testing). In Malawi, retesting for verification was "introduced in 2011 for all patients enrolling into pre-ART or ART to rule out any possibility of mix-up of test results or fraudulent access to ART." With the decision to scale up universal ART in 2016, the Malawi MOH was "actively strengthening the full implementation of this policy through refresher trainings and during supportive site supervision." Retesting for verification is undertaken either at enrolment into pre-ART or when initiating ART. However, the policy was not adhered to uniformly: between April and June 2016, "the number of confirmatory tests was less than half of the number of new ART initiations, suggesting that confirmatory testing [i.e., retesting for verification] was not routinely implemented at all sites."

Of the retesting for verification results in Malawi between April and June 2016, 99% (38,270) of results were concordant positive and 1% (474) were classified as discordant.[xxvi] The unexpectedly high number of clients who had discordant retest results may be explained by selective retesting for verification among clients with doubts about their previous positive status. This finding underscores the importance of both routine retesting for verification before ART initiation as well as the need to continue strengthening QA initiatives.

Scale-up of retesting for verification in Malawi has been inconsistent due to a number of barriers, particularly human resources barriers. Despite clear policy recommendations and updated registers, during the initial scale-up phases many healthcare providers (particularly in rural areas) had not yet been trained on retesting for verification; therefore, they were confused about how to record retesting activities in the registers, did not understand the importance of the policy, and, as such, could not communicate to clients why they had to be retested. However, the MOH put into place a rigorous strategy to ensure that anyone providing HTS must go through the MOH HTS certification program and training. A skills-intensive training curriculum was developed and piloted, and all active HTS providers were either trained or re-certified (2012–2013). In addition, retesting policy was integrated into both the ART and HTS national guidelines, and national quarterly reporting on retesting to inform programming has been implemented since 2013. To address some of the challenges in rural areas, the MOH is implementing quarterly monitoring and supervision visits to address these training gaps. Some facilities in Malawi have inadequate human resources to have a second person conduct the retest for verification; as such, the retesting for verification is conducted by the same person who conducted the initial HIV testing event (but using a second specimen). Furthermore, a cadre of dedicated HTS personnel responsible for HTS in facilities, called HIV Diagnostic Assistants (HDAs), was developed and has been key to rolling out retesting for verification throughout Malawi.

Source: Government of Malawi Ministry of Health. Integrated HIV Program Report, April–June 2016.

14. Roles and Responsibilities of Program Staff

In "Section 12: Stepwise Approach to Implementation," planning and implementation were described as multi-sectoral, multi-step processes. It is vital that scale-up include the input of a wide range of stakeholders from all cadres of healthcare providers affected by this change, all levels of the health service, and from civil society. Assuming the planning stage was conducted in line with the ten steps, there should be wide support for the strategic plan that outlines the process of scale-up developed during the planning and targeted rollout phases. From there, support from healthcare providers and managers during the scale-up should be relatively easy; that is, if national program managers are successful in supporting local program managers to remove barriers to implementation. The roles and responsibilities of healthcare providers and managers at all levels of the health system are listed in Tables 3 and 4.

Table 3. Roles and responsibilities of staff in initiating and implementing retesting for verification at national level

National authority	General roles/responsibilities
Ministry of Health	• Update national HTS policy/guideline and QA to include retesting for verification • Revise tools for capturing data for monitoring services (registers/database) to include retesting for verification; pilot test tools and roll out nationally • Revise standards and criteria for accreditation/certification of testing sites to take into account retesting for verification • Strengthen national QA coordination team; ensure the team understands their role in supporting rollout of retesting for verification and the need for enhanced QA during implementation • Procure, store, and distribute test kits/supplies; ensure supply chain management of test kits has been revised to meet increased test kit demand with retesting for verification • Revise training curriculum where necessary to include retesting for verification, train trainers, roll out revised training and mentoring • Develop SOPs that include retesting for verification and revised training curriculum for supportive supervision to include retesting for verification; develop criteria and mechanism for identifying supervisors (if not already established) • Develop a national health worker sensitization campaign (if applicable) to support retesting for verification • Ensure testing sites' readiness for site and staff certification (if certification is undertaken) that includes retesting for verification criteria (laboratories, clinical facilities) or site registration (stand-alone sites, community programs)
National Reference Laboratory or designee	• Monitor the performance of national algorithms for testing and retesting for verification and validate new ones • Perform lot verification testing for post-market surveillance • Produce QC specimens and EQA/proficiency testing scheme panels to support enhanced QA to support retesting for verification • Evaluate data (EQA schemes) from all districts/provinces to suggest corrective actions • Develop SOPs and job aids to support scale-up of retesting for verification • Participate in the process of revising monitoring and evaluation tools to include retesting for verification • Support training using a standardized hands-on curriculum that has been updated to include retesting for verification

Table 4. RACI Matrix: Implementation of national directives at subnational level

R = Responsible; A = Accountable; C = Consulted; I = Informed					
Definition of levels 0 Community — Outside of facilities (home-based, mobile, outreach) 1 Primary — Facility-based (stand-alone, clinical, laboratories) 2 District — Includes both district clinical and laboratory facilities 3 Provincial — Includes provincial/regional/state clinical and laboratory facilities 4 National — Includes Ministry of Health or National Reference Laboratory					
	0 Community	1 Primary	2 District	3 Provincial	4 National
Counselling/Messaging: • Ensure staff are trained and certified in counselling and testing, including retesting for verification • Ensure all steps in counselling and testing, including retesting for verification, are followed	R	R	A	A, C	I
• Provide supportive supervision of counselling in levels 0, 1, 2, ensure retesting for verification counselling messages are effective	A	A	R	R, C	I
• Conduct client exit interviews to monitor for feedback on HTS, including retesting for verification	R	R	R, A	C	I
Testing: • Adhere to SOPs, including those on retesting for verification	R	R	A	A, C	C, I
• Conduct QC • Participate in EQA schemes • Implement other QA/QI-related activities	R	R	R, A	A, C	C, I
Record-keeping: • Keep accurate testing records, including retesting for verification records • Where retesting for verification is conducted at a different facility from the initial testing event, ensure sharing of records and good communication so it is clear which agency conducts retesting for verification • Report on retesting for verification	R	R	R, A	A, C	I
• Where retesting for verification activity is suboptimal, suggest and implement recommendations to increase uptake of retesting for verification	A	A	R	R	I
Supplies: • Ensure sufficient test kits and supplies for initial and retesting events	R	R	A	A, C	A, I
• Order test kits/supplies from national level • Distribute QC specimens and EQA scheme panels	C	C	R	R	A, C

Adapted from: WHO (July 2015) *Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection*. P119.[xxvii]

15. REVIEW AND UPDATE DOCUMENTS

One of the early steps in implementing retesting for verification is to update policy; possible wording for national policy edits are included as Appendix 3.

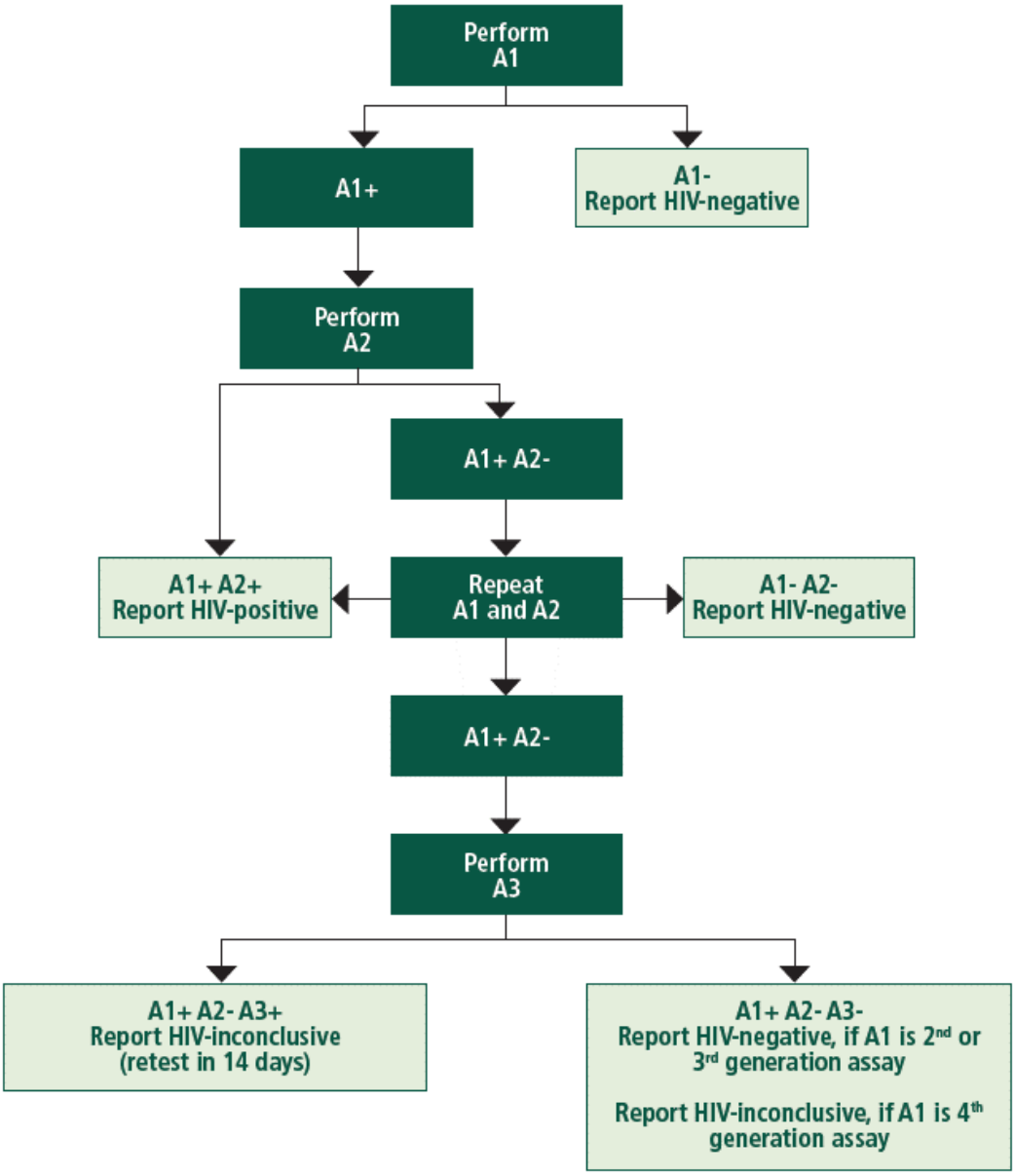
What other documents need updating? In addition to updating national policies and guidelines, the following documents also need updating:

- National training curricula for healthcare providers conducting HIV testing, care and treatment services, and laboratory workers
- Clinic-level SOPs
- Job aids
- Referral forms
- Patient-held cards
- Registers/databases used to collect information about HTS and ART (discussed in "Section 9: Monitoring and Evaluation of HIV Retesting for Verification" of this *Handbook*)

Some countries will also want to review their testing algorithm(s) at this time.

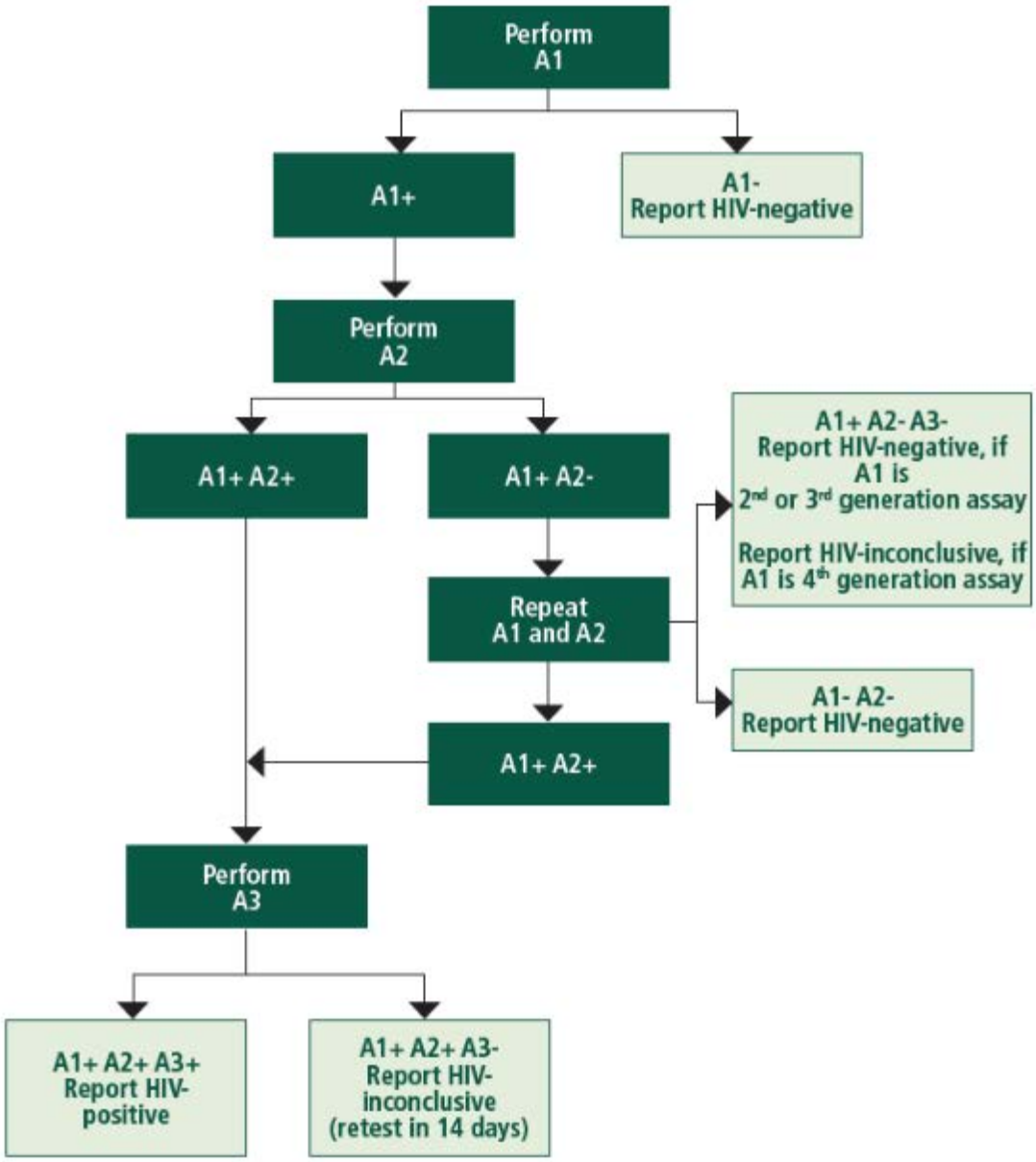
APPENDIX 1: TESTING STRATEGIES FOR HIV DIAGNOSIS IN HIGH AND LOW PREVALENCE SETTINGS

Figure 4. Testing strategy for HIV diagnosis in high prevalence settings



Source: WHO. (June 2016). *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach, Second Edition.* Annex 6. http://www.who.int/hiv/pub/arv/arv-2016/en/

Figure 5. Testing strategy for HIV diagnosis in low prevalence settings



Source: WHO. (June 2016). *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach, Second Edition*. Annex 7. http://www.who.int/hiv/pub/arv/arv-2016/en/

APPENDIX 2: EXAMPLE OF A STANDARDIZED LOGBOOK FOR RDT

Below is an example of a standardized logbook/register for RDT including retesting for verification that can be used in settings where both the initial and retesting for verification event will occur in the same location or in different locations. The below logbook/register includes the minimal demographic characteristics and testing information that should be collected by a national program. Programs can include, as needed, additional variables that are relevant to inform and meet the national program requirements (such as breastfeeding, pregnancy, client contact information, etc.). In addition, the below example includes the **minimum** variables for documenting retesting for verification. These include a column that 1) defines what the testing event is, i.e., the initial testing event or the retesting for verification event; 2) a column for who conducted the testing; and 3) a column for comments to address resolving any discordant results.

Example Standardized Logbook for RDT with minimum information for collecting retesting for verification information

HIV RAPID TEST RESULTS SHEET

Facility Name. …… **District** …… **Region**……

Type of HIV Testing Site *(Circle one)* **: VCT PITC PMTCT Lab C&T Other** *(Specify)* ……

No	Date (DD/MM/YYYY)	Client Name or unique ID	Sex/Pregnancy			Date of Birth (DD/MM/YYYY)	Age	Last HIV Test Result					Time Since Last HIV Test (specify days, months, or years) if applicable	Type of Testing		Test 1			Test 2			Test 3 *(if applicable)*			Final HIV Result Given to Client			Provider Name or Initials	Comments
			Male	Female Non-Preg.	Female Pregnant			Never Tested	Last Negative	Last Positive	Last Expos. Infant	Last Inconclusive		Initial Testing Event	Retesting for Verification	Name _____ Lot No _____ Exp._____			Name _____ Lot No _____ Exp._____			Name _____ Lot No _____ Exp._____							
1	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
2	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
3	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
4	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
5	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
6	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
7	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
8	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
9	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
10	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
11	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
12	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
13	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
14	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
15	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
16	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
17	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
18	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
19	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
20	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin		IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
Page totals																													

Key: VCT: voluntary counseling and testing, **PITC**: provider initiated testing and counseling, **PMTCT**: prevention to mother-to-child transmission, **Lab:** Laboratory, C&T, ART clinic, **IT**: Initial testing; **RT**: Retesting for Verification; **NR:** non-reactive, **R**: reactive, **INV**, invalid, **P:** positive, **N**: negative, **I**: indeterminate or Inconclusive

The two sections of the logbook are shown in greater detail as below.

Section 1: Demographic Characteristics

HIV R

Facility Name. …… District ……..

Type of HIV Testing Site *(Circle one)* **: VCT PITC PMTCT Lab C&T Other** *(Specify*

No	Date *(DD/MM/YYYY)*	Client Name or unique ID	Sex/Pregnancy			Date of Birth *(DD/MM/YYYY)*	Age	Last HIV Test Result				
			Male	Female Non-Preg.	Female Pregnant			Never Tested	Last Negative	Last Positive	Last Expos. Infant	Last Inconclusive
1	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
2	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
3	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
4	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
5	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
6	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
7	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
8	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
9	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
10	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
11	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
12	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
13	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
14	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
15	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
16	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
17	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
18	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
19	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
20	---- /---- /-----					---- /---- /-----		LNev	L-	L+	Lex	Lin
Page totals												

Key: VCT: voluntary counseling and testing, **PITC**: provider initiated testing and counseling, **PMTCT**: prevention to mother-to-child tra
indeterminate or Inconclusive

Section 2: Initial Testing Event or Retesting for Verification

RAPID TEST RESULTS SHEET

…… **Region**……

jy) ……

Time Since Last HIV Test (specify days, months, or years) if applicable	Type of Testing		Test 1			Test 2			Test 3 *(if applicable)*			Final HIV Result Given to Client			Provider Name or Initials	Comments
	Initial Testing Event	Retesting for Verification	Name _____ Lot No _____ Exp._____			Name _____ Lot No _____ Exp._____			Name _____ Lot No _____ Exp._____							
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		
	IT	RT	NR	R	INV	NR	R	INV	NR	R	INV	P	N	I		

nsmission, **Lab:** Laboratory, C&T, ART clinic, **IT**: Initial testing; **RT**: Retesting for Verification; **NR:** non-reactive, **R**: reactive, **INV**, invalid, **P:** positive, **N**: negative, **I**:

The red circle above highlights the column that identifies whether it is an initial testing event (IT) or a retesting for verification (RT) event.

APPENDIX 3: MODEL NATIONAL POLICY WORDING ON RETESTING FOR VERIFICATION

Country programs wishing to update their national policies in support of retesting for verification might want to consider using the following recommended edits:

Policy and section	Possible additional text in support of retesting for verification
Policy: HTS national policy ART national policy Laboratory policies **Section:** Definition of terms	**Retesting**: There are certain situations in which individuals should be retested after a defined period of time: (1) HIV negative people with recent or ongoing risk of exposure, (2) people with an HIV inconclusive status, and (3) HIV positive people before they enrol in care or initiate treatment. Reasons for retesting before initiation of care or treatment include ruling out laboratory or transcription error and either ruling in or ruling out seroconversion.[xxvii] **Retesting for verification:** testing of a new specimen for newly diagnosed individuals and those previously diagnosed but not yet initiated on ART, conducted by a different provider using the same testing algorithm, prior to, or at the time of initiation of ART.
Policy: HTS national policy **Section:** Introduction to the 5Cs	**Ensure "Correct Result" includes discussion of retesting for verification:** Correct Result: Providers of HIV testing should strive to provide high-quality testing services, and QA mechanisms should ensure that people receive a correct diagnosis. QA may include both internal and external measures and should receive support from the National Reference Laboratory. **All people who receive a positive HIV diagnosis should be retested to verify their diagnosis before/at initiation of ART.**
Policy: HTS national policy ART national policy Laboratory policies **Section:** Rationale for retesting for verification	Where national program staff want to include the rationale for retesting for verification, wording can be adapted from either this *Handbook*, Section 4: "Operationalizing Global Recommendations," or the resources listed at this end of this *Handbook*.
Policy: HTS national policy ART national policy **Section:** HIV testing	It is a priority to retest all people who are diagnosed HIV positive prior to, or at the time of, ART initiation for verification in order to verify their serostatus. Failure to do this may lead, in rare cases, to people being diagnosed incorrectly, with potentially serious adverse long-term consequences. Retesting for a person diagnosed HIV positive for verification should include: • Retesting of a new specimen for newly diagnosed individuals and those previously diagnosed but not yet initiated on ART, preferably conducted by a different provider using the same testing algorithm, as part of ART initiation; • Retesting for verification is preferably conducted at the site where the decision about ART initiation will be made.

Policy and section	Possible additional text in support of retesting for verification
	Retesting for verification aims to rule out possible technical or clerical errors, including specimen mix-up through mislabelling and transcription errors, as well as random error either by the provider or the test device. Some services that provide ART for all patients living with HIV are programmatically organized to conduct HIV testing, provide a diagnosis, and offer initiation of ART. In these programs, it may not make sense to retest for verification at a different site, although it should usually be feasible for a different provider to conduct retesting for verification on a new specimen. If the HIV status is the same upon retesting, the person's HIV positive status should be considered verified. If the status is not the same upon retesting for verification, the person or their specimen should be referred for additional follow up testing at a higher-level facility.
Policy: HTS national policy ART national policy **Section:** Initiation of ART in context of retesting for verification	Retesting for verification should NOT be a seen as a barrier to ART initiation. All people (especially pregnant/breastfeeding women, infants and children, and those with advanced WHO stage) should be started on ART, even if verification of HIV status by additional follow-up testing in a higher-level laboratory is pending. If additional testing confirms HIV negative status, ART should be discontinued and the patient (or in case of a child, the caregiver) should be informed and counselled.
Policy: HTS national policy **Section:** retesting for verification in community settings and HIVST	See relevant sections in this *Handbook,* "Section 5: When and Where of Retesting for Verification."
Policy: HTS national policy ART national policy **Section:** Risks of retesting for verification if on ART	Individuals established on ART should not be retested for verification, as there are potential risks of incorrect diagnosis. The effect of ART in suppressing viral replication may extend to suppression of the immune response and therefore of antibody production. Once a person is started on ART, low antibody titres—particularly if oral fluid-based rapid diagnostic tests are used—make it challenging to discern whether an individual is indeed HIV positive. People undergoing HIV testing must be made aware of the risk of incorrect diagnosis if they do not disclose that they are on ART. All people receiving HIV testing should be asked if they have been tested previously and told that they are HIV-infected and/or if they are now on ART or have ever received ART.
Policy: HTS national policy	Include retesting for verification in algorithm, either as part of the flowchart or as a notation at the bottom of the flowchart, stating: Before, or at the time of ART initiation, all individuals testing HIV positive must be retested using a new specimen, preferably conducted by a

Policy and section	Possible additional text in support of retesting for verification
ART national policy Laboratory policies **Section:** Algorithm	different provider using the same testing algorithm. Retesting for verification is conducted, ideally, at the site where the decision about ART initiation will be made.
Policy: HTS national policy **Section:** HIV counselling	Discuss messages for those testing HIV positive before they undergo retesting for verification. Messages are included in this *Handbook* in "Section 7: Counselling Messages."
Policy: ART national policy **Section:** Initiating ART	Before starting a patient on ART, initiate a detailed discussion about the willingness and readiness of the patient to initiate ART, the regimen, dosage, scheduling, likely benefits, possible adverse effects, and the required follow-up and monitoring visits. In the case of children with HIV, this conversation should directly involve the caregiver and include discussion about disclosing their HIV status. Retesting for verification of all newly diagnosed individuals and those previously diagnosed but not yet initiated on ART at the time of or before initiating ART is recommended to ensure a correct diagnosis of HIV infection. Initiation of ART should always consider nutritional status, any co-morbidities, and other medications being taken, in order to assess for possible interactions, contraindications, and dose adjustment.

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More information about quality management can be found in the following resources:

- WHO, Clinical and Laboratory Standards Institute, CDC. (2011). *Laboratory Quality Management System Handbook*. http://apps.who.int/iris/bitstream/10665/44665/1/9789241548274_eng.pdf
- WHO and CDC. (December 2015). *Improving the Quality of HIV-related Point-of-care Testing: Ensuring the Reliability and accuracy of Test Results.* http://www.who.int/hiv/pub/toolkits/handbook-point-of-care-testing/en/

[i] WHO. (October 2014). WHO Information Note: Reminder to retest all newly diagnosed HIV-positive individuals in accordance with WHO recommendations. http://www.who.int/hiv/pub/vct/retest-newly-diagnosed-plhiv-full/en/
[ii] WHO. (July 2015) Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection. P110. http://apps.who.int/iris/handle/10665/179870
[iii] WHO. (July 2015) Consolidated Guidelines on HIV Testing Services, 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection. P106. http://apps.who.int/iris/handle/10665/179870
[iv] WHO. (July 2012) Service Delivery Approaches to HIV testing and Counselling (HTC): A Strategic Policy Framework. Page 41. http://www.who.int/hiv/pub/vct/htc_framework/en/
[v] WHO, HIV/AIDS Programme. (April 2012). Programmatic Update Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants, Executive Summary. http://www.who.int/hiv/PMTCT_update.pdf
[vi] WHO. (June 2016). Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach, Second Edition. P xxxi. http://www.who.int/hiv/pub/arv/arv-2016/en/
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14. A report on the misdiagnosis of HIV status. WHO (2015). http://apps.who.int/iris/bitstream/10665/180231/1/WHO_HIV_2015.33_eng.pdf?ua=1

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