

Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist Guide

SPI-RT Checklist Guide

Version 12/02/2021

SECTION	REQUIREMENTS	RATIONALE	GUIDE
1.0 PERSONNEL TRAINING AND CERTIFICATION			
1.1	Have all HTS service providers undergone the approved training program?	HTS should be offered by personnel who; <ul style="list-style-type: none"> • Have been adequately trained using approved curriculum • Training certificates for HTS providers should available at site/facility for verification of training • Have undergone regular refresher training to: <ul style="list-style-type: none"> ✓ Obtain program updates ✓ Access new information ✓ Strengthen identified gaps 	Look for genuine NASCOP Certificate on VCT, PMTCT,PITC,DTC, HTC, HTS trainings <ul style="list-style-type: none"> • If none is trained score “No” • If some are trained score “partial” • If all are trained score “YES”
1.2	Are training certificates available in the testing sites/facility?		Filed/displayed /accessible copies of HTS certificates. <ul style="list-style-type: none"> • If not for all score “No” • If some score “partial” • If all are score “YES”
1.3	Have all service HTS providers undergone refresher training/CME in the last two years?		Look for HTS training records done in the last two years <ul style="list-style-type: none"> • If not for all score “No” • If some score “partial” • If all are score “YES”

1.0 PERSONNEL TRAINING AND CERTIFICATION SCORE

2.0 QUALITY ASSUARENCY IN COUNSELLING

2.1	Have all the HTS provider attended counselor support supervision in the quarter?	All HTS providers/sites should participate in quality improvement activities	Check for documentation on counselor support supervision for the the last quarterly <ul style="list-style-type: none"> • If no documentation score “No” • If not all providers are documented counselor support supervision report score “partial” • If counselor support supervision is documented for all providers score “YES”
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2.2	Have all the HTS providers conducted provider self-assessment in the last one week?		<p>Check for filled provider self-assessment forms and monthly summaries of self-assessment</p> <ul style="list-style-type: none"> • If no documentation for any provider, score “No” • If no documentation for some but all providers in the last one week, score “partial” • If documentation for all provider, score “YES”
2.3	Has the facility conducted client exit interviews on the quality and their satisfaction of HTS services received in the last year?		<p>Check for filled questionnaires on client exit interview</p> <ul style="list-style-type: none"> • If no filled questionnaires, score “No” • If client exit interview is well documented score “YES”
2.4	Have all the HTS providers had an observed practice in the last 6 months?		<p>Check for documentation/checklist on observed practice</p> <ul style="list-style-type: none"> • If no documentation for any provider, score “No” • If documentation is for some of the providers, score “partial” • If documented for all counselor , score “YES”
2.5	Has the sub-county health management team provided administrative support supervision in the last quarter?		<p>Check the facility supervisory book for documentation.</p> <ul style="list-style-type: none"> • If no documentation score “No” • If feedback is well documented score “YES”
2.6	Has the County health management team provided administrative support supervision in the last year?		<p>Check the facility supervisory book for documentation.</p> <ul style="list-style-type: none"> • If no documentation score “No” • If feedback is well documented score “YES”

2.0 QUALITY ASSURANCE IN COUNSELLING SCORE

3.0 PHYSICAL FACILITY

3.1	Is there a designated area for HTS provision?		<p>Look for a dedicated room/tent/screen used for HTS</p> <ul style="list-style-type: none"> • If HTS is not provided in any dedicated room/tent/screen, score “No” • If HTS at times not provided in dedicated room/tent/screen, score “partial” • If HTS at all times provided in dedicated room/tent/screen “YES”
3.2	Does the designated area have sufficient space for HTS?		<p>Check for sufficient space to accommodate two chairs, table, and all other physical requirements used for HTS</p> <ul style="list-style-type: none"> • If insufficient space “No” • If sufficient space “YES”
3.3	Does the HTS site have facilities to accord confidentiality?	<p>HTS should be offered in a designated area that:</p> <ul style="list-style-type: none"> • Has sufficient space • Has facilities to accord confidentiality • Is clean and organized • Has suitable facilities for secure storage of test kits within manufacturer’s instructions 	<p>Assess level of privacy (lockable room or shield with a sign indicating on session or off session)</p> <ul style="list-style-type: none"> • If no privacy measures score “No” • If some privacy measures score “partial” • If privacy measures score “YES”
3.4	Is the testing area clean and organized for service provision?		<p>Look for the uncluttered area</p> <ul style="list-style-type: none"> • If cluttered score “No” • If uncluttered score “YES”
3.5	Is there sufficient lighting in the designated testing area?		<p>Look for sufficient light (windows, electric lighting or any other source of light)</p> <ul style="list-style-type: none"> • If no lighting “No” • If not well lit, score “partial” • If sufficient lighting score “YES”
3.6	Are there suitable facilities for secure storage of test kits?		<p>Check for lockable cabinets, secure and appropriate storage of test kits</p> <ul style="list-style-type: none"> • If no cabinets/cupboards score “No” • If unlockable cabinets/cupboards score “partial” • If lockable cabinets/cupboards score “YES”

3.0 PHYSICAL FACILITY SCORE

4.0 SAFETY

4.1	Is there provision for running water (tap or engineered bucket)?	<p>During HTS provision, measures should be put in place to protect:</p> <ul style="list-style-type: none"> • Service provider and colleagues/workmates • HTS clients • Environment and community 	<p>Look for functional tap with running water or engineered bucket.</p> <ul style="list-style-type: none"> • If none score “No” • If tap/ engineered bucket not functional “partial” • If functional tap/engineered bucket with running water score “YES”
4.2	Is soap hand sanitizers/available for hand washing?		<p>Look for availability of soap/ hand sanitizers</p> <ul style="list-style-type: none"> • If none score “No” • If available but not used score “partial” • If available of soap/ hand sanitizers score “YES”
4.3	Is there waste segregation facilities?		<p>Look for coded bins, bin liners and sharps containers.</p> <ul style="list-style-type: none"> • If none score “No” • If some of the required facilities not available, score “partial” • If all required facilities available score “YES”
4.4	Is waste segregation done at the HTS site?		<p>Observe the waste segregations practices</p> <ul style="list-style-type: none"> • If not done score “No” • If segregation done score “YES”
4.5	Is PEP protocol available in case of exposure to blood and needle stick injury, splash or any other sharps injury?		<p>Check for the availability of the PEP protocol</p> <ul style="list-style-type: none"> • If none score “No” • If available, score “Yes”
4.6	Is PEP protocol followed in case of exposure to blood and needle stick injury, splash or other sharps injury?		<p>Check for documentation/knowledge e.g. incidence/occurrence book or register. If available</p> <ul style="list-style-type: none"> • If none score “No” • If partial documentation or knowledgeable, score “Partial” • If documentation or knowledgeable, score “Yes”

4.0 Safety score

5.0 PRE-TESTING PHASE

5.1	Are there Job aides for disposal of infectious and non-infectious waste at the testing site?	<p>Before testing, HTS sites are required to have the following in place:</p> <ul style="list-style-type: none"> • Job aides that provide step by step instructions on the routine tasks • Practices that ensure the quality of results during testing 	<p>Look for availability of job aides at site and displayed /accessible.</p> <ul style="list-style-type: none"> • If none score “No” • If available but not used score “partial” • If available score “YES”
5.2	Are there job aids for blood spills/body fluids management?		<p>Look for availability of job aides/displayed/accessible.</p> <ul style="list-style-type: none"> • If none score “No” • If available but not used score “partial” • If available score “YES”
5.3	Is there job aide outlining the national HTS algorithm?		<p>Look for availability of job aides/displayed /accessible (HTS algorithm).</p> <ul style="list-style-type: none"> • If none score “No” • If available but not used score “partial” • If available score “YES”
	Is DUO HIV/ Syphilis test being used?		<p>Yes/No : No score to be awarded</p>
5.4	Is there job aides outlining the correct Duo HIV/Syphilis procedure?		<p>Look for the availability of correct Duo HIV/Syphilis procedure in the job aides</p> <ul style="list-style-type: none"> • If none score “No” • If available JA has incorrect content • If correct procedure are available score “YES”
5.5	Is there job aids outlining the correct Determine procedure?		<p>Look for the availability of determine procedure in the job aides</p> <ul style="list-style-type: none"> • If none score “No” • If available JA has incorrect content • If correct procedure are available score “YES”
5.6	Is there job aids outlining the correct First Response procedure?		<p>Look for the availability of first response procedure in the job aides</p> <ul style="list-style-type: none"> • If none score “No” • If available but don’t know how to use score “partial” • If procedure are available score “YES”

5.7	Is kit expiry date observed before testing?		<p>Observe the physical kit being used; check also on the register the documented kits used</p> <ul style="list-style-type: none"> • If kit in use or on register record is/was expired, score “No” • If kit in use is not expired and no records of expired kit, score “YES”
5.8	Are test kits kept/stored as per manufacturer’s instructions?		<p>Observe kits kept away from direct sunlight, kits components are kept in the pack and where temperature appears above 30^{0c} or below 2^{0c} if measures are in place to temperature variance.</p> <ul style="list-style-type: none"> • If kits not kept as instructed score “No” • If some instructions are followed score “partial” • If all instructions are fully followed score “YES”
5.9	Is Quality control for test kits done on receiving new consignment?		<p>Ask and also check to confirm if new consignment are checked for kit damage, expiry date, delivery note and the inventory.</p> <ul style="list-style-type: none"> • If no documentation available score “No” • If not all documentation done score “partial” • If all documented, score “YES”
5.10	Is quality control done before using a new kit lot?		<p>Ask and also check to confirm from the HTS register whether new kit lots are tested using QC materials.</p> <ul style="list-style-type: none"> • If no documentation available score “No” • If not all documentation done score “partial” • If all documented, score “YES”
5.11	Is quality control for test kits done at the beginning of every month?		<p>Ask and also check to confirm from the register if test kits are tested against QC materials every month.</p> <ul style="list-style-type: none"> • If no documentation available score “No” • If not all documentation done score “partial” • If all documented, score “YES”
5.12	Are QC results properly recorded?		<p>Look for records from the HTS register. Check for the results in the HTS register.</p> <ul style="list-style-type: none"> • If not properly recorded score “No”

			<ul style="list-style-type: none"> • If well recorded but not always score “partial” ➤ If always recorded score “YES”
5.13	Are appropriate steps taken and documented when QC results are incorrect and/or invalid?		<p>Check for troubleshooting and documentation from the HTS register of incorrect/invalid QC</p> <p>Check for corrective action done and completed. If never experiences, assess knowledge on process.</p> <ul style="list-style-type: none"> • If action not recorded score and not knowledgeable, “No” • If action not always recorded/knowledge incomplete, score “partial” • If action is always recorded/knowledge is complete, score “YES”

5.0 Pre-Testing Phase Score

6.0 TESTING PHASE			
6.1	Is the HTS algorithm always followed?	<p>During testing of clients HTS providers should :</p> <ul style="list-style-type: none"> ○ Follow/adhere to procedures and protocols ○ Correctly use appropriate accessories ○ Interpret results correctly 	<p>Ask and also check if test one is documented as determine, test two is documented as first response confirm from the HTS register. Check for negative results, only determine, positive results determine and first response.</p> <ul style="list-style-type: none"> ➤ If not followed score “No” ➤ If followed but not always score “partial” ➤ If algorithm strictly followed score “YES”
6.2	Is Duo HIV/Syphilis test algorithm always followed?		<p>Ask and also check if test one is documented as Duo HIV/Syphilis, test two is documented as first response confirm from the HTS register. Check whether Duo kit is used only on ANC clients with unknown HIV status or known HIV negative. Check for negative, only Duo kit used, positive results Duo kits used as the first test and first response.</p> <ul style="list-style-type: none"> ➤ If not followed score “No” ➤ If followed but not always score “partial” ➤ If algorithm strictly followed score “YES”
6.3	Are sample collection devices (e.g., capillary tube,,		<p>Confirm by asking the service provider type of sample collection devices used per specific test, also by seeing a sample of the</p>

	disposable pipettes, etc.) used accurately?		device. <ul style="list-style-type: none"> ➤ If not accurately used score “No” ➤ If used but not always score “partial” ➤ If accurately used and always score “YES”
6.4	Is the procedure for Determine test followed?		Ask how to harvest blood, how many drops of chase buffer used in a test, incubation time. <ul style="list-style-type: none"> ➤ If not followed score “No” ➤ If followed but not always score “partial” ➤ If strictly followed score “YES”
6.5	Is the procedure for Duo HIV/Syphilis test followed?		Ask how to harvest blood, how many drops of diluents used in a test, incubation time. <ul style="list-style-type: none"> ➤ If not followed score “No” ➤ If followed but not always score “partial” ➤ If strictly followed score “YES”
6.6	Is the correct procedure First Response followed?		Ask how to harvest blood, how many drops of diluents used in a test and incubation time. <ul style="list-style-type: none"> ➤ If not followed score “No” ➤ If followed but not always score “partial” ➤ If strictly followed score “YES”
6.7	Are functional timers available for HIV rapid testing?		Check for functional timers/accessible. <ul style="list-style-type: none"> ➤ If none score “No” ➤ If available but not functional score “partial” ➤ If Available and functional timers score “YES”
6.8	Are timers routinely used for HIV rapid testing?		Confirm by asking the service provider to operate the timer. <ul style="list-style-type: none"> ➤ If not routinely used score “No” ➤ If used but not always score “partial” ➤ If routinely used score “YES”
6.9	Are test results correctly interpreted?		Ask and Check the records from the register on different scenarios of results interpretation <ul style="list-style-type: none"> ➤ If not correctly score “No” ➤ If some results interpreted correctly score “partial” ➤ If correctly score “YES”

6.0 Testing Phase Score

7.0 POST TESTING PHASE-DOCUMENTATION AND RECORDS

7.1	Are QC records routinely reviewed by the person in charge?	Records generated from HTS are supposed to be: <ul style="list-style-type: none"> • Correctly, completely captured in a timely manner • Routinely reviewed by the persons responsible to identify any possible quality issue • All records should be securely kept and archived to enhance confidentiality 	Check for review records from the HTS register. Check for supervisor signature and date of review in the HTS register. <ul style="list-style-type: none"> ➤ If not reviewed score “No” ➤ If reviewed but not always score “partial” ➤ If always reviewed score “YES”
7.2	Is there a national standardized HIV rapid testing register available and in use?		Look for the availability of the national standardized HIV rapid register. <ul style="list-style-type: none"> ➤ If none score “No” ➤ If available but not national standardized register. score “partial” ➤ If available national standardized HTS register. score “YES”
7.3	Does the HIV testing register include all of the key quality elements? E.g. kit name, expiry date, kit lot number.		Look for key quality elements in HIV testing register. <ul style="list-style-type: none"> ➤ If none score “No” ➤ If available but not all key elements. score “partial” ➤ If key quality elements available score “YES”
7.4	Are all the elements in the register recorded/captured correctly? (e.g., client demographics, kit names, lot numbers, expiration dates, HTS provider name, individual and final HIV results, etc.)?		Check for records from the HIV testing register. <ul style="list-style-type: none"> ➤ If not recorded at all score “No” ➤ If records is done but not all elements score “partial” ➤ If all the elements are found in the register score “YES”
7.5	Is the total summary at the end of each page of the register compiled accurately?		Check for records of summary from the HIV rapid testing register per page. <ul style="list-style-type: none"> ➤ If no summary done score “No” ➤ If accurate summary is done but not all the pages score “partial” ➤ If accurate summary done in all the pages score “YES”
7.6	Are invalid tests results properly recorded in the register?		Check for invalid test results tested and repeated and properly recorded in the register. Also ask if there has been an experience of invalid results. <ul style="list-style-type: none"> ➤ If yes for invalid test results done but not repeated and not recorded properly score “No”

			<ul style="list-style-type: none"> ➤ If invalid test results not always repeated and not recorded score “partial” ➤ If invalid test results are always repeated and recorded properly score “YES”
7.7	Are invalid tests repeated and results properly recorded in the register?		<p>Check for invalid test results tested and repeated and properly recorded in the register. Also ask if there has been an experience of invalid results.</p> <ul style="list-style-type: none"> ➤ If yes for invalid test results done but not repeated and not recorded properly score “No” ➤ If invalid test results not always repeated and not recorded score “partial” ➤ If invalid test results are always repeated and recorded properly score “YES”
7.8	Are all client documents and records securely kept throughout all phases of the testing process?		<p>Observe for confidentiality of document and record during testing</p> <ul style="list-style-type: none"> ➤ If records and documents are open during testing score “No” ➤ If some documents and records are left open score “partial” ➤ If all records and documents are securely kept during testing score “YES”
7.9	Are all registers and other documents kept in a secure location when not in use?		<p>Check for the availability of lockable cabinets/cupboard at the testing sites</p> <ul style="list-style-type: none"> ➤ If no lockable cabinet /cupboard available score “No” ➤ If cabinet/cupboard available but not lockable score “partial” ➤ If cabinet /cupboard available and lockable score “YES”
710	Are registers properly labeled and archived when full?		<p>Observe the labeling of registers in the archived area e.g. to indicate start date and end date, site of testing.</p> <ul style="list-style-type: none"> ➤ If archived registers not labeled score “No” ➤ If archived registers not fully labeled a score “partial” ➤ If archived registers fully labeled score “YES”

7.0 POST TESTING PHASE SCORE

8.0 ETERNAL QUALITY ASSESSMENT (PT, SUPERVISION)

8.1	Are all the HTS provider enrolled in the national PT program?	All HTS providers are required to participate in EQA as a means of monitoring their performance All HTS providers are required to participate in EQA as a means of monitoring their performance	Ask if the participant has the PT id and check in the national database <ul style="list-style-type: none"> ➤ If none is enrolled score “No” ➤ If some enrolled score “partial” ➤ If all enrolled score “YES”
8.2	Do all enrolled HTS providers test the PT samples?		Check their feedback from the participated PT round, Refer to the PT data base. <ul style="list-style-type: none"> ➤ If none has the feedback score “No” ➤ If some have the feedback score “partial” ➤ If all has the feedback score “YES”
8.3	Do all enrolled HTS providers return results to NPHL for performance evaluation (using web-based system/submitting hard copy) after testing the PT samples?		Ask if the PT participant can log on the online or they have delivered the hard copy results to the sub-county coordinator/ implementing partners <ul style="list-style-type: none"> ➤ If none has submitted the PT results in either of the methods score “No” ➤ If some have submitted the PT results in either of the methods score “partial” ➤ If all have submitted the PT results in either of the methods score “YES”
8.4	Are PT performance feedback reports received (online or hard copy) by all participants?		Check their feedback from the participated PT rounds and ask the participants by which means they received their feedback. <ul style="list-style-type: none"> ➤ If none has the feedback score “No” ➤ If some have the feedback score “partial” ➤ If all have the feedback score “YES”
8.5	Are received performance feedback reports reviewed by HTS providers and/or the person in charge at the testing point?		Check their feedback from the participated PT rounds for signage indicating review by in charge/supervisor. <ul style="list-style-type: none"> ➤ If none reviewed and signed score “No” ➤ If some reviewed and signed score “partial” ➤ If all reviewed and signed score “YES”

8.6	Are received performance feedback reports filed at site/facility?		<p>Check their feedback report in the respective files.</p> <ul style="list-style-type: none"> ➤ If no feedback report filed score “No” ➤ If some feedback report filed score “partial” ➤ If all feedback report filed score “YES”
8.7	Is corrective action implemented in case of unsatisfactory performance?		<p>Check for the corrective action reports files and records.</p> <ul style="list-style-type: none"> ➤ If no corrective action implemented score “No” ➤ If some corrective action implemented score “partial” ➤ If all corrective action implemented score “YES”
8.8	Do service providers receive periodic technical supervisory visits?		<p>Check the facility supervisory book for documentation.</p> <ul style="list-style-type: none"> ➤ If no supervision score “No” ➤ If some supervision score “partial” ➤ If periodically supervised score “YES”
8.9	Is mentorship/retraining done as required during the supervisory visit?		<p>Check for the documentation of mentorship and training e.g. observed practice</p> <ul style="list-style-type: none"> ➤ If no mentorship/training score “No” ➤ If some mentorship/training score “partial” ➤ If mentorship/training done as required score “YES”
8.10	Is feedback provided during supervisory visits and documented?		<p>Check the facility supervisory book for documentation.</p> <ul style="list-style-type: none"> ➤ If no documentation score “No” ➤ If verbal feedback with no documentation score “partial” ➤ If feedback is well documented score “YES”

8.0 EXTERNAL QUALITY ASSESSMENT (PT, SUPERVISION AND RETESTING) SCORE

