THE RAPID SYPHILIS TEST TOOLKIT

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IMPLEMENTATION 3

Training Package for Rapid Syphilis Testing

London School of Hygiene & Tropical Medicine · CIDRZ · CDC China · ciSne · Fundação Alfredo da Matta · National Institute for Medical Research · Les Centres GHESKIO · SDI · Elizabeth Glaser Pediatric AIDS Foundation · SD Syphilis Screening Program · Universidad Peruana Cayetano Heredia · TDR For research on diseases of poverty · UNICEF · UNDP · World Bank · WHO

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Training Package for Rapid Syphilis Testing

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Appendices

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Abbreviations

ANC: Antenatal care

ASSURED: Affordable, Sensitive, Specific, User-friendly, Robust, Equipment-free, Deliverable to those who need them

CIDRZ: Centre for Infectious Disease Research in Zambia

CME: Continuing Medical Education

DTS: Dried Tube Specimens

EDTA: Ethylenediaminetetracetic acid

EGPAF: Elizabeth Glaser Pediatric AIDS Foundation

EQA: External Quality Assurance

FTAA: Fluorescent Treponemal Antibody Absorption Assay

HCW: Health Care Worker

HIV: Human Immunodeficiency Virus

LMIS: Logistics Management Information System

MOH: Ministry of Health

OJT: On-the-Job Training

PMTCT: Prevention of Mother to Child Transmission

PT: Proficiency Testing

QA: Quality Assurance

QC: Quality Control

RPR: Rapid Plasma Reagin

RST: Rapid Syphilis Testing

SOP: Standard Operating Procedure

STAT: Same-Day-Testing-and-Treatment

STI: Sexually Transmitted Infection

TPHA: *Treponema pallidum* Haemagglutination Assay

TPPA: *Treponema pallidum* Particle Agglutination Assay

VDRL: Venereal Disease Research Laboratory

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1. Welcome to the Rapid Syphilis Testing Training of Trainers Workshop

This training manual is designed to accompany the Training of Trainers Workshop. Through a series of lectures, discussions, classroom activities and practical exercises in the laboratory, the workshop will bestow participants with the knowledge, skills and confidence not only to perform rapid syphilis testing safely and accurately, but to pass along these knowledge and skills to health care providers confidently and effectively.

The manual outlines the objectives of the workshop and provides a summary of each information session. Each summary is followed by a list of questions trainers may encounter and should be prepared to address. This training workshop aims to provide sufficient knowledge that trainers will feel confident to answer even the most unexpected questions. In addition, the appendix contains:

- Reference booklet for training slides
- Standard Operating Procedures for performing finger-pricks and rapid tests
- Examples of quality and stock management documentation
- Example of a certification of completion

1.1 Goal

To educate participants and provide the tools and skills required to host a rapid syphilis testing training workshop confidently.

1.2 Target Audience

This document is aimed at:

- Senior health care providers
- Programme officers and/ or managers
- Laboratory supervisors
- Heads of logistics
- Internal monitors/ supervisors
- Any individual responsible for performing rapid syphilis testing training in a formal or informal setting

1.3 Workshop Length

The Training of Trainers Workshop will take place over five days.

1.4 Evaluations

Before the workshop begins, participants will be asked to complete a brief pre-training evaluation quiz. The purpose of this evaluation is to determine how much participants already know about training, syphilis, rapid syphilis testing, and quality assurance. The outcome of this evaluation will in no way affect the participants' enrolment in the workshop or their ability to complete the training modules successfully. At the end of the workshop, participants will complete a written post-training evaluation. This will enable trainers to gauge how much was learned over the five days. The evaluation will also have a practical component: participants will be observed performing rapid syphilis tests during the final laboratory practicum on day five. **In order to receive a certificate, participants must attend 100% of the sessions, and score a minimum of 80% on the written component and 100% on the practical component of the final evaluation.**

1.5 Certification

At the close of the workshop, participants will be presented with a certificate to document their attendance and successful completion of the Rapid Syphilis Testing Training of Trainers Workshop.

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2. Preparation

Careful planning, using the information provided below, will help ensure your workshop is a success. This part of the manual describes the activities you should carry out before the workshop, which will enable you to achieve the goals and objectives of the Rapid Syphilis Testing Training workshop.

2.1 Participants

The Rapid Syphilis Testing Training Workshop is designed for all levels of health care workers, especially those working in antenatal care and with high risk populations, and laboratory staff responsible for performing rapid syphilis testing. Some of the content may be more applicable to health care workers, and some may be more applicable to laboratory staff. It is important to be well prepared for training and have a strong understanding of the content so that you can highlight areas that are relevant to the audience. This will be particularly important when workshop participants have a range of professional backgrounds.

2.1.1 Understanding the Participants

Every participant will have a different level of background knowledge, which may vary with education, experience, or job responsibilities. It is important for the trainer to understand participants' baseline knowledge. This enables the trainer to adjust the timing of presentations to ensure everyone understands the concepts. By asking participants questions on their own personal experiences throughout the workshop, the trainer will be able to address their fears and ensure the entire class receives a certificate in rapid syphilis testing.

During the training workshop in Tanzania, trainers discovered that health care workers who had been trained in HIV rapid testing and were performing PMTCT (Prevention of Mother to Child Transmission) at their clinic learned how to perform rapid syphilis tests much faster than those who had never been trained in rapid testing before. The trainers also discovered that there was no difference between the skills of health care workers who had been trained to perform Rapid Plasma Reagin for syphilis and those who had not. After learning the participants' baseline knowledge, the trainers were able to provide health care workers who were performing a rapid test for the first time with extra instruction. By the end of the workshop, all health care workers could confidently perform the rapid syphilis test!

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2.1.2 The ideal number of participants and trainers

The size of a training workshop is an important factor in determining how successful it will be. The class cannot be too big: otherwise participants will have no opportunity to share experiences and fully engage in the learning experience. Nor can it be too small: otherwise there will not be enough variety of experience and viewpoints to provoke fruitful discussion. It is recommended that a rapid syphilis testing training workshop have no more than *20 participants* with a minimum of *2 trainers*. The optimal number of trainers is between 4 and 6: this allows each participant the opportunity to ask questions during demonstrations and practical exercises.

2.1.3 Participant notification letter

All participants will need written notification of the workshop. A letter stating the name, goal, date, time, and location of the workshop should be circulated well in advance. The letter should also include information about transport allowances and per diems.

2.1.4 Breaks and lunch

It is important to give participants regular breaks so that they do not lose focus or become tired during lectures or practical sessions. Before the workshop, you will need to arrange catering for morning and afternoon tea/ coffee breaks and lunch. Bottled water should be provided throughout the day, except when the module is being held in the laboratory where all food and drink are prohibited.

2.2 Facilities and Equipment

2.2.1 Training Classrooms

Two rooms should be made available throughout the training workshop. One classroom will be needed for lectures, discussions, and written exercises. This room must be well lit, with enough tables and chairs for all participants. To facilitate discussion, participants should sit in a semi-circle. You should also check that there are electrical outlets in convenient locations for a computer and projector to be plugged in.

A second room will be needed for the hands-on practical laboratory exercises. This room will be used to practice syphilis testing. You will need to put the appropriate biosafety measures in place and ensure capacity for disposal of biohazardous waste material. There must be sufficient benches or tables for all participants to practice syphilis testing at the same time without being cluttered or crowded.

2.2.2 Classroom Equipment and Supplies

Arrangements to secure and transport the equipment and supplies needed for the classroom should be made well in advance. Any unused supplies should be held for future workshops.

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The class room should contain the following equipment and supplies:

Equipment	Supplies
■ 2 flipcharts with easel ■ Laptop computer ■ Projection monitor which is compatible with the computer ■ Extension cord ■ Wastebasket	■ Markers ■ Masking tape ■ Note pads ■ Pens and pencils

2.2.3 Practical Exercises: Materials and Supplies

Arrangements to secure and transport the equipment and supplies needed for the laboratory should be made well in advance. Any unused supplies should be held for future workshops.

Below is a table you can use to prepare for the workshop:

Materials and Supplies	# Required	√ for completion
70% Alcohol or methylated spirit swabs		
Cotton gauze or wool		
Sterile Lancets*		
Sharps bin or disinfectant jar for lancets		
Timer (stopwatch, clock, wrist watch)		
Markers, Pens		
Biohazard stickers/ labels		
Plastic bags for biohazard waste		
Transfer or precision pipettes*		
Pipette Tips		
Gloves		
Aprons or laboratory coats		
Paper towels		
Soap or hand sanitizer for hand washing		
Disinfectant (Jik, Chlorox etc)		
Spray bottle for disinfectant		

*Sterile Lancets and Transfer pipettes may be included in the syphilis test kit. Check with the manufacturer or distributor to find out what is included in the test kits and what will need to be ordered separately.

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2.3 Test kits

The following table is designed to assist you to prepare for practical sessions and the practical component of the evaluation. Using it will ensure that there you have an adequate number of tests to conduct the workshop. The test used should be approved for use in your national testing algorithm and should be the same test that will be used in clinics and laboratories as part of the syphilis testing programme.

The number of tests required for each practical session can be calculated using *equation 1*.

Equation 1:
(# Participants) x (# Tests/Participant) + (Demo & Extra) = Total # Tests

2.3.1 Number of Tests Required for Each Practical

Practical Orientation to Rapid Syphilis Testing (4.6) Part I Each participant conducts tests using one positive and one negative sample				
Test	# of Participants	# Tests/ Participant	Demo & Extra	Total # Tests
Syphilis Test ( )	( )	2	15	( )

- Write the name of the syphilis test in the column "Test", e.g. "SD Bioline"
- Write the number of participants in the column "# of participants", e.g. "20"
- To calculate the total # of tests needed for each practical, use *equation 1*

For example, if there were 20 participants, a total of 55 tests would be needed for Module 4.6 Part I.

(# Participants) x (# Tests/Participant) + (Demo & Extra) = Total # Tests

Participants: 20
Tests/ Participant: 2 (listed in table)
Demo & Extra: 15 (listed in table)
(20) x (2) + (15) = 55

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Practical Orientation to Rapid Syphilis Testing (4.6) Part II Each participant conducts tests using five blinded samples				
Test	# of Participants	# Tests/ Participant	Demo & Extra	Total # Tests
Syphilis Test ( )	( )	5	25	( )

- Write the name of the syphilis test in the column "Test", e.g. "SD Bioline"
- Write the number of participants in the column "# of participants", e.g. "20"
- To calculate the total # of tests needed for each practical, use *equation 1*

For example, if there were 20 participants, a total of 55 tests would be needed for Module 4.6 Part II.

(# Participants) x (# Tests/Participant) + (Demo & Extra) = Total # Tests

Participants: 20
Tests/ Participant: 5 (listed in table)
Demo & Extra: 25 (listed in table)
(20) x (5) + (25) = 125

Practical Testing with Dried Tube Specimens (4.15) Each participant conducts tests using five blinded samples				
Test*	# of Participants	# Tests/ Participant	Demo & Extra	Total # Tests
Syphilis Test ( )	( )	5	25	( )

- Write the name of the syphilis test in the column "Test", e.g. "SD Bioline"
- Write the number of participants in the column "# of participants", e.g. "20"
- To calculate the total # of tests needed for each practical, use *equation 1*

For example, if there were 20 participants, a total of 55 tests would be needed for Module 4.15.

(# Participants) x (# Tests/Participant) + (Demo & Extra) = Total # Tests

Participants: 20
Tests/ Participant: 5 (listed in table)
Demo & Extra: 25 (listed in table)
(20) x (5) + (25) = 125

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Evaluation: Practical Component Each participant conducts tests using five blind samples				
Test*	# of Participants	# Tests/ Participant	Demo & Extra	Total # Tests
Syphilis Test ( )	( )	5	20	( )

- Write the name of the syphilis test in the column "Test", e.g. "SD Bioline"
- Write the number of participants in the column "# of participants", e.g. "20"
- To calculate the total # of tests needed for each practical, use *equation 1*

For example, if there were 20 participants, a total of 55 tests would be needed for the practical evaluation.

(# Participants) x (# Tests/Participant) + (Demo & Extra) = Total # Tests

Participants: 20
Tests/ Participant: 5 (listed in table)
Demo & Extra: 20 (listed in table)
(20) x (5) + (20) = 125

2.3.2 Total Number of Tests and Kits Required for a Rapid Syphilis Testing Training Workshop

The total number of tests required for the Training of Health Care Workers Workshop can be calculated using *equation 2*.

Equation 2:
(Total # Tests Module 4.6 Part I) + (Total # Tests Module 4.6 Part II) + (Total # Tests Module 4.15) + (Total # Tests Evaluation) = Total # Tests for Workshop

For example, if there were 20 participants, a total of 425 tests would be needed for the Training of Health Care Workers workshop. Using *equation 2*:

Total # Tests Module 4.6 Part I: 55
Total # Tests Module 4.6 Part II: 125
Total # Tests Module 4.15: 125
Total # Tests Evaluation: 120
(55) + (125) + (125) + (120) = 425

The total number of *test kits* required for the Training of Health Care Workers Workshop can be determined by completing the table below using the instructions listed as bullet points.

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Test	Total # Tests Required	# of Tests/Kit	Total # Test Kits Required
Syphilis Test ( )	( )	( )	( )

- Write the name of the syphilis and HIV test in the "Test" column, e.g. "Syphilis Test (SD Bioline)"
- Write the total number of tests needed for the workshop (from *equation 2*) in the column "Total # Tests Required"
- Write the number of tests packaged in one kit in the column "# Tests/Kit". This will be found on a package of tests or on a supply invoice.
- The number of tests kits required is equal to the total number of test kits required divided by the number of tests per kit. It can be calculated using *equation 3*.

Equation 3:

$$\frac{\text{Total \# Tests Required}}{\text{\# Tests/Kit}} = \text{Total \# Kits Required}$$

For example, if there were 20 participants needing 425 tests, and each kit contained 30 tests, a total of 15 test kits would be required for a Training of Health Care Workers Workshop. Using equation 3:

Total # Tests Required: 425
Tests/ Kit: 30 (example)
(425) / (30) = 15

In this situation, the exact answer to *equation 3* is 14.17 but you cannot order a portion of a kit! 14.17 was therefore rounded up to 15 to ensure there would be enough tests. It is far better to have too many tests for the training workshop than not enough. As long as the foil pouch of the test has not been opened, the test can be stored and used by the central laboratory in the quality programme, by another training workshop, or by the supervisor/ internal monitor. **Any extra tests should be stored in a cool, dry room, on a shelf and not on the floor. They should not be used – even for training – beyond the expiration date listed on the side of the kit.**

2.4 Composition of Panels for Practical Sessions

The composition of the known positive and known negative samples and blind samples used during the practical sessions is specified as whole blood. Whole blood should be stored in ethylenediaminetetraacetic acid (EDTA) vials to prevent coagulation.

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The dried tube specimens should be manufactured at an accredited laboratory according to the attached Standard Operating Procedure for the preparation of dried tube specimens **(Appendix 6).**

A possible source of whole blood for samples is the local blood bank. Most blood banks screen donations for syphilis and discard any blood found to be positive. All blood should be re-tested at the accredited laboratory. At least one treponemal test (e.g. *Treponema Pallidum* Particle Agglutination technique (TPPA) or *Treponema Pallidum* Haemagglutination Test (TPHA)) and one non-treponemal test (e.g. Rapid Plasma Reagin (RPR) or Venereal Disease Research Laboratory (VDRL)) should be performed on each incoming lot to characterize the samples as positive or negative. Records of this should be signed, dated and filed in a dedicated folder in the laboratory.

2.4.1 Preparing for Practical Orientation to Rapid Syphilis Testing (4.6) Part I
During Module 6 Part I, participants will be introduced to the laboratory setting and to rapid syphilis testing. Each participant will perform the test twice, using one positive and one negative sample.

Prepare a whole blood panel consisting of two samples (one syphilis positive and one syphilis negative) for each workshop participant. Label each vial with the expected test result ("positive" or "negative"), lot number and expiration date. The lot number allows the vial to be traced to the original source material and records of confirmatory testing. Allow 4-5 days for the preparation and testing of panels prior to the workshop.

The total sample volume required for preparing panels for Module 6, Part I can be calculated using *equation 4*.

Equation 4:
(Volume/ Vial) x (# of participants) + (10% for Overage) = Total Volume Required

This equation can be broken down into three parts:

4a. (Volume/ Vial) x (# of participants) = Volume for Participants
4b. (Volume for Participants (4a)) x (0.10) = 10% for Overage
4c. (Volume for Participants (4a)) + (10% for Overage(4b)) = Total Volume Required

For example, if there were 20 participants, the total sample volume required for each vial in Module 6, Part I would be:

Volume/ Vial: 0.5 mL (from table)	4a. (0.5 mL) x (20) = 10 mL
# of participants: 20	4b. (10 mL) x (10% or 0.10) = 1 mL
10% for Overage: 1 mL (from 4b)	4c. (10 mL) + (1 mL) = 11 mL

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Sample Volume Required for Preparing Panels Module 6, Part I

Syphilis Expected RST Result	Sample Reactivity	Volume/ EDTA Vial	# of Participants	Extra 10% for overage	Total Volume Required
Positive	Strong Positive	0.5 mL	( )	( )	( ) mL
Negative	Negative	0.5 mL	( )	( )	( ) mL

- Enter the # of participants in the "# Participants" column
- The Extra 10% for overage can be calculated using *equation 4b*
- Total Volume Required is calculated using *equation 4*

2.4.2 Preparing for Practical Orientation to Rapid Syphilis Testing (4.6) Part II

During Module 6 Part II, participants will practice testing using 5-blinded samples. This will give participants an opportunity to practice reading and interpreting the results of a rapid test. Each participant will require a total of 10 blinded samples (2 panels of 5). One panel (5 samples) will be used in Module 6 Part II, and a second panel (5 samples) will be used in the final practical evaluation.

Each panel will be made up of five samples: 2 strong positives, 2 weak positives and 1 negative.

It is advisable to have extra panels on hand in case of problems or spillage. Allow 4-5 days for preparation and testing of panels prior to the workshop.

The total sample volume required for preparing panels for Module 6, Part I can be calculated using *equation 5*.

Equation 5:
(# Samples/ Participant) x (# of participants) x (Volume/ Vial) + (10% for Overage) = Total Volume Required

This equation can be broken down into four parts:

5a. (# Samples/ Participant) x (# of participants) = # Samples
5b. (# Samples (5a)) x (Volume/ Vial) = Volume for participants
5c. (Volume for Participants (5b)) x (0.10) = 10% for Overage
5d. (Volume for Participants (5b)) + (10% for Overage (5c))
= Total Volume Required

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For example, if there were 20 participants, the total sample volume required for a strong positive panel member would be:

# Samples/ participant: 4 (from table)	5a. (4) x (20) = 80
# of participants: 20	5b. (0.5 mL) x (80) = 40 mL
Volume/ Vial: 0.5 mL (from table)	5c. (40 mL) x (10% or 0.10) = 4 mL
10% for Overage: 1 mL (from 5c)	5d. (40 mL) + (4 mL) = 44 mL

Sample Volume Required for Preparing Panels for Module 6, Part II and Final Practical Evaluation

Syphilis Expected RST Result	Sample Reactivity	# Samples/ Participant	# Participants	Volume/ Vial	Extra 10% for overage	Total Volume Required
Positive	Strong Positive	4	( )	0.5 mL	( )	( ) mL
Positive	Weak Positive	4	( )	0.5 mL	( )	( ) mL
Negative	Negative	2	( )	0.5 mL	( )	( ) mL

- Enter the # of participants in the "# Participants" column
- The Extra 10% for overage can be calculated using equation 5c
- Total Volume Required is calculated using equation 5

For *Module 6 Part II*, make 4 sets of 5 panels each containing 5 sample vials labelled according to the table below:

Labelling Vials and Panels

Panel Code	# of Sets	Strong Positive 1	Strong Positive 2	Weak Positive 1	Weak Positive 2	Negative 1
A	4	A1	A2	A3	A4	A5
B	4	B1	B2	B3	B4	B5
C	4	C1	C2	C3	C4	C5
D	4	D1	D2	D3	D4	D5
E	4	E1	E2	E3	E4	E5

- Each participant will receive one panel.
- If the workshop has more or less than 20 participants, adjust the number of sets of panels.

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For the Final Practical Evaluation, make 4 sets of 5 panels each containing 5 sample vials labelled according to the table below:

Panel Code	# of Sets	Negative 1	Weak Positive 1	Weak Positive 2	Strong Positive 1	Strong Positive 1
A	4	A1	A2	A3	A4	A5
B	4	B1	B2	B3	B4	B5
C	4	C1	C2	C3	C4	C5
D	4	D1	D2	D3	D4	D5
E	4	E1	E2	E3	E4	E5

Note: for the Final Practical Evaluation, the labelling has been changed from Module 6 Part II.

2.4.3 Preparing for Practical Testing with Dried Tube Specimens (4.15)
During Module 15, participants will have an opportunity to practice rapid syphilis testing using the dried tube specimens (DTS) they re-constituted at the end of Module 6, Part II. Each participant will practice testing using 5 samples.

You will need to prepare the dried tube specimens according to the Standard Operating Procedure **(Appendix 6)**, using two strong positive samples, two weak positive samples, and one negative sample.

Label dried tube specimen vials with a panel code, lot number and expiry date. The lot number allows the vial to be traced to the original source material, manufacturing records, and results of confirmatory testing. The dried tube specimens should be labelled in a similar manner to the panels used in Module 6 Part II.

It is advisable to have extra panels on hand in case of problems or spillage. Allow 2 weeks for dried tube specimen manufacture and for the preparation and testing of panels prior to the workshop.

2.4.5 Preparing for Evaluation: Practical Component
During the final practical evaluation, participants will perform rapid syphilis tests using a panel of 5 blinded samples. The purpose of the evaluation is to ensure that participants are able to perform rapid syphilis testing safely, confidently and accurately and correctly interpret the test results.

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2.5 Validation of Panels

All panel samples used during the practical laboratory sessions MUST be validated before the workshop to ensure that the expected result is obtained on the rapid syphilis test kit used. You can do this by sampling vials from each lot and testing them using the test kits. A record of the validation of panels should be filed in the folder containing the results of the initial sample characterization.

2.6 Print Materials Needed During Training

It is the responsibility of the workshop trainer or facilitator to ensure each participant has the appropriate materials at the start of the workshop.
Each participant will need:

- Workshop agenda
- Rapid Syphilis Testing Training of Health Care Workers Manual which includes:
  - A pre-course and post-course written evaluation
  - A form to complete during the post-course practical evaluation
  - Presentation slides
  - Forms to complete during laboratory practical sessions
  - Forms to complete during classroom practical sessions
  - Standard Operating Procedures for performing a finger-prick, performing rapid syphilis testing, re-constituting Dried Tube Specimens and testing with Dried Tube Specimens
- Name tents
- Name badges

2.6.1 Presentation Slides

A series of presentations slides have been prepared as part of the training package **(Appendix C).** These are available online at **http://www.lshtm.ac.uk/itd/crd/research/rapidsyphilistoolkit/index.html** and are designed to assist trainers during Training of Healthcare Facility Staff Workshops. One slide set has been prepared for each of the 14 classroom lectures. The content of the slides is described in the Trainers Notes.

The slide set provided is generic and *must be modified by trainers before* the workshop to reflect the date and location of the workshop, and programme specifics. Not all slides may be applicable in your setting and many may need to be modified to reflect programme objectives and national guidelines. It is important that trainers read through the presentation slides and training notes carefully, and make the appropriate changes *before* the slides are printed and distributed to participants.

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The following list has some suggestions of changes you may need to make to the presentations slides before the workshop:

- Insertion of date and location of workshop
- Insertion of the logo of the implementing organization or MOH
  - Permission may be needed: contact programme manager for more information
- Deletion of slides that are not relevant
  - Updating of programme specific information such as programme goals, objectives, quality management system, data collection forms
- Updating of country specific information such as treatment guidelines, partner management, supply chain management, local supervision

After you have made all the updates, it may be helpful to have the programme manager and a ministry or district health official review the presentation slides to ensure they are consistent with both the programme goals and objectives and national guidelines.

One module, Orientation to Rapid Syphilis Tests, has a set of blank presentation slides which must be updated based on the standard operating procedure (SOP) used in training. This objective of this module is to introduce and familiarize participants with the process of performing rapid syphilis tests before they have an opportunity to perform the tests in the laboratory. Trainers should therefore refer to the programme's Standard Operating Procedure (SOP) for Rapid Syphilis Testing throughout this session.

2.7 Training Certificates

Each participant who attends the workshop and fulfils the certification criteria will receive a certificate.

Certification Criteria

- Minimum score of 80% on the written evaluation
- Score of 100% on the practical evaluation
- 100% attendance to all classroom lectures and practical laboratory sessions

Before the workshop, you should identify the individual(s) who will sign the certificate, verify the spelling of participants' names, and make any final amendments to the Certificate of Training template (**Appendix 3**). You will need to print certificates before the workshop so that they are ready to distribute on day 2 after final evaluations have been scored.

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2.8 Length of Workshop

The Training of Health Care Workers Rapid Syphilis Testing Workshop has been designed to take place over *two days*. Each day will finish with a practical exercise in the laboratory. There will be a written and practical evaluation at the end of day 2. You may be able to adjust the timing of the workshop depending on the baseline knowledge and experience of the participants; however, the materials provided in the training package have been designed for a *two day* training session.

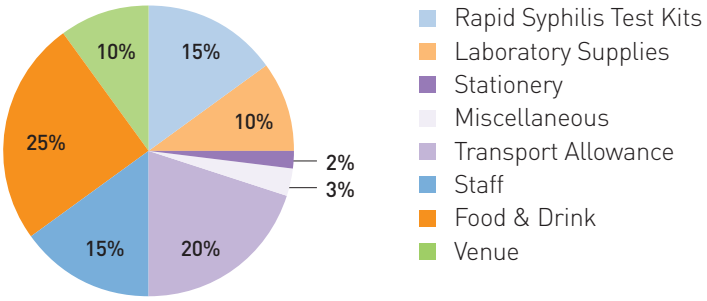
2.9 Budgeting for Training

When preparing to host a Rapid Syphilis Testing Training Workshop, future trainers will need to be able to create a budget outlining the items which will need to be purchased, the cost of each item and the total cost for the workshop. Your budget should describe the workshop, the number of days, the number of facilitators and participants and the venue. Budget items will include:

- Staff salaries
- Renting a venue and equipment
- Food and drink for lunches and coffee breaks
- Travel allowances for participants or per diems
- Test kits for participants to use during the practical exercises
- Laboratory supplies required to manufacture sample panels and DTS for use during the practical modules
- Stationery
- Printing training packages
- An additional allotment for miscellaneous or unexpected costs incurred during the planning stages or during the workshop

Below is an outline of the approximate allocation of the training workshop budget:

Estimated Workshop Costs



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2.10 Ready... Set... Go! Preparation Checklist

Below is a checklist summarizing all the preparations you need to make before the Rapid Syphilis Test workshop.

Put a check in the "completed" column once the activity has been carried out. If someone else is responsible for carrying out one of the preparatory activities, make sure they finish their task in time for the workshop. It is your responsibility as the trainer to ensure everything is ready to go at the start of the workshop.

Preparing for Rapid Syphilis Test Workshop: Checklist

Activity: 6-8 weeks before the workshop	Individual Responsible	(√) Check when Complete
Identify target audience.		
Verify training budget.		
Agree on maximum number of participants.		
Finalize names of trainers.		
Identify training site.		
Send letter of invitation to co-trainers.		
Meet with co-trainers to coordinate roles and responsibilities.		
Review the participant manual and other training material.		
Adapt course content based on national guidelines.		
Determine training supplies and materials needed for workshop.		
Develop a detailed agenda setting time-frame for course and speakers.		
Set DATE and LOCATION for workshop. Verify that the date does not coincide with major events, religious holidays or other training workshops.		
Identify and contract an accredited laboratory to manufacture DTS.		

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Activity: 4 weeks before the workshop	Individual Responsible	(√) Check when Complete
Agree on per-diem and travel allowance for co-trainers and participants.		
Confirm arrangements for travel and lodging for co-trainers, if necessary.		
Confirm arrangements for travel and lodging for participants, if necessary.		
Develop workshop announcement and registration materials.		
Mail workshop announcement and registration materials to target audience.		
Send letter of confirmation to co-trainers.		
Develop course flyer and registration materials.		
Order training equipment and materials including pencils, pens, reagents, and test kits.		
Provide deadlines for co-trainers for submitting audiovisual materials, audiovisual needs and handouts for printing.		

Activity: 3 weeks before the workshop	Individual Responsible	(√) Check when Complete
Reserve audiovisual equipment and check working condition.		
Obtain flip charts, pointers, felt tip markers and all training materials.		
Confirm training venue location and check the location has adequate light, space, seating, tables/ benches and appropriate laboratory biosafety and biohazard regulations.		
Adapt pre and post written evaluations to reflect revised presentations and National Guidelines.		

Activity: 2 weeks before the workshop	Individual Responsible	(√) Check when Complete
Print and assemble participant manual including handouts, pre and post-evaluations, agenda, SOPs, worksheets.		
Check progress of preparation of panels and DTS at laboratory.		
Check progress of participant registration.		
Assemble audiovisual materials (power point files, videos, overheads).		

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Activity: 1 weeks before the workshop	Individual Responsible	(√) Check when Complete
Make name tags for participants and co-trainers.		
Develop a sign in sheet for participants.		
Finalize and print course certificate. Have appropriate individuals sign certificates.		
Confirm audiovisual reservations.		
Prepare training supplies and materials for transport to training site.		
Review and rehearse training curriculum.		
Prepare welcome and directional signs for the training site.		

During the workshop	Individual Responsible	(√) Check when Complete
Day 1: One hour before start time — Place welcome and directional signs at the facility — Set up a table participants registration/ sign in and to hand-out name-tags and participant manual — Check set up of room audiovisual equipment, supplies, temperature — Place bottled water on each table		
Day 1: — Conduct the training according to agenda — Conduct pre-workshop evaluation		
Day 2: — Check set up of room — Check audiovisual equipment — Adjust temperature — Place bottled water on each table — Check all supplies are in place — Conduct post-workshop evaluation		

Immediately after the workshop	Individual Responsible	(√) Check when Complete
Debrief with co-trainers.		
Assemble and score pre-and post-evaluations.		
Prepare report of training.		

1-3 months after the workshop	Individual Responsible	(√) Check when Complete
Follow up with participants to verify if they were able to apply knowledge and skills obtained during the workshop.		
Identify additional technical assistance or further training needed.		

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3. How to Train

3.1 Role and Responsibility of a Trainer

The role of a trainer is to bestow information and skills; to answer and address questions and queries; and, as a result of this, to equip health care providers and workshop participants with the practical knowledge and ability they need to perform rapid syphilis testing confidently in a clinical setting.

For trainers to do this effectively, they will need to have a good understanding of the programme protocol, the training materials, national guidelines, and their audience. Trainers also need to be prepared to train, to manage the training, to communicate effectively throughout the training, to engage participants and to employ visual aids.

3.1.1 Know your audience

Knowing the audience is an essential component of being an effective trainer. A good understanding of the target audience will enable the trainer to design the workshop so that it is interesting and relevant, and so that the skills and knowledge acquired over the two days will be effectively implemented in the clinical setting.

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The table below outlines how the design of the workshop might alter based on the audience:

Audience	Effect on Workshop Design
Knowledge	Participants' baseline knowledge will help you decide when to spend more time explaining a concept, and when to go through information more quickly or even delete it from the agenda.
Skills	Participants' background skill is important when designing practical laboratory sessions and planning the amount of time and number of demonstrations that are needed.
Attitudes	Understanding participants' attitudes towards the content of the workshop can help you address traditionally held beliefs, fears, or concerns during training.
Experience	Knowing the level of participants' experience will help you design the content of lectures and practical sessions. It will also help you to identify participants who have a breadth of experience to contribute to discussions.
Job Title/ Position	This will allow you to relate the material in the lectures and practical exercises to participants' jobs.
Workshop expectations	Understanding participants' expectations of the workshop can help you to alter the timing of lectures or practical sessions to ensure everyone is satisfied at the completion of the workshop.

3.1.1b Ways to Learn about the audience

There are many ways to learn about the audience, both before the workshop begins and throughout the workshop.

Before the workshop begins, conduct a needs assessment. You can do this by asking participants to complete a questionnaire about their job, experience with rapid testing, and knowledge of syphilis. If participants are working in rural areas, it may be hard to collect the forms from them before the workshop begins. In this situation, you might find it helpful to speak with a coordinator or supervisor at the district to gain an understanding of the jobs, experience and training of participants. There will also be time during the registration session to speak with participants about this.

During the training workshop, you could use an "ice-breaker" or introductory activity to get participants to introduce themselves, their job title and clinic, their experience with rapid testing, and one experience they've had with syphilis, syphilis testing or rapid testing. Asking questions throughout the workshop sessions and during the breaks will also help you to understand the audience.

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3.1.2 Be prepared to train

A trainer must arrive at the workshop prepared to train. This means:

- Knowing the goals and objectives of the training workshop
- Having a good understanding of the content of each of the modules
- Being able to answer questions and explain the content in detail
- Knowing the training material

You will need to read over the training package, review the slides, practice presenting and review practical exercises.

You may find it helpful to practice presenting the material in front of a mirror, family member or friend to get feedback on your clarity, volume and speed of delivery. It is also important to practice presenting with a watch to ensure that no session goes over the allotted time and cuts into the next module or exercise – and also that sessions do not end too early.

Before the workshop begins, you will need to prepare the training room:

- Check that all audiovisual equipment is working correctly
- Arrange tables and chairs in a semi-circle so that all participants have an unobstructed view of the projector screen
- Have all materials, supplies and equipment in place
- Put out water on each table
- Check whether you need to adjust the temperature

You should also check the classroom that will be used for the practical exercises to ensure that all equipment, materials and supplies are in place. These include:

- Aprons or gowns
- Test kits
- Test panels
- Biohazard waste disposal bins
- Disinfectants and soap

No matter how organized and well prepared a trainer is, problems can still occur. It is a good idea to have a back-up plan so that the workshop is not disrupted. This may include having extra materials and supplies, or having hand-outs for the presentations in case the electricity cuts out. It is important that you remain calm and make the best of the situation.

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3.1.3 Manage the training

The trainer is also the manager of the training workshop. It is the responsibility of the trainer to make sure the goals and objectives of the workshop are met in the allotted time. This will require careful management of time, participants and the setting.

Keeping on *time* is important so that participants can know what to expect and no presentation has to be rushed or cut short.

Ways to keep on time include practicing the presentations aloud using a watch. You should also practice using the audiovisual equipment. If you are familiar with the presentations, you will know what material you can cover quickly in a time-crunch and what you can delete in order to keep to the agenda.

Make sure that you can see a clock while you are giving presentations. This will help you avoid going over the time limit or cutting a presentation short. It may be necessary to have a co-trainer give a visual signal to show there are five minutes left so that you can begin to wrap up the lecture.

Give a time next to each activity on the agenda. This will reinforce the amount of time each presentation, activity or break is supposed to take.

If a discussion starts to go over the time allotted for a session, suggest continuing during the breaks or over lunch or have participants write the topic on a flip charts so that it can be picked up again when there is more time. Adjust the schedule when things take longer by shortening breaks or lunch, lengthening the day or deleting an activity.

Managing *difficult participants* is another one of the trainer's responsibilities. Difficult participants can disrupt the workshop and ruin the experience of the other participants. The table below lists examples of difficult participants and how to manage their behaviour:

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Types of difficult participants behaviour	Description	Ways to manage behaviour
Dominates the conversation	These individuals tend to have a lot of experience and knowledge and are very eager to share with other participants.	— Thank them for their valuable contribution and mention the need to hear from other participants — Mention that they have already provided a lot to the discussion and it would be valuable to hear from others — Use body language (not looking at them or standing in front of them looking at other participants when asking for responses) or ignore them — It may become necessary to interrupt them and summarize their comments before hearing from other participants — Give them a task to do that supports the course objectives — If necessary, speak to them privately outside the training room
Interrupts others	These individuals have a habit of interrupting others.	— Mention that the other person was not finished speaking — If necessary, speak to them privately outside the training room
Know-it-all	These participants think they know everything and will make remarks to undermine the knowledge or authority of the trainer.	— Acknowledge their valuable experience and ask if there are other opinions — When they ask a question, ask them what they think the answer is or open up the question to others — Give them a task to help with the training — If necessary, speak to them privately outside the training room
Does not participate	These participants may be shy or uninterested, or might have been forced to attend the training. They may not be the appropriate person to be attending the training. They will not respond or speak up during discussions.	— Use body language to encourage them to participate — Look directly at them when asking to hear from people who have not contributed — Stand beside them and look at them when asking questions — Talk to them outside the training room to establish a good rapport — Find out about their experience and knowledge and ask targeted questions — Ask them to help during training (writing on flip chart, passing out papers, summarising key concepts) — If necessary, speak to them in private and ask why they are not involved in the training

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Types of difficult participants behaviour	Description	Ways to manage behaviour
Does not want to be at the training	These participants have been forced to come to workshop by a supervisor. They can resent the training and see it as a punishment.	— During the introduction, mention that everyone has different reasons for coming to training. Remind participants to be open minded because there is something to be learned from any situation — Emphasize the value of each individual and their contribution to the success of the workshop — Describe the follow-up process after the workshop has finished, emphasizing that participants may need to demonstrate the skills acquired as part of their job requirements
	Some participants like to attend trainings to earn extra money through the per diem or because it gets them away from the office. They may not think their participation is necessary.	— Emphasize the value of each individual and how they will contribute to the success of the training. — Ask them to help during training (writing on flip chart, passing out papers, summarising key concepts)

Other difficulties you will have to manage include *location of training, the classroom, equipment* and *materials*.

You should consider the *location* of the training course carefully. It is important that it be held away from participants' work and families so that they are not distracted. Participants will be more likely to arrive on time and be focused throughout the course if they stay in a hotel away from distractions. It is also important that the workshop is not too difficult to get to, as this may discourage participants from attending. Transporting participants over long distances will also increase the cost of the workshop.

The *classroom* may not be ideal. If the room is too hot or cold, participants may become distracted. Try to find a temperature that is comfortable for the majority of participants. There should be electrical outlets at the front of the classroom so that the laptop and projector can be plugged in. If there is not a conveniently located outlet, you will need an extension cord – but be careful it is secured or taped to the floor so nobody trips. Ensure that the lighting is bright enough for participants to read the hand-outs but not so bright that it is difficult to view the slides on the projector screen. You should also inspect the size of the training room. It is important that all participants can be seated comfortably without being crowded.

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Equipment failures or problems with materials may disrupt the training workshop. You should consider possible problems and try to brainstorm solutions before the workshop so that you are prepared for any situation. All equipment should be checked before the workshop to avoid unexpected problems.

3.1.4 Communicate effectively

Part of being a good trainer or facilitator is being a good communicator. Communication involves more than speech: to be the most effective communicator possible, it is important to use all the tools available to you.

Use *facial expressions* to set the tone of the training. Convey a friendly, approachable expression, and be positive and enthusiastic. This will create a positive atmosphere and encourage participants to speak up and be enthusiastic about learning.

Use your *voice* to set the tone of the training, emphasize content, show enthusiasm, encourage participants, provide positive reinforcement or manage difficult participants. You will need to project your voice so that everyone can hear. Use a comfortable pace so that participants don't miss any important information because you are speaking too fast, or fall asleep because you are speaking too slowly.

Use your *eyes* to communicate with participants and observe what is happening. You can use your eyes to communicate by showing enthusiasm, encouragement and positive reinforcement, or to give a stern look to a difficult participant. Your eyes are also valuable for observing participants to see whether they are engaged and understanding the material or tired and drowsy, and to identify non-participators.

Use your *ears* to listen to participants. It is important to pay attention to their questions and comments so that you can gauge their level of understanding and identify any concerns that may need to be addressed.

Use your *hands* to show expression, emphasize content, describe a process, encourage participation or when demonstrating procedures.

Use your *feet* to move around the training room to encourage participation and engage with participants. It will also make you more accessible and encourage participants to ask questions. Walking can help to ease your nervousness in front of the classroom – but be careful it doesn't turn into nervous pacing! Moving around the room can provide variety so that participants are not always looking at one spot but be careful not to move too far from the projector screen.

Use your *mind*. It is important to be adaptable and resourceful, to manage problems calmly so that they do not disrupt training. All situations are learning experiences: turn a negative situation or unexpected occurrence into a learning situation. Lectures can also be boring, so be creative and think up new activities or ways to involve participants.

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Use your *heart* to show respect to all participants. Participants will come from diverse backgrounds and as a facilitator you need to show respect for all individuals and points of view, even if you do not agree with them. This will set the tone of the workshop as accepting and respectful, and encourage all participants to contribute to discussions and respect one another. It is also important to show support when people make mistakes so that nobody becomes embarrassed or shies away from contributing to discussion.

3.1.5 Engage the participants

In order for training sessions to be effective, it is important to engage participants as much as possible. This may be difficult at times but it can result in an interactive and highly rewarding training environment.

There are several techniques you can use to engage participants and to help them stay engaged throughout the entire training session. These include:

- Using a variety of approaches and media. Ask participants questions throughout presentations, vary the presentation styles, include short practical exercises at the end of a lecture session.
- Relate the material to the local situation and participants' jobs and environments.
- Where appropriate, use humour or share experiences from the field.

Ask questions:

- Asking questions engages and stimulates the audience.
- Asking questions encourages all participants to contribute to discussions and share their opinions, knowledge and experience.
- Asking questions helps participants to stay alert throughout training modules.
- Asking questions can be a valuable way to understand participants' baseline knowledge.

There are two different types of questions: *Closed-ended* and *Open-ended*. *Closed-ended* questions elicit yes or no responses. They limit what participants say and do not generate discussion. These types of questions can be useful for a final answer, in conclusion or for confirmation. These are some examples of closed-ended questions:

- Have you ever used a rapid syphilis test?
- Does your facility have a quality assurance/ quality control programme?
- Is Rapid Plasma Reagin a treponemal or non-treponemal test?

Open-ended questions encourage participants to share their opinions, ideas and experiences. Examples of open-ended questions include questions that can begin with how, why, tell me about, what would you... Open-ended questions can also be used to probe for more information. Some examples of probing questions include:

- Tell me more about...
- Could you explain...
- Would you elaborate...

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Using probing questions encourages participants to share more details and go into greater depth.

Questions can be asked during any situation but it is important to use them effectively during training. They should focus on the most important information participants need to know, or potentially challenging topics. If the audience looks confused during part of a presentation, it is a good idea to ask one or two questions to ensure everyone understands the subject matter. If one participant looks confused, it is likely that more are struggling to understand the material.

When asking questions, try not to single anyone out. Give everyone an opportunity to answer to avoid embarrassing an individual and putting them on the spot. Encourage all participants to respond and give positive feedback when participants contribute to create a positive learning environment. After a question has been answered, repeat the question and summarize the answer to ensure that all participants have heard both question and response.

At the beginning of the workshop participants are often shy and reluctant to answer questions. If participants do not respond to a question, try the following tactics:

- Maintain a deliberate silence.
- Repeat or rephrase the question.
- Use body language or eye contact to encourage participants to contribute
- Encourage answers with positive statements such as "take your time" or "I know some of you have had experiences with this and I would like to hear about them."
- Give an example or a prompt.

As a last resort, answer the question yourself.

3.2 Types of Training

In Peru the training SOP includes two eye examinations, one for visual acuity and one for colour blindness. These examinations must be completed by all Health Care Workers before performing rapid syphilis testing to ensure eyesight is adequate for reading test strip.

A copy of the SOP for training in Peru, including the eyesight check, is available at **http://www.proyectocisne.org/**

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3.2.1 Training Workshop

A training workshop is the ideal training forum. It provides the optimum surroundings to host a workshop. If well prepared, trainers can be assured that they will have all the materials and equipment needed for the workshop to be a success. Part 1, Preparation for Training, provides information on how and what to prepare in order to host an rapid syphilis testing training workshop.

3.2.2 On-the-Job Training (OJT)

Often, due to time or transport restraints, it is not possible to organize a one or two-day training workshop at a central location. In these situations, instead of bringing the participants to the trainer, the trainer can go to the participants and conduct training while they are working. This on-the-job training allows the participant to acquire the same knowledge and skills as those attending the workshop whilst catering to specific circumstances at a facility and preventing staff absences. Using this manual and the Training of Health Care Workers manual, a trainer could conduct training at a health facility for staff in the local area. This training workshop may not last a full two days. It should focus on:

- Safety
- Preparing for testing
- Performing the test
- Testing with Dried Tube Specimens
- Quality control
- Quality assurance
- Supply chain management

You will need to bring some materials and equipment with you when you visit the facility:

Materials	Equipment
☐ Training of Trainers Manual	☐ Rapid syphilis test kits
☐ Training of Health Care Workers Manual	☐ Biohazard waste bin
☐ Pens	☐ Sharps bin
☐ Evaluations	☐ Dried Tube Specimens panel for testing
☐ Certificates	☐ Gloves
	☐ Disinfectant

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In Zambia, turnover of staff at all facilities in Lusaka and Mongu districts is significantly higher due to transfers and training programs. This creates difficulties in ensuring that sufficient numbers of staff at each facility are adequately trained in rapid syphilis testing. It is hoped that a formally trained nurse will provide adequate on-the-job training to his/her colleagues before leaving, but this cannot be presumed. Training records allow internal monitors to track staff that attended formal training sessions and ensure that those who received informal training are fully qualified.

The internal monitoring team has designed a system for training the remaining staff on-site at the health facilities. These heath care workers commonly receive training on site from colleagues who attended the formal training workshop provided by Elizabeth Glaser Pediatric AIDS Foundation/Centre for Infectious Disease Research in Zambia (CIDRZ). To ensure proficiency of training and quality of testing and diagnosis, the internal monitoring team assesses the performance of the staff in operating and interpreting the rapid syphilis test using a health care worker certification checklist (Appendix 11.2). The internal monitoring team can guide the health care worker during testing if required. Once satisfied that the test is performed and interpreted correctly, the internal monitors issue the health care worker with a training certificate, which is filed on site.

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In Uganda workshop participants trained colleagues upon return to facility using training materials supplied at the workshop.

Continuing Medical Education (CME) sessions are held routinely in Jinja district. This gives the study team an opportunity to provide ongoing training and re-training, addressing the concerns that were raised during internal monitoring visits.

3.2.3 Refresher Training Workshop

A refresher training workshop can be a useful tool to address some of the main issues raised during monitoring/supervisory visits and to ensure no bad habits have formed among health care workers performing rapid syphilis tests. A refresher training workshop can be integrated with refresher training workshops such as HIV or malaria rapid testing to reduce the time health care workers are absent from facilities. The refresher training should review how to prepare for testing and how to test using whole blood and dried tube specimens. The workshop should also cover safety, quality assurance/ quality control, and supply chain management. The workshop could also provide an opportunity for health care workers to ask questions they may have after a year of performing rapid syphilis tests as part of routine care.

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4. Trainers Notes

Workshop Overview

The workshop overview provides an introduction to each of the modules you will be taught, either in the classroom or in the laboratory.

All classroom sessions have this symbol: 

All practical sessions have this symbol: 

The Learning Objectives outline the knowledge and skills you will have learned upon completion of the module. They reflect the content contained within module slides.

The Questions to consider are a series of questions that follow each set of module slides. They are also summarized at the end of the training manual. The questions are designed to help you relate the information or skills you have learned to your own experiences. They will also help you consider how rapid syphilis testing will be performed at your own facility.

The Module Slides are for you to use throughout the training workshop. The trainer will explain and elaborate on the information and it may be helpful for the you to make notes on the slides or on in a separate notebook. You may also like to write questions or make notes on discussions on the slide set for personal use after the training workshop. The trainer will hand out slide sets on the first day of the workshop.

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Module 1. An Overview of Syphilis

Format

This session will be presented as a lecture and will provide information on *Treponema pallidum*, the bacteria that cause syphilis; the stages of the disease; transmission; and the global epidemiology of syphilis.

Learning Objectives

By the end of the session, participants should:

1. Have an understanding of the global epidemiology of syphilis and congenital syphilis
2. Be able to describe the three phases of syphilis infection
3. Be able to clinically identify the signs of infection
4. Have an understanding of syphilis transmission and the risk of infection during pregnancy

Summary

Syphilis infection is caused by the bacteria *Treponema pallidum*.
The disease has three stages:

Primary syphilis presents as a single, painless chancre that resolves in 2-6 weeks. In women, the chancre may form in the vaginal cavity or cervix and go unnoticed.

Secondary syphilis occurs as the bacteria spread throughout the body. It is a systemic infection with a number of symptoms, including a skin rash, fever and muscle pain. This stage lasts 2-6 weeks and is followed by an asymptomatic latent phase.

The third phase, tertiary syphilis, occurs years later and presents as a series of complications arising from the systemic infection. This includes bone and tissue destruction resulting from progressive inflammation.

Syphilis is transmitted during sexual intercourse, through blood transfusions and from pregnant women to their foetuses during pregnancy. Pregnant women are most likely to spread the infection to their foetus if the woman is newly infected. Up to 75% of women infected with syphilis will experience an adverse birth outcome. Transmission usually occurs between 16-28 weeks gestation. This is why it is important to test women early in their pregnancy.

Congenital syphilis is the infection of the foetus because of transmission of the bacteria during pregnancy. Congenital syphilis causes miscarriage, stillbirth and preterm labour. Newborns born to syphilis-infected mothers may have a low birth weight (this is a risk factor for many other diseases), abnormal liver or spleen, anaemia, jaundice, lesions on the palms and soles, and neurological problems. Only half of newborns infected with syphilis can be clinically identified.

Frequently Asked Questions

- Which stage is most infectious?
- Can a woman still transmit the infection to her baby if she has secondary or latent syphilis?

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Module 2. Syphilis Testing Technologies

Format

This session is presented as a lecture and will provide basic information on the immune response to syphilis and the types of tests available to detect syphilis infection.

Learning Objectives

By the end of the session, participants should be able to:

1. Describe the difference between a test that detects bacteria and a test that detects antibodies
2. Understand the definitions of antigen and antibody
3. Describe the main characteristics of treponemal and non-treponemal tests
4. Describe the characteristics and benefits of rapid diagnostic tests

Summary

Syphilis can be diagnosed by visualizing bacteria recovered from the primary ulcer or by detecting antibodies produced by the body in response to infection.

Bacteria collected from a swab of an ulcer can be visualized using a microscope but this technique cannot be used in later stages of infection or for screening. Serological tests detect antibody responses to non-specific or specific treponenmal antigens and are appropriate tools to screen for syphilis infection.

Treponemal tests detect antibodies specific to the syphilis bacteria, *Treponema pallidum*. These tests include *Treponema pallidum* particle agglutination assay (TPPA), *Treponema pallidum* haemagglutination assay (TPHA), and fluorescent treponemal antibody absorption assay (FTA-ABS).

Rapid point-of-care treponemal tests do not require any refrigeration or equipment and can be used in all health care settings to give a result in 20 minutes, thereby allowing immediate treatment of positive cases. The acronym **ASSURED** describes the characteristics of ideal Rapid Diagnostic Tests:

A: AFFORDABLE
S: SENSITIVE
S: SPECIFIC
U: USER-FRIENDLY
R: ROBUST
E: EQUIPMENT FREE
D: DELIVERABLE TO THOSE WHO NEED THEM

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The advantages of Rapid Diagnostic Tests are that they do not require refrigeration, they can be used on whole blood by non-laboratory personnel, and they provide results within 30 minutes. Rapid Diagnostic Tests enable the expansion of syphilis screening to include peripheral facilities that do not have refrigeration or electricity.

Non-treponemal tests detect a non-specific antibody. These tests include Rapid Plasma Reagin (RPR) and venereal disease research laboratory (VDRL). The antibody detected by non-treponemal tests declines after treatment and these tests can be used to monitor treatment outcomes and to distinguish past-treated from current infections. The antibody that is detected is also produced during infection with malaria, hepatitis, and sometimes during pregnancy leading to a high number of biological false positives (BFPs). Non-treponemal tests are relatively simple to perform but the reagents do need to be refrigerated, limiting their use in peripheral health facilities.

Frequently Asked Questions

- If rapid tests detect treponemal antibodies, how can you tell if a patient has been cured?

Module 3. Treatment for Syphilis

Format

This session is presented as a lecture and will discuss the WHO-recommended treatment for syphilis and congenital syphilis. This session will need to be adapted to reflect National Guidelines for syphilis treatment.

Learning Objectives

By the end of this session, participants should be able to:

1. Describe the recommended treatment and dose an adult for syphilis as per national guidelines
2. Describe the alternative treatment and dosean adult for syphilis as per national guidelines
3. Describe how to manage an infant born to a mother who tested positive during pregnancy as per national guidelines
4. Describe how to manage the partner of a syphilis-positive individual as per national guidelines
5. Describe the potential risks and adverse outcomes for the recommended and alternative treatment for syphilis for an adult and infant
6. Describe the potential risks and adverse outcomes if treatment is not administered

Summary

Benzathine penicillin is the treatment recommended by the World Health Organization. Studies have shown that a single 2.4mg dose of benzathine penicillin administered during pregnancy will protect the baby from the effects of maternal syphilis infection and ensure a healthy pregnancy.

It is critical to present workshop participants with country-specific treatment regimens as these are the most relevant for practicing health care workers. Refer to National Guidelines for further information on the medication, dose, duration and method of administering treatment. You must also describe the alternative treatment to be administered to patients with a history of penicillin allergy.

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Partner management is another aspect of treatment that may vary between countries so refer to national guidelines for the current practice in your country.

As a trainer, you will need to research this information before the training workshop and explain it to participants. Complete the charts below to help guide the preparation of Module 3: Treatment of Syphilis:

Patient Population	Recommended Regimen	Alternate Regimen (Penicillin allergies)
Adults testing positive for syphilis		
Infants born to mothers who tested positive during pregnancy		
Infants born with the signs and symptoms of congenital syphilis		
Patients presenting with the signs and symptoms of anaphylactic shock		

The National Guidelines for partner management state that partners of syphilis-positive patients should be: *(Circle the response that matches the National Guidelines or write the appropriate partner management strategy on the line below)*

a. Treated presumptively as a contact

b. Tested with a rapid syphilis test and treated regardless of test result

c. Tested with a rapid syphilis tet and treated according to test result

d. Other:_____

If the National Guidelines are unclear about the treatment for syphilis or partner management, contact a representative at the Ministry of Health (MOH) for further instruction. You should be familiar with the guidelines and prepared to answer participants' questions about training during the workshop. As the trainer, it is your responsibility to be well prepared and ready to handle any question that might come your way.

Frequently Asked Questions

- Is it okay to give an injection of benzathine penicillin if a woman hasn't eaten breakfast?
- What are the signs of an allergic reaction and how should it be treated?
- If a patient does not like needles, is it okay to give them a different antibiotic?

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In Zambia, during training several health care workers expressed concerns over the treatment of a positive case with an injection of benzathine penicillin if the pregnant woman had not yet eaten that morning, fearing an adverse reaction. Most facilities do not have food or drinks available: it is common for women to go all morning and into the late afternoon without eating any food. Elizabeth Glaser Pediatric AIDS Foundation enlisted the help of an established midwife working on the Centre for Infectious Disease Research in Zambia Preventing Mother-To-Child Transmission programme, Maureen Mzumara, to help alleviate concerns of health care workers. During training sessions, you should emphasize that there is no evidence demonstrating adverse reactions to treatment on an empty stomach.

Module 4. Integration of Services: Providing a Package of Care

Format

This session is presented as a lecture and will describe how to integrate rapid syphilis testing alongside other services offered at the clinic site.

Learning Objectives

At the end of the session, participants should be able to:

1. Describe the current patient flow at their clinic
2. Describe when and where rapid syphilis testing would take place
3. Provide three examples of how syphilis testing could be integrated with other services

Summary

In the clinic setting, syphilis services will be offered alongside antenatal care (ANC) and Sexually Transmitted Infection (STI) services or as part of an outreach program. It is important for workshop participants to understand how rapid syphilis testing can be introduced alongside existing services in their clinic setting without disrupting patient flow or causing a large increase in staff workloads.

Two service models are presented below. The first shows the patient flow in an antenatal care clinic with HIV testing services but without rapid syphilis testing, while the second shows the patient flow in an antenatal care clinic with integrated HIV and syphilis testing services.

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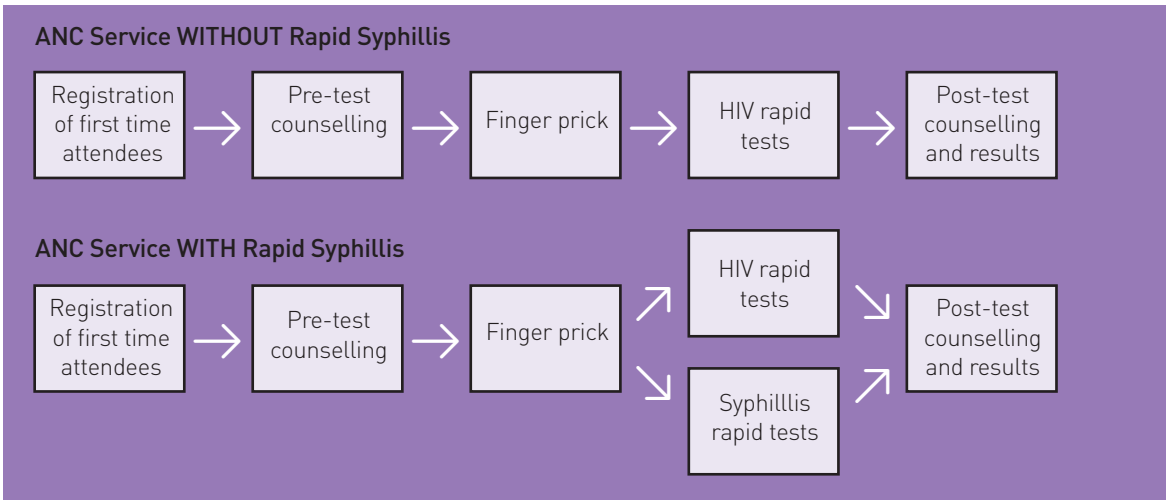
This is an example of how rapid syphilis testing can be integrated into an existing clinic setting:



There are several opportunities to integrate services throughout the testing process. This includes pre-test (counselling, preparation), during testing, and post-test (communicating results).

When preparing for testing, a health care worker should prepare all the materials for all tests s/he is going to perform. All materials, including the register for recording results and the standard operating procedures, should be present for every test which will be performed. (See Module 6 for more details.) If the test cassettes have a similar appearance (e.g. white and rectangular), the health care worker may find it helpful to label each cassette with the name of the disease. For example, s/he could use "HIV" to identify the HIV test, "SYPH" for syphilis, "MAL" for malaria. This will vary according to the type of tests used but it is important that each test can be clearly identified to avoid mixing up test results and mismanaging a patient.

Before any test is performed, all clients/ patients should be counselled. In counselling, the client/ patient should be informed of:

- The disease for which s/he is going to be tested.
- Test procedure.
- Risks associated with testing (pain from finger prick/ blood draw).
- Possible outcomes (positive or negative test result).
- The implications of test outcomes (positive for a syphilis, risk of transmission to partners or to unborn baby).
- Treatment options (there is a cure for syphilis).

The information communicated to a client/ patient should be in accordance with National Guidelines.

After a client/ patient has received counselling and consented to having the test performed (as per National Guidelines), the health care worker is responsible for performing the test in accordance with the standard operating procedures.

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Any blood draw or finger prick performed to collect a sample for testing is an opportunity to perform rapid syphilis testing. In the model above, rapid syphilis testing is performed at the same time as HIV rapid testing for each new pregnant women attending antenatal care. This means that with a single finger prick, two tests can be performed and the patient can receive two diagnoses on the same day.

An integrated patient register may reduce the amount of paperwork a health care worker has to complete after testing. Records can be integrated by adding a column for syphilis testing to an existing register. The extent of integration with respect to record keeping will depend on the type of information the ministry of health is interested in collecting from each client/ patient tested. The health care worker's ability to integrate registers will depend on National Guidelines.

After the test is performed, patients will need to be counselled about the results. It is important that clinic attendees understand what a positive or negative result means, their future risks, and options for managing the disease. Partner notification should also be discussed at this time. This is an opportunity for patients to ask questions. The health care worker should take the time to ensure that all patient concerns are addressed.

Post-test counselling should address:
- The risk of the disease to the patient
- For pregnant women, the risk to the unborn baby
- How to practice safe sex to avoid contracting the disease
- Future risks of contracting the disease
- The availability of treatment to cure syphilis
- The importance of having a partner treated to prevent re-infection

Performing multiple tests at one time, and in particular managing to interpret test results within the time restrictions outlined in the standard operating procedures, could be a potential challenge. Being well prepared before initiating testing, labelling the test cassettes and having a timer at the testing bench will help health care workers adapt to performing multiple tests. Staying organized is key to offering clients/ patient quality testing services.

Module 5. Safety at the Testing Site

Format
This session is presented as a lecture and will detail the safety precautions that need to be taken whenever testing is being performed.

Learning Objectives

At the end of the session, participants should be able to:
1. Define safety
2. Identify potential hazards associated with rapid syphilis testing
3. Describe how to dispose of biohazardous materials
4. Describe the safety precautions which must be observed when testing for syphilis

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Summary

Safety is the state of being safe and protected from danger, harm, or infection. All sites must have safety procedures in place outlining how to handle biohazardous material safely. These procedures need to be visible and must be followed by all personnel working at the facility.

These are some examples of safety procedures that should be clearly posted and visible in facilities that perform testing:

- Instructions on the correct use of gloves, hand-washing, handling and disposing sharps, containing and decontaminating spills and splashes.
- General policies prohibiting eating, drinking, smoking, unauthorized persons in the testing area.
- Policies enforcing the wearing of lab coats and closed toe shoes.

Safety procedures are designed to protect staff, clients, and members of the community. If sharps and biohazardous materials are not disposed of correctly, members of the community could be exposed to discarded materials.

Full safety requirements for testing blood or serum specimens are very detailed. Any site performing testing should have a complete set of the guidelines used in their country. All staff should read and understand the safety manual before beginning work. Staff are responsible for personal and co-worker safety. Some examples of safety precautions include:

- Washing hands before and after each patient.
- Changing gloves with each patient.
- Using the sharps bin to dispose of finger prickers.
- Using a biohazard bin to dispose of all contaminated materials.

It is important that *all* specimens and materials are handled as if capable of transmitting an infectious disease.

It is also recommended that all persons performing syphilis rapid tests know their own syphilis and HIV status.

Frequently Asked Questions

- If there are no gloves available, should testing still be carried out?
- What is the best way to dispose of waste in the clinic?

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Module 6. Preparation for Testing

Format

This session will be presented as a lecture and will outline how to prepare for performing syphilis testing:

Learning Objectives

By the end of this session, participants should be able to:
1. List and identify all the supplies required for rapid syphilis testing
2. List and identify all the components of test kits for rapid syphilis testing

Summary

Before performing a syphilis test, staff should review this simple checklist:

- Do you know what test you are going to perform?
- Are all supplies and material needed to performing the test arranged on your workspace?
- Have you counter-checked the sample against the working list?
- Have you read the Standard Operating Procedures (SOPs)?
- The Standard Operating Procedures should be read before starting and reviewed at every step.

All the materials and supplies needed for testing shouldbe arranged on the testing bench and the Standard Operating Procedures should be visible. This will allow the health care worker to perform tests without having to stop the process and search for a missing piece of equipment. This will also help the health care to follow the Standard Operating Procedures throughout the testing process.

Module 7. Orientation to Rapid Syphilis Tests

Format

This session is presented as a lecture and will describe how to perform the rapid syphilis test, step-by-step. It gives further detail of the materials that are needed before testing can begin and how to correctly perform a finger prick. Refer to programme Standard Operating Proceudre for Performing a Finger Prick and Standard Operating Proceudre for Rapid Syphilis Testing.

Learning Objectives

By the end of this session, participants should be able to:
1. List the guidelines for the use of rapid tests
2. Describe how to perform a finger prick
3. Describe how to perform a rapid syphilis test
4. Interpret the result of a rapid syphilis test

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Trainers Notes

Summary
Standard operating procedures for SD Bioline 3.0 Syphilis and for collecting blood by a finger prick are provided in the Appendix (**Appendix 2** and **Appendix 1**). It is important that the standard operating procedures presented here in Module 7 be the same standard operating procedures to be used during the practical sessions distributed to facilities.

Frequently Asked Questions

- If there is a faint positive, should I repeat the test?
- If I am unable to read the test within 20 minutes, will the results change?
- Can I use the same buffer reagent for the HIV test and the syphilis test?

Module 8. Performing the Test

Format
This session is a laboratory practical and will introduce participants to the rapid syphilis tests and their use. There will be two parts to the practical. In part I, participants will learn how to perform rapid syphilis tests using one positive and one negative sample. In part II, participants will perform the rapid syphilis test on five blind samples and learn how to interpret the results.

Practical Objectives

By the end of this session, participants should be able to:
1. Identify each of the items in the slides as either a document or a record
2. Correctly perform a rapid syphilis test by following the standard operating procedures
3. Interpret the result of a rapid syphilis test
4. Re-constitute dried tube specimens according to the standard operating procedures

Module 9. Documents and Records

Format
This session is presented as a lecture and will describe the difference between a document and record and the importance of each.

Learning Objectives

By the end of this session, participants should be able to:
1. Tell the difference between a document and a record
2. Explain the rationale for maintaining documents and records
3. Provide examples of documents and records kept at a test site

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Summary

Documents are the written policies, process descriptions, procedures, and any blank forms used in the testing process. Documents developed within the quality system include:

- Written Standard Operating Procedures.
- Safety policies.
- Personnel policies.
- All standard blank forms, such as reporting forms or stock cards.

Documents should be consistent with national policy, to assure uniformity and adequacy of data. All documents need to be managed with a tracking system, to assure that all testing sites have current information on hand, and that outdated documents are archived and ultimately discarded to avoid confusion at the worksite. All documents and records should have a standardized numbering system with version numbers and dates of update.

Records result from carrying out processes and procedures within the testing process. Examples include:

- Worksheets
- Test result reports
- Labels
- Temperature and maintenance charts
- Quality control results and charts
- External Quality Assurance (EQA) activities with results and corrective action
- Inventory lists

The records include everything used to capture information, activities, or results when performing a procedure. They may be kept on paper, or electronically using a computer system.

Records for syphilis testing sites should be standardized across all facilities. They should be organized by date and kept in a bound folder. All records should be signed and dated by responsible facility personnel.

Practical Exercises

- Identify each of the items in the **Appendix** as either a document or record.
- Practice completing the syphilis testing registrar and quality assurance/ quality control forms.

Frequently Asked Questions

- Why is it important to sign and date all records?

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Module 10. Standard Operating Procedures (SOPs)

Format

This session is presented as a lecture and will discuss the importance of Standard Operating Procedures and their use during testing.

Learning Objectives

By the end of this session, participants should be able to:

1. Describe the importance of a standard operating procedure
2. Describe when a standard operating procedure should be used and where it should be stored
3. Give five examples of standard operating procedures

Summary

A standard operating procedure is a detailed, written instruction of how to perform a process. This may refer to a finger prick, rapid syphilis testing, or even how to clean up a spill. For a rapid syphilis testing programme, standard operating procedures must be developed to provide detailed instructions on all aspects of the testing.

A written standard operating procedure should be available at each testing site. It should always be followed when conducting tests. The test site must have written instructions on all policies and procedures that need to be followed when conducting tests, including such things as personnel training and certification requirements, competency checks, confidentiality policies and safety.

This training package includes five standard operating procedures providing instructions on testing and quality control in the appendix. Countries may have more standard operatig procedures outlining safety procedures, stock management, or treatment. During the Training of Health Care Workers workshop, all relevant programme and national standard operating procedures should be introduced to health care workers.

Programme Standard Operating Procedures covered in the Training of Health Care Workers workshop include:

- Performing a Finger Prick
- Performing a Rapid Syphilis Test, including test interpretation
- Re-constituting Dried Tube Specimens
- Performing a Rapid Syphilis Test using DTS
- Daily Quality Control Testing

Frequently Asked Questions

- I've been performing the test for several months and know how to do it without the Standard Operating Procedures, do I still need to read them?
- How do I manage all of the Standard Operating Procedures listed as part of the rapid syphilis testing programme?

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Module 11. Supply and Stock Management

Format

This session is presented as a lecture and will discuss the importance of Logistics Management Information Systems (LMIS) and their tools.

Learning Objectives

By the end of this session, participants should be able to:

1. Identify and describe the different Logistics Management Information System tools
2. Understand and appreciate the importance of these Logistics Management Information System tools in commodity management and reporting and ordering supplies in a timely manner
3. Describe the procedures required to complete Logistics Management Information Systems

Summary

It is essential that supplies are available in the facility so that health care workers can offer adequate syphilis testing services. If there is a stockout of test kits, the health care worker cannot offer testing. If there are no syringes in stock, the health care worker cannot administer the benzathine treatment. If there is no benzathine penicillin in stock, positive patients cannot be treated and may continue to transmit the infection to their partners or babies.

Stock management is a critical component of any health intervention, including rapid syphilis testing. Stock management involves:

- Forecasting and ordering sufficient supplies
- Receiving and correctly storing supplies
- Documenting consumption of supplies
- Re-ordering supplies in time for the delivery to arrive before a stockout occurs

Stock management is also known as inventory control.

Stock cards are central to a good supply management system. Stock cards should be completed every time a supply is consumed. For supplies such as gloves this may be daily, whereas for vaccines it may be weekly. A stock card should record:

- Name of stocked item
- Lot number
- Expiry date
- Date of consumption
- Quantity of stocked items in the morning
- Quantity of items removed from the stock room or consumed
- Balance of stock remaining at the end of the day

The stock card should be signed by the health care worker responsible and stored with the stocked item it is intended to track. An example of a stock card can be found in the Appendix **(Appendix 4)**.

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Ordering supplies on a regular basis in accordance with national and district policies can help you to avoid stockouts. It is important to know the ordering schedule and protocols for your country so that forms are submitted to the correct place/ person in a timely fashion. When ordering supplies, it is important to use the appropriate forms so that a record can be kept at the facility.

The form should detail the date of requisition, the items requested and the quantity of each item requested. The individual responsible should sign the record and keep a copy in a designated folder at the facility.

The quantity of supplies ordered will depend on consumption as tracked using stock cards. It should include a buffer stock in case attendance at the healthcare facility is higher than expected or there is a delay in receiving the next shipment. The amount of buffer required will depend on national policy, frequency of ordering, rate of consumption, and turnaround time. The turnaround time is the time it takes for supplies to be delivered after a request or order has been submitted.

When supplies are received at the facility, they should be inspected for damage during that could have been incurred during transport. Supplies should then be stored in a storeroom and this should be recorded on the stock card. If there is a separate form for tracking deliveries, the order should also be recorded here. When recording that an order has been received, it is important to record the date of delivery, the items included in the delivery, and the quantity of each item delivered. This form should be signed by the person who received the supplies and the person responsible for the delivery. The storeroom should have a window for ventilation but it should be covered to prevent rain or sun from damaging supplies. The storeroom should have shelves so that supplies can be kept off the floor, and should be locked to prevent theft.

Use of test kits should follow the "first expired, first out" rule. According to this rule, tests that are due to expire first should be the first tests to be used by health care workers. Following this rule will help prevent wastage of test kits due to expiration.

Frequently Asked Questions

- How often should the stock card be updated?
- Should stock cards be kept for all supplies or just for test kits and medications?
- How will I know when to order more supplies?
- How can I determine the quantity of supplies to order?

Module 12. Monitoring and Evaluation

Format

This session is presented as a lecture and will discuss the importance of monitoring and evaluation in a syphilis control programme.

Learning Objectives

By the end of this session, participants should be able to:

1. Define "monitoring" and describe its purpose
2. Define "evaluation" and describe its purpose
3. Describe the key differences between monitoring and evaluation
4. Describe the roles of health care workers and supervisors/ internal monitors during a monitoring visit

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Summary

What is Monitoring? Monitoring is an ongoing process to observe progress, identify challenges, and come up with local solutions.

What to Monitor? A series of indicators is calculated from the information collected through the monitoring and evaluation activities. These indicators are calculated from routine information recorded by health care providers and will be used to demonstrate the benefit of increased access to Sexually Transmitted Infection diagnostics.The information collected at the health facility will depend on the goals of the programme and the population where testing is introduced.

Collecting data compiled on patient attendance at antenatal clinics and on the proportion provided with Same-Day-Testing-and-Treatment (STAT) will enable the Programme Manager to determine the impact of introducing rapid syphilis tests. Collecting data supply chain data from facilities enables supply-chain problems to be identified. It can also provide an explanation for low rates of HIV/ syphilis testing and/or treatment. It is therefore important to account and document these issues, both for the study and for the benefit of the health system.

How to Monitor? Monitoring is done through a combination of visual observation and structured interviews with health care workers and/or laboratory staff. The monitor should have a checklist to follow so that each visit is focused on the same key components of testing. The visit will directly involve the monitor, the health care worker and/or the laboratory technician, with the purpose of providing active supervision and enabling real-time problem solving.

The frequency of monitoring visits will decrease as the programme becomes established in a given setting. It is advisable to provide health care workers and laboratory staff with additional support during the initial months of implementing rapid syphilis testing. However, as the programme components become integrated with routine care, the frequency of monitoring may be reduced to bi-monthly and finally quarterly visits. The final frequency of monitoring should be modelled and integrated alongside routine supervision so that a single individual can perform the two tasks benefitting the future sustainability of the programme.

Monitoring visits should be planned alongside routine supervisory visits if the two tasks are to be carried out by separate individuals. Once confident and capable, the supervisor may then subsume the responsibilities of the monitor, or the two may continue to work side-by-side, depending on the programme's and district's resources.

What is Evaluation? Evaluation takes place at the conclusion of a program to summarize the progress made towards reaching goals. Unlike monitoring, evaluation reflects on the overall success (or failure) of a program and is not intended to generate problem solving initiatives.

Frequently Asked Questions

- What should I do to prepare for a monitoring visit?
- What should I do during the visit?
- How will I know what information to collect from a patient?
- What if the monitor doesn't visit the health facility regularly/ at all?
- How will I know when the monitor is going to arrive?

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Module 13. Quality Assurance and Quality Control

Format

This session is presented as a lecture and will introduce participants to the concepts of quality assurance and quality control. It also describes the importance of quality assurance and quality control to rapid syphilis testing.

Learning Objectives

By the end of this session, participants should be able to:

1. Define quality control and quality assurance
2. Describe trouble shooting
3. List the benefits of quality control in rapid testing
4. Differentiate between internal quality control and external quality control
5. Describe the process of maintaining quality control records

Summary

Quality Assurance activities assess the ability of health care workers to perform rapid tests correctly. This includes proficiency testing using a panel of un-labelled specimens to test the health care worker's ability to perform and interpret test results correctly. The quality assurance process guarantees that the final results are as accurate as possible.

Quality Control testing assesses the test's ability to identify samples that are known to be positive or known to be negative correctly.

In-built procedural control Many rapid diagnostic tests have in-built procedural controls in the form of a test control line. In some kits, these controls may be provided as a separate material, but will still be used with each test. The in-built control verifies that the specimen was adequate and that the complex of specimen and reagent flowed through the device as intended. It does not validate the testing process or the tester.
The operator should follow manufacturer's instructions and explanation of the location and functioning of the in-built procedural control.

Internal quality control evaluates the accuracy of the test and verifies the operator's ability to perform the test and interpret the test result correctly. It ensures reliability of the test result on the day of testing. Internal quality control should include the testing of at least one known syphilis-positive and one known syphilis-negative specimen. If possible, a weakly positive syphilis specimen should also be included.

It may also be called the procedural control. It demonstrates test validity: is the sample correctly migrating up the strip? Has enough sample and buffer been deposited in the well? The control line should always appear during testing. If it does not, the test is invalid and should be repeated.

Quality control measures may include:

- Having standard operating procedures for all clinical procedures.
- Assessing kits before they are distributed to sites by checking each lot for test performance (incoming inspection).
- Repeat testing of a given percentage of samples by the reference laboratory.
- Using a Dried Tube Specimen proficiency panel.
- A combination of these activities.

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Frequently Asked Questions

- If the test has a built in control line, why do I need to perform more quality testing?
- If it is a good test, why is quality control testing necessary?
- Won't quality control testing increase my already heavy workload?

Module 14. External Quality Assurance/ Dried Tube Specimens

Format

This session is presented as a lecture and will discuss the role of external quality assurance and dried tube specimens as part of a quality system for a syphilis testing programme.

Learning Objectives

By the end of this session, participants should be able to:

1. Describe the benefit of Dried Tube Specimens
2. Describe the purpose of Routine Quality Control Testing and Proficiency Panel Testing and the differences between the two procedures
3. Correctly complete all forms required by the Quality System

Summary

External Quality Assessment: Through external quality assessment, the performance of a testing site can be independently evaluated from outside the laboratory or testing site. Methods for external quality assessment include traditional proficiency testing using Dried Tube Specimen, re-testing of specimens, and careful on-site monitoring using a checklist and knowledgeable assessors.

Dried tube specimens are vials containing specimens that have been diluted and air-dried so that they can be transported and stored at *room temperature*. Dried tube specimens are manufactured from syphilis-positive and syphilis-negative specimens at the Central Laboratory and distributed to health facilities for testing. After adding several drops of a buffer reagent to the vial, the specimen is diluted and can be used with rapid syphilis tests in the same manner as whole blood or plasma. Dried tube specimens are very useful for quality assurance programmes and can be used for syphilis and HIV tests. This module will focus on the uses of dried tube specimens in a rapid syphilis testing programme.

Use the appropriate form (see **Appendix 5**) to record:

- Dried tube specimen lot number and expiry date
- Rapid syphilis test kit lot number
- Date of testing
- Name of staff member performing routine quality testing
- Expected test result
- Actual test result

All documents pertaining to a quality system should be stored in a Quality Folder or Log book.

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Dried Tube Specimens can be used for Proficiency Panel Testing. Unlike Internal Quality Control Testing, Proficiency Panel Testing uses dried tube specimen vials whereby the healthcare worker does not know the sample status. Instead, they are labelled with a code and expiry date.

After preparing the dried tube specimen in accordance with the standard operating procedures, the health care worker performs the rapid syphilis test and interprets the test result. The dried tube specimen vial codes, expiry dates and test results are recorded on a form, along with the name of the health care worker and date of testing. The results are submitted to the internal monitor or central laboratory for marking and the scores returned to the facility. This is a way to assess the healthcare worker's ability to perform and interpret a rapid syphilis test correctly. A proficiency panel should contain at least one positive sample, one negative sample, and one weak positive – although the number and characterization of samples will differ between programmes.

Frequently Asked Questions

- What is proficiency testing (PT)?
- Why is proficiency testing important?
- What are dried tube specimens?
- How long can I keep dried tube specimens after the buffer has been added?
- Is it better to store dried tube specimens in a refrigerator?
- Is the specimen still contagious?
- What if I added too much buffer? Can I still use the sample for testing?

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Module 15. Testing with Dried Tube Specimens

Format

This session is a laboratory practical and will introduce participants to rapid syphilis tests and their use.

Practical Objectives

By the end of this session, participants should be able to:

1. Prepare dried tube specimens in accordance with standard operating procedures
2. Perform rapid syphilis test and correctly interpret the results in accordance with standard operating procedures using a re-constituted dried tube specimen

Frequently Asked Questions

- Do I test my dried tube specimens any differently than I test patient specimens?
- Do I need to keep records of my proficiency testing?
- How long do I have to test and report the proficiency testing samples?
- What should I do after receiving my proficiency testing results from the lab/clinic supervisor?
- What must I do if I do not get a passing score?

4.16 Additional Frequently Asked Questions that may arise at the end of the workshop

- Which stage of syphilis is most infectious?
- Can a woman still transmit the infection to her baby even if she has secondary or latent syphilis?
- Is it okay to give an injection of benzathine penicillin if a woman hasn't eaten for several hours before attending the clinic?
- What are the signs of an allergic reaction and how should it be treated?
- If a patient does not like needles, is it okay to give them a different antibiotic?
- If there is a faint positive, should I repeat the test?
- If I am unable to read the test within 20 minutes, will the results change?
- What types of quality control are available for rapid syphilis testing?
- I've been performing the test for several months and know how to do it without the Standard Operating Procedures, do I still need to read them?
- If there are no gloves available, should testing still be carried out?
- How often should the stock card be updated?
- Should stock cards be kept for all supplies or just for test kits and medications?
- What is the best way to dispose of waste in the clinic?

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5. References

Centers for Disease Control and Prevention.HIV Rapid Testing Training Package (2006).
http://wwwn.cdc.gov/dls/ila/hivtraining/default.aspx

Appendices

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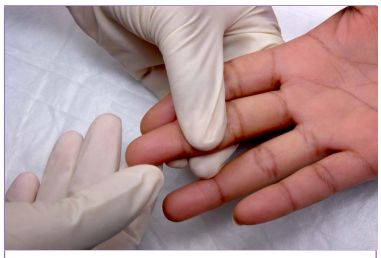
Appendix 1. Standard Operating Procedures for performing a Finger-Prick

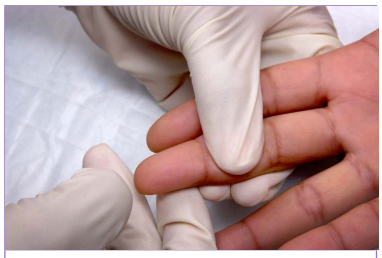
Always use universal safety precautions.

This outline is not intented to replace the product insert or your standard operating procedure (SOP).

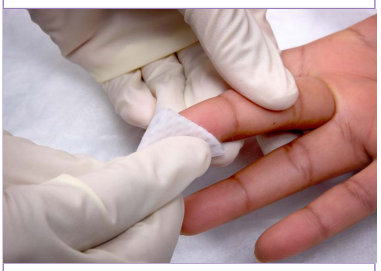
1. Collect supplies.



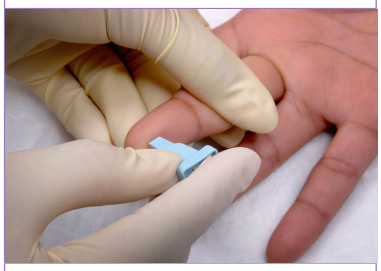
2. Position hand palm-side up. Choose whichever finger is least calloused.



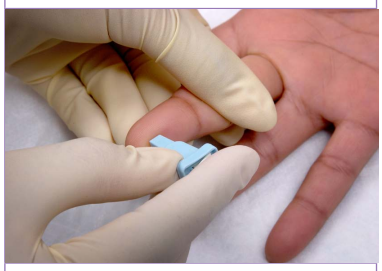
3. Apply intermittent pressure to the finger to help the blood to flow.



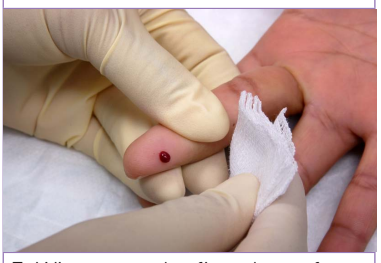
4. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.



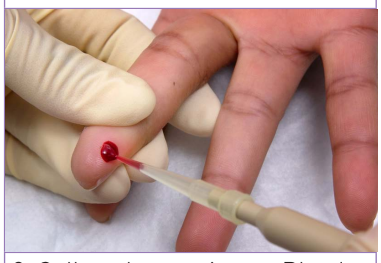
5. Hold the finger and firmly place a new sterile lancet off-center on the fingertip.



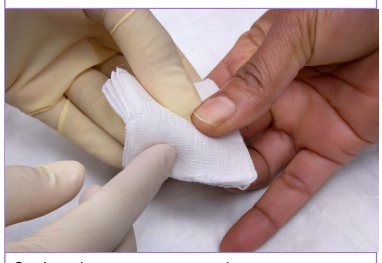
6. Firmly press the lancet to puncture the fingertip.



7. Wipe away the first drop of blood with a sterile gauze pad or cotton ball.



8. Collect the specimen. Blood may flow best if the finger is held lower than the elbow.



9. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops.

10. Properly dispose of all contaminated supplies.

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Appendix 2. Standard Operating Procedures for performing a rapid syphilis test

Work Instructions for Use of Standard Diagnostics Bioline Syphilis 3.0 rapid test

Intended Use

The SD Bioline Syphilis 3.0 test is a solid phase immunochromatographic assay for the qualitative detection of antibodies of al isotypes (IgG, IgM, IgA) against Treponema pallidum. This test method is intended for professional use as an aid in the diagnosis of syphilis.

Principle of the Procedure

The SD Bioline Syphilis 3.0 contains a membrane strip which is pre-coated with recombinant *Treponema pallidum* antigens (17, 15KDa) on the test band region. When the patient sample with sample diluent is added to the sample well, it moves with the recombinant *Treponema pallidum* antigen-colloid gold conjugate (17, 15KDa) along the membrane chromatographically to the test region (T) and forms a visible line as the antigen-patient antibody-antigen gold particle complex forms. The formation of a visible line in the test region (T) indicates a positive result for the detection of *Treponema pallidum* specific antibodies (IgG, IgA and IgM). When the *Treponema pallidum* specific antibodies (IgG, IgA and IgM) are absent in the sample, there is no visible colour band in the test region (T).

Kit Contents

- SD Bioline 3.0 test device
  Each test device contains colloidal gold conjugated to recombinant T. pallidum antigen (17, 15KDa) on test line and control line
- 1 bottle of Assay Diluent
- Disposable specimen droppers
- Instructions For Use

Materials required but not provided with the kit

- Gloves
- Timer or stopwatch
- Blood collection devices (lancets, capillary tubes, test tubes)

Storage and Stability

1. The test device should be stored at room temperature.
2. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch.
3. Do not use beyond the expiration date
4. The shelf-life of the kit is indicated on the outer package.
5. Do not use the test kit if the pouch is damaged or seal is broken.

Quality Control

Good Laboratory Practice (GLP) requires the use of control specimens to ensure proper device performance at least once daily.

A built in procedural control on the test device indicates that the test is functioning correctly. A purple band should always appear at the control widow.

Internal and External controls should be run daily prior to analyzing patient/client specimens. Results should be recorded on the quality control log. Patient/client reports should only be reported if quality control results are acceptable.

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Precautions

1. The SD Bioline Syphilis 3.0 Test is intended for in vitro use. DO NOT RE-USE test device
2. The instructions for use must be followed exactly to give accurate results. Personnel performing the test must be trained in its use and must be experienced in laboratory procedures.
3. Collect whole blood using a suitable coagulant, and centrifuge whole blood to obtain plasma or serum specimen.
4. If specimens are not immediately tested, they should be refrigerated at 2 - 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature before use.
5. Specimens containing precipitate may yield inconsistent test results. Such specimens should be filtered prior to assaying.
6. Whole blood may be used for testing immediately or may be stored at 2 - 8°C for up to three days.
7. Test results are not affected by anticoagulants such as ethylenediaminetetraacetic acid (EDTA), heparin or citrate.
8. Interference from haemolytic samples, rheumatoid factor-contained samples, lipemic samples and icteric samples can impair test results.
9. Use separate disposable pipettes or pipette yips for each samples in order to avoid cross contamination of samples, which could lead to erroneous results.
10. Do not eat or smoke while handling specimens.
11. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
12. Avoid splashing or aerosol formation.
13. Clean up spills thoroughly using an appropriate disinfectant.
14. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials as if they were infectious waste in a biohardous container.
15. Do not mix and interchange different specimens.
16. Care should be taken to avoid contamination of the end of the bottle when dropping assay diluent into sample well.

Test Procedure

1. Remove the test device from the foil pouch, and place it on a flat, dry surface
2. Trasnfer the specimen by pipette or dropper:
   a. To use a pipette: Transfer 10µl of serum or plasma (or 20µl of whole blood) to the sample well (S) of the test device, then add 3-4 drops of assay diluent (approximately 110µl) and start the timer.
   b. To use a Disposable Specimen Dropper: Hold the dropper vertically, draw the specimen (serum or plasma) up to the Fill Line (approximately 10µl). Transfer the specimen to the sample well (S) of the test device. In the case of whole blood, draw and transfer the specimen by the same method twice (approximately 20µl in total) and then add 3-4 drops of assay diluent (approximately 110µl) and start the timer.
3. As the sample moves chromatographically along the test membrane, a purple colour can be seen in the result window located in the centre of the test device.
4. The result should be interpreted within 5-20 minutes of addition of the sample. A positive sample will not change once it has been established after 20 minutes. However, in order to prevent any incorrect results, the result should not be interpreted after 20 minutes.
5. When whole blood is used, the test result should be interpreted within 10 minutes.
   Caution: The above interpretation time is based on reading the test result at room temperature. If room temperature is significantly lower than 10°C, the interpretation time should be extended to a further 10 minutes.

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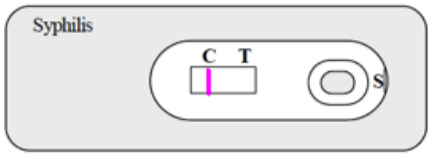
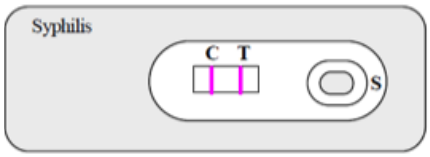
Interpretation of Test Results

1. A colour band will appear in the left section of the result window to show that the test is working properly. This band is the Control Band (C)
2. The right section of the result window indicates the test result. This is the Test Band (T).
3. **Negative Result:** The presence of only one purple colour band in the Control (C)region of the result window indicates a negative result.



Positive Result: If a colour band appears in Control (C) region and Test (T) region, the test result is positive for *Treponema Pallidum* antibodies.



Invalid result: If the purple colour band is not visible in the the Control (C) region after the test has been performed, the result is deemed invalid. It is recommended that the specimen be re-tested.

Limitations of the Test

1. SD Bioline Syphilis 3.0 test procedure and interpretation of results must be followed closely when testing for the presence of syphilis antibodies in serum, plasma or whole blood.
2. The SD Bioline Syphilis 3.0 test will only indicate the presence of *Treponema Pallidum* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *Treponema Pallidum* infection.
3. As with all diagnostic tests, all results must be interpreted alongside other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *Treponema Pallidum* infection.

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Appendix 3. Example of a certification of completion

[Enter Logos of all affiliated organizations]

Certificate of Participation

This is to certify that

[Enter Name of Participant]

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attended the workshop on

"[Enter Name of Workshop]"

organised by

[Enter names of organizations responsible for the testing programme and organizing the workshop]

[Enter date of workshop]
[Enter location of workshop]

[Signature]

Name of Programme Manager
Affiliated Organization

[Signature]

Name of Trainer
Affiliation Organization

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Appendix 4. Examples of quality and stock management documentation (including stock card)

Stock Card

Item Name: _____ Unit: _____

Manufacturer: _____

Kit: _____ Lot #:_____ Expiration Date: _____

**Minimum Stock (Re-Order Level):

Date	Received From	Issued To	Quantity Received	Quantity Issued	*Balance	Lot #	Signature

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Appendix 5. Example of Quality Control Documentation

Daily Record of Quality Control Results

Kit: _____ Lot #:_____ Expiration Date: _____

Date	Negative Control Result	Neg Control Lot #	Acceptable? Y / N	Positive Control Result Low Pos	Pos	Pos Control Lot #s Low Pos	Pos	Acceptable? Y / N	Initials	Reviewed by & Date

Corrective Actions

Date	Action Taken	Initials	Reviewed by & Date

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Appendix 6. Standard Operating Procedure for the preparation of dried tube specimens

1.0 Purpose:

This procedure provides instructions on the manufacture of dried tube specimens to be used as a quality control as part of a proficiency testing programme

2.0 Equipment and Materials

2.1 Equipment

- Multi-channel Pipettes
- Biosafety cabinet (BSC)
- Timer
- RPR Rotator

2.2 Materials

- 2.0mL conical bottom Sarstedt tubes
- Trypan Blue dye (0.1% stock solution)
- Pipette tips
- Disposable transfer pipettes
- Freezer boxes
- Tube racks
- Cryo labels
- Storage bottles
- Zip lock bags
- Labels
- 5mL disposable syringes
- Disposable filter unit 0.2µl
- Rapid plasma reagin kits
- *Treponema Pallidum* Particle Agglutination test/ *Treponema Pallidum* Haemagglutination technique kits
- Phosphate buffered saline with Tween 20 (Sigma)

3.0 Handling Conditions

- Wear protective clothing while handling dried tube specimens
- Handle dried tube specimens as if capable of transmitting an infectious agent
- Do not interchange vial caps, as this may lead to cross contamination of specimens
- Leave the dried tube specimens in the biosafety cabinet (BSC) for overnight drying

4.0 Procedure

4.1 Plasma/Serum selection

- Obtain rejected plasma units from the local blood bank, sera from the diagnostic laboratory with a high syphilis titre (RPR titre ±1:128) and some RPR negatives. Store specimens at 2 - 8°C until further testing has been conducted.
- Verify the syphilis reactivity of all samples collected using a trepenomal (*Treponema Pallidum* Particle Agglutination test/ *Treponema Pallidum* Haemagglutination technique) and a non-treponemal test (Rapid Plasma Reagin), following the manufacturers' instructions and including positive and negative controls in the test run.

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4.2 Dilution of serum/plasma

- Select the serum/plasma from a high titre source
- Titrate the serum using rapid plasma reagin, initially by 10-fold dilutions, then by 2-fold dilution in a negative serum
- Make a 4-fold dilution of the strongest positive serum in negative serum to yield a medium positive
- Make a 4-fold dilution of the medium positive in negative serum to yield a faint positive serum
- Note the dilutions giving these results
- Verify the dilutions using *Treponema Pallidum* Particle Agglutination test/ *Treponema Pallidum* Haemagglutination technique and rapid plasma reagin according to manufacturers' instructions and including positive and negative controls in the test run.
- Select dilutions that represent a high titred and a low tittered sample, based on the sample/cut-off ratios (criteria for RPR and TPPA?)

4.3 Preparation of Dried Tube Specimens

1. Prepare a 1:1000 dilution of Trypan Blue: Serum, e.g. add 1 µL of dye to 1 mL of specimen. Vortex the specimen to mix the dye.
2. Transfer 20 µL of Trypan blue - serum/plasma solution to each Sarstedt tube. Tubes should be labelled with specimen identification and expiry date.
3. Leave the tubes uncapped and allow to dry overnight in a biosafety cabinet, ensuring that different specimens are kept in separate racks in the BSC
4. The following day, ensure that all specimens are thoroughly dried before capping each tube.
5. A visible coloured pellet should have formed in the bottom of the tube.
6. Store the capped dried tube specimens at 2-8°C until ready for shipping to participating laboratories.

4.4 Preparation of DST buffer (PBS/Tween-20)

1. Dissolve one foil pouch of phosphate buffered saline with Tween 20, Ph 7.4 inn 1L of deionised water.
2. Filter the solution through a 0.2µm filter flask.
3. Prepare 1.8mL aliquots of Proficiency Testing buffer in pre-labelled 2ml screw capped tubes.
4. Label the tubes the identification "Proficiency Testing buffer", with an expiry date of 1 year.

4.5 Preparation and Packaging of Dried Tube Specimen Panels

1. Create a panel of at least 6 samples from the characterized specimens with a combination of grades of reactivity for syphilis, including truly high titre positives and negatives.
2. Carefully blind the panel assigning a new identification (ID) to each sample, e.g. DTS-A1 to DTS-A6. Ensure there is traceability between the original ID and new ID.
3. Label each tube with the appropriate new ID.
4. Depending on the number of laboratories enrolled in the proficiency testing programme, prepare 10 to 20 extra sets and store at the central laboratory.
5. Proficiency panels for shipping to participating laboratories should contain:
   - One member of each panel
   - One vial of Proficiency Testing buffer
   - Two plastic transfer pipettes (dropper)
   - One instruction sheet
   - One reporting form
6. Put all contents into a zip lock bag labelled with identification, expiry date and storage conditions.
7. The bagged Proficiency Panels can be stored at 2-8°C until shipment or delivery to testing sites.

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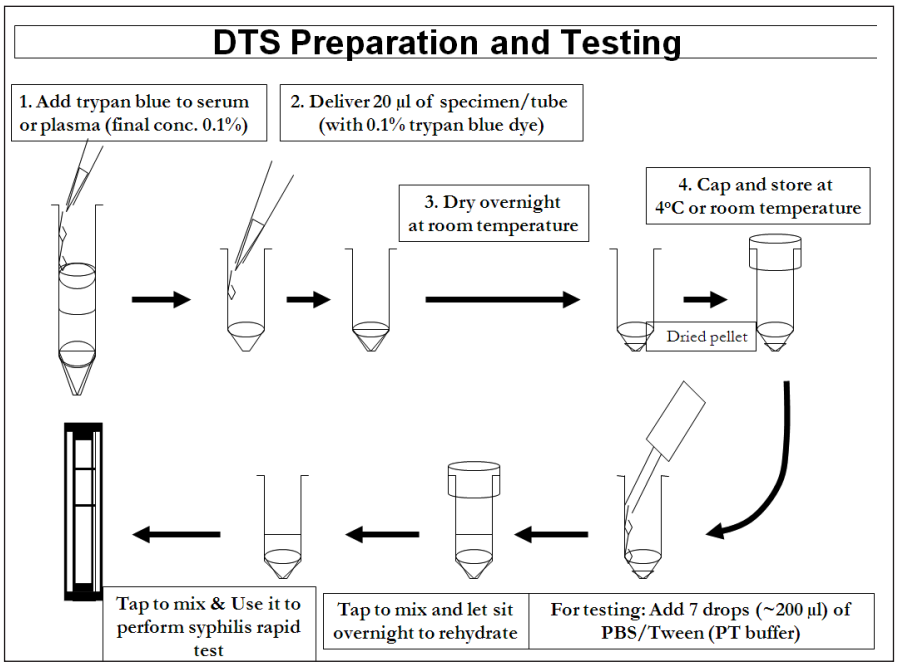
4.6 Reconstitution of Dried Tube Specimens

1. Tap the dried tube specimen tube gently to ensure that the colored pellet falls to the bottom of the tube.
2. Using the dropper provided, add 7 drops of proficiency testing buffer to each dried tube specimen to be tested. Cover the tube, tap gently and leave overnight at room temperature.
3. The following day, mix the specimen by gently tapping the tube.
4. Test the re-constituted dried tube specimen with the appropriate syphilis tests.
5. Report the results using the report form provided.

4.7 Results Analysis

1. Collect report from all participating laboratories
2. Enter data in the Excel spreadsheet
3. Analyze the data and submit final report to all the participating laboratories
4. Follow up with supervisor and/or additional training for those laboratories who do not receive a 100% agreement.



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Appendix 7. DTS testing instructions diagram