THE RAPID SYPHILIS TEST TOOLKIT

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IMPLEMENTATION 3

Training Package for Rapid Syphilis Testing

Appendix C
Sample Presentation Slides for Training

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Sample Presentation Slides for Training

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Module 1. An Overview of Syphilis

Overview of Syphilis

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

By the end of this module, participants should:

1. Understand of the global epidemiology of syphilis and congenital syphilis
2. Describe the stages of syphilis infection
3. Clinically identify the signs of infection
4. Understand syphilis transmission and the risk during pregnancy

Overview of Syphilis

- Syphilis is a sexually transmitted infection
- Caused by a bacteria, *Treponema pallidum*
- Initial infection causes a genital ulceration
  - Raised painless lesion
- Genital ulcer disease can be caused by other organisms as well
  - Herpes simplex, Haemophilis ducreyi (chancroid)

Syphilis and HIV Co-infection

- Co-infection of syphilis and HIV is common
  - Systematic review of developed and developing country data estimating 9.5% of HIV positive persons co-infected with syphilis
- Co-infection of HIV and syphilis among pregnant women is a significant risk factor for mother-to-child transmission of HIV
- Integrating HIV testing and syphilis screening for pregnant women will enhance prevention of vertical transmission of HIV and prevent the adverse pregnancy outcomes of untreated syphilis throughout pregnancy

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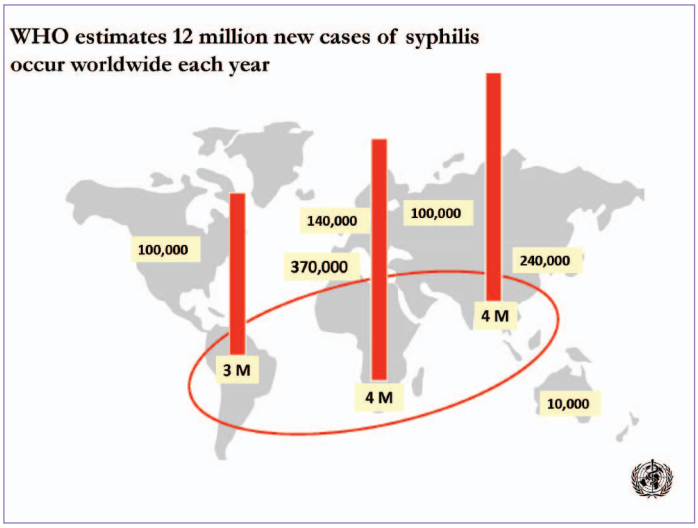

Syphilis Prevalence

- In [Sub-Saharan Africa/ Latin America/ South-East Asia], the prevalence of syphilis infection ranges from [lowest estimate]-[highest estimate]%
- In [Enter name of country], the prevalence of syphilis is [enter national prevalence]%

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Modes of Transmission

- Syphilis is transmitted through
  - Contact with the genital ulcer
  - Mother to child (vertical transmission) during pregnancy
  - Blood transfusion

Clinical Presentation

- Syphilis presents in multiple stages
  - Primary, secondary, early latent, late latent and tertiary
- Primary syphilis presents as a painless ulcer
  - Mainly on external genitals, vagina, anus, or rectum
    - In women, the ulcer may be deep in the vagina and go unnoticed
  - Can also be on fingers, lips, or mouth

Primary Syphilis

- Primary syphilis occurs 3 weeks after infection (9-90 days)
- Primary syphilis is characterized by a painless, indurated ulcer (or chancre)
- After 1-5 weeks, the ulcer spontaneously resolves without treatment
- This stage is highly infectious

Secondary syphilis

- The bacteria have spread to all organs and body fluids
- Symptoms develop 1-5 weeks after the ulcer
- Characterized by a generalized rash
- Symptoms spontaneously resolve after 2-6 weeks
- This stage is also highly infectious

Early Latent Syphilis

- Asymptomatic
- Occurs <1 after infection
- Less infectious than primary and secondary syphilis
- Vertical transmission can still occur

Late latent syphilis

- Occurs 2 years after initial infection and may last the patient's lifetime
- Asymptomatic
- Lower risk of transmission during this stage than earlier stages of infection

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Tertiary Syphilis

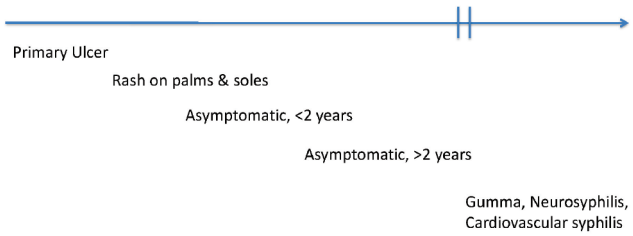
- Occurs anytime after secondary syphilis and may not occur at all
- Result of widespread infection during secondary syphilis
- Symptoms include gumma (lesions) of the skin, muscles, eyes, bones
- Also includes cardiovascular syphilis and neurosyphilis

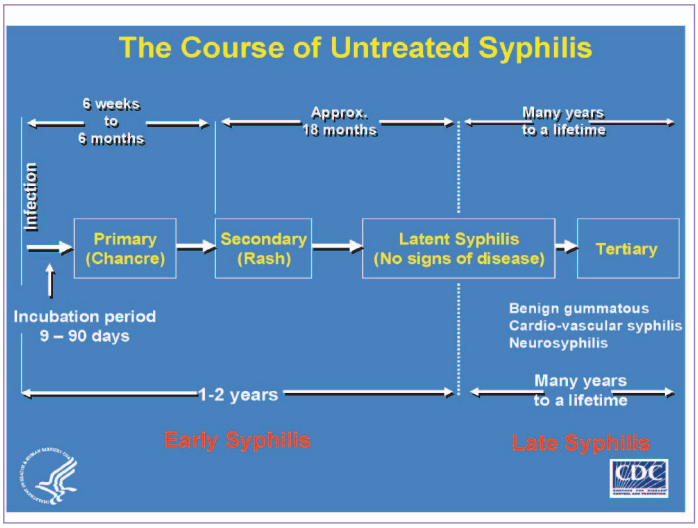
Congenital Syphilis

- Causes stillbith, miscarriage, and preterm labour
- Babies born to syphilis positive mothers may have low-birthweight, abnormal liver or spleen development, anemia, jaundice, lesions on the palms and soles, or neurological problems
- Only half of newborns infected with syphilis can be clinically identified at birth

Infectivity of Syphilis

1° > 2° > Early Latent > Late Latent & 3°





Conclusions

- Syphilis is a major health concern and causes stillbirth, low-birthweight babies and congenital syphilis
- Syphilis is transmitted through contact with a genital ulcer, through sexual intercourse, vertically from mother to baby during pregnancy or through blood transfusions
- Syphilis has multiple stages

Questions for Participants

- Have you ever seen a case of syphilis?
  - Was it primary, secondary or tertiary syphilis?
- Have you ever seen a baby with congenital syphilis?

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Module 2. Syphilis Testing Technologies

Syphilis Testing Technologies

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

By the end of this module, 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.

Syphilis diagnostics

Diagnosis of syphilis infection is based on detection of:

1. *Treponema pallidum* bacteria

1. Antibodies

Detection of Bacteria

The following diagnostic tests diagnose syphilis infection based on the detection of the *Treponema pallidum* bacteria:

- Microscopy
- Dark field
- Fluorescent

The Immune Response

- Antigen (Ag)
  - Is a substance recognized by the body or immune system as foreign
  - It may be the whole organism or part of it (protein, lipids, ect.)
  - An antibody is produced by the immune system in response to the detection of an antigen
- Antibody (Ab)
  - A protein produced in response to an Ag
  - The antibody will attack the Ag as part of the immune response

Syphilis Antibody Response

Two types of antibodies are produced during a syphilis infection

1. Treponemal Antibodies
   1. These are produced against an Ag *specific* to syphilis
2. Non-treponemal Antibodies
   1. These are produced against a non-specific Ag, reagin/ cardiolipin
   2. Reagin/ Cardiolipin is also produced when tissue is damaged during infection (Tb, malaria), auto-immune conditions (rheumatoid arthritis) or pregnancy

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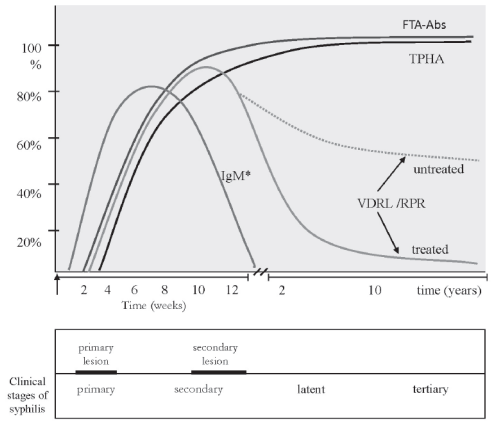
Syphilis Antibody Response



Detection of the Antibody

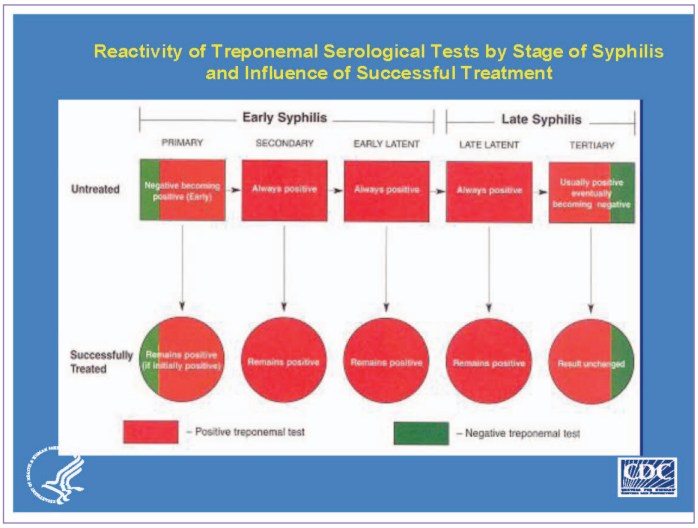
- Serological tests for syphilis diagnosis detect either the treponemal or non-treponemal Ab
- Treponemal tests detect the antibody specific to syphilis
- Non-treponemal tests detect the reagin/ cardiolipin antibody that is produced during syphilis infection but is not specific to syphilis

Types of Treponemal Tests

1. Agglutination Assays (TPPA, TPHA)
2. Fluorescent Assays
3. *Treponema pallidum* Immobilisation (TPI) test
4. ELISA Assays
5. Western Blot
6. Chromatographic tests (POC)

Treponemal Tests

- Detect antibodies specific to *T. pallidum* antigens
- They become positive early in infection
- Can be used to:
  - Confirm a clinical diagnosis, OR
  - Confirm positive result for non-treponemal test
- Remain positive for many years, even after successful treatment
- Detect life-time syphilis exposure



Treponemal Tests

- Most are limited to research laboratories
  - POC tests are the exception
- Samples have to be transported to established labs
- Results are not available for several days or weeks
- Individuals may not return for results
  - Resources are wasted
  - Positive may not be treated leading to adverse pregnancy outcomes or onward transmission

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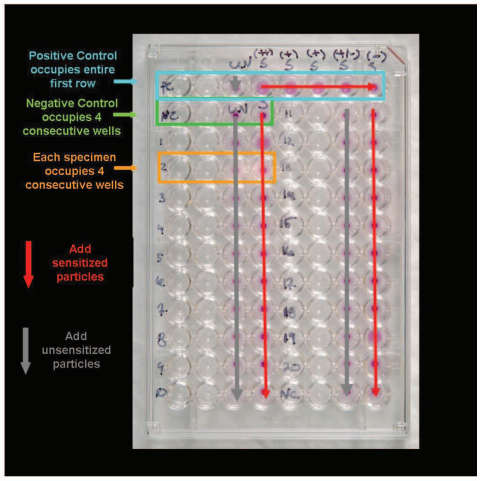
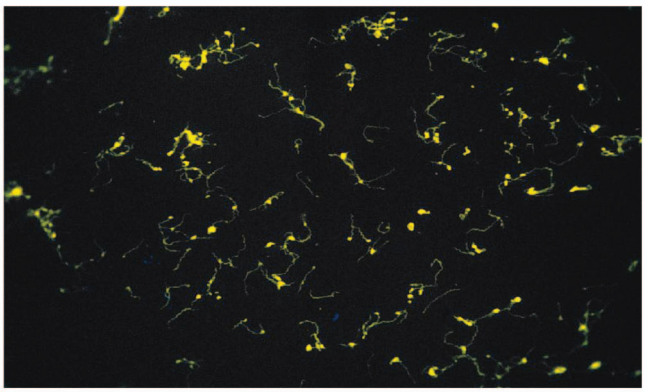
How to Perform TPPA/ TPHA

- Add sample diluent to wells 1-4
- Add serum sample to well number 1
- Mix and transfer to well number 2
- Repeat this process to well number 4
- Mix and discard same volume transferred from well 3
- Add unsensitized RBCs/ Gelatin particles to well number 3
- Add sensitized particles/ RBs to well 4
- Read results in a light box after incubation



Fluorescent Treponemal Antibody Test



Simple Treponemal Tests

Rapid Syphilis Tests (RST):

- Are simple to perform
- Can be used at primary health centres, at the point of care
- Give results in less than 30 minutes
- Use whole blood, collected from a finger prick
- Enable treatment to be give the same day as testing

Simple Treponemal Tests

Like all treponemal tests, RSTs:

- Detect antibodies specific to *T. pallidum*
- Can be used early to detect infection
- Remain positive even after successful treatment

Simple Treponemal Tests

- Important for control programmes
- Use whole blood, serum or plasma
- Can be integrated into other programmes (VCT, PMTCT, STD, ANC)
- Have high sensitivity (85-98%)
  - This is a measure of the ability of a test to detect infection
- Have high specificity (93-98%)
  - This is a measure of the ability of a test to exclude infection

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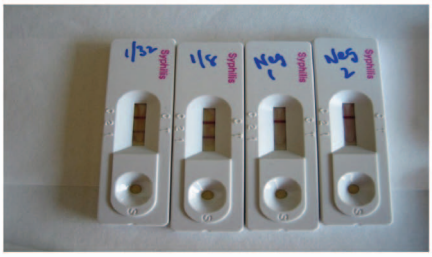
Format of RST

- Strips
- Cassettes (ex. SD Bioline)



Performing RST

- Follow the manufacturer's instructions or a national SOP
- SOP or Standard Operating Procedure provides detailed instructions on how to perform the test
- NOTE: Written SOPs should always be available at each testing site, and must *always* be followed when performing testing

RST Procedure

- Prepare the testing area and put on gloves and gown/ apron
- Remove the test cassette from the foil pouch
- Place it on a flat surface and label it with the client/ patient number
- Add patient specimen (serum/ whole blood/ plasma) to sample well S
- Add diluent buffer to sample well S
- Read the results after the specified time
- Enter results on record form/ register
- Dispose of all materials in biohazard waste/ sharps container

Advantages of Rapid Tests

- Do not require equipment
- Simple and rapid
- Use whole blood, serum or plasma
- Require minimal technical skills
- Can be performed at the Point of Care (POC)
- Increase access to testing
- Increase coverage of testing and treatment
- Results are easy to interpret

RPR vs. Rapid Tests

RPR (non-treponemal test)	Rapid Syphilis Test (treponemal test)
Can be used to distinguish active from past treated infection	Cannot distinguish active infection from past treated infection
Test of cure	Measures lifetime exposure to syphilis
Serum/ plasma	Whole blood/ serum/ plasma
Needs laboratory facility & trained personnel	Can be done in primary health care settings
Test only takes 8 minutes but patients often need to return for results and treatment	Results in less than 30 minutes and treatment can be given at the same visit
Interpretation of results requires a high degree of training and experience	Results are simple to interpret
Reagent needs refrigeration	Test and reagents can be transported and stored at room temperature
False negative results due to prozone effect and biological false positives	No prozone effect or biological false positives

Interpretation of RST Results

- Unable to distinguish between active infection and past treated infection
- A positive RST result indicates the client/ patient has been exposed to syphilis during their lifetime

[REFER TO NATIONAL GUIDELINES FOR FURTHER GUIDANCE ON CONFIRMATORY TESTING, TESTING ALGORITHMS, AND TREATMENT STRATEGIES]

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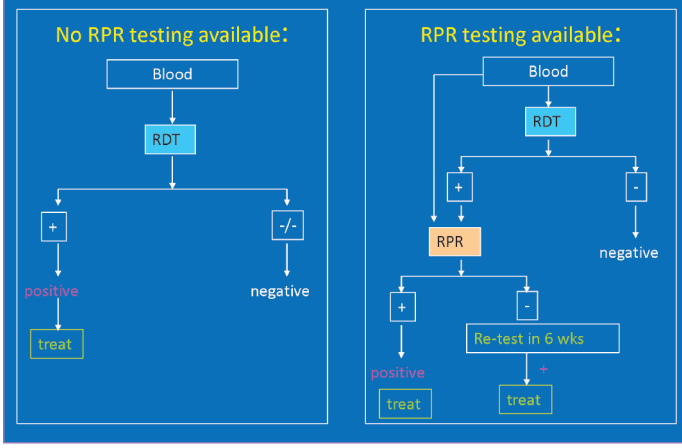
Syphilis: Proposed Testing Algorithms



Non-Treponemal Tests

- *T.pallidum* infection produces non-specific antibodies (non-treponemal antibodies)
- These are detected by non-treponemal tests (RPR, VDRL)
- Non-treponemal (reagin/ cardiolipin) antibodies arise from:
  - Lipoidal antigens that are the same on bacterial cells and host cells

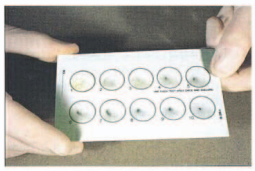
Types of Non-treponemal Tests

- Flocculation
  - Antigen-antibody complex
  - Ag-Ab complex remains suspended (visible)
  - Ex. RPR, VDRL, TRUST
- Complement Fixation Test
  - Wasserman reaction test

Rapid Plasma Reagin (RPR)

- Relatively simple
- Requires equipment and skill to perform and interpret results
  - Results are subjective
- Less sensitive than Treponemal tests in early syphilis infection
- Tend to be negative during late syphilis
- After successful treatment, becomes negative (Test of Cure)
- Prozone effect causes false negatives
- Other infections cause biological false positives

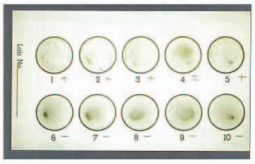
Rapid Plasma Reagin (RPR) Test



Sensitivity: 85-95%

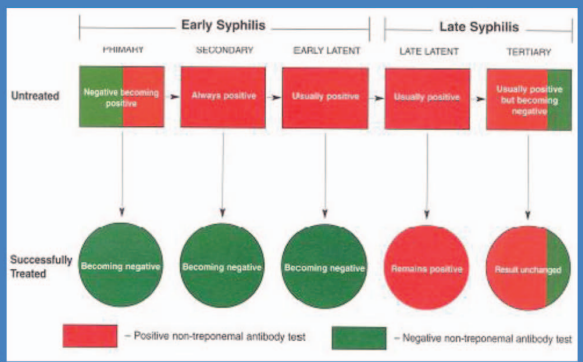
Specificity: 95-98%

Cost/test = $ 0.2



- Needs electricity for:
  - centrifuge
  - shaker
  - reagent storage
- Requires training
- Humid atmosphere

Reactivity of Non-treponemal Serological Tests by Stage of Syphilis and Influence of Successful Treatment



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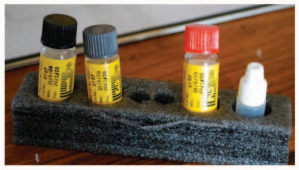
Non-treponemal Tests

- Detect non-specific antibodies formed during syphilis infection
- Examples:
  - Rapid Plasma Reagin (RPR)
  - Venereal Disease Research Laboratory (VDRL)



Use of Diagnostic Tools for the Prevention and Control of Syphilis

	RPR	Rapid	TPHA	EIA
Diagnosis	+	+*	+	+
Screening	+	+*	+/-	+
Tx efficacy	+	-	-	-
Re-infection?	+	-	-	-
Surveillance	+	+	+	+

* can be used with whole blood

Non-treponemal Tests

- Detect non-specific antibodies formed during syphilis infection
  - cardio-lipin antigen

    eg. Rapid Plasma Reagin (RPR)

    eg. Venereal Disease Research Laboratory (VDRL)

Questions for Participants

- Have you ever performed a syphilis test and if so, which one?
- Was it a treponemal or non-treponemal test?
- How user-friendly do you think it was?

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Module 3. Treatment of Syphilis

Treatment of Syphilis

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

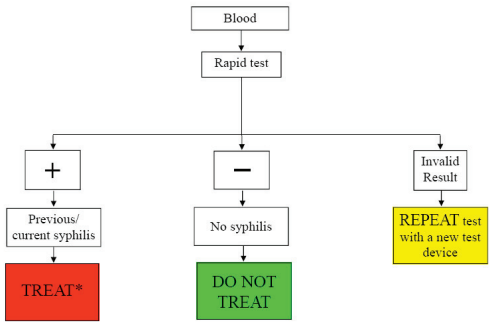
By the end of this module, participants should be able to:

1. Describe the recommended and alternative treatment and dosage for an adult with syphilis infection
2. Describe how to manage an infant born to a mother who tested positive for syphilis during pregnancy
3. Describe how to manage the partner of a syphilis positive individual
4. Describe the potential reactions to the recommended and alternative treatment for syphilis
5. Describe the potential risks and adverse outcomes if treatment is not administered

When Do You Treat A Patient?

- If a pregnant woman tests positive for syphilis
- If a patient at the STI clinic tests positive for syphilis
- If a patient at the delivery ward tests positive for syphilis

When Do You Treat A patient



*Some patients may be over treated

How To Treat Syphilis

- Before treating a patient, it is important to provide them with counseling
  - Explain what a positive result means and the risk of transmission to a partner or baby
  - Explain the treatment options available and that syphilis is a curable disease
  - Obtain consent from the patient

Counseling

1. REVIEW Pre-test information

2. HELP the patient understand the meaning of the result
   - A positive result means you are infected with syphilis
   - Syphilis can be cured with antibiotics
   - Syphilis infection can harm your unborn baby

3. DISCUSS any immediate concerns and ANSWER any questions
   - Having syphilis once does not mean you will not get it again
   - You can still be re-infected after successful treatment
   - You should not have sex until the syphilis sores are completely healed

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Counseling

4. ENCOURAGE safer sex practices in preventing reinfection and/or transmission
   - Use condoms
   - Have long-term relationships where neither of you have other partners
   - Limit your sex partners
5. ADVISE on telling partners
   - You should tell all your sexual partners that your are positive for syphilis and that they should go to a health clinic to be tested and treated [REFER TO NATIONAL GUIDELINES]
6. FOLLOW-UP Services
   - You should be tested for HIV infection
   - You should come in to be tested again in XXX weeks [REFER TO NATIONAL GUIDELINES]
   - You should have regular STI check-ups

Counseling

Counseling

1. **RECAP pre-test information:** 1. OVERVIEW OF SYPHILIS
2. **HELP the patient understand the meaning of the result**
3. **DISCUSS any immediate concerns and ANSWER any questions**

SAMPLE MESSAGES

- Having syphilis does not mean that you will not get it again
- You can still be re-infected after successful treatment
- You must not have sex until the syphilis sores are completely healed

4. **ENCOURAGE safer sex practices in preventing reinfection and/or transmission**

- Use condoms
- Have long-term relationships where neither of you have other partners
- Limit your sex partners

5. **ADVISE on telling partners:**
Stress the importance of treatment and prevention in keeping the unborn baby healthy

- You should tell your sex partners that you are positive for syphilis and that they should also be tested and receive treatment if necessary

6. **FOLLOW UP services:**

- Offer support, information and referral for subsequent counselling sessions and/or counselling for couples if necessary
- Ensure continual access to treatment if needed
- Ask the patient to come in to be tested in the third trimester

- You should be tested for IIIV infection
- You should come in to be tested again in xxx weeks
- You should have regular STI check-ups

How To Treat Syphilis

- The National Guidelines recommended treatment for an adult testing positive for syphilis is:
- [All patients with a positive test result should be treated regardless of treatment history in a previous pregnancy]
- IMPORTANT: Treatment should be given on the SAME DAY as Testing

How to Manage Partners

- [REFER TO NATIONAL GUIDELINES FOR PARTNER MANAGEMENT]
- DETAIL IF THE PARTNER IS TO BE TESTED AND TREATED ONLY IF POSITIVE, OR PRESUMPTIVELY TREATED AS A CONTACT WITHOUT TESTING

How To Treat Syphilis

- REFER TO NATIONAL GUIDELINES FOR ALTERNATIVE TREATMENT REGIMENS IF A PATIENT IS ALLERGIC TO PENICILLIN
- DETAIL THE MEDICATION, DOSAGE, AND DURATION OF THE ALTERNATIVE TREATMENT REGIMEN AND METHOD OF ADMINISTRATION (ORAL, IV, INJECTION)

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How To Treat Syphilis

- Infants born to mothers who tested positive for syphilis during pregnancy need to be treated according to the National Guidelines
- REFER TO NATIONAL GUIDELINES
- DESCRIBE THE MEDICATION, DOSAGE, DURATION OF REGIMEN, AND ADMINISTRATION (ORAL, IV, INJECTION)
- DESCRIBE THE ALTERNATIVE MEDICATION, DOSAGE, DURATION OF REGIMEN, AND ADMINISTRATION (ORAL, IV, INJECTION)

Infants with Congenital Syphilis

- Infants born with the signs and symptoms of Congenital Syphilis need to be treated according to the National Guidelines
- DESCRIBE THE MEDICATION, DOSAGE, DURATION OF REGIMEN, AND ADMINISTRATION (ORAL, IV, INJECTION)
- DESCRIBE THE ALTERNATIVE MEDICATION, DOSAGE, DURATION OF REGIMEN, AND ADMINISTRATION (ORAL, IV, INJECTION)

Syphilis Treatment

Age Group	Recommended regimen	Alternative regimen	Remarks
Adult syphilis			
Adults (including pregnant women)			
Congenital syphilis			
Infants born to mothers who tested positive for syphilis			
Infants with signs and symptoms of congenital syphilis			

Penicillin Allergy: Anaphylactic Shock

- All patients must be asked for a history of allergy to penicillin
- **Clinical Features:** sudden collapse, hypotension, excessive sweating, thin pulse
- **Differential Diagnosis:** other causes of shock, including bleeding and severe dehydration

Management of Anaphylactic Shock

- Determine and remove the cause
- Keep the patient warm
- Secure the airway
- Restore the BP
  - lay the patient flat and raise his/her feet

REFER TO NATIONAL GUIDELINES FOR FURTHER INFORMATION

Management of Anaphylactic Shock

- REFER TO NATIONAL GUIDELINES
- DESCRIBE THE MEDICATION, DOSAGE, DURATION OF REGIMEN, AND ADMINISTRATION (ORAL, IV, INJECTION)
- DESCRIBE THE ALTERNATIVE MEDICATION, DOSAGE, DURATION OF REGIMEN, AND ADMINISTRATION (ORAL, IV, INJECTION)

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Questions for Participants

- Have you ever had to treat anaphylactic shock? Can you describe how you identified it? How did you manage it? What was the outcome?
- In your experience, how do people react to hearing that they have syphilis?

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

Integration of Services

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

At the end of this module, 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

Integration

- Rapid syphilis testing will be introduced to facilities already offering several testing services
- Integrating services can reduce the work load of HCW and make it easier to perform multiple tests
- Other rapid testing services are ideal for RST integration

Syphilis and HIV Coinfection

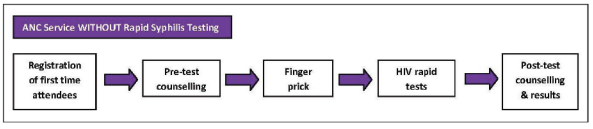
- Co-infection of syphilis and HIV is common
  - Systematic review of developed and developing country data estimating 9.5% of HIV positive persons coinfected with syphilis
- Co-infection of HIV and syphilis among pregnant women is a significant risk factor for motherto-child transmission of HIV
- Integrating HIV testing and syphilis screening for pregnant women will enhance prevention of vertical transmission of HIV and prevent the adverse pregnancy outcomes of untreated syphilis throughout pregnancy

Integration & Patient Flow

- Patient Flow describe how patients move throughout the facility to receive services
- Each Facility will have it's own unique patient flow
- Integration of services will differ at each facility according to its patient flow

ANC Clinic: Patient Flow

- Patient flow at an ANC clinic offering HIV rapid testing services and *no syphilis testing services*



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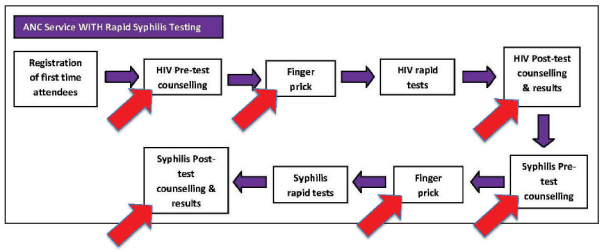
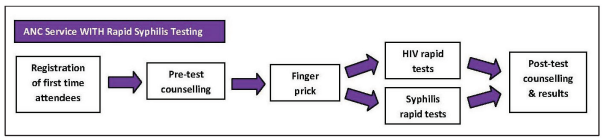
ANC Clinic: Patient Flow

- Patient flow at an ANC clinic offering HIV and syphilis rapid testing services without integration



ANC Patient Flow: Integrated Approach

- Patient flow at an ANC clinic offering integrated HIV rapid testing services and syphilis testing services



Possibilities for Service Integration

- HIV PMTCT
- HIV PICT or VCT
- Rapid Malaria Testing
- Hb Testing
- Other diagnostic tests requiring a finger-prick of blood draw

Integrated Patient Flow

- DESCRIBE WHAT INTEGRATION OF SERVICES WILL OCCUR IN YOUR PROGRAMME
- DESCRIBE HOW SERVICES WILL BE INTEGRATED IN YOUR PROGRAMME

Integrated Patient Flow

- CREATE A DIAGRAM SHOWING PATIENT FLOW FOR THE SERVICES THAT WILL BE INTEGRATED WITH RAPID SYPHILIS TESTING
- THIS SHOULD BE DONE IN THE SAME STYLE AS ABOVE
- THE DIAGRAM SHOULD HIGHLIGHT WHERE INTEGRATION IS GOING TO OCCUR IN THE CLINIC
- INSERT DIAGRAM ON THIS SLIDE

Health Care Worker Responsibilities

- Continue to provide clients/ patients with a high degree of care
- Continue to follow the SOPs for each test procedure
- Continue to provide clients/ patients with

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Possible Challenges

- Mixing up tests (forgetting which is which during testing)
- Mixing up buffer reagents
- Incorrect entering of results in register
- Timing

Solutions

- Be well prepared for testing
- Have each SOP present on the testing bench
- If the test cassettes have a similar appearance, label them (ex. "HIV" and "syph")
- Keep the buffer reagents next to the test kit during test
- Have the register near the testing bench and carefully transfer results
- Prepare both tests simultaneously and start the timer when the buffer reagent is added to the first test

Questions for Participants

- What services does your facility currently integrate?
- What opportunities are there for further integration?
- In your experience, has integrating services been beneficial for the health care provider? For the client/ patient? Why?

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Module 5. Safety at the Testing Site

Safety at the Testing Site

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

By the end of this module, 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 need to be observed when testing for syphilis

Performance Objectives

By the end of this module, participants will be able to:

1. Adhere to personal health and safety practices
2. Maintain a clean and organized workspace
3. Disinfect and dispose of infectious materials
4. Take appropriate actions following accidental exposure to potentially infectious specimen
5. Follow written safety procedures and keep proper safety records

What Is Safety?

Safety is the state of being safe and protected from danger, harm, or *infection*

Why Is Safety Important?

- Coming in contact with human blood or blood products is potentially hazardous
- Safety involves taking precautions to protect yourself and the client against infection
- All specimens should be treated as potentially hazardous

What Else Needs Protection?

- Other people who may come in contact with testing by-products
- The testing materials
- The environment (from hazardous material)

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Universal Precautions

Every specimen should be treated as though it is infectious

Apply Safety Practices Throughout the Testing Process

- Before Testing (Pre-analytical)
  - Specimen collection
  - Specimen preparation
  - Specimen transport
- Testing (Analytical)
  - Testing
- After Testing (Post-analytical)
  - Disposal

Develop Personal Safe Work Habits

- Wash hands before and after testing specimens
- Wear a fresh pair of gloves at a lab coat or apron
- Dispose of contaminated sharps and waste immediately after use

Develop Personal Safe Work Habits

- Pipetting by mouth is *strictly forbidden*
- Never eat, drink or smoke at the test
- Do not keep food in the laboratory refrigerator
- Do not leak anything in the lab (ex. pen, pencil)

Maintain Clean & Orderly Work Space

- Keep work areas clean and organized
- Disinfectant work surfaces daily
- Restrict or limit access to test area when working
- Keep supplies locked in a safe and secure area
- Keep emergency eye wash units in working order and within expiry date

Take Precautions to Avoid Needle Stick Injury

What can cause needle stick injury?

- Lack of concentration
- Inexperience
- Lack of concern for others
- Improper disposal of sharps

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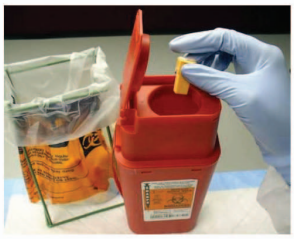
Dispose of Used Sharps in Special Containers

Do's and Don't of Waste Disposal

- DO NOT: break, bend, re-sheath or re-use lancets, syringes or needles
- DO NOT: shake sharps containers to create space



Do's and Don'ts: Sharps and Waste Containers

What's wrong with this picture?

15

Never Place Needles or Sharps in Office Waste Containers

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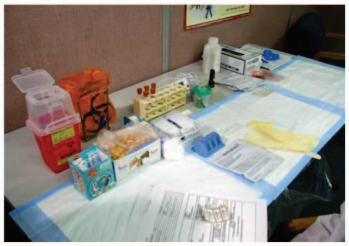
Sharps Containers Must Be

Placed near workspace
Closed when not in use



Sealed when ¾ full

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Do's and Don't of Waste Disposal

- DO NOT EVER place needles or sharps in office waste containers
- DO: place sharps containers near workspace
- DO: close sharps containers when not in use
- DO: seal sharps containers when ¾ full

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Policy for Handling Sharps

- The user is responsible for disposal of sharps
- Must dispose of sharps after each use
- Must place sharps in sharps containers
- Do not drop sharps on the floor or in the office waste bin
- Place sharps container near your workspace
- Seal and remove when container is ¾ full
- Dispose of all waste appropriately

Incineration of Waste

- Incineration is burning of contaminated waste to destroy and kill micro-organisms
- Incineration is:
  - Effective against potential re-use
  - Protects the environment and nearby communities
  - Must be supervised

Disinfect Work Areas

- Use an approved disinfectant (ex. JIK)
- Disinfectant:
  - Kills germs and pathogens
  - Keeps work surface clean
  - Prevents cross-contamination
  - Reduces risks of infection

In Case of a Spill or Splash

- Wear clean disposable gloves
- Immediately and thoroughly wash any skin splashed with blood
- Large spills: Cover with paper towels and soak with 0.5% Jik and allow to stand for at least 5 minutes
- Small spill: Wipe with paper towel soaked in 0.5% Jik
- Discard contaminated towels in infectious waste containers

In Case of an Accident

- What types of accidents can happen?
  - Potential Injury (needle sticks, falls)
  - Environmental (splashes, spills)
  - Equipment damage
- What should you do?
  - Report to your supervisor immediately
- Assess and take action
  - Record using form
- Monitor situation

Action Plan for Implementing Safety Practices

- Identify hazards
- Establish and implement safety policies and procedures
- Conduct safety specific training
  - Must be a priority
  - Communication is key
- Perform regular audits or assessments

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Safety Documentation

- Full safety requirements for testing blood/ serum specimens are very detailed
- Any site performing testing should have a complete set of country guidelines
- Every staff member should read and understand the safety manual before being allowed to work
- Everyone is responsible for personal safety and the safety of their co-workers

All procedures should be posted or visible in the workspace

Questions for Participants

- What is safety and why is it important?
- What is the universal precaution you must take when dealing with specimens? Is this something that you observe at your job?
- What safety procedures do you have in place at your clinic or laboratory?
- Have you ever encountered a spill? How did you manage it?

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Module 6. Preparation for Testing

Preparation for Testing

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

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

1. List and identify all the supplies required to perform rapid syphilis testing

1. List and identify all the components of a test kit for rapid syphilis testing

Guidelines For The Use of RSTs

Do NOT:

- Use kits beyond the expiry date
- Use damaged kits, materials or supplies
- Re-use tests, materials or supplies
- Expose kits to direct sunlight
- Mix lot numbers
- Use Reagents from one kit with those of another

Guidelines For The Use of RDTs

Do:

- Use old kits first

- Use a test immediately once opened

Preparing for Testing

Before performing a syphilis test, staff should review the following checklist:

- Do you know what test you are going to perform?

- Are all supplies and materials needed to perform the test arranged on your workspace?

- Have you read the SOP?

- Have you counter-checked the sample against the working list?

- ☐ Syphilis Rapid Test Kit
- ☐ Surgical gloves
- ☐ Alcohol or Alcohol swabs
- ☐ Sterile lancet
- ☐ Lancet bin or Disinfectant jar
- ☐ Cotton wool/gauze
- ☐ Pipette, pipette tips, Loop
- ☐ Chase buffer
- ☐ Contaminated Waste bin
- ☐ Band-aids or plasters
- ☐ Timer, clock or watch
- ☐ Pens for labelling
- ☐ Logbook
- ☐ Bleach, Disinfectant

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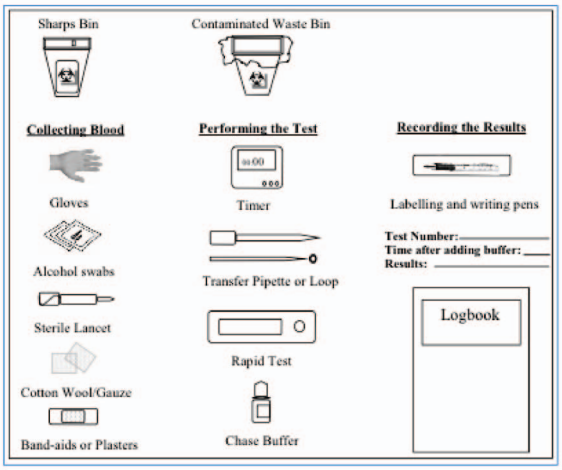


Gloves

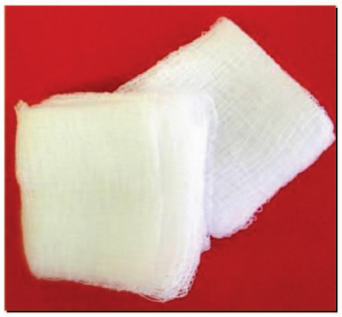
- Single use disposable gloves
- Latex or polypropylene
- Without evidence of holes or tearing

8

Alcohol Swabs

9

Cotton Gauze or Cotton Balls



Single-use, hazardous waste disposal

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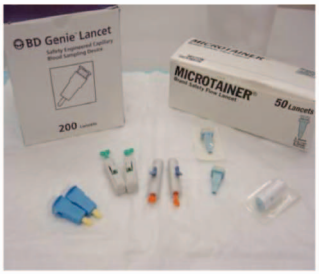
Sterile Lancets



Single-use, hazardous waste disposal

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Pipette

Transfer Pipette

Automatic Pipette

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Timer

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Standard Operating Procedures and forms.

14

Labeling Pens & Writing Pens

Labeling Pens (Markers)

- Writing Pens

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Sharps container / Disinfectant Jar

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Proper Disposal of Contaminated Materials

17

Waste Disposal

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Jik and Container or Spray Bottle

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Examine Test Kits

- Display test kits used in-country
- Examine the different components found in each of the Rapid Test kits, for example
  - Desiccant packet – This is not used when performing the test. It only serves to keep the packet contents dry before use. It should be discarded when the test kit packet is opened.
  - Buffer solution – Required by some kits

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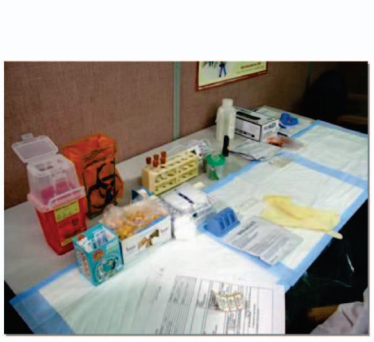
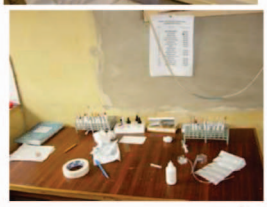
Organize Your Work Area





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Questions for Participants

- What is each of these items used for:
  - Gloves
  - Alcohol swabs
  - Cotton balls or gauze
  - Sterile lancets
  - Pipette
  - Timer
  - Standard operating procedures
  - Marking pens
  - Sharps disposal bins
  - Disinfectant jar
  - Jik

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Questions for Participants

- List the components of a Rapid Syphilis Test Kit:

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Module 7. Orientation to Rapid Syphilis Testing

Orientation to Rapid Syphilis Testing

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

At the end of this module, participants should be able to:

1. Describe how to perform a finger prick
2. Describe how to perform a rapid syphilis test
3. Interpret the result of a rapid syphilis test

Performing a Finger-Prick

ENTER THE STEPS FROM THE PROGRAM-SPECIFIC SOP FOR PERFORMING A FINGER PRICK

Performing a Finger-Prick

INSERT THE STEPS FROM THE PROGRAM-SPECIFIC SOP FOR PERFORMING A FINGER PRICK

Rapid Syphilis Testing

INSERT THE STEPS FROM THE PROGRAM-SPECIFIC SOP FOR PERFORMING A RAPID SYPHILIS TESTING

Rapid Syphilis Testing

INSERT THE STEPS FROM THE PROGRAM-SPECIFIC SOP FOR PERFORMING A RAPID SYPHILIS TESTING

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Rapid Syphilis Testing

INSERT THE STEPS FROM THE PROGRAM-SPECIFIC SOP FOR PERFORMING A RAPID SYPHILIS TESTING

Rapid Syphilis Testing

INSERT THE STEPS FROM THE PROGRAM-SPECIFIC SOP FOR PERFORMING A RAPID SYPHILIS TESTING

Interpreting the Results

INSERT THE INFORMATION FROM THE SOP ON HOW TO INTERPRET THE RESULTS OF A RAPID SYPHILIS TEST (POSITIVE, NEGATIVE, INVALID)

DETAIL WHEN TO REPEAT THE TEST (INVALID RESULT ONLY)

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Module 9. Documents and Records

Documents and Records

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

By the end of this module, 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 the test site
4. Describe how to properly keep and maintain test site documents and records

What are Documents and Records?

Documents

- WRITTEN policies, process descriptions, procedures, and blank forms
- Used to communicate information

Records

- Information captured on worksheets, forms, charts and computer databases

3

Documents Are the Backbone of the Quality System

Verbal instructions are often:

- Not heard
- Misunderstood/ Misinterpreted
- Quickly forgotten
- Ignored

Policies, standards, processes, and procedures must be written down, approved, and communicated to all concerned.

Record-Keeping

- Proper record-keeping makes quality management possible
- Record-keeping allows a test site to:
  - Communicate accurately and effectively
  - Minimize error
  - Monitor quality system
  - Assist management in:
    - Developing plans & policy
    - Monitoring and evaluating programs
  - Stock management
  - Enhance Operational Research

On-site Records

Records that should be kept on-site include:

- Specimen transfer logs
- Syphilis request/ client test result
- Lab/ Test register
- Accident records
- Personnel records
- Worksheets
- Temperature logs
- Equipment maintenance logs
- Inventory records
- Quality assessment:
  - Monitoring reports
  - Retesting reports
  - Corrective action

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Good Record-Keeping

- Understand the information to be collected
- Record the information every time; at the right time
- Record all the information
- Record the information in the same, standard way every time

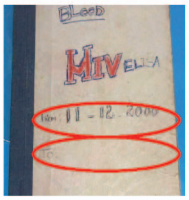
Records: Permanent, Secure, Traceable

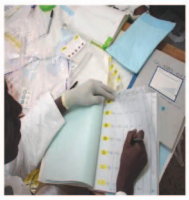
Permanent:
- Keep books bound
- Number pages
- Use permanent ink
- Control (limit) storage

Secure:
- Maintain confidentiality
- Limit access
- Protect from environmental hazards

Traceable:
- Date and sign every record

Logbooks Are Cumulative Records of Test Site Operations





- Should be indexed to allow for easy retrieval of data
- Should be stored to minimize deterioration

Client/ Patient Records

- Should be completed when the client/ patient is present
- Writing should be legible
- All records should be signed and dated by the responsible HCW
- Should be stored in a secure location for patient confidentiality

Retaining Records

The length of time records should be stored at a facility depends on:

- National policies
- Secure storage space at a test facility

Key Messages

- Written policies and procedures are the backbone of the quality system
- Complete quality assurance records make quality management possible
- Keeping records facilitates meeting program reporting requirements

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Exercise!

Which of the following are documents and which are records?

- Country testing algorithm
- Safety manual
- Clinical test results
- SOPs
- Manufacturer test kit inserts
- Summary form of findings from monitoring report

Exercise!

Which of the following are documents and which are records?

- Report of corrective actions
- Temperature log (blank form)
- Daily maintenance log (completed)
- Stock cards and stock book (completed)
- EQA specimen transfer log (completed)

Questions for Participants

- What are some examples of documents and records maintained at your facility?
- How long are records kept at your facility?
- Does your facility have enough secure storage space to store records?
- Why do you think all records should be signed and dated?

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Module 10. Standard Operating Procedures (SOPs)

Standard Operating Procedures

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

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

1. Describe the importance of an SOP
2. Describe when an SOP should be used and where it should be stored
3. Give five examples of SOPs

Standard Operating Procedure

- SOPs are written procedures which describe how to perform an activity
- SOPs should be located directly at the working place
- Only the current version should be present
- SOPs should describe how procedures work and not how they are *supposed* to work
- SOPs should be written or thoroughly reviewed by instrument's operators

Standard Operating Procedures

- Describe how to perform various tasks in a testing site
- Provide step-by-step instructions
- Assure:
  - Consistency
  - Accuracy
  - Quality
  - Standardization

Importance

- SOPs define how to carry out protocol specified activities
- Standardizing techniques facilitates comparison of results
- Essential component of a quality system

Content of SOPs

- Unique SOP number and version number
- Page number and total number of pages
- Objectives/ purpose of the SOP
- Scope
- Responsibility
- Principle
- Procedures/ instructions
- Reference

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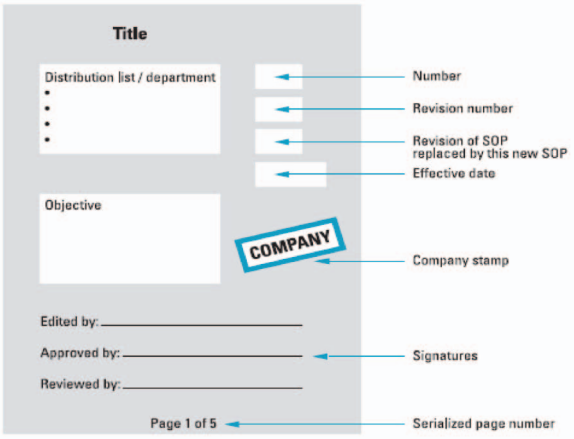
Content of SOPs

- Safety
- Storage
- Specimen collection
- Specimen storage
- Test requirements (pre-test)
- Validity of test
- Interpretation of results

Content of SOPs

For equipment testing an SOP should contain:

- Performance acceptance criteria
- Recommended corrective actions
- Template for continuous entries of test results and corrective actions



Controlled Documents

- SOPs are controlled documents
- SOPs must be approved for use in-country
- SOPs must have document control features
- SOPs must be kept up-to-date

Manufacturer Product Inserts

- Do not rely solely on manufacturer product inserts
- Product inserts do not provide specific information for test sites
- Examples additional material include:
  - Materials required, but not in the kit
  - Materials in the kit that may not be used in some settings
  - Specific safety requirements
  - External quality control requirements

Examples of SOPs

- SOP: Performing a Finger Prick
- SOP: Performing a Rapid Syphilis Test
- SOP: Re-constituting Dried Tube Specimen
- SOP: Testing with a Dried Tube Specimen
- SOP: Routine Quality Control Testing
- SOP: Proficiency Panel Testing
- SOP: Monitoring

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SOPs At the Test Site

- Daily routine schedule/ duty roster
- Country testing algorithm
- Safety manuals
  - Safety precautions
- Blood collection:
  - Fingerprick, venipuncture, DBS
- Test procedures
- Quality Control and Quality Assurance Procedures
- Internal assessments
- Reordering of supplies and test kits
- Equipment use and maintenance

SOPs Must Be Followed

- Why is it important to follow SOPs?
- What are the consequences if you don't?

Questions for Participants

1. In your setting, who writes the SOPs?
2. What is your opinion on this arrangement in your setting?
3. Peter photocopied an SOP and gave the copy to a friend who is not working in his office. Is there anything wrong here?

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Module 11. Supply Chain and Stock Management

Supply & Stock Management

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

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

1. Identify and describe the different supply management tools
2. Understand and appreciate the importance of these tools in commodity management and reporting and ordering supplies in a timely manner
3. Describe the procedures in completing the tools

Stock Keeping Records

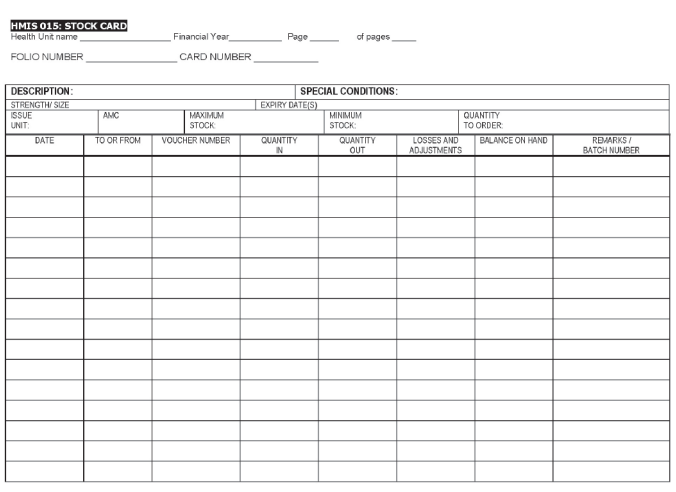
- Track stock on hand
- Useful for determining consumption in the absence of dispensed-to-user data
- Track losses and adjustments
- Track expiry dates
- Useful tools for accountability problems

Physical Count

- Process of counting by hand the actual usable quantities of a given commodity available at a given time
- Recommended at the end of the report period before placing an order

Importance of Physical Count

- To check that recorded stock card balances match actual quantities on the shelves
- To verify product quality
- Identify any losses/adjustments
- To identify and correct errors in the stock card
- Accountability



HMIS 015: STOCK CARD
Health Unit name _____ Financial Year_____ Page_____ of pages____
FOLIO NUMBER _____ CARD NUMBER _____

DESCRIPTION:				SPECIAL CONDITIONS:			
STRENGTH/ SIZE			EXPIRY DATE(S)				
ISSUE UNIT:	AMC	MAXIMUM STOCK:		MINIMUM STOCK:		QUANTITY TO ORDER:	

DATE	TO OR FROM	VOUCHER NUMBER	QUANTITY IN	QUANTITY OUT	LOSSES AND ADJUSTMENTS	BALANCE ON HAND	REMARKS / BATCH NUMBER

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Stock Records

- Track quantities of goods/ medicines/ test kits dispensed to clients or used in a given period of time
- Consumption information vital guide for facility re-supply quantities or needs

Stock Cards

- Should be completed every time a stock is consumed or moved between locations
- Records:
  - Balance at the beginning of the day
  - Quantity consumed, moved or added (if delivery was received)
  - Balance at the end of the day
- Stock cards should be signed and dated by the HCW responsible for stock management

Types of Consumption Data

- Dispensed-to-user data:
  - Information about the quantity of goods actually put in the hands of end users
- Issues data:
  - Information about the quantity of goods moved from one level of the system to another
  - eg. Store room to facility or pharmacy

How to Order

- On-time
  - According to local schedule
- Sufficient quantity
  - The quantity of any supply will depend on how often deliveries are received, the turnaround time, and the quantity consumed during one month
- Correct forms
  - It is important to submit requisitions for equipment and supplies using national forms and to keep a record at the facility

*Turnaround time is how long it takes for an order to be received from the time the request is submitted

Order Quantity

- Order a sufficient quantity of supplies to cover the period until the next order plus a buffer stock
- Buffer stock
  - Quantity of a supply, in addition to that needed for routine patient flow, to prevent stock outs
  - Should reflect the maximum turnaround time
  - Does not need to be replaced every month

Example!

- Schedule: Every 3 months
- Maximum turnaround time: 2 weeks
- Remaining buffer stock: 1 week
- Monthly consumption: 100 tests (25/ week)
- What quantity of tests should be ordered?

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Answer!

Facility Consumption= (tests consumed/ month) x (number of months until next order)

Buffer Stock= (tests consumed/ week) x (maximum turnaround time) – (remaining buffer stock)

Order Quantity = Facility Consumption + Buffer Stock

Answer!

Facility Consumption: (100 tests/ month) x (3 monthly ordering schedule) = 300 tests

Buffer Stock: (25 tests/ week) x (2 weeks – 1 week) = 25 tests

Order quantity: 300 tests + 25 tests = 325 tests

Receiving Supplies

When receiving supplies it is important to:

- Record the date of delivery and quantity of supplies delivery
  - The record should be signed by the individuals who received and delivered the supplies
- Check the supplies for damage
- Store supplies off the floor in the storage room
- Update the stock card with the quantity of supplies delivered

Storage Room

A storage room should have:

- A lock
  - To prevent theft
- A window
  - For ventilation
- A window cover
  - To prevent rain from entering the room
- Shelving
  - All supplies should be stored off the floor
- A thermometer
  - To monitor temperature
- Stock cards
  - All stock cards should be kept with the item

Questions for Participants

- How often does your facility order supplies?
- How much buffer stock does your facility maintain?
- What is the maximum turnaround time at your facility?
- How much buffer stock should your facility maintain given the maximum turnaround time?

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Module 12. Monitoring and Evaluation

Monitoring & Evaluation

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

By the end of this module, 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 a HCW and supervisor/ monitor during a monitoring visit

Monitoring

- Ongoing, routine activity
- Purpose:
  - Observe progress
  - Identify challenges
  - Come up with local solutions
  - Provide support to health care facility staff

What to Monitor

- Personnel & Training
- Biosafety
- Facility
- Documents and Records
- Quality System
- Stock and Supply Chain Management

Personnel & Training

- Every individual responsible for performing rapid syphilis testing should:
  - Have a certificate or evidence of training at the facility
  - Be able to describe the goals of the program and quality system

Biosafety

- Every facility offering rapid syphilis testing services should have in the testing area:
  - A sharps disposal bin
  - A lined biohazard waste disposal bin
  - A protocol for disposal/ incineration of facility waste

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Biosafety

- All staff involved in the testing process should:
  - Be wearing closed toe shoes
  - Be wearing scrubs or an apron
  - Have his/ her hair tied back
  - Have access to soap and water for hand washing
  - Have access to gloves

Facility

- Every facility offering rapid syphilis testing services should have:
  - A table, counter or lab bench with adequate space for performing testing
  - Windows or electrical lighting to light the testing area
  - Access to water
  - Ability to communicate with referral centers (personal cell phone, facility cell phone, landline, email/ internet, two-way radio)

Documents & Records

- Every facility offering rapid syphilis testing services should:
  - Have a patient or testing register (or both) to record test result and treatment outcome
  - Store the patient or testing register (or both) in the testing area
  - Record if partners were treated
  - Regularly update the register(s) and sign next to test results
  - Ensure the register (s) are organized and the writing is legible

Quality System

- Every facility offering rapid syphilis testing should:
  - Have a dedicated folder for quality system records and SOPs
  - Have an up-to-date record of proficiency panel testing and routine quality testing results
  - Document all actions taken in the event of a out-of-specification result (Routine Quality Testing)
  - Have documentation of the results of the proficiency panel testing and any corrective actions taken
  - Have quality records signed by a facility in-charge or supervisor

Stock & Supply Chain Management

- Every facility offering rapid syphilis testing should have:
  - Locked store room/ cupboard
  - Complete and up-to-date stock cards for all testing materials
  - Requisition and delivery records stored in a bound folder
  - A schedule/ knowledge of order frequency
  - Knowledge of facility's buffer stock
  - Current stock of essential supplies for RST

How to Monitor

- Routinely
  - Bi-weekly, monthly, quarterly
- By trained monitor or trained supervisor
- Using a program specific checklist and interviews with facility staff

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How Often to Monitor

- More intensive after initial test introduction
- Decreased frequency after 3 months
- In-line with national and district supervisory visits
- Depends on available resources and accessibility of facilities

Responsibilities of Facility Staff

- To record client/ patient information in the national register
- To record syphilis test result, treatment and partner treatment (if any) in the client/ patient or syphilis testing register
- To maintain daily stock card and complete requisition and delivery supply records
- To perform routine quality control testing/ proficiency panel testing as per program guidelines and record results appropriately

Responsibilities of Monitor

- To routinely visit health care facilities
- To conduct a monitoring visit in a professional manner, using the checklist as a guide
- To interview facility staff (experiences with test, supply chain, quality system)
- To identify any potential barriers/ challenges to testing based on the results of the visit and interviews
- To work with facility staff to come up with workable solutions to the challenges
- To provide facility staff with support throughout program implementation

Evaluation

- Summative process
- Takes place at the end of a program
- Purpose is to summarize program project towards meeting objectives and achieving goals
- Reflects on overall success or failure of a program
- Does not generate problem solving initiatives

Questions for Participants

- What support have you received from supervisors or monitors in the past?
- How has this been helpful?
- How often is monitoring/ supervising carried out in your district/ region?
- What is the current role of the HCW and supervisor during the visits?

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Module 13. Quality Assurance and Quality Control

Quality Control

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning objectives

By the end of this module, participants should be able to

- Define Quality Control
- Describe trouble shooting
- List the benefits of QC in rapid testing
- Differentiate between internal Quality Control and External quality control
- Describe the process of maintaining QC records

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What is Quality Control (QC)?

- Comprises those measures that must be included during each test run to verify that the test is working properly.
- These are activities performed to detect and correct errors that may occur during testing

•If an error occurs, do not release or report results until you have corrected the error.

3

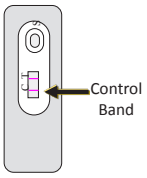
Quality Control

In-built procedural control:

- Included in the testing device or as part of the kit
- To determine if adequate quantity of specimen has been added to the well

Internal Quality Control:

- Not included in the test device or kit
- Specimens labeled with expected result are used to validate the reliability of the test cassette



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Internal Quality Control

- Involve the use of known positive and negative or control materials
- These may be purchased from a manufacturer or made locally (usually by reference lab)
- These positive and negative specimens are used to evaluate the accuracy of the test cassette
- Usually tested periodically in order to ensure the kits are accurately detecting treponemal antibodies

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Internal Quality Control Samples

- Manufactured at Central Laboratory or/ purchased from commercial retailers
- Store according to SOP or local instructions
- Record date when opened
- Use before expiry date
- Do not contaminate

Quality Control Samples are potentially infectious and should be treated with appropriate safety precautions and disposed as biohazardous waste

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Sources of Internal Quality Control Samples

Prepared by Reference Laboratory

Commercially prepared

Store according to instructions
Record date when opened
Use before expiry date
Do not contaminate

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Frequency of Use: When Should You Test Internal Control Samples?

- Once a week, beginning of the week
- New shipment of test kits
- Beginning a new lot number of test kits
- When environmental conditions exceed range needed for stability of kits

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Invalid Results – What Do You Do?

- Repeat test using a new test cassette from same kit
- Repeat test using new test cassette from a new test kit
- Repeat test using a new test cassette and a new control sample

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Invalid Results – What Do You Do?

- If repeatedly invalid:
  - assume problem with test kit or procedure
- Inform supervisor
- Take corrective actions
- Document testing, invalid result, any repeat testing or corrective action taken, sign and date record, have supervisor sign record

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Troubleshooting Invalid Results

Problem	Potential Cause	Action
No control line or band present	• Damaged test device or controls • Proper procedure not followed • Expired or improperly stored test kits or controls	• Repeat the test using new device and blood sample • Follow each step of testing according to SOP • Re-check buffer and/or specimen volumes • Wait for the specified time before reading the test • Check expiration date of kits or controls. Do not use beyond stated expiration date • Check temperature records for storage and testing area

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Troubleshooting Invalid Results – Cont'd

Problem	Potential Cause	Action
Positive reaction with negative external control, i.e. false positive	Incubation time exceeded recommended time (SOP)	Re-test negative control using a new device and read results within specified time limit
Extremely faint control line	The control line can vary in intensity	No action required. Any visible line validates the results.

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Exercise #1: Interpreting Syphilis Rapid Test Results

- Refer to the handout in your participant manual
- Read the test results and write your interpretation in the space provided.
- Time: 2 minutes

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Quality Control Records

- Testing Sites Information should include:
  - A standard worksheet that includes spaces for recording QC results
  - A separate register for QC results to which Information will be transferred from the worksheet.
  - A flow chart for Corrective action showing steps followed when the QC results do not read as expected and how to refer problems back to the reference laboratory.
  - The qualified Officer should regularly review all QC data with responsibility for testing site.

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Maintaining Quality Control Records

▪WHY?
Trouble-shooting
Part of routine inventory – proof of reliable test results

▪HOW?
Use standard worksheets

WHEN?
▪Each time QC materials are tested
▪Record all invalid results and inform supervisor

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Daily Record of Quality Control Results

Kit: _____ Lot #:_____ Expiration Date: _____

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

Corrective Actions

Date	Action Taken	Initials	Reviewed by & Date

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Periodic Review of Records

- Review of internal control results before accepting test results
- Review of external control results by test performer
- Weekly or monthly review of external quality control results by testing site supervisor
- Periodic audits or assessments

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Questions for Participants

- What would you do if your external control tested invalid.
- Give examples of problems encountered with QC results, how they occurred and how to correct them
- Why is it important to maintain records of QC results

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Module 14. External Quality Assurance/ Dried Tube Specimens

External Quality Assurance & Dried Tube Specimens

Rapid Syphilis Testing:
Workshop for the Training of HCW
[Enter date, location of workshop]

Learning Objectives

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

1. Describe the benefit of DTS
2. Describe the purpose of Internal Quality Control Testing and Proficiency Panel Testing, and the differences between the two procedures
3. Correctly complete all forms required by the quality system

Dried Tube Specimens

- Dried Tube Specimens (DTS) are vials containing dried out plasma samples
- Specimens can be syphilis positive or negative, HIV positive or negative, or any combination of syphilis and HIV positive or negative
- Can be transported and stored at room temperature

Preparation of DTS

- Manufactured by central laboratory
- Use syphilis (or HIV) confirmed positive and negative plasma samples
- Blue dye is added to sample
- 20ul of sample with dye is distributed into the vial
- Vial is left under biosafety hood for 24 hours to dry

Preparation of DTS

- Once dry, vials are labeled, capped, and frozen for long-term storage
- Vials can be distributed to facilities as part of quality system
- For transport and short-term storage (2 weeks), DTS can be stored at room temperature

How to Use DTS

First need to Re-Constitute:

- Gently tap the tube to ensure colored pellet is at the bottom of the tube
- Add buffer using pasteur pipette
- Cover the tube (close cap) and tap gently to mix
- Leave overnight at room temperature

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How to Use DTS

The next day:

- Mix the specimen by gently tapping the tube
- The specimen can be now be used for testing
- Follow the SOP for Performing Rapid Syphilis Testing
- Record results using appropriate forms

Caution!

Gloves and appropriate bio-safety precautions should be taken when handling DTS (re-constitution and testing)

The specimen should be treated as potentially infectious

DTS and Quality Systems

- DTS is a valuable tool in quality systems
- It can be used for routine quality testing, proficiency panel testing or incoming inspections of test kits
- DTS can be sent to peripheral labs and facilities because it can be stored at room temperature

Internal Quality Control

- Uses DTS which are labeled either positive or negative
- The label also contains lot number and expiry date
- Vials are called 'known' because the expected test result is know (written on label) before the test is performed

Internal Quality Control: Purpose

- Purpose: to assess the ability of the test cassette to correctly identify positive and negative samples
  - Answer the question "Is the test working?"
- Ensure tests were not damaged during transport to the facility or during storage at the facility

Internal Quality Control: Results

- If the known positive gives a positive result and the known negative DTS gives a negative result, the tests are said to be "in specification"
- If the known positive DTS gives a negative result or the known negative DTS gives a positive result, the tests are said to be "out of specification"

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Internal Quality Testing: Results

- The lot number, expiry date, expected result and actual results should be recorded on the appropriate form along with the date, and name of tester and signature of tester
- If the result is out of specification, the tester should follow the corrective actions steps to determine the problem
- The actions should be recorded an signed off by a facility supervisor/ in-charge

Corrective Actions

- If there is an out of specification result, it may be because the test was invalid, the test kit was damaged or the DTS sample was damaged during transport and storage
- To determine if the problem was with the test cassette, repeat quality testing using a new test cassette from the same test kit

Corrective Actions

- If the test result is still out of specification, repeat the test using a new test cassette from a different test kit
- If the test result is still out of specification, re-constitute a new vial of DTS and repeat using a test from the first kit
- If the test result is still out of specification, do not use either test kit in the clinic and contact the monitor/ supervisor for further instructions
- If the test result is in specification, this means the problem was with the vial of DTS and not the tests, continue using the tests in the clinic

Internal Quality Testing: Frequency

- May be performed every week, every two weeks, every month, or for every new kit
- Frequency will depend on the volume of patients being testing and the rate of test consumption at a facility

Proficiency Panel Testing

- Also uses DTS
- DTS labels contain an identification code and expiry date *but not the expected test result*
- Purpose: to determine if the facility/laboratory staff member is correctly performing and interpreting the results of a rapid syphilis test

Proficiency Panel

- May contain up to six DTS
- May include strong and weak positive samples and negative samples
- DTS are reconstituted a day before testing
- Tests should be performed and interpreted according to the SOP

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Proficiency Panel: Documentation

- Date of testing, DTS identification code and expiry date, test result, name of tester and signature of tester are recorded on the correct form
- Results are submitted to central laboratory
- Monitor will provide facility with written copy of results and overall score
- Any corrective actions will be documented in the facility's quality systems folder

Who Should Perform the Proficiency Panel?

- Should be performed by all facility staff who perform rapid syphilis testing as part of routine care
- Each person should conduct testing using the panel independently and should not share result
- The panel is to identify individuals in need of support and is intended as a tool to improve the quality of testing services for the benefit of the client/ patient

Proficiency Panel: Results

- Facility score can identify individuals or groups of individuals having trouble performing the test or interpreting results
- Highlights where monitor should focus attention
- Can be used to identify when and where on-the-job retraining or large re-fresher training workshops are required

Questions for Participants

- What question is proficiency panel testing trying to answer?
- What are the key differences between internal quality control testing & proficiency panel testing?
- Do any other programs at your facility have a quality system in place?