

# Module 2

# Testing of HIV-exposed Infants



## Module 2 Table of Contents

<b>Module 2, Part 1: Trainer Guide .....</b>	<b>2</b>
Overview for the Trainer .....	2
Session 2.1: Identifying HIV-exposed Infants.....	4
Session 2.2: Recommendations on Timing of Infant HIV Testing.....	7
Session 2.3: Overview of NAT.....	10
Session 2.4: Overview of Serological Testing.....	12
• Exercise 1.....	15
• Exercise 2.....	17
<b>Module 2, Part 2: Course Content.....</b>	<b>21</b>
Session 2.1 Course Content: Identifying HIV-exposed Infants.....	21
Section 2.2 Course Content: Recommendations on Timing of Infant Testing .....	24
Session 2.3 Course Content: Overview of NAT .....	29
Session 2.4 Course Content: Overview of Serological Testing .....	31
<b>Appendix 2A: Pre-test Counselling Session for Maternal or Infant HIV Testing with RDT ..</b>	<b>34</b>
<b>References.....</b>	<b>37</b>

# Module 2, Part 1: Trainer Guide



**Total Module Time: 125 minutes (2 hours, 5 minutes)**

## Overview for the Trainer

### Session 2.1: Identifying HIV-exposed Infants

Activity/Method	Time
Interactive trainer presentation and large group discussion	20 minutes
Questions and answers	5 minutes
Total Session Time	25 minutes

### Session 2.2: Recommendations on Timing of Infant HIV Testing

Activity/Method	Time
Interactive trainer presentation and large group discussion	25 minutes
Questions and answers	5 minutes
Total Session Time	30 minutes

### Session 2.3: Overview of NAT

Activity/Method	Time
Interactive trainer presentation and large group discussion	15 minutes
Questions and answers	5 minutes
Total Session Time	20 minutes

### Session 2.4: Overview of Serological Testing

Activity/Method	Time
Interactive trainer presentation and large group discussion	15 minutes
Exercise 1: Making sense of RDT results: Group game	10 minutes
Exercise 2: Making sense of virological testing results: Group game, re-match	15 minutes
Questions and answers	5 minutes
Review of key points	5 minutes
Total Session Time	50 minutes

## Materials Needed



- Slide set for Module 2
- Flip chart and markers
- Tape or Bostik (adhesive putty)
- Ensure participants have:
  - Copies of the Participant Manual; the Participant Manual contains background technical content and information for the exercises.
  - Copies of the antenatal (ANC) card and child health card

## Special Instructions



- Review both of the exercises. Adapt both the scenarios and answers to ensure they are believable, culturally relevant, and that answers reflect national guidelines.
- If this module has not already been adapted to include **national** HIV testing guidelines or PMTCT guidelines, ensure you bring with you enough copies of the relevant national guidelines document(s) to give one copy to each participant. Refer participants to the national guidelines as appropriate throughout this training.

# Session 2.1: Identifying HIV-exposed Infants



Total Session Time: 25 minutes

## Session Objective

After completing this session, participants will be able to:

- Identify HIV-exposed infants in the clinical setting



## Trainer Instructions

Slides 1–11

### Step 1:

#### Session Objective

Point out the session objectives (listed above). Ask participants if they have any questions before moving on.

### Step 2:

#### Testing: The Terminology

Introduce this module by defining some of the key terms relevant to HIV testing of HIV-exposed infant. Engage participants by asking:

- *What is meant by nucleic acid testing or NAT?*
- *What is the difference between infant HIV testing and EID (or early infant diagnosis)?*

Define birth testing. Then ask:

- *What is the difference between point-of-care testing and near point-of-care testing?*

Use the information in Section 2.1 Course Content to fill in participant responses. Avoid going into too much detail at this point, as all terminology will be discussed in depth later in this module and in Module 3. If there are questions, add them to the “Car Park”.



## Make These Points

- HIV-exposed infant testing is one element of the HIV-exposed infant package of comprehensive care. Infant HIV testing includes:
  - Nucleic acid testing (NAT) at 4–6 weeks of age: The NAT at 4–6 weeks is referred to as early infant diagnosis (EID). Some countries offer testing at birth, which would also be considered EID.
  - Tests during and after the breastfeeding period: Infants should be tested for HIV during the breastfeeding period (typically at 9

months of age) and have a final test done 3 months after the end of breastfeeding or at 18 months of age, whichever is later. [Refer to national guidelines for testing algorithm in your country.]



## Trainer Instructions

Slides 12–17

### Step 3:

#### Identifying HIV-exposed Infants

Discuss the identification of all HIV-exposed infants in a clinical setting. Initiate the discussion by asking:

- *How would you identify an HIV-exposed infant?*
- *If a mother does not know her HIV status, what should you do?*
- *How do you obtain consent/agreement for infant testing if the parent is not available?*
- *When might you test an infant of an uninfected mother for HIV?*

### Step 4:

Review national HIV testing guidelines for women who are breastfeeding. If you have enough copies of the national HIV testing guidelines for all participants, open up the guidelines and point out the relevant paragraphs.

### Step 5:

Hand out copies of the relevant national health cards (child health card, antenatal health card, adult health card). Point out where you will find the HIV status of the mother.



### Make These Points

- HIV-exposed infants are usually identified through careful follow up of all mothers with HIV.
- Pregnant women should be tested for HIV antenatally. In high HIV prevalence settings, women who test negative during antenatal care should be re-tested in third trimester pregnancy or labour and delivery and during the postnatal period to detect new maternal infections. [Follow national guidelines on HIV testing in pregnant and breastfeeding women.]
- HIV testing of pregnant and breastfeeding women ensures that women with HIV receive the care and treatment they need and their infants are provided with the HIV-exposed infant comprehensive package of care including testing.

- Caregivers who decline HIV testing of their infants should never be forced to agree to HIV testing, but rather provided with counselling to address their concerns.

**Step 6:**

Allow 5 minutes for questions and answers on this session.

# Session 2.2: Recommendations on Timing of Infant HIV Testing



Total Session Time: 30 minutes

## Session Objectives

After completing this session, participants will be able to:

- List the recommended ages for testing of HIV-exposed infants and the tests recommended at each age
- Explain the importance of national testing algorithms



## Trainer Instructions

Slides 18–22

### Step 1:

#### Session Objectives

Begin by reviewing the learning objectives for this Session. Ask participants if they have any questions before moving on.

### Step 2:

#### Introduction

Before you start, as background, ask participants:

- *What are “maternal antibodies”? [Answer: antibodies that passed from the mother to the foetus through the placenta before birth. Maternal antibodies help to protect the infant from infection early in life, when the newborn’s immune system is still immature.]*

Then introduce this section by briefly introducing virological vs serological testing (both will be discussed in detail later). Use Section 2.2 Course Content for reference.

### Step 3:

#### When and which test?

Provide a summary of infant testing recommendations. Engage participants by asking:

- *At what age are HIV-exposed infants tested for HIV?*



#### Make These Points

- WHO recommends that HIV-exposed infants are tested for HIV at 4–6 weeks of age and if negative, then re-tested at 9 months of age and again at 18 months of age or 3 months after weaning, whichever is later. [1]

- Some countries have added NAT testing at birth. However, NAT testing at birth does not replace a 4–6 week test.

**Step 4:**

Point out where, on the antenatal and child health cards, information on HIV testing is documented.



## Trainer Instructions

Slides 23–29

**Step 5:**

### Birth Testing

If birth testing is conducted in your country, or will be conducted in the near future, then provide an overview of birth testing. Engage participants by asking:

- *What do you think are the advantages of birth testing?*
- *How about the disadvantages?*
- *How would you minimize the disadvantages?*

**Step 6:**

### HIV Testing for Sick Infants

Stress the importance of testing an HIV-exposed infant or child at any age, regardless of national or global recommendations, if that child is symptomatic for HIV disease. Ask participants:

- *If you were providing care for an 8 month old HIV-exposed infant who had symptoms that might suggest he was infected with HIV, would you wait a month to test him as per recommendations? [Answer: no, test him immediately!]*



### Make These Points

- Some countries now recommend virologic testing of infants at birth, in addition to the test at 4–6 weeks of age. Follow your country's national guidelines.
- If birth testing is provided, it is very important that the infant is also tested at 4–6 weeks of age because HIV acquired during delivery will not be diagnosed with birth testing.
- Always test sick infants immediately; do not wait until the recommended testing age.
- **A positive NAT result should always be confirmed using a new blood specimen**, typically drawn during the post-test counselling session. Initiate ART immediately, never wait for the confirmatory test result.
- **HIV-exposed infants should receive HIV testing at multiple time points** to rapidly detect HIV infections acquired during pregnancy,



delivery, and breastfeeding. If the infant’s first HIV test is negative, ensure that the caregiver understands the importance of keeping regular appointments and returning for HIV testing at the recommended time points.



## Trainer Instructions

Slides 30–32

### Step 7:

#### HIV Testing Algorithm

Ask participants:

- *What is an HIV testing algorithm?*
- *Why is it important to follow our national testing algorithm?*

Use Section 2.2 Course Content as reference.

### Step 8:

Take 3–5 minutes to talk participants through the testing algorithm, either the WHO algorithm that appears in Figure 2.1 or, preferably, the national algorithm. Start with the rectangle that is labelled “HIV-exposed infant or child (4–6 weeks to 18 months)” and trace the paths used for testing the infant throughout the period of HIV exposure. Start with the scenario of negative test results at all time points (4–6 weeks, 9 months, 18 months), then consider the scenarios where test results are positive at various time points.



#### Make These Points

- It is important that healthcare providers follow the national testing algorithm

### Step 9:

Allow 5 minutes for questions and answers on this session.

## Session 2.3: Overview of NAT

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**Total Session Time: 20 minutes**

### Session Objectives

After completing this session, participants will be able to:

- Describe how and why NAT is used to diagnose HIV in infants
- Interpret NAT results, whether positive or negative



### Trainer Instructions

Slides 33–37

#### Step 1:

#### Session Objectives

Begin by reviewing the objectives for this session, which are listed above. Ask participants if they have any questions before moving on.

#### Step 2:

#### Laboratory Diagnosis of HIV Infection—NAT

Provide an overview of NAT technologies for DNA and RNA PCR testing, as outlined in the course content section.

#### Step 3:

Take a minute to define the following concept.

- *What does “window period” refer to? [Answer: the time it takes from infection to the development of enough virus or antibodies to be detectable.]*

Discuss window period using the content in the course content section.



### Make These Points

- Virological testing, using nucleic acid testing (NAT) technologies, detects HIV virus parts, and can be used to diagnose HIV in infants and children under the age of 18 months. The DNA PCR test is one type of HIV virological test procedure. DNA PCR is the method used for early infant diagnosis.
- RNA PCR testing is used for viral load testing. Viral load testing is done for patients who are already on ART, to monitor their response to treatment.



### Trainer Instructions

Slides 38–39

#### Step 4:

#### Testing Procedures

Provide an overview of the high throughput and point-of-care (POC) technologies available for NAT.



#### Make These Points

- NAT can be conducted on high throughput analysers and POC analysers.
- The high throughput analysers are laboratory-based instruments that require dedicated trained staff. Most virological testing is still conducted using high throughput analysers.
- POC virological testing is becoming more widely available. The main advantages of this technology are that it can be used at or near point-of-care and it yields a test result in 90 minutes or less.



### Trainer Instructions

Slide 40

#### Step 5:

#### Meaning of HIV Test Results, Virological Testing

Discuss the meaning of the virological test result. Use Section 2.3 Course Content as a reference.



#### Make These Points

- The infant with a positive HIV virological test result is infected with HIV.
- The infant with a negative HIV virological test result is either not infected with HIV or was infected within the past 3 months but the virus is still not yet detectable.

#### Step 6:

Allow 5 minutes for questions and answers on this session.

## Session 2.4: Overview of Serological Testing



Total Session Time: 50 minutes

### Session Objectives

After completing this session, participants will be able to:

- Describe when serological testing is used in the context of infant HIV testing
- Interpret serological testing results, whether positive or negative, in the context of infant HIV testing



### Trainer Instructions

Slides 41–46

#### Step 1:

#### Session Objectives

Begin by reviewing the learning objectives for this session. Ask participants if they have any questions before moving on.

Remind participants that RDT is not routinely used in HIV-exposed infants and children under the age of 18 months. It is used to diagnose HIV infection in children who are 18 months of age or older. It can also be used to establish HIV-exposure status, but as you will see, the result must be interpreted with caution.

#### Step 2:

#### Laboratory Diagnosis of HIV Infection—Serological Testing

Start this session by providing an overview of serological testing. Initiate the discussion by asking:

- *What is the difference between serological testing and virologic testing? [Answer: the serological testing procedure detects antibodies to the virus, whereas the virologic testing procedure detects the actual virus or viral parts.]*

#### Step 3:

Explain that, before we discuss the types of laboratory tests, we are going to take a minute to define some important concepts.

- *The first is “reactive”, what does it mean if a test gives a “reactive result”? [Answer: antibodies to an infection or a particular organism that can cause an infection—such as a virus—were found by a single test kit.]*
- *What does “nonreactive” mean? [Answer: no HIV antibodies to a particular infection or organism were detected.]*
- *What is the difference between reactive and positive? [Answer: reactive/nonreactive describes the result from a single test kit; whereas positive/negative describe the result once the testing algorithm is completed.]*

Then provide an overview of the types of serological testing procedures and the window period for RDT, using the course content section.



### Make These Points

- The most widely used testing procedure to diagnose HIV infection is the rapid diagnostic test (RDT), which is a serological or antibody test.
- The primary disadvantage of RDT is that it cannot differentiate between maternal and infant antibody in the child under the age of 18 months, so it cannot be used to diagnose HIV infection in infants or children under 18 months of age.
- RDT is not used to diagnose HIV in infants and children under the age of 18 months. However, it is used to diagnose HIV in children and adults over the age of 18 months.
- Infants and children below 18 months of age testing HIV antibody positive are HIV-exposed. Virologic testing (NAT) is required to determine if the child is HIV-infected.
- A negative RDT result in a child 4–18 months of ages does not necessarily mean that the child was not HIV-exposed. The child may be HIV-exposed but has already lost most or all maternal antibody.



### Trainer Instructions

Slides 47–49

#### Step 4:

#### RDT: Interpreting the Test Result

- Provide an overview of what a positive or negative RDT result means in children under the age of 18 months. Use Section 2.4 Course Content as a reference.

#### Step 5:

Ask participants:

- *What information about the child do we need to interpret a negative RDT result? [Answer: age and timing of last exposure to HIV (i.e., date the child last breastfed), as well as whether or not the child has signs or symptoms of HIV infection.]*



### Make These Points

- The result of RDT needs to be interpreted in light of the child's age (less than 4 months, between 4 and 18 months of age, or older than 18 months of age), last exposure to HIV (i.e. whether the child is

breastfeeding or has breastfed in the past 3 months), and clinical status (i.e., whether or not the child is symptomatic for HIV disease).



## Trainer Instructions

Slide 50

### Step 6:

#### Testing HIV-exposed Sick Infants and Children

Discuss the testing of sick infants. Use Section 2.4 Course Content as a reference.



#### Make These Points

- If you, as a clinician, suspect that a child is HIV-infected based on symptoms, it is important to act quickly, as this child may be at grave risk of death. Provide HIV testing to a sick child even if it is not part of the HIV-exposed infant testing schedule/algorithm.
- In a sick child, run virological testing in any infant under 18 months of age. Use RDT in children 18 months of age or older.
- If you suspect the child is HIV-infected and you are still awaiting test results, start the child on ART immediately. It can always be stopped later if it turns out the child is HIV-uninfected.



## Trainer Instructions

Slide 51

### Step 7:

Lead participants through Exercise 1, which provides an opportunity to apply their knowledge of RDT to various scenarios involving children under the age of 18 months.

## Exercise 1

Exercise 1: Making sense of RDT results: Group game	
<b>Purpose</b>	To review the interpretation of RDT results in infants and children.
<b>Duration</b>	10 minutes
<b>Advance Preparation</b>	Review the scenarios (below) and suggested answers, adapt to ensure they are appropriate and typical and that answers reflect national guidelines. Give the babies in each scenario a local name, rather than referring to them as “Baby A” or “Baby B”.
<b>Introduction</b>	We will now break into 2 teams to play a game that will test your and your team’s understanding of RDT in infants and children.
<b>Activities</b>	<ol style="list-style-type: none"> <li>1. Break participants into 2 teams based on where they are sitting.</li> <li>2. Ask each of the 2 teams to identify a team captain. The team captain is the team spokesperson, only the team captain can speak on behalf of the team.</li> <li>3. Explain to participants that you will read a scenario and question, the first team to answer the question correctly will win 1 point. After all 7 scenarios have been read and answered, the team with the most points is the winning team. <b>Team captains are expected to consult with their teams before indicating (by raising their hand) that they have the correct answer.</b></li> <li>4. Start the game by reading the first scenario and question. Wait for the first team captain to raise his/her hand indicating that the team has agreed on an answer. If the answer is correct, that team wins a point, if not, the other team may answer and (if correct) win the point.</li> <li>5. Explain in brief, the correct answer after a point is earned.</li> </ol> <p><b>Debrief in large group</b></p> <ol style="list-style-type: none"> <li>6. Ask participants if they have questions on RDT in infants and children or questions on any of the scenarios.</li> <li>7. Congratulate the winning team. Provide prizes if available (sweets, pens, or other small item; alternatively, you could give the winning team a privilege such as queuing up for lunch before the losing team).</li> </ol>

Exercise 1: Making sense of RDT results: Group game	
<ul style="list-style-type: none"> <li>• <b>If Baby A is 18 months old, HIV-exposed, and stopped breastfeeding at one year of age, what does it mean if she tests HIV-negative by RDT?</b> <ul style="list-style-type: none"> <li>• <i>Answer: Baby A is HIV-negative.</i></li> </ul> </li> <li>• <b>If Baby B is 19 months old, HIV-exposed, and stopped breastfeeding when she was 17 months of age, what does it mean if she tests HIV-negative?</b></li> </ul>	

- *Answer: Baby B is unlikely to be HIV-infected but should be retested 3 months after completion of breastfeeding, i.e. at 20 months of age (in 1 month's time).*
- **If Baby C is 21 months old, HIV-exposed, and still breastfed, what does it mean if she tests HIV-positive by RDT?**
  - *Answer: Baby D is HIV-infected. Confirm test result/retest as per national guidelines.*
- **Baby D is 5 months old, formula fed since birth, and her mother died with unknown HIV status. What does it mean if she tests HIV-positive by RDT?**
  - *Answer Baby E is HIV-exposed.*
- **If Baby E is 25 months old and was weaned 3 months ago, what does it mean if she tests HIV-positive by RDT?**
  - *Answer Baby F is HIV-infected.*
- **If Baby F is 6 months old, HIV-exposed, and still breastfeeding, what does it mean if she tests HIV-negative by RDT?**
  - *Answer: Baby G may have lost maternal antibodies, but she is still HIV-exposed. Because Baby A is still breastfeeding she is at risk of HIV infection, she should be retested at 9 months (using NAT if available or as per national recommendations).*

Note to trainers: answers to all scenarios and case studies need to be modified based on national guidelines.



## Trainer Instructions

Slide 52

### Step 8:

Conduct Exercise 2, which focuses on the application of virological testing to given clinical scenarios.



## Exercise 2

<b>Exercise 2: Making sense of virological testing results: Group game, re-match</b>	
<b>Purpose</b>	To review the interpretation of virological testing results in infants and children.
<b>Duration</b>	15 minutes
<b>Advance Preparation</b>	Review the scenarios (below) and suggested answers, adapt to ensure they are appropriate and typical and that answers reflect national guidelines. Give the babies in each scenario a local name, rather than referring to him/her as “Baby H” or “Baby J”. If the teams in Exercise 1 were not evenly matched, move a couple people from one team to another. Encourage teams to engage all their team members in deciding on responses.
<b>Introduction</b>	We are going to have a re-match of Exercise 1. Everybody should be (or most people will be) in the same team as for Exercise 1. Each team should elect a new Team Captain to give someone new an opportunity in this role. This time we’re going discuss primarily virological testing results. There are a total of 13 questions, and therefore 13 points.
<b>Activities</b>	Same as Exercise 1.  <b>Debrief in large group</b> <ol style="list-style-type: none"> <li>1. Ask participants if they have questions on virological testing in infants and children or questions on any of the scenarios.</li> <li>2. Congratulate the winning team. Provide prizes if possible.</li> </ol>

<b>Exercise 2: Making sense of virological testing results: Group game, re-match</b>	
<ul style="list-style-type: none"> <li>• <b>If Baby H is 6 weeks old, HIV-exposed, and still breastfeeding, what does it mean if she tests HIV-negative by virological testing?</b></li> <li>• <i>Answer: At this time Baby H is not HIV-infected; however, Baby H is still at continued risk of HIV infection while breastfeeding and will require close follow up and retesting as recommended by national guidelines.</i></li> <li>• <b>If Baby I is 6 weeks old, HIV-exposed, and breastfeeding, what does it mean if she tests HIV-positive by virological testing?</b></li> <li>• <i>Answer: Baby I is HIV-infected. She should be initiated on ART immediately and a repeat virological test should be performed to confirm the diagnosis.</i></li> <li>• <b>If Baby J is 4 months old, HIV-exposed, and never breastfed, what does it mean if she tests HIV-negative by virological testing?</b></li> <li>• <i>Answer: Infant is not HIV-infected, but follow up testing is recommended after a negative 4–6 week test to account for potential false negative results or where breastfeeding was not disclosed; always re-test as per country guidelines.</i></li> <li>• <b>If Baby K is 12 weeks old, HIV-exposed, and never breastfed, what does it mean if she tests HIV-positive by virological testing?</b></li> </ul>	

- *Answer: Baby K is HIV-infected. She should be initiated on ART immediately and a repeat virological test should be performed to confirm the diagnosis.*
- **Case Study: Baby L (Mother not available)** Now let's try a longer case study: **Baby L\_\_\_\_\_** is a 6 month old girl brought to the clinic by her aunt who says the baby has chronic diarrhoea. Baby L\_\_\_\_\_’s mother went to South Africa to work and left the baby with the aunt. Upon questioning we learn that the aunt does not know the HIV status of Baby L’s mother. We also learn that the mother went to South Africa **5 weeks ago** and has not been seen since. Clinic staff agree that in order to diagnose the chronic diarrhoea correctly, they need to know the baby’s HIV status. **Which test would you use first to determine Baby L\_\_\_\_\_’s HIV status?**
- *Ideally you will want to test the mother first. As the mother is not available and the baby is symptomatic, conduct RDT first to find out if the baby is HIV-exposed. The serological test, assuming it is RDT, should give a result in 20 minutes and confirm HIV exposure, however a negative test does not rule out HIV exposure.*
- **Continuing with Baby L\_\_\_\_, what does it mean if her RDT indicates that she is antibody negative?**
- *It does not give a clear answer on whether Baby L is HIV-exposed. Either Baby L has not been exposed to HIV, and therefore the underlying cause of her diarrhoea is not HIV disease, **or** she tested HIV-negative due to waning maternal antibody (and is, in fact, HIV-exposed).*
- *If there is a high index of suspicion for HIV, as in this case, perform NAT using DBS or point-of-care testing.*
- *Note: If point-of-care NAT is available, and the index of suspicion is high, perform NAT because the RDT is not reliable to confirm HIV-exposure in infants > 4 months and would give a diagnosis (not just exposure status).*
- **Again, continuing with Baby L\_\_\_\_, what does it mean if Baby L\_\_\_\_\_ tested HIV antibody positive?**
- *She is HIV-exposed, but not necessarily HIV-infected.*
- **Let’s assume Baby L\_\_\_\_\_’s HIV antibody test came back HIV-positive. Now what do you do?**
- *Draw blood for virological testing, explain that the second blood specimen will be sent for virological testing but the result won’t be back for 2–4 weeks. In the meanwhile, start co-trimoxazole and other preventive treatments. A clinician should thoroughly examine the child and decide if the child meets criteria for presumed HIV—if so, Baby L should start ART while waiting for virological test result.*
- *Again, when the infant or child is ill, point-of-care NAT is preferred, if available, because it provides a result on the same day, allowing the healthcare provider to make a timely diagnosis and confidently start ART immediately.*
- **Baby L only had mild diarrhoea and was well nourished with an otherwise normal exam so was not started on ART. The aunt returns to the clinic 4 weeks later; Baby**

**L\_\_\_ is now 7 months old. If Baby L\_\_\_'s DNA PCR was negative, what does that mean?**

- *That Baby L is NOT HIV-infected. But, as the baby was weaned just 5 weeks before the test was administered, it is important that Baby L\_\_\_ be retested 3 months after weaning. If Baby L\_\_\_ is still ill, run the second virological test today, even though it has only been 9 weeks since Baby L\_\_\_ was weaned. If Baby L is now well and her symptoms no longer look like HIV infection, then conduct the second virological test 3 months after weaning.*
- **If Baby L\_\_\_'s virological testing result was HIV-positive, what would that mean?**
- *That Baby L is HIV-infected. Initiate ART immediately and draw a blood sample for confirmatory testing by NAT.*

**Case Study: Baby M\_\_\_ (Mother dropped out of care)**

- **Baby M\_\_\_'s mother has been HIV-infected since she was 18 years old, she is now 21. Her HIV-infection was confirmed during her first antenatal visit 2 years ago. She was started on ART, but she disappeared shortly after that visit and just returned to the village this week, with 19-month old Baby M\_\_\_.** This is Baby M\_\_\_'s first visit to the clinic. Based on questioning, it is clear that Baby M\_\_\_ has never been tested for HIV. Baby M\_\_\_ appears healthy and is growing normally. How would you test him for HIV?
- *RDT, or other HIV serological testing procedure.*
- **Baby M\_\_\_ is still breastfeeding. How does this affect the test procedure?**
- *An RDT should still be done, but Baby M will need to be tested again after breastfeeding. If Baby M tests reactive on RDT, it means he is HIV-positive because she has already cleared her maternal antibody. But if HIV-negative, he may be in the window period or may acquire a new infection since he is still breastfeeding. NOTE: Baby M\_\_\_ should be retested 3 months after cessation of breastfeeding, sooner should he develop symptoms of HIV. (Note: Infant feeding recommendations in these cases will be discussed further in Module 3.)*
- **What if Baby M\_\_\_ was extremely ill, would that change the testing procedure?**
- *No, you would still conduct RDT. But, because Baby M\_\_\_ is ill, should the result be negative, it would increase your suspicion that the result is in the window period. Perform NAT since Baby M is sick and your index of suspicion is high. In the meanwhile, consider if symptoms warrant initiating Baby M\_\_\_ on ART immediately, even in the absence of a definitive diagnosis.*

**Note to trainers: answers to all scenarios and case studies need to be modified based on national guidelines.**



**Trainer Instructions**

Slides 53-57

**Step 9:** Allow 5 minutes for questions and answers on this session.

**Step 10: Module key points**

Ask participants what they think the key points of the module are. What information will they take away from this module? Summarize the key points of the module, using participant feedback and content below.

**Module 2: Key Points**

- Most HIV-exposed infants are identified through follow-up with the mother who is already enrolled in PMTCT services. When screening infants in other clinical settings (OPD, hospital, immunization clinic, well child) for HIV exposure, review the mother's antenatal card or child health card, for the mother's HIV test results. If the mother's HIV status is unknown or she has not been tested recently (according to national guidelines for retesting in pregnancy and breastfeeding), she should be tested using RDT. If the mother is not available, then test the infant for HIV exposure using RDT.
- WHO recommends that HIV-exposed infants are tested for HIV at 4–6 weeks of age using NAT. All HIV-exposed infants who tested HIV-negative should be retested at 9 months of age and again at 18 months or 3 months after cessation of breastfeeding (whichever is later). [1]
- Some countries may also recommend testing at birth of all or some HIV-exposed infants. Birth testing should only be implemented in parallel with efforts to strengthen and expand existing testing strategies for infants age 4–6 weeks.
- Testing algorithms define the sequence of specific HIV tests used for a particular population. Each country will have their own HIV testing algorithm. It is important that all health providers follow the national algorithm for infant HIV testing.
- Virological testing using NAT is used to diagnose HIV infection in HIV-exposed infants and children under the age of 18 months.
- A negative RDT result in an infant less than 4 months of age means that the infant is not HIV-exposed. However, in children, 4–18 months of age, RDT is not reliable for determining HIV exposure. These children should be retested according to national guidelines.
- In children over the age of 18 months, RDT can be used to diagnose HIV infection.

**Step 11:** Ask if there are any questions or clarifications.

# Module 2, Part 2: Course Content

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## Session 2.1 Course Content: Identifying HIV-exposed Infants

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### Testing: The Terminology

Infant HIV testing is just one component of the comprehensive package of care that all HIV-exposed infants should receive, starting at birth and extending to 3 months after breastfeeding has ended (or 18 months of age, whichever is later), by which time all infants should have a final HIV status determined. The HIV-exposed infant comprehensive package of care is further discussed in Module 3.

Within HIV testing services, an early test at 4–6 weeks (or even birth) is just one element within the HIV testing cascade. In this *Manual*, the following terms will be used and are reflected in the revised titles:

Within this guide, the following terms will be used:

- **Nucleic acid testing (NAT):** an infant virologic testing procedure that diagnoses infection by detection of HIV virus nucleic acid. NAT detects DNA, RNA or both. NAT uses polymerase chain reaction (PCR) technology, and is sometimes referred to as PCR testing.
- **Infant HIV testing:** any HIV test included in the testing algorithm; this includes NAT (virologic) and rapid diagnostic testing (serologic testing).
- **Early infant diagnosis (EID):** a virologic test at 4–6 weeks of age or earlier for diagnosis of HIV infection; EID is one component of the infant HIV testing cascade.
- **Birth testing:** a test at or around birth (0–2 days) which complements current 4–6 week testing but does not replace it
- **PoC testing:** PoC testing is when patients are tested on-site at a health facility and receive their results during the same visit or day. Testing at PoC brings test results closer to the patient[2].
- **Near PoC testing:** Near PoC testing is when PoC technology is located at a health facility, district or other non-central laboratory where needed infrastructure (such as electricity) is consistently accessible[2].
- **Conventional testing** refers to the conventional diagnostic technologies located in the central or regional laboratories that make up the backbone of national testing services. These technologies require sophisticated laboratory infrastructure, stable electricity supply and highly trained technicians[2].
- **HIV-exposed infant care:** a comprehensive package of care that all HIV-exposed infants should receive; HIV testing is just one component of HIV-exposed infant care and EID is just one component of the infant HIV testing cascade.

All of these concepts will be explored in more depth in this and the next module. This session focuses on the identification of all infants and children who are HIV-exposed. The next sections focus on HIV testing of infants, both virological testing using nucleic acid testing (NAT) and serological (antibody) testing using rapid diagnostic tests (RDTs).

## Identifying HIV-exposed Infants

An HIV-exposed infant is an infant whose mother was living with HIV or acquired HIV while pregnant or while breastfeeding that infant.

The key to finding all HIV-exposed infants is to identify the HIV status of all mothers at every visit, whether the visit is for IMCI/immunization, sick child, routine maternal antenatal or postnatal, or sick mother visit. At every patient encounter, for an infant/young child who is still breastfeeding:

- Review the mother's health card to see if her HIV testing history has been recorded.
- If HIV status/HIV-exposure status is not documented, then ask the mother when she was last tested for HIV.
- If the mother previously tested HIV-positive, then she is considered to be HIV-infected. If she is not yet on ART, provide retesting for verification of HIV positive status and immediate ART initiation (retesting for verification should never be a barrier to ART initiation). [3] Always follow national protocol.
- If mother does not have documentation of recent testing and reports previously testing HIV-negative, then routinely offer testing as per national guidelines [Review national guidelines about HIV testing frequency for pregnant and breastfeeding women at this time].

### HIV testing in health facilities should be routine

HIV testing of all mothers, HIV-exposed children, children of unknown exposure status, and sick children should be routine (also referred to as "provider-initiated"). Parents and guardians of children who are tested need to be informed that testing is urgent as the medications used to treat HIV infection are life-saving and will prevent early death if the child is found to be HIV-infected. Also, if a child is sick, knowing the HIV status of the child will help the clinician to treat the child appropriately (for example, to give the correct medicines for diarrhoea or pneumonia).

### Infants of mothers of unknown HIV status

Mothers of unknown HIV status (either never tested or prior testing was not recent or not documented) should be provided with the pre-test information session and rapid diagnostic testing (RDT), following the national testing algorithm. If the mother tests HIV-positive, her baby is HIV-exposed. Follow the national guidelines on re-testing the mother to verify HIV status after an HIV-positive test result prior to ART initiation.

Testing the *mother* rather than the infant is the preferred way to determine the infant's HIV exposure status for 2 reasons:

- It will provide a diagnosis for the mother, who will also benefit greatly by referral to care and initiation of ART.
- Limited accuracy of RDT in infants (this is discussed further in Session 2.4).

Refusal of routine testing, particularly when it provides access to potentially life-saving treatment, is rare.

- If a mother declines HIV testing and her baby is ill, ask permission to test the infant. If permission is given, test the infant using the appropriate test for age.
- Very rarely, a mother or other caregiver will refuse testing for herself and her infant. In such circumstances, provide the caregiver with the information and reassurance s/he needs to agree to testing, focusing on the benefits of testing. Convey to caregivers that testing is strongly recommended because it provides access to life-saving treatment. Ensure all other services are provided to this family. Services should never be withheld because a caregiver refuses to consent to testing. If the caregiver refuses testing for the infant and the infant is strongly suspected of having HIV infection, follow guidelines and regulations in your country about consent for testing of children and ethical review of caregiver refusal of testing and treatment.
- Refusal of HIV testing should be documented in maternal and child health cards and HIV testing discussed at the next clinic visit.

### **Mother unavailable (infants younger than 18 months of age)**

If the mother's HIV status is not known and the mother is not available for testing (for example, if she has died), then provide the legal guardian with pre-test information, obtain agreement to test, and test the infant using RDT, following the national algorithm. The RDT will provide information on whether or not the child is HIV-exposed, but it will not give an HIV diagnosis.

Interpretation of infant RDT results and guidance for determining when virologic testing is needed will be discussed further in Sections 2.3 and 2.4.

The pre-test session for both scenarios (mothers of unknown HIV status and guardians of infants of unknown HIV-exposure status) follows the same checklists/scripts used when testing pregnant women in antenatal care. Checklists outlining these pre-test sessions are included as *Appendix 2A: Pre-test Counselling Session, Maternal HIV Status Unknown*. Guidance on the post-test counselling sessions for infants under 18 months of age screened using RDT can be found in Module 5, *Appendix 5A: Post-test Counselling Session for Infants Less than 18 Months Tested by RDT*.

### **Infants of HIV-uninfected mothers**

Infants of mothers who test HIV-negative by RDT during pregnancy should be offered testing again as per national guidelines. Ideally women who tested negative early in pregnancy should be tested again in the third trimester **and** during the postpartum period. Infants whose mothers test HIV negative would not normally be tested for HIV unless:

- The infant shows signs of chronic illness, severe acute illness, growth retardation, poor milestone development, chronic diarrhoea, repeated chest infections, or TB (this is discussed further in Module 3), or
- The mother has a history consistent with acute HIV infection

## Section 2.2 Course Content: Recommendations on Timing of Infant Testing

**Note:** This material presents the WHO guidelines, but should be revised to reflect national guidelines if national guidelines are different from WHO guidelines.

### Introduction

There are 2 general categories of diagnostic testing procedures used for infant HIV testing: serological and virological testing.

- **Serological testing:** Most participants will be familiar with serological testing, which includes RDT. This is the testing procedure used to diagnose HIV in anyone 18 months of age or older.
- **Virological testing:** The diagnosis of HIV in infants and children younger than 18 months of age requires virological testing using nucleic acid testing (NAT) technologies. NAT is typically conducted using dried blood spot (DBS) samples, which are collected on special filter paper. Until recently, NAT was conducted *only* at central laboratories using DBS samples. Using the newer point of care (PoC) NAT technology, virological tests can be conducted in the health clinic or at local laboratories.

Serological tests are not accurate for diagnosing HIV infection in infants and young children due to maternal antibodies, which can be present in the infant until as late as 18 months of age. Diagnosis of HIV in infants and children less than 18 months of age requires NAT. However, RDT can be used to identify infants who are HIV-exposed. Presence of maternal antibodies in the infant is discussed further in Session 2.4.

### When and which test?

WHO recommends that all infants are tested for HIV as follows:

**Table 2.1 HIV testing by age, WHO recommendations for HIV-exposed infants [1]**

Category and age	Recommended test
HIV-exposed infant, at <b>birth</b> (0–2 days), provide testing <i>if</i> recommended by national guidelines	HIV <b>virological testing</b> using NAT, as per national guidelines
HIV-exposed infant, at <b>4–6 weeks of age</b> , or as soon as possible thereafter	HIV <b>virological testing</b> , using NAT
HIV-exposed infant, at <b>9 months of age</b>	HIV <b>virological testing</b> , using NAT *
HIV-exposed infant, at <b>18 months of age</b> or 3 months after breastfeeding ends (whichever is later) for final assessment of HIV status	HIV <b>serological testing if 18 months of age or older; HIV virologic testing if final test prior to 18 months of age (requires breastfeeding cessation prior to 15 months of age)</b>
* Prior to July 2018, WHO recommended HIV <b>serological testing</b> of HIV-exposed infants who were 9 months of age. If positive, they then recommended <b>virological testing</b> using NAT. WHO now recommends using <b>NAT</b> for infants 9 months of age due to concerns	



about ability of an antibody test to identify all HIV-infected infants and to minimize “the challenges of interpretation and simplify the infant testing algorithm.”

Source: WHO, 2018

## Birth Testing

In their 2016 guidelines, WHO described birth testing using NAT as having potential benefits “as it provides an additional opportunity for testing and enables earlier identification of infected infants”. [1] However, there has been little experience implementing birth testing outside a limited number of countries.

HIV testing of infants at birth is most likely to identify infants infected *in utero* who are at greatest risk for early mortality. Birth testing will not detect infections that may have taken place during or shortly after delivery. In contrast, 4–6 week testing will identify infants who acquired the infection *in utero*, during delivery, or in the early postpartum period. Therefore, a NAT at birth can be **added to** a routine 4–6 week test, however it will **not replace** a 4–6 week test. A high-functioning system for early infant diagnosis at 4–6 weeks of age and excellent follow up is important to ensure that all HIV-exposed infants who acquired HIV in utero and during delivery are identified.

**Potential advantages of birth testing:** Birth testing provides an earlier opportunity to diagnose HIV in infants who acquired the infection *in utero*. This, in turn, provides an earlier opportunity to start ART. This is important because infants infected *in utero* or intrapartum are at a higher risk of early death. Studies suggest that 30–40% of these babies will die by 3 months of age. [4]

**Potential disadvantages of birth testing:** The disadvantages of birth testing include:

- **Potential of reducing the uptake of 4–6 week testing:** Standardized counselling messages for caregivers of HIV-exposed infants who test HIV-negative at birth about the importance of repeat testing at 4–6 weeks of age, 9 months and again at 18 months of age (or 3 months after breastfeeding cessation, whichever is later) are important to ensure that caregivers are aware of the need for subsequent testing.
- **Cannot detect all perinatal infections:** Birth testing will only detect *in utero* infections; therefore, infections that occurred during delivery or shortly after birth through early breastfeeding will not be identified with birth testing. In addition, the presence of ARVs (maternal or infant) may reduce the sensitivity of the NAT to detect infant HIV infection. An analysis of two studies found that birth testing with NAT identifies only about 2 of every 3 infants who are infected. [5] This highlights the importance of retention in care and repeat testing, particularly at 4–6 weeks.

## HIV Testing for Sick Infants

Do not wait to test a sick baby. If an infant is sick before the standard age for conducting the test, test earlier!

### **IMPORTANT!! Retesting for Verification (also called Confirmatory Testing)**

A positive virological test result indicates HIV infection. The test result should always be confirmed with a virological test using a second specimen. Ideally the second specimen

should be collected before starting ART, but never delay treatment initiation pending the result of the confirmatory test! Always initiate the infant on ART as soon as possible after providing the initial test result to the caregiver (ideally, on the same day). Counsel the caregiver about the need for confirmatory testing.

## **HIV Testing Algorithm**

Algorithms are defined as the combination and sequence of specific tests used in a given strategy. Testing algorithms are typically developed at a national level and, like clinical guidelines, often based on global guidance. Development of a country-specific testing algorithm must take into account a number of factors, including test performance in country, local prevalence of HIV infection, test availability in country, programme needs (e.g., can test use DBS? How is blood collected—phlebotomy vs finger, heel or toe stick?), ease of use, type of specimen, cost, and potential need to differentiate between HIV-1 and HIV-2. Interpretation of this algorithm for clinical use requires consideration of HIV treatment criteria, age of the child, ongoing exposure to HIV through breastfeeding, and point of contact within the healthcare system.

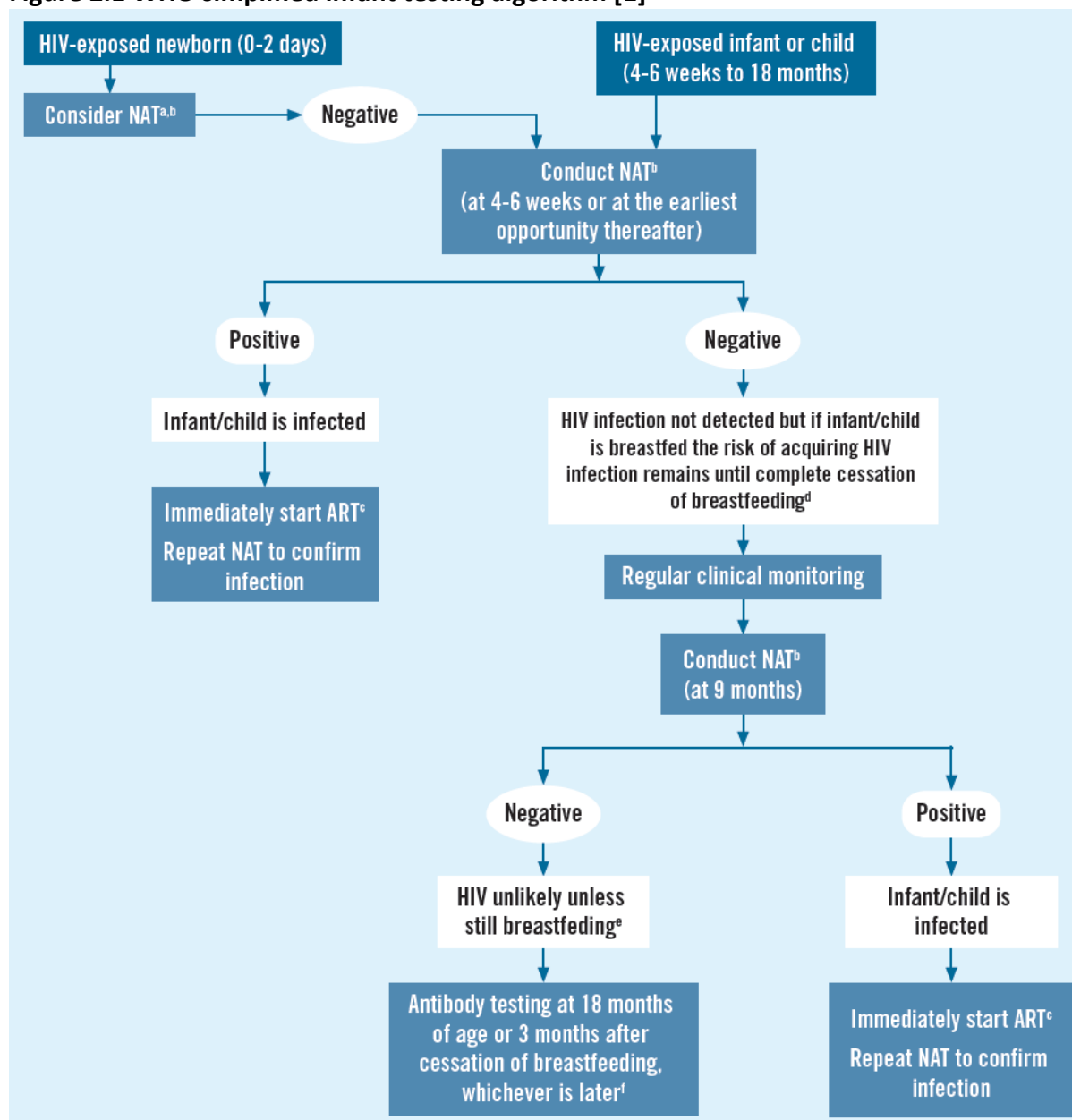
### **Advantages of national testing algorithms**

Nationally adopted testing strategies and algorithms facilitate:

- Country-level standardization of tests: Supporting a limited number of tests is more feasible and practical than many different tests.
- Procurement and supply management: using standardized tests allows for bulk procurement and better cost control.
- Training: Implementation of a national training programme is easier when test sites follow the same testing algorithm, and it allows trained staff to move between sites/regions without requiring re-training.
- Quality assurance: National oversight of quality of testing operations is easier when test sites use the same tests and have similar operations.

Given the research that goes into developing the national algorithm and the resources invested in supporting its implementation and accuracy, it is important that programme staff adhere to the national testing algorithm. The WHO infant HIV testing algorithm is in Figure 2.1.

Figure 2.1 WHO simplified infant testing algorithm [1]



**Notes:**

- a. Based on 2016 WHO Consolidated ARV Guidelines, addition of NAT at birth to the existing testing algorithm can be considered.
- b. PoC NAT can be used to diagnose HIV infection as well as to confirm positive results.
- c. Start ART without delay. At the same time, retest to confirm infection. As maternal treatment is scaled up and MTCT transmission rates decrease, false-positive results are expected to increase: retesting after a first positive NAT is hence important to avoid unnecessary treatment, particularly in settings with lower transmission rates. If the second test is negative, a third NAT should be performed before interrupting ART.
- d. For children who were never breastfed, additional testing following a negative NAT at 4–6 weeks is included in this algorithm to account for potential false-negative NAT results.
- e. The risk of HIV transmission remains as long as breastfeeding continues. If the 9-month test is conducted earlier than 3 months after cessation of breastfeeding, infection acquired in the

- last days of breastfeeding may be missed. Retesting at 18 months or 3 months after cessation of breastfeeding (whichever is later) should be carried out for final assessment of HIV status.
- f. If breastfeeding extends beyond 18 months, the final diagnosis of HIV status can only be assessed at the end of breastfeeding. If breastfeeding ends before 18 months, the final diagnosis of HIV status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies). For infants younger than 18 months of age NAT should be performed to confirm infection. If the infant is older than 18 months, negative antibody testing confirms that the infant is uninfected; positive antibody testing confirms infant is infected.

Source: WHO, 2018

## Session 2.3 Course Content: Overview of NAT

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### Laboratory Diagnosis of HIV Infection—NAT

This session will discuss virological testing. Serological testing will be covered in the Section 2.4.

WHO states that HIV infection in children under 18 months of age can be diagnosed only by virological testing using nucleic acid testing (NAT) technologies. NAT detects viral nucleic acid (i.e., viral RNA or viral DNA). Different manufacturers use different techniques. One of these techniques is a process called PCR. There are 2 types of PCR testing:

- **Qualitative PCR** is a NAT procedure that detects whether or not the HIV virus is present. There is extensive experience using DNA PCR testing for infant diagnosis, and PCR works well on dried blood spot (DBS) samples.
- **Quantitative PCR** tells how much of the virus is present (typically, number of copies per millilitre of blood). This is the procedure used for viral load (VL) testing.

Once infected with HIV, it takes about 10 days for HIV to replicate so that there is enough virus in the blood to be detectable by DNA PCR. [3] The time to detection, or window period, can vary depending on the individual and the test—it typically takes 1–3 weeks to detect presence of the virus using NAT in comparison to 3–5 weeks to detect antibodies via serological testing.

#### Window period

The term “window period” is used to describe the time it takes from HIV infection to detection on a diagnostic test.

This can refer to the time it takes to develop enough antibodies to be detectable using an **antibody test**, or the time it takes to develop enough virus to be detectable using **NAT**.

### Testing Procedures

Infant HIV diagnosis can be conducted on high throughput (conventional, laboratory-based) or point-of-care (POC) instruments. There are a number of analysers that are validated for high throughput and POC infant HIV testing.

#### High throughput, laboratory-based testing

This is the conventional method of infant HIV virological testing. Specimens are typically collected in the clinic by dried blood spot (DBS) and transported to a central or regional laboratory for testing by trained laboratory technicians. Turn-around time from specimen collection to return of test results to the facility can be 4 weeks or longer.

#### Point-of-care and near point-of-care technologies

Point of care (PoC) virological testing using NAT technologies for infant HIV diagnosis (which for these purposes includes *near* point of care) is becoming widely available. Two NAT PoC and near-PoC virological testing procedures have earned the CE-IVD Marking<sup>1</sup> and WHO prequalification:

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<sup>1</sup> The CE Marking, which stands for "Conformité Européene", means that a product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. CE Marking on

- Alere™ q HIV-1/2 Detect (made by Abbott)
- Xpert® HIV-1 Qual Assay (made by Cepheid AB).

These technologies can be used to diagnose infants at the point-of-care (or near to the point-of-care) in as little as an hour. Both tests use disposable cartridges that are pre-loaded with the chemicals needed to identify HIV in a blood sample.

**Alere™ q HIV-1/2 Detect:** blood is collected by heel/toe or fingerstick into a sample capillary in a testing cartridge. The Alere platform is portable and can run on a battery for up to eight hours, making it more suitable for use in remote and rural areas where there is no laboratory infrastructure and often few skilled health workers.

**Cepheid AB Xpert® HIV-1 Qual Assay:** blood is collected from the patient using heel/toe, fingerstick or venipuncture in a sterile tube using EDTA (lavender top) as the anticoagulant. This technology can also be used on DBS[6]. The Xpert® test runs on the same technology that is already used to diagnose tuberculosis. Xpert is not portable and is considered a “near PoC” device; it needs a continuous power supply and other infrastructure needed by high-throughput platforms (temperature control for operation, reduced dust, a computer and printer for results) but reduced maintenance needs and less training requirements

NAT POC virological testing platforms may be operated by health care workers without previous specialized laboratory training. However, hands-on POC assay training and competency led by both the manufacturer and laboratory staff within the country are critical to successful implementation.

## Meaning of HIV Test Results, Virological Testing

- **An HIV-positive test** result means that the child has HIV and will require confirmatory testing and initiation of ART.
- **An HIV-negative test**
  - **In the child who has not been exposed to HIV in the past 3 months:** indicates that the child is not HIV-infected
  - **In the child who has been exposed to HIV either during pregnancy, delivery, or through breastfeeding at any time in the past 3 months:** indicates that the child is either not infected with HIV or infected and still in the window period. The child who is currently or recently exposed should be retested as per national guidelines (see Figure 2.1 for WHO guidelines). Retest, regardless of age, if the child is sick.

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a product ensures the free movement of that product within the European Free Trade Association and European Union.

## Session 2.4 Course Content: Overview of Serological Testing

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### Laboratory Diagnosis of HIV Infection—Serological Testing

Serological testing detects specific antibodies, such as HIV antibodies in blood or saliva. HIV antibodies are produced by the immune system in response to infection with HIV. HIV serological testing can diagnose HIV in adults and children 18 months of age or older.

#### Types of serological testing procedures

Serological tests for HIV include the rapid diagnostic test (RDT), enzyme-linked immunosorbent assay (ELISA or EIA), and Western blot (WB) testing.

- The ELISA and WB must be conducted in a laboratory, whereas the RDT can be conducted at point of care or in a laboratory.
- The ELISA requires a larger blood sample, so specimens are usually taken by venipuncture; whereas RDT needs only a drop of blood, so samples can be obtained by finger, toe or heel prick.
- With RDT, it is possible to have test results within 20 minutes. Patients can know their result on the same day their blood is drawn.

**For simplicity, serological testing will be referred to as RDT, as rapid HIV tests are the most commonly used serological testing procedure in the clinical setting.**

#### Note that:

- RDT does not detect the HIV virus itself, it detects antibodies to HIV.
- When testing an infant or child under the age of 18 months, RDT cannot differentiate between the child's own antibodies to HIV and the antibodies that passed to the child through the placenta before birth, i.e., **maternal antibodies**. These maternal antibodies help to protect the infant from infection early in life, when the newborn's immune system is still immature. Maternal HIV antibodies are passed to the infant through the placenta before birth, but they are not passed during breastfeeding.
  - Usual: Most infants clear maternal antibodies between 6 and 9 months of age.
  - Maximum: It may take **as long as** 18 months for some infants to fully clear all maternal antibodies.[3] What this means at a clinical level is that an HIV antibody positive result in an infant less than 18 months of age, does not necessarily indicate that the infant is HIV-infected. Instead, it means that the infant is HIV-exposed.
  - Minimum: Many infants who are HIV-exposed will clear maternal antibody before 5 months of age. What this means at a clinical level is that RDT in infants age 4–18 months will not identify all infants who are HIV-exposed. Some HIV-exposed infants may have a negative RDT result at this age.
- A negative RDT result in an infant 4–18 months of age does not necessarily rule out HIV exposure. A negative RDT might also occur in an infant that is HIV-exposed but has lost all or most of the maternal antibodies. [3]

## Window Period for RDT

It can take the body a few weeks or more to develop antibodies in response to an infection, and so it can take the RDT a similar amount of time to become **reactive** after HIV infection has been acquired. This explains why the **window period** for HIV antibody testing (the time it takes from infection to the development of enough antibody to be detectable) is up to 3 months, depending on the test used.

WHO recommends final testing of HIV-exposed infants with a serological test at 18 months of age or 3 months after breastfeeding has ended, whichever is later. The “window period” of 3 months is different from the typical 3–5 week window period to detect antibodies because 3–5 weeks is based on when **most** people will test HIV-positive (after infection), the 3 months is the amount of time it takes for **almost everyone** to test HIV-positive after infection.

## RDT: Interpreting the Test Result

In the context of infant HIV testing, RDT is used to identify infants and children under 18 months of age who are HIV-exposed.

- **An HIV-positive RDT** result means:
  - Child < 18 months of age: HIV-exposed
  - Child ≥ 18 months of age: HIV-infected
- **An HIV-negative RDT** result means:
  - Infant < 4 months of age: not HIV-exposed
  - Child 4–18 months of age: HIV exposure cannot be ruled out. If known HIV-exposed and breastfed within the past 3 months, child could still be HIV-infected but cleared maternal antibody. Retest as per national guidelines (3 months after stopping breastfeeding).
  - Adult or child 18 months of age or older: HIV-uninfected, unless still breastfeeding, or breastfed within the past 3 months. Repeat RDT 3 months after stopping breastfeeding.

NOTE: An HIV-infected infant initiated on ART at a very early age (before 12 weeks of age) may have a negative RDT test. This is because ART can stop the antibody response if initiated very early in life.[7] So, children on ART should not be re-tested using RDT.

If a sick infant or child less than 18 months of age tests HIV-negative by RDT and if index of suspicion for HIV is high, conduct virologic testing.

**Table 2.2 Use of RDT for identification of HIV-exposed infants, based on age and breastfeeding practice**

Age group	Unknown HIV exposure status
0–4 months	<b>Test mother</b> <b>If mother is not available:</b> <ul style="list-style-type: none"><li>• RDT in the child can reliably assess exposure</li></ul>
5–18 months	<b>Test mother</b> <b>If mother is not available:</b>



	<ul style="list-style-type: none"> <li>• A positive RDT establishes exposure. Infants with positive RDT should get NAT to confirm infection.</li> <li>• A negative RDT for the child does not fully rule out exposure. Perform NAT to assess HIV infection status in any sick child**</li> <li>• Infants with negative RDT who are still breastfeeding will need testing 3 months after cessation of breastfeeding</li> <li>• If sick, or index of suspicion is high, conduct virologic testing.</li> </ul>
<b>&gt;18 months</b>	<ul style="list-style-type: none"> <li>• Serological testing (including RDT) is recommended to assess HIV infection status unless breastfed within the last 3 months or still breastfed.</li> <li>• If still breastfed, RDT should be provided 3 months after cessation of breastfeeding.</li> </ul>
<p><b>**Consider initiating ART for presumed HIV infection if there is high degree of suspicion while waiting for NAT results, especially if RDT positive.</b>  <b>NAT = Nucleic acid testing, a virological test</b></p>	

Adapted from: WHO, 2018

## Testing HIV-exposed Sick Infants and Children

If an infant is sick with signs and symptoms that could be explained by HIV infection, then test the child using the correct test for age (see Table 2.1 HIV testing by age, WHO recommendations for HIV-exposed infants).

## Appendix 2A: Pre-test Counselling Session for Maternal or Infant HIV Testing with RDT

Key point	<i>Script/Key points:</i> Maternal status unknown RDT testing <i>of mother</i>	<i>Script/Key points:</i> Maternal status unknown and mother unavailable RDT testing <i>of infant</i>
1. <b>Assess knowledge</b> of HIV and the diagnostic procedure.	<p>Use a question and answer format to gauge her level of understanding:</p> <ul style="list-style-type: none"> <li>• <i>What is HIV?</i></li> <li>• <i>What is AIDS?</i></li> <li>• <i>How is HIV passed from one person to another?</i></li> <li>• <i>How is HIV passed from mother to baby?</i> Explain that if she tests HIV-positive there is a risk that her baby may have acquired HIV in the womb, at delivery or through breast feeding, so her baby will need to be tested. If she is HIV-infected, her baby will be tested today, but using a different type of testing (virological testing).</li> <li>• <i>How can HIV be prevented?</i> Recommend she bring her partner in for HIV testing. If she is HIV-negative, she can still acquire HIV. If she gets HIV while pregnant or breastfeeding, her risk of passing the virus to the baby is very high. Stress the importance of using condoms to prevent infection.</li> </ul>	<ul style="list-style-type: none"> <li>• <i>In order to make an informed diagnosis of the baby's illness, I need to run a number of laboratory tests. One of the tests I will be running is the HIV antibody test</i></li> </ul> <p>Use a question and answer format to gauge level of understanding:</p> <ul style="list-style-type: none"> <li>• <i>What is HIV?</i></li> <li>• <i>What is AIDS?</i></li> <li>• <i>How is HIV passed from one person to another?</i></li> <li>• <i>How is HIV passed from mother to baby?</i></li> <li>• <i>How can HIV be prevented?</i></li> </ul>

2. HIV testing is <b>routine</b>	<ul style="list-style-type: none"> <li>Emphasize that HIV testing of <i>mothers</i> is routine.</li> </ul>	<ul style="list-style-type: none"> <li><i>HIV testing is routine in babies who are sick or who are potentially HIV exposed.</i></li> </ul>
3. How the test will be <b>conducted</b>	<ul style="list-style-type: none"> <li>Explain process, e.g., <i>blood is taken using a finger prick and results are usually available in 20 minutes.</i> Script should be adapted to process and test kit to be used.</li> </ul>	
4. Confidentiality	<ul style="list-style-type: none"> <li><i>The test result and anything we discuss today is confidential/private and will not be shared with anyone else unless you give permission.</i></li> </ul>	
5. Explanation of result		
5A. What a <b>positive result</b> means	<ul style="list-style-type: none"> <li><i>If you are HIV-positive, that means that you are HIV-infected. We will provide you with ART to help keep both you and your baby healthy.</i></li> </ul>	<ul style="list-style-type: none"> <li><i>The test we will conduct looks for HIV antibody in the baby's blood. If the test comes back positive, indicating that antibody was found, then we know that the baby's mother was HIV-infected, the baby is referred to as "HIV-exposed". The test does not tell us if the baby is actually HIV-infected. We will conduct a second type of blood test to find out if the baby is actually infected</i></li> </ul>
5B. What a <b>negative result</b> means	<ul style="list-style-type: none"> <li><i>If you are HIV-negative, that means you are not infected with the HIV virus. You should get</i></li> </ul>	<ul style="list-style-type: none"> <li><b>If &lt;4 months of age:</b> <i>If the baby is antibody negative, this means that the child is most likely not HIV exposed.</i></li> </ul>

	<p><i>tested for HIV regularly (according to testing guidelines).</i></p>	<ul style="list-style-type: none"> <li>• <b>If age 4–18 months:</b> <i>If the baby is HIV antibody negative, this does not necessarily mean that he isn't HIV-exposed. We might still need to conduct a second type of blood test.</i></li> </ul>
6. <b>Return*</b>	<ul style="list-style-type: none"> <li>• <i>You will need to return to the clinic for follow up care (well woman, family planning, sick visits) and any test results that are not available today.</i></li> <li>• <i>In addition, you will need to bring the baby back to the clinic for his growth and immunization visits.</i></li> <li>• <i>Your next visit is in ____ weeks, on ____ (date).</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>You will need to bring the baby back to the clinic for his growth and immunization visits and for any test results that are not available today. Your next visit is in ____ weeks, on ____ (date).</i></li> </ul>
7. <b>Client questions</b>	<ul style="list-style-type: none"> <li>• <i>What questions do you have about HIV testing?</i></li> </ul>	

\*RDT results should be given same day, so typically you would also be giving post-test counselling as well. Since return plans may be different based on test results, you could wait until post-test counselling to discuss follow-up.

# References



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