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# BIOMARKER MANUAL: MALARIA INDICATOR SURVEY

**Training Program for Measuring and  
Testing for Biomarkers**

[DOCUMENT SUBTITLE]

The DHS Program is a five-year project to assist institutions in collecting and analyzing necessary data to plan, monitor, and evaluate population, health, and nutrition programs. The DHS Program is funded by the U.S. Agency for International Development (USAID). The project is implemented by ICF in Rockville, Maryland USA, in partnership with the Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs, PATH (formerly, the Program for Appropriate Technology in Health), Avenir Health, Blue Raster, and EnCompass, IFORD, and AFIDEP.

The main objectives of The DHS Program are to: 1) provide improved information through appropriate data collection, analysis, and evaluation; 2) improve coordination and partnerships in data collection at the international and country levels; 3) increase host-country institutionalization of data collection capacity; 4) improve data collection and analysis tools and methodologies; and 5) improve the dissemination and utilization of data.

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# Chapter I. INTRODUCTION AND OVERVIEW

## I.A. About this manual

This manual is used as part of the Training Program for Measuring and Testing for Biomarkers, and provides the core content needed to acquire the following skills during the training:

- How to identify eligible respondents in households for biomarker measurement
- How to obtain informed consent from parents/responsible adults for children
- How to complete the Biomarker Questionnaire
- How to perform capillary blood collection on children
- How to select the appropriate equipment; collect samples; conduct tests and record, report, and document results for the following, as needed:
  - Rapid diagnostic tests (RDTs) [and microscopy] for malaria
  - Demonstrate appropriate universal safety precautions
  - Demonstrate appropriate disposal of biohazardous waste

## I.B. About this training program

Biomarker measurements can serve as diagnostic tools to identify diseases or conditions in their early stages and can be used as surveillance tools to track changes in disease patterns or to evaluate intervention programs. In population-based surveys, biomarkers help assess the prevalence or occurrence of diseases or conditions in a population; they can also be used at a macro level to measure the long-term effect of policies and programs. In The Demographic and Health Surveys (DHS) Program, biomarkers are measured to estimate the prevalence of specific diseases and health conditions at the population level.

This training program is designed to equip biomarker technicians with skills and techniques to efficiently and effectively measure and test biomarkers in field conditions, and accurately record and report the results as part of the survey process. In addition, this training program will equip biomarker technicians to collect, process, and package biological specimens for transport to a laboratory for testing.

## I.C. Training program structure

In combination with classroom instruction and practical experience, this manual will be used to teach you how to collect blood samples and conduct basic tests to measure biomarkers for the [YEAR] [COUNTRY] Malaria Indicator Survey (MIS). Before each training session, you should study this manual and the Biomarker Questionnaire carefully. You are encouraged to ask questions during training and to discuss problems encountered to avoid making mistakes during fieldwork. Training consists of the following phases:

- Phase I. The chapters of this manual are reviewed in a classroom setting where you learn

how to identify eligible children; record biomarker measurements or test results in the Biomarker Questionnaire or on appropriate field forms; and handle technical procedures involved in blood collection, testing, [storage and transportation of smears], and other related instructions. You observe the trainers demonstrating the skills. Then, you will have the opportunity to practice the procedures, with other trainees, which will include finger pricks for blood collection.

- Phase II. You will visit a health facility and practice measuring biomarkers from children with the consent of their parent or responsible adult.
- Phase III. You will be assigned to a survey trainee team in the field where you will measure biomarkers from eligible children exactly as you would during the survey. Households that are visited will be in clusters that are not part of the survey sample.

At the end of the training, your overall performance will be assessed, and the top performers will be selected to work in the survey.

Your training does not end at the start of fieldwork. Rather, it is a continuous process. Your team supervisor and the [COUNTRY] MIS coordinators will play important roles in continuing your training and in ensuring the quality of data you collect throughout the survey. They will:

- Observe your fieldwork activities periodically to ensure that you are conducting yourself professionally, obtaining informed consent from respondents, and following the sample collection and biomarker measurement protocol correctly
- Spot check that you visited the correct households and collected blood samples and measured biomarkers only from eligible respondents;
- Collect blood specimens for transport to the laboratory and consolidate the field record forms; and
- Meet with you regularly to discuss your performance and assign future work assignments.

Note: A biomarker technician who is not performing at the level necessary to produce the high-quality data required for a successful [COUNTRY] MIS may be released from service.

#### **I.D. Overview of the survey**

The [YEAR, COUNTRY] MIS is a nationally representative household survey to be conducted during high malaria transmission seasons to measure a wide range of internationally recognized malaria indicators to include:

- Household ownership of insecticide-treated mosquito nets and their use, especially by children under age five years and pregnant women;
- Intermittent preventive treatment against malaria during pregnancy;
- The type and timing of treatment of high fever in children under age five years;
- Diagnostic blood testing of children under five for malaria

The survey gathers background information on the characteristics of household members such as age and sex as well as information about households including access to electricity, source of drinking water, and ownership of assets such as radios, vehicles, and farm animals.

The [YEAR] XMIS is the [NUMBER] MIS survey conducted in [COUNTRY] following [INSERT PREVIOUS MALARIA INDICATOR SURVEYS AND YEAR]. The [YEAR] XMIS will include malaria RDT [and thick blood smears]. Results from this survey will produce population-based estimates of malaria prevalence among children age 6-59 months.

### **I.E. Overview of biomarker measurement**

A biomarker may be thought of as a characteristic that can be independently measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic response to a therapeutic intervention<sup>1</sup>. Biomarker measurements can serve as diagnostic tools to identify diseases in their early stages and can be used as surveillance tools to track changes in disease patterns or to evaluate intervention programs. In population-based surveys, biomarkers help assess the prevalence or occurrence of diseases or conditions and can also be used at a macro level to measure the long-term effect of policies and programs. In the MIS, biomarkers are measured to report levels of malaria on a population level. Specific to the [YEAR] XMIS, the following biomarkers will be measured and/or collected: malaria RDT [and thick smears]. This training manual will discuss the proper biomarker testing and/or collection techniques and how to appropriately record test results in the biomarker questionnaire, and the malaria brochure or severe malaria referrals if needed.

Biomarkers measured in the [YEAR] XMIS and what they are used for:

<b>Biomarker</b>	<b>Purpose</b>
<b>Histidine-Rich Protein II (HRP-II)</b>	Estimate the prevalence of malaria
<b>Malaria parasite</b>	Estimate the prevalence of malaria

### **I.F. Overview of tests in an MIS and the biomarker technician’s role**

Malaria is a vector borne infection. Malaria parasites are transmitted into a susceptible host through the bite of a mosquito. Malaria is a major cause of illness and death especially among children under 5 years, pregnant women and immunocompromised individuals (WHO, 2017). [PROVIDE COUNTRY STATS ON MALARIA]

Children age 6-59 months in the XMIS will be eligible for malaria testing.

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<sup>1</sup> Biomarker Definitions Working Group, National Institutes of Health, 2001

### ***Rapid diagnostic testing (RDT)***

Capillary blood from a finger or heel prick will be used for malaria testing. A malaria RDT will be performed in the household to test the child's malaria status. If the malaria RDT is positive, the child will be further screened to determine if he/she has symptoms of severe malaria. Children with symptoms of severe malaria will be referred to a health facility for immediate attention. Malaria medication will be provided in the household to children eligible for treatment. The biomarker technician will provide all households with an informational malaria pamphlet.

### ***Preparation of thick blood smear for microscopy***

A thick blood smear will be prepared in the household and transported to the central laboratory for the detection of malaria parasites by microscopy, the current gold standard method.

### **I.G. Social media policy**

The use of social media and other digital media is now common and continues to grow in popularity. Platforms and applications including blogs, social networking sites (such as Twitter or Facebook), video streaming sites (such as YouTube), and digital messaging applications (WhatsApp), have made it easy for anyone to reach a wide audience very quickly. Public and private companies and their staff also use these platforms and sites to share work experiences, images, or videos taken in the workplace, or to seek professional advice from colleagues or friends. However, in the XMIS, the use of social media may break the promise we make to our respondents to maintain their privacy and keep all information confidential. The XMIS has also made a promise to the ICF Institutional Review Board and the [COUNTRY] Institutional Review Board to maintain anonymity of all survey respondents.

To fulfil our promise to all survey respondents to maintain strict confidentiality, all fieldworkers are obligated to follow these rules:

Social media rules for maintaining confidentiality of survey respondents	
1.	Survey staff have an ethical obligation to always maintain respondent privacy and confidentiality.
2.	Limiting access to social media postings by using privacy settings is not enough to ensure privacy or maintain the confidentiality of respondents.
3.	Do not transmit any respondent-related image or video that includes the respondent, respondent household members, or their homes, through any social media platform.
4.	Do not identify respondents, enumeration areas, or clusters by name through any social media platform. Do not post any information that may lead to the identification of a respondent or an enumeration area.
5.	Do not take any photos or videos of respondents or their homes – not even if the



	respondent gives permission – on personal mobile devices - including mobile phones, tablets, and cameras.
6.	Turn off or disable geolocation or geotagging permissions in social media applications on personal mobile devices while conducting fieldwork.
7.	Consult with a supervisor before making any work-related postings.
8.	Promptly report any violations of privacy or confidentiality.

### ***What is geolocation and geotagging?***

Geolocation or geotagging refers to identifying an object (for example a photo) by its location. Many social media platforms, including Twitter and Facebook, now include geolocation or geotagging, so users can add location information to their messages. The location information can be a broad location such as a city or village, or a precise location with the exact latitude and longitude of the location from which a message was sent. A fieldworker who posts a geolocated or geotagged social media message from the field violates confidentiality by disclosing the location of the cluster.

Geolocation or geotagging in social media applications may also have security implications. In security-risk countries, where fieldwork must undergo stringent protocols to protect field teams, it is imperative that survey-related staff disable geolocation from their personal devices to not give away secure locations.

### ***Common Misunderstandings of Social Media***

Misuse of social media is often unintentional and the result of misunderstandings of how social media platforms function. Many factors may contribute to survey-related staff inadvertently violating survey respondent privacy and confidentiality while using social media.

Test your knowledge:

TRUE or FALSE?

Q 1. A communication or post is private and can only be seen by the intended recipient. True or False?

FALSE. Why? Once you send or post something, it can be sent by someone else to others, without you knowing.

Q 2. You can always delete posted content and make it “go away”. True or False?

FALSE. Why? What happens on the Internet, stays on the Internet.

## Chapter 2. GENERAL PROCEDURES FOR COMPLETING THE PAPER QUESTIONNAIRE

### *Learning objective*

- Confirm the eligibility of respondents for biomarker collection
- Understand the elements of informed consent
- Know the structure and content of the Biomarker Questionnaire
- This part of the training manual is designed to familiarize you with the [COUNTRY] MIS paper questionnaire that you will use for field data collection

### **2.A. Introduction**

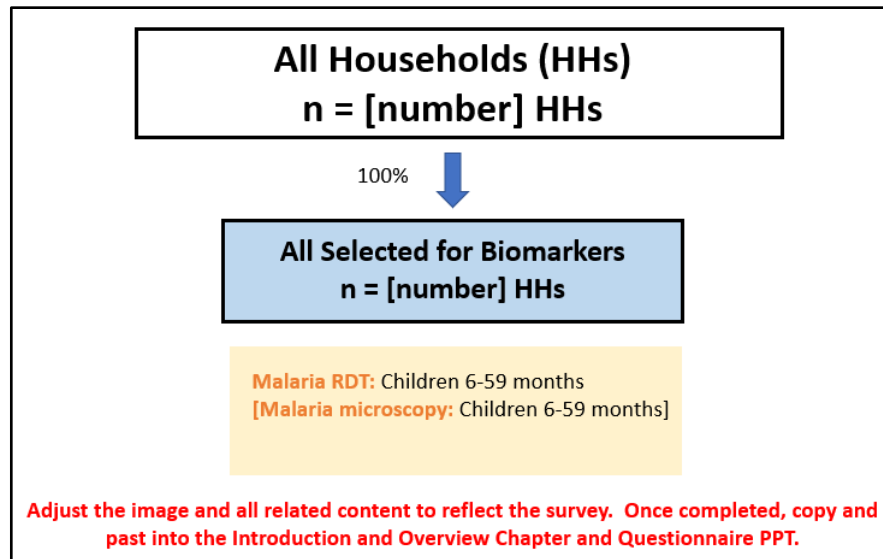
This chapter describes the [subsample of households selected for biomarker collection,] requirements for eligibility and informed consent. To collect the information needed by the [COUNTRY] MIS, you must understand how to ask each question, what information the question is attempting to collect, and how to handle problems that might arise during the interview. You must also know how to correctly record the answers the respondent gives and how to follow special instructions in the questionnaire.

### **2.B. Identifying respondents eligible for Biomarker Questionnaire**

#### *Eligible respondents*

[Not all households are eligible for biomarker measurement and testing.] There are [NUMBER] households per cluster, [half of which were selected for biomarker collection.] This means you as a biomarker technician will visit [NUMBER] households per cluster for biomarker collection.]

The hierarchy below summarizes which households are eligible for biomarker collection.



Not everyone in a household is eligible for biomarker measurement. Within selected households, those eligible for biomarker measurement and testing are: children age 6 – 59 months (4 years) who are usual household residents or visitors who have stayed in the house the night before the household interview took place.

Groups eligible for biomarker measurement	Malaria
Children age 6 months–4 years	<b>X</b>

### ***Obtaining Eligibility from Computer Assisted Personal Interviewing (CAPI)***

The Household Questionnaire and Individual Questionnaires use computer assisted personal interviewing (CAPI) for face-to-face interviews. However, the Biomarker Questionnaire is still completed on paper. This means that the interviewer will need to transfer the list of eligible children from the report generated by the CAPI system using information collected in the Household Questionnaire to the Biomarker Questionnaire. Only then will the biomarker technician be able to start the process of identifying eligible respondents, obtaining informed consent, collecting a blood sample and testing for biomarkers.

On the cover page of the Biomarker Questionnaire, the interviewer will record all the information required to identify the household. When you receive a Biomarker Questionnaire, the interviewer should have already recorded the following into the identification box:

- Place Name
- Name of Household Head
- Cluster Number
- Household Number

You will notice that for both the Cluster Number and Household Number four boxes are provided. When a number has fewer digits than the number of boxes provided, the leading zeros should be filled in. For example, if the cluster number is 1 and household number 3, this information should be recorded on the cover page (by the interviewer) as cluster number 0001 and household number 0003.

IDENTIFICATION (1)			
PLACE NAME	Fill with appropriate place name		
NAME OF HOUSEHOLD HEAD	Fill with appropriate name		
CLUSTER NUMBER	0	0	0 1
HOUSEHOLD NUMBER	0	0	0 3

Using the CAPI function to list those eligible for individual interviews and biomarkers, the interviewer will record the number of respondents in the household potentially eligible for biomarker collection. An example of a list is shown below:

```

CLUSTER: 0001    HOUSEHOLD: 0003
Name of household head: GENEVIEVE DUPUIS

Children Eligible for Biomarker Collection
-----
Line Sex Age Name
-----
02  2  02  JULIA FLEURET
04  1  04  MATT TURBYFILL
    
```

Check the cover page of the Biomarker Questionnaire to identify the number of children who are potentially eligible for biomarker collection. This information can be found under “Fieldworker Visits.”

[FIELDWORKER] VISITS							
	1	2	3	FINAL VISIT			
DATE	_____	_____	_____	DAY <table border="1"><tr><td> </td><td> </td><td> </td></tr></table>			
[FIELDWORKER'S] NAME	_____	_____	_____	MONTH <table border="1"><tr><td> </td><td> </td><td> </td></tr></table>			
NEXT VISIT: DATE	_____	_____	_____	YEAR <table border="1"><tr><td> </td><td> </td><td> </td></tr></table>			
TIME	_____	_____	_____	TOTAL NUMBER OF VISITS <table border="1"><tr><td> </td><td> </td></tr></table>			
NOTES:	_____ _____ _____ _____			TOTAL ELIGIBLE CHILDREN <table border="1"><tr><td> </td><td> </td></tr></table>			

Where to find the number of eligible children

## 2.C. Verifying information for eligible children

Check each page of the Biomarker Questionnaire; individual children are listed on separate pages. Verify that the interviewer has completed Qs. 102-106 for each eligible child. If this section is incomplete, return the questionnaire to the interviewer to fill in Q. 102-106 for each eligible child.

### MALARIA TESTING FOR CHILDREN AGE 6 MONTHS TO 4 YEARS

101	CHECK CAPI OUTPUT FOR "LIST ELIGIBLE INDIVIDUALS/BIOMARKERS". RECORD THE LINE NUMBER AND NAME FOR ALL ELIGIBLE CHILDREN AGE 0-5 YEARS IN QUESTION 102 ON THIS PAGE AND SUBSEQUENT PAGES STARTING WITH THE FIRST ONE LISTED. IF MORE THAN THREE CHILDREN, USE ADDITIONAL QUESTIONNAIRE(S).	
CHILD 1		
102	CHECK CAPI OUTPUT AND RECORD NAME AND LINE NUMBER OF CHILD.	NAME _____ LINE NUMBER ..... <input type="text"/> <input type="text"/>
103	IF MOTHER INTERVIEWED: COPY CHILD'S DATE OF BIRTH (DAY, MONTH, AND YEAR) FROM PREGNANCY HISTORY.  IF MOTHER NOT INTERVIEWED ASK: What is (NAME OF CHILD)'s date of birth?	DAY ..... <input type="text"/> <input type="text"/> MONTH ..... <input type="text"/> <input type="text"/> YEAR ..... <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
104	IF MOTHER INTERVIEWED: COPY CHILD'S AGE FROM PREGNANCY HISTORY.  IF MOTHER NOT INTERVIEWED ASK: How old was (NAME OF CHILD) at (NAME OF CHILD)'s last birthday?  COMPARE AND CORRECT 103 AND/OR 104 IF INCONSISTENT.	AGE IN COMPLETED YEARS <input type="text"/>
105	CHECK 104: CHILD AGE 0-4 YEARS? YES <input type="checkbox"/> NO <input type="checkbox"/>	→ 135
106	CHECK 103: IS THE CHILD AGE 0-5 MONTHS OR OLDER <input type="checkbox"/> AGE 0-5 MONTHS <input type="checkbox"/>	→ 135

Although Qs. 105 and 106 will be completed by the interviewer, they are described below so that you will understand how they are used by the interviewer to determine which children are eligible for malaria testing. It is also good practice to check that they were completed correctly.

### Q. 105: CHECK 104: CHILD AGE 0-4 YEARS?

A child whose age in the Household Questionnaire is listed as being age 0-5 is eligible for the Biomarker Questionnaire, but only those age 6-59 months are eligible for malaria testing. Qs. 105 and 106 are used to identify children in this age range and eliminate those children who are either too old for testing (age 5 years) or too young for testing (age 0-5 months).

To complete Q. 105, the interviewer will check the age in Q. 104. If it is 0,1,2,3 or 4, they will put an 'X' in the box next to 'YES' and proceed to Q. 106. If the child is age 5 or older, they will put an 'X' in the box next to 'NO,' and skip to the end of the section, in this example, Q. 135.

Why, you might be thinking, do we have the interviewers enter children in the Biomarker Questionnaire Qs. 102-104, if we know from the Household Questionnaire that they are too old

(age 5) to qualify for malaria testing? The reason is that often respondents to the Household Questionnaire are uncertain of the exact age of children in the household and/or they round up a child's age.

*Example:* The respondent to the Household Questionnaire might say a child is age 5 when in fact the child is age 4, and therefore eligible for testing.

To reduce the chance of mistakenly eliminating children who are eligible for testing, The DHS Program has made the decision to not rely on the information from the Household Questionnaire for the exact age of children.

Rather, we will use the date of birth and age information obtained from the child's mother's birth history (for children whose mother were interviewed) or by asking an adult responsible for the child for the child's date of birth and age information (for children whose mothers were not interviewed).

#### Q. 106: CHECK 103: IS THE CHILD AGE 0-5 MONTHS OR IS THE CHILD OLDER?

Children age 0-5 months (i.e., <6 months), are not eligible for blood collection and are therefore not eligible for malaria testing. In Q. 106, the interviewer uses the date of birth information entered in Q. 103 to determine if the child is age 0-5 months or older. If the child is age 1-4 years, they are clearly older than age 0-5 months and the interviewer should put an X in the box next to 'OLDER'. If, however, the child is age 0 years, the interviewer needs to determine if they are age 0-5 months or older (age 6-11 months). If they are age 6 months or older, an 'X' is put in the box next to OLDER. If they are 0-5 months, an 'X' is put in the box next to 'AGE 0-5 MONTHS' and the skip to Q. 135 is followed.

*Example:* if you are visiting the household on 9 July [YEAR], a child born 16 January [YEAR] is not eligible for blood collection. Any child born 10 January [YEAR] or more recently (February, March, April, May, June, or July [YEAR]) is under age 6 months. Put an X next to 'AGE 0-5 MONTHS' and skip to Q. 135. If the child is 6 months or older, put an X in the box next to 'OLDER'.

## **2.D. Documenting [fieldworker] visits on the cover page**

As described above, the interviewer will provide the information on the cover page to identify the household and the total number of eligible children. It is the responsibility of the biomarker technician to document when he/she visited the household to collection biomarkers under the section labeled, [FIELDWORKER] VISIT. You have at least three opportunities to visit the household to complete the biomarker collection. On your first visit to the household, you will record the date and write your name. If you do not complete biomarker collection for all the eligible respondents in your first visit, it will be necessary to make a second visit. You must arrange this second visit with the respondents or parent/responsible adult and ask when is the best day and time for you to return. You must record this date and time on the cover page of the Biomarker

Questionnaire at NEXT VISIT. When you return a second time, you must document again the date of your second visit and write your name. When you have finished a household, on your last visit, you must enter the date under FINAL VISIT as DAY-MONTH-YEAR and record your TOTAL NUMBER OF VISITS. It is also acceptable for the first and second visit to occur on the same day if the respondent or the parent/responsible adult requests it. However, if you return to that household on the same day and the child still is not present, you are required to make two additional visits to that household.

Example: In a household there are 3 eligible children. You arrive at the house for your first visit on 16 July 2020 and complete malaria testing for 2 of the 3 children. You are told by the mother to return on 17 July at 8:00 AM to test the third child. You make a second visit to the household on 17 July at 8:00 AM and complete the malaria testing for the third child. You finished testing all 3 children on 17 July and made 2 visits to the household. It is important to complete the FIELDWORKER VISITS section daily. Do not wait until you finish a household to complete this section. You will enter your final visit only once you have completed the household. You or the interviewer can record notes in the NOTES section that pertain to the household or children. For example, recording the phone number of a respondent or information about the locating the household.

[FIELDWORKER] VISITS								
	1	2	3	FINAL VISIT				
DATE	16 July 2020	17 July 2020	_____	DAY <table border="1"><tr><td>1</td><td>7</td></tr></table>	1	7		
1	7							
[FIELDWORKER'S] NAME	Rachel	Rachel	_____	MONTH <table border="1"><tr><td>0</td><td>7</td></tr></table>	0	7		
0	7							
				YEAR <table border="1"><tr><td>2</td><td>0</td><td>2</td><td>0</td></tr></table>	2	0	2	0
2	0	2	0					
NEXT VISIT: DATE	17 July 2020	_____		TOTAL NUMBER OF VISITS <table border="1"><tr><td>2</td></tr></table>	2			
2								
TIME	08:00 AM	_____						
NOTES: _____ _____ _____ _____				TOTAL ELIGIBLE CHILDREN <table border="1"><tr><td>0</td><td>3</td></tr></table>	0	3		
0	3							

The language of the questionnaire is already prepopulated. You are responsible for recording the language of the interview and native language of the respondent using the LANGUAGE CODES on the cover page. You also must indicate if 'YES' a translator was used by entering 1, or 'NO' a translator was not used by entering '2' in the space provided.

LANGUAGE OF QUESTIONNAIRE**	<table border="1"><tr><td>0</td><td>1</td></tr></table>	0	1	LANGUAGE OF INTERVIEW**	<table border="1"><tr><td>0</td><td>1</td></tr></table>	0	1	NATIVE LANGUAGE OF RESPONDENT**	<table border="1"><tr><td>0</td><td>1</td></tr></table>	0	1	TRANSLATOR (YES = 1, NO = 2)	<table border="1"><tr><td>2</td></tr></table>	2
0	1													
0	1													
0	1													
2														
LANGUAGE OF QUESTIONNAIRE**	ENGLISH	**LANGUAGE CODES: 01 ENGLISH      03 LANGUAGE 3      05 LANGUAGE 5 02 LANGUAGE 2      04 LANGUAGE 4      06 LANGUAGE 6												

## 2.E. Asking Questions and Reading Informed Consent Statements

It is very important that you ask each question and read the consent statement exactly as it is written in the questionnaire. Always speak slowly and clearly so that the respondent will have no difficulty hearing or understanding the question or consent statement. At times you may need to repeat the question or consent statement to be sure the respondent understands it. In those cases, do not change the wording, but repeat it exactly as it is written.

If, after you have repeated a question or consent statement, the respondent still does not understand it, you may have to restate it. Be very careful when you change the wording, however, that you do not alter the meaning of the original question or consent statement.

Prior to biomarker measurement, one of the primary tasks is to explain the purpose of the measurement or test to eligible respondents or, in the case of children, to the parent or responsible adult, and to obtain their consent before collecting blood samples or conducting biomarker measurements. In the absence of a parent, the consent of a responsible adult who is at least 18 years of age is required. If the parent or responsible adult does not consent to the test, the test must not be performed.

### ***Process of obtaining informed consent for children:***

Group	Process
<b>Children (age 6-59 months)</b>	Obtain the consent of one of the child's parents, or, in the absence of a parent, the consent of a responsible adult who is at least 18 years of age. If the parent or responsible adult does not consent to the test, do not perform the test.

To ensure that these individuals can make an “informed” decision about whether to have their children tested, the Biomarker Questionnaire includes a consent statement which you must read to the parent/responsible adult. These consent statements include the following basic elements:

- *Introduction and type of study*
- *Importance of study to the subject and/or others (what will be improved, how results will be used, benefits to specific others and/or society)*
- *Procedures – what is going to be done to/with subject*
- *Reasonably foreseeable risks or discomforts*
- *Duration of involvement*
- *Extent to which records will be confidential*
- *Participation is voluntary; refusal to participate will involve no penalty or loss of benefits*

If you have to reword the consent statement so that the respondent understands it, you must still include these seven elements of informed consent listed above.

You will notice that some questions contain one or more words in parentheses. As shown below,



the presence of parentheses indicates that a sentence needs to be adapted to fit the respondent's specific situation.

***Parentheses that indicate a substitution must be made:***

*Example:*

<p>ASK CONSENT FOR MALARIA TEST FROM PARENT/RESPONSIBLE ADULT:</p> <p>As part of this survey, we are asking children all over the country to take a test to see if they have malaria. Malaria is a serious illness caused by a parasite transmitted by a mosquito bite. This survey will assist the government to develop programs to prevent and treat malaria. We ask that all children age 6 months through 4 years take part in malaria testing. The tests require a few drops of blood from a finger or heel. The equipment used to take the blood is clean and completely safe. It has never been used before and will be thrown away after each test.</p> <p>The blood will be tested for malaria immediately, and the results will be told to you right away. [A few blood drops will be collected on slide(s) and taken to a laboratory for testing. You will not be told the results of the laboratory testing.] All results will be kept strictly confidential and will not be shared with anyone other than members of our survey team.</p> <p>Do you have any questions? You can say yes or no. It is up to you to decide. Will you allow {NAME OF CHILD} to participate in the malaria test?</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Notice that the word in parentheses is in all capital letters. **Words in all caps are instructions to biomarker technicians that are not meant to be read out loud.** Instead, in this example, you should substitute in the name of child for which you are seeking informed consent for testing. For instance, if you are seeking informed consent for malaria testing from a woman who has a son named Barack, ask “Will you allow Barack to participate in the malaria test?”

**2.F. Recording Responses**

All biomarker technicians should use pens with blue ink to complete all paper questionnaires. Never use a pencil to complete the survey questionnaire.

There are generally three types of questions in the [COUNTRY] MIS Biomarker Questionnaire: 1) questions that have precoded responses; 2) questions that do not have precoded responses, i.e., those that are “open-ended;” and 3) filters.

***Questions with precoded responses***

For some questions, we can predict the types of answers a respondent will give or you know how the procedure in question was performed. The responses to these questions are listed in the questionnaire. To record a respondent's answer, you merely circle the number (code) that corresponds to the reply. Make sure that each circle surrounds only a single number.

*Example:*

Does (NAME) suffer from any of the following illnesses or symptoms:	YES	NO
a) Extreme weakness?	a) EXTREME WEAKNESS 1	(2)
b) Heart problems?	b) HEART PROBLEMS . 1	(2)
c) Loss of consciousness?	c) LOSS OF CONSCIOUS 1	(2)
d) Rapid or difficult breathing?	d) RAPID BREATHING . 1	(2)
e) Seizures?	e) SEIZURES ..... 1	(2)
f) Abnormal bleeding?	f) BLEEDING ..... 1	(2)
g) Jaundice or yellow skin?	g) JAUNDICE ..... 1	(2)
h) Dark urine?	h) DARK URINE ..... (1)	2

In some cases, precoded responses will include 'OTHER.' The OTHER code should be selected only when the respondent's answer is different from any of the precoded responses listed for the question or when you have encountered an issue in the field that does not permit you to proceed with the biomarker collection. Before using the OTHER code, you should make sure the answer does not fit in any of the specified categories.

*Example:*

CONDUCT TEST AND RECORD RESULT OF THE MALARIA RDT HERE AND IN THE [INFORMATIONAL PAMPHLET].	[TEST POSITIVE] .....	1	} → 1
	[TEST NEGATIVE] .....	2	
	NOT PRESENT .....	4	
	REFUSED .....	5	
	OTHER .....	6	

In this case, an acceptable use of 'OTHER' would be receiving permission from the parent/responsible adult collect blood for malaria testing of the child, but you faced an issue with the rapid diagnostic test that would not allow you to complete the test.

### ***Recording responses that are not pre-coded***

The answers to some questions are not pre-coded but require that you write the appropriate response in the space provided or the respondent's results.

*Example*

RECORD NAME OF PARENT/RESPONSIBLE ADULT FOR THE CHILD.	NAME <u>Monica</u>	
	LINE NUMBER ..... <input type="text"/>	

## **2.G. Marking Filters and Following Skip Patterns**

### ***Marking Filters***

Filters require you to look back to the answer to a previous question and then mark an 'X' in the appropriate box.

*Example:*

106	CHECK 103: IS THE CHILD AGE 0-5 MONTHS OR OLDER <input checked="" type="checkbox"/>	AGE 0-5 MONTHS <input type="checkbox"/>	→ 135
-----	-------------------------------------------------------------------------------------	-----------------------------------------	-------

To ensure the proper flow of a paper questionnaire, you will sometimes be directed to check a respondent's answer to an earlier question, indicate what the response was by marking a box with an 'X', and then follow the relevant skip instruction. Questions of this type are called "filters"; they are used to prevent a respondent from being asked the same question multiple times. Use caution when answering filters. Filters involve skip patterns so ensure you are following them correctly.

### Following Skip Patterns

It is very important not to ask a respondent any questions that are not relevant to his or her situation. For example, you should not read a malaria consent statement to a parent/responsible adult of a child age 0-5 months because children in this age group are too young to be tested. In cases where a particular response makes subsequent questions irrelevant, an instruction is written in the questionnaire directing you to skip to the next appropriate question.

Example:

106	CHECK 103: IS THE CHILD AGE 0-5 MONTHS OR OLDER <input type="checkbox"/>	AGE 0-5 MONTHS <input checked="" type="checkbox"/>	→ 135
-----	--------------------------------------------------------------------------	----------------------------------------------------	-------

Always follow the skip patterns!

Unless a skip pattern is present, always move directly to the next question.

## 2.H. Correcting Mistakes

When working with a paper questionnaire, it is very important that you record all answers neatly. For precoded responses, be sure that you circle the code for the correct response carefully. When recording responses that are not precoded, the reply should be written legibly so that it can be easily read. If you made a mistake in entering a respondent's result, the respondent wishes to change his/her reply, or you have made a mistake, be sure that you cross out the incorrect response and enter the right answer. Do not erase an answer. Just put two diagonal lines through the incorrect response.

**Here is how to correct a mistake:**

Example:

124	CONDUCT TEST AND RECORD RESULT OF THE MALARIA RDT HERE AND IN THE [INFORMATIONAL PAMPHLET].	[TEST POSITIVE] ..... ① [TEST NEGATIVE] ..... ② NOT PRESENT ..... 4 REFUSED ..... 5 OTHER ..... 6	→ 135
-----	---------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------	-------

Remember that if you are not careful to cross out mistakes neatly, it may not be possible to determine the correct answer when the data are entered later into the CAPI system.

## 2.1. Key points to remember

The following steps are important to remember when completing the Biomarker Questionnaire:

- **Children should be measured after the mother is interviewed.** If the mother is not present in the household or does not live in the household, children should be measured after the responsible adult has given consent for biomarker collection.
- **Measure and/or test for biomarkers one respondent at a time.** All the biomarker measurements for the [COUNTRY] MIS should be performed on one respondent before moving on to the next eligible respondent. Complete the measurement of all biomarkers from one respondent before proceeding to the next. Failure to do so may lead to the results of one respondent being recorded for another respondent.
- **Never alter any responses or information transferred by the interviewer from the CAPI list of individuals eligible for the Biomarker Questionnaire** without consulting the interviewer who completed the Household Questionnaire. Even in cases where there are concerns about a respondent's eligibility for testing, proceed with the biomarker collection. Record in the notes section of the Biomarker Questionnaire a description of the problem. Provide as many details as possible. The field organization/central office will decide later what will be done about the test results for the respondent in question.
- **Read the applicable consent statements to each parent/responsible adult exactly as they appear in the Biomarker Questionnaire.** When you arrive at the household and begin talking about the blood tests with the respondent, you may informally discuss items included in the informed consent statement. However, before beginning the testing procedures, you must still read the informed consent statements exactly as they appear in the Biomarker Questionnaire. If the respondent finds the statements repetitive, tell him or her that you are required to read the statements to ensure that they are given all the appropriate information.
- **Read the informed consent statements clearly.** Practice reading the consent statements out loud so that you become comfortable delivering them in a clear, natural voice and manner. Avoid speaking rapidly or in a monotone.
- **Never attempt to force or coerce consent.** Some respondents may be suspicious or fearful of having their blood collected for biomarker testing. Others may have questions or want to discuss the procedures before giving consent. Take time to patiently respond to all questions.
- Some parents/responsible adults may be reluctant to allow testing of a child without consulting someone not present at the time of your visit (for example, a woman may want to consult her husband before giving permission). In such cases, **make an appointment to return to the household later at an agreed upon time.** If you believe it will help, ask the team supervisor to visit a household where eligible respondents express fear or reluctance to be tested.

## Chapter 3. CAPILLARY BLOOD COLLECTION

### *Learning objectives*

- List supplies for blood collection
- Determine the site of blood collection for the appropriate age group
- List steps involved in obtaining a capillary blood sample from the finger
- Perform steps involved in obtaining a capillary blood sample from the finger
- List steps involved in obtaining a capillary blood sample from the heel
- Apply steps involved in obtaining a capillary blood sample from the heel
- List best practices and precautions to observe when collecting blood

### **3.A. Introduction**

This chapter describes the materials needed for and, the steps involved in, capillary blood collection.

Capillary blood will be collected as part of the survey to test for malaria. Capillary blood can be obtained from the palm side of the tip of a finger or from a heel. For children age 12 months and older, a finger should be used. For children less than age 12 months, the heel should be used. For children who are undernourished or skinny a heel puncture is also recommended because the finger tissue can be thin, and the lancet may pierce the bone.

### **3.B. Materials and supplies for performing finger or heel pricks**

The capillary blood drops collected for biomarker testing will be drawn from a finger or heel. The following supplies and materials will be used in performing the finger or heel prick.

**Disposable nitrile gloves:** Used to reduce the risk of bloodborne diseases. Gloves must be worn by the biomarker technician and by anyone else who may assist with the blood collection.



**Absorbent paper sheets:** The surface area where your supplies will be placed while you collect the blood. Place the plastic/shiny side of the absorbent sheet face down (the absorbent side without plastic on it should be facing up).



**Alcohol preps:** Used for cleaning the skin prior to pricking the finger or heel.



**Safety lancets:** The lancet is a single-use, disposable device used to prick the fingertip or heel. The blade is retractable; when in contact with the finger and pressure is applied, a surgical blade quickly ejects from the device, punctures the skin, and then automatically retracts.



**Sterile gauze pads:** Used to wipe away the first drop(s) of blood to stimulate capillary blood flow.



**Adhesive bandages:** Applied to the puncture site to minimize the risk of infection.



<p><b>Biohazardous waste bags:</b> Plastic bags that are provided to hold all the biohazardous waste generated during the day except sharps. All waste bags are labeled with “biohazard” logo.</p>	
<p><b>Sharps containers:</b> All biohazardous sharps that have pointed tips such as lancets, as well as inverted cups, [applicator sticks, and microscope glass slides].</p>	

**3.C. How to put on gloves**

***Donning (putting on gloves)***

1. Measure your hand using the glove-sizing chart before choosing a glove to reduce the potential for tearing.
2. If possible, thoroughly wash hands before donning gloves and after each glove change.
3. Open glove at the cuff and extend opposite hand until thumb crotch is to the cuff of the glove.
4. Once the hand is properly aligned in the glove, move your fingers down into the glove's fingers.
5. Roll the cuff of the glove down the wrist until the glove is secure.
6. Replace gloves frequently, including whenever changing tasks.

***Doffing (taking off gloves)***

1. Pull the glove from above the cuff up on the hand inside out to trap potential contaminants inside the used glove.
2. Place the used glove into the palm of the opposite hand (which remains gloved).
3. Repeat step 1 on the opposite hand, trapping the first glove inside the second.
4. Discard gloves and wash hands.



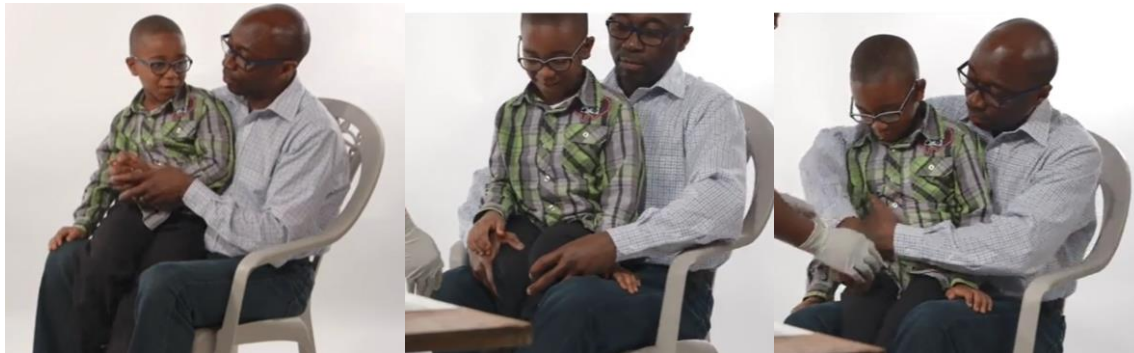
### 3.D. Steps in obtaining capillary blood from the finger

The following steps describe how to obtain a capillary blood drop sample from the finger. They apply to the collection of samples from children age 12 months and older. Remember, the informed consent statement must be read, and consent must be granted, for each eligible child before malaria testing.



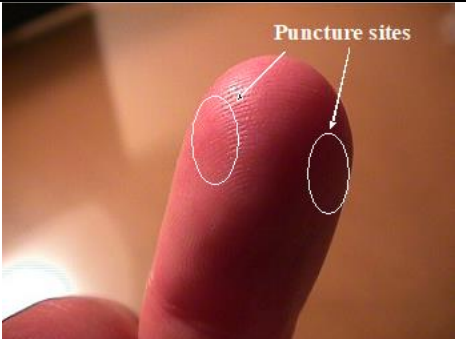


#### *Preparing the session*

1. If possible, find an **indoor site** to encourage privacy. The site should have a table or other furniture with a flat surface where you can lay out the supplies. A couch, bed, or mat should be readily available if the child feels faint and needs to lie down. If you must do the testing outdoors, find a site in the full shade and away from rain, dust, and other environmental elements that might affect the sample.
2. **Describe to the parent or responsible adult exactly what will be done** during the collection of the blood sample and how they can assist by holding the child on their lap and holding the child's hand during the collection of the sample.
3. When collecting blood from a child, note that the child may be fearful or anxious about what is going to happen. Therefore, using a calm and reassuring manner is important as you begin to collect the blood sample. Remember that nonverbal communication is important, so maintain eye contact with the child as you prepare to take the sample. Encourage the parent/responsible adult to hold the child on his or her lap and place the child's legs in between his or hers so that the child does not kick the table and place his or her arms around the child.

**Figure X-1. How a parent should hold a child for a finger prick.**



### 3.E. Collecting the blood from a finger prick

<p>1. <b>Put on gloves</b> before beginning the collection of the blood sample from the first child.</p>	
<p>2. <b>Kneel on the side of the child opposite to the hand/heel from which you will collect blood.</b> For example, if you want to collect the sample from the left hand, place yourself to the right side of the child. Do not sit on a chair.</p>	
<p>3. <b>Use the third or fourth finger for collecting blood.</b> Do not use a finger with a scar, a wound or cut, swelling, a deformity, a rash, or an infection.</p>	
<p>4. <b>Ask the parent/responsible adult to warm the child's hand</b> by briskly rubbing the child's fingers in between their palms.</p>	
<p>5. <b>Set up your station:</b></p> <ul style="list-style-type: none"> <li>• Take out a clean absorbent paper sheet and spread the shiny side down over a flat surface</li> </ul>	




where you will lay out your supplies.

- Open the sterile gauze package. Separate the two pieces of gauze and lay them down on the package so they do not touch the absorbent pad.
- Open the outer package of the adhesive bandage. Place the bandage on the packaging. Open the alcohol prep package.
- Remove the blade slot cover of the lancet. Prepare the lancet for use. Simply twist the blade slot cover 360° until the cover comes out. Do not remove the blade slot cover from the lancet other than as instructed here, as this may damage the lancet and cause it to malfunction.

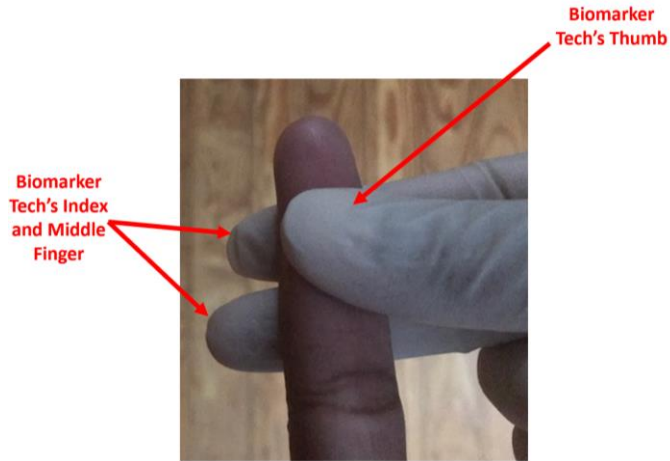


6. **With an alcohol prep pad, clean the skin of the finger thoroughly.** If the skin is dirty, use a second pad. Clean the finger before pricking.



<p>7. <b>Allow the finger to air dry completely. Do not blow on the area to dry the alcohol.</b> Blowing may allow bacteria to contaminate the site. Allow the alcohol to air dry. If the finger is not properly dried, you run the risk of mixing alcohol with the blood. It takes 15-20 seconds for the alcohol to dry. If the alcohol used to clean the puncture site mixes with the blood, it can cause hemolysis of the sample leading to errors in the test results.</p>	
<p>8. <b>Position the hand palm side facing up.</b> Form a pad with your index and middle finger behind the base of the child's middle finger and your thumb in front of the child's finger.</p>	
<p>9. <b>Using a rolling movement of your thumb, push blood from the base of the finger to the tip.</b> This action will stimulate a flow of blood to the fingertip. It may be helpful if the parent or responsible adult assists you by holding the child's hand.</p>	

**Note:** Never “milk” the finger. Milking is excessive massaging or squeezing of the finger, which will cause tissue juice to mix with and dilute the blood. This will result in erroneous test results. Instead, the biomarker technician should employ only mild pressure by using the thumb and the index and ring fingers to support the base of the finger.



This position will make the connective tissue underlying the skin more porous and allow the capillary blood to flow easily after the incision.

10. Hold the lancet by the grooved area on the lancet body and **gently place the white lancet tip against the skin**. Look to confirm that you have selected a good puncture site and reposition if necessary. **Apply pressure against the fingertip to trigger the lancet to prick the skin**. The lancet will automatically trigger when the correct amount of pressure is applied. (The tip of the blade ejects through the blade slot, producing a micro-incision in the skin, and immediately retracts into the device.) After pricking the skin, drop the used lancet into the sharps container.



**Note:** Avoid placing the lancet on the very tip of the finger, near the fingernail, or on the sides beyond the palmar area. You can first check the position of the puncture by placing the lancet against the finger without applying pressure that might trigger the lancet. Re-adjust the placement of the lancet if needed.

11. When your thumb reaches the fingertip, maintain a gentle pressure to **trap the blood in the fingertip**.



12. **When the blood appears, use a sterile gauze pad to wipe away the first blood drop.** Collect the second blood drop for the malaria RDT and [the third blood drop thick smear].



13. **When blood collection is completed, apply a piece of sterile gauze at the prick site to stop the blood flow.**

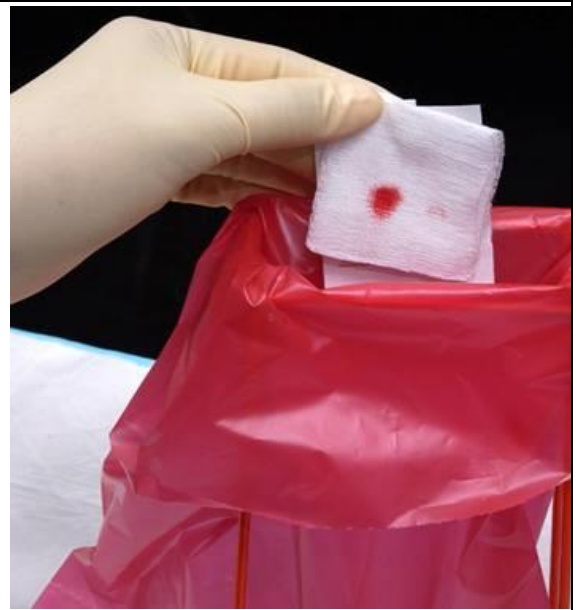


**14. Apply an adhesive bandage to the prick site.**







**15. Properly dispose of all materials used in blood collection:**

- Lancets should always be discarded in a sharps container
- All other materials used in the blood collection procedure can be discarded in a labeled biohazardous waste bag.



### **3.F. Obtaining capillary blood from a child's heel**

The heel is the puncture site for children age 6 - 11 months, or malnourished (skinny) children whose fingers are very thin. A lancet that punctures to a depth of 1.8 – 2.0 mm will be used to puncture the heel. The following describes the steps that are involved in obtaining a capillary blood drop from the heel.

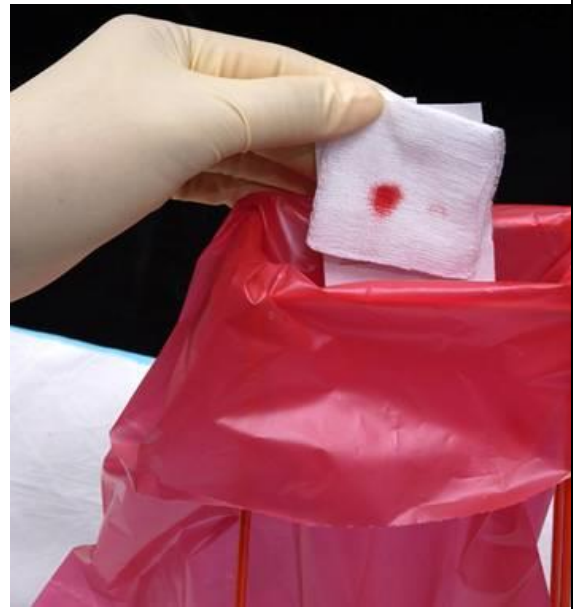
<p>1. <b>Prepare to prick</b> outside an imaginary line drawn from the middle of the big toe to the heel or outside an imaginary line drawn from the area between the fourth and fifth toes to the heel. Take care to avoid the central area of the foot (to avoid injury to the nerves and tendons) or the center of the heel (to avoid piercing the heel bone).</p>	
<p>2. <b>Hold the heel firmly.</b> Apply moderate pressure near the puncture site by wrapping the heel using your thumb and second finger.</p> <p>3. <b>Clean the site with an alcohol prep wipe.</b> Make sure the site is dry before puncturing the skin with the lancet. In selecting a puncture site, avoid any areas of the skin that are broken or infected.</p>	
<p>4. <b>Place the blade-slot surface against the skin and press the trigger.</b> Ensure the free flow of blood.</p>	
<p>5. When the blood appears, use a <b>sterile gauze pad to wipe away the first one drop of blood</b>, use the second for malaria testing, [and the third drop for the thick smear.]</p>	



6. **Apply an adhesive bandage to the prick site.**

7. **Properly dispose of all materials used in blood collection:**

- Lancets should always be discarded in a sharps container
- All other materials used in the blood collection procedure can be discarded in a labeled biohazardous waste bag.



### 3.G. Precautions to observe when collecting blood samples<sup>2</sup>

This section describes the universal (general) precautions to be followed during blood collection.<sup>3</sup> You should take precautions when collecting blood to prevent exposure to bloodborne infections such as hepatitis B or HIV. Follow the steps below to ensure protection against bloodborne infections.

- **If you must prick a child a second time**, do not prick the same finger or heel.
- **Do not use the same pair of gloves for more than one child.** If you have worked with one child and your gloves do not appear soiled, you must still discard them and put on a fresh pair of gloves when working with a different child. It is also possible that you use more than one pair of gloves when working with just one child if the gloves have become heavily soiled.
- **Keep intermittent pressure** on the finger or heel during the blood collection process.
- **Do not milk the finger:** milking the finger may cause the interstitial fluid to mix with blood and dilute the blood sample giving false results. Also, if a large volume of tissue fluid mixes with the blood, the sample will be like a plasma sample instead of a whole blood sample.
- **If your gloves are soiled with blood**, complete the blood collection process and change them immediately once you have finished with that child.

<sup>2</sup> Adapted from National Committee for Clinical Laboratory Standards (NCCLS) 1997

<sup>3</sup> For the universal precautions regarding bloodborne pathogens, see the U.S. Centers for Disease Control and Prevention guidelines and the U.S. Occupational Safety and Health Administration (OSHA) standards for protection from exposure to bloodborne pathogen.

- **Wear disposable gloves.** Gloves help to prevent skin and mucous-membrane exposure to blood. Gloves should be worn during blood collection, until the specimen(s) from a child is collected and all waste materials produced during the collection are disposed. At that point, the used gloves should be treated as biohazardous waste. A new pair of latex gloves should be used with each child. **Gloves must never be re-used!**
- **Avoid penetrating injuries.** Although gloves can prevent blood contamination of intact and non-intact skin surfaces, they cannot prevent penetrating injuries caused by the instruments used for finger or heel pricks. Safety lancet devices reduce the risk of penetrating injuries.
- **Do not use lancets for purposes other than a single finger or heel prick** to collect blood for the biomarker testing. The lancets should not be broken or destroyed for curiosity or other purposes. After the device is used, it should be placed in a puncture-resistant sharps container.
- **Wash contaminated areas.** If an accident occurs, any skin surfaces or mucous membranes that become contaminated with blood, should be immediately and thoroughly washed with running water or a large quantify of water from a bucket or basin.
- **Never eat or drink during the testing.** Eating or drinking while collecting blood samples may result in contaminating yourself and is prohibited during the blood collection and testing procedures.
- **Properly dispose of all biohazardous materials.** All materials coming in contact with blood must be placed in a biohazardous waste container after use and disposed of according to the survey's policy on infectious waste disposal ([see Chapter 6]). Take precautions when storing and transporting the waste during the fieldwork.

### 3.H. Good blood collection practices

- **Good position in relation to the child.** Position yourself well before you make a puncture on the child's finger or heel, such as kneeling below the child's heart level.
- **Do not prick the finger or heel if it is cold!** Warm the hands (or heel) by asking the parent/responsible adult to rub the child's hand or heel vigorously.
- **Never "milk" the finger.** Excessive massaging or squeezing of the finger or foot will cause tissue juice to mix with and dilute the blood.
- **Never mix alcohol with the blood.** If the alcohol used to clean the puncture site mixes with the blood, it can cause hemolysis of the sample leading to errors in the testing results. To avoid this problem, the finger or heel must be air dried completely before being punctured.
- **Avoid obstructing blood flow.** It is important to hold the finger properly to allow the accumulation of blood at the puncture site. Holding the finger too tightly can obstruct blood flow to the finger.
- **Push lancet in firmly to avoid shallow punctures.** A deep puncture should be made for

better blood flow and to have a representative concentration of red blood cells.

- **Dispose of biohazard materials as they are used.** Keep the biohazard bag and sharps container open during blood collection and drop each disposable item in the appropriate container as you finish using it.
- If blood flow stops before all biomarkers are collected/tested, lay out all new supplies to make a second prick.
- **NEVER** leave behind or give biohazardous waste to parents/responsible, even if they request it.

## Chapter 4. MALARIA TESTING

### **Learning objectives**

- Define malaria and its causes
- List the supplies for testing for malaria
- List steps for malaria testing
- Demonstrate proper use of the malaria RDT
- [Demonstrate proper storage and transport of malaria slides]<sup>4</sup>
- List precautions in malaria testing
- List steps in providing test results, treatment for malaria, and referrals for severe malaria

### **4.A. Introduction**

Malaria is a parasitic disease that is transmitted by the bite of a *Plasmodium*-infected mosquito. Symptoms of malaria include fever, chills, headache, and vomiting, in addition to other flu-like symptoms; if left untreated, severe cases of malaria can quickly become life threatening. In the [YEAR, COUNTRY] MIS, children age 6- 59 months will be tested for malaria with the [SD Bioline P.f] rapid diagnostic test (RDT). [The results of the RDT will be confirmed in a laboratory by microscopic examination of a thick blood smear collected from the same individual. The thick blood smear allows lab technicians to detect the presence of malaria parasites.] These data will be used to generate national and regional malaria prevalence estimates.





This chapter presents detailed instructions on using the SD Bioline P.f test kit as well as on preparing and storing thick blood smears and transferring them to the laboratory. In accordance with the [COUNTRY] national treatment guidelines, children who test positive for non-complicated malaria by the RDT will be provided with treatment; the treatment protocol is also described in this chapter.

### **4.B. Materials and supplies for malaria testing**

In addition to the supplies required for capillary blood collection in Chapter X, and the Biomarker Questionnaire, the following materials and supplies are required for malaria testing:

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<sup>4</sup>Note: If the [YEAR, COUNTRY] MIS does not include preparation of thick blood smears, this module will need to be adapted accordingly.

<p><b>SD Bioline P.f. RDT:</b> will be used for home-based malaria testing. This test detects malaria antigens (Plasmodium proteins) and produces results in 15 minutes. It is discussed in greater detail below.</p>	 <p>The image shows a vertical, grey plastic diagnostic device labeled 'MALARIA P.f.' at the top. It features a sample port at the bottom with a yellow arrow pointing to it. Above the port is a circular window containing a purple disc. To the right of the window are two small blue triangles labeled 'C' and 'Pf'. The device is designed for rapid testing of malaria antigens.</p>
<p><b>Sample Collection Cup:</b> Small plastic tubes with a cup on the end to collect the blood sample from the finger or heel prick and deposit it in the sample port of the test device.</p>	 <p>The image displays two small, clear plastic tubes. The tube on the left is shown in profile, highlighting its thin, tapered shape. The tube on the right is shown from a different angle, revealing a small red cup at its tip, which is used for collecting blood samples from a finger or heel prick.</p>
<p><b>Assay Diluent:</b> To facilitate capillary flow of embedded reagents and the blood sample.</p>	 <p>The image shows a small, clear plastic bottle with a white cap, held in a person's hand. The label on the bottle reads 'SD BIOLINE Malaria Ag P.f. Assay Diluent'. The bottle is used to facilitate the capillary flow of reagents and the blood sample during the test.</p>
<p><b>Timer:</b> for precisely timed reading of results</p>	 <p>The image shows a white, round analog timer with a white dial and black markings. The dial is marked with numbers from 5 to 60 in increments of 5. The timer is used to precisely time the 15-minute reading period for the malaria test results.</p>

**[FIRST LINE ACT]:** is provided to children testing positive for malaria, who do not exhibit symptoms of severe malaria, or who are not currently taking medication for malaria. Children who have tested positive and received [FIRST LINE ACT] treatment in the last 2 weeks are not eligible for additional treatment.



**4.C. Materials and supplies for preparing, storing and transporting blood smears**

**Glass microscope slides:** Used for preparing thick blood smears. The slides are non-sterile but clean.



Additional use of the glass slides is to spread the blood drops on the slide for thin and/or beveled edge of a slide for thick smear preparation.

**Barcode Labels:** The malaria testing in the [YEAR] [COUNTRY] MIS is anonymous; i.e., an individual's name is never written on the glass slide. Instead, barcode labels are used to link the thick smears to the data recorded in the Biomarker Questionnaire. You will be provided with sheets of "peel-off" adhesive barcode labels. The barcodes are arranged in rows. The codes on each label are the same across one row. A different row of barcode labels on the sheet should be used for each individual for whom a thick blood smear is prepared. In the [YEAR] [COUNTRY] MIS, barcodes will be used to label all smears.



**Cardboard slide tray:** The thick blood smears should be placed in slots inside the cardboard slide tray to drying. The tray protects the thick smears from dust and insects and facilitates the safe transport of slides while in the field.



**Blue slide storage box:** Once out of the field, dried thick blood smears should be transferred to a slide box; each box holds 25 slides.



**Ziploc® storage bags:** Sealable plastic bags will be used to store the cardboard slide tray and slide boxes containing the thick blood smears.



**Desiccant packets:** Drying agents that absorb moisture from the air. Desiccants are used to keep the smears dry during transport to the laboratory. The granules inside the packets change color from blue to pink as they absorb moisture. Treat used desiccants as biohazardous waste and throw them away in a



<p>biohazardous waste bag.</p> <p><b>Microscope Slide Transmittal Form:</b> Used to track the movement of the thick smears from the field to the laboratory. For each individual who provided a blood sample, the Microscope Slide Transmittal Form should have a barcode with the same unique identifier as the barcode label attached to the glass slide and the Biomarker Questionnaire. See <a href="#">Appendix X</a> for a sample Microscope Slide Transmittal Form.</p>	<p style="text-align: center;">[YEAR] [COUNTRY] [MALARIA INDICATOR] SURVEY MICROSCOPE SLIDE TRANSMITTAL FORM (FRONT SIDE)</p> <p style="text-align: center;">FIELD/CLUSTER NUMBER <span style="float: right;">CLUSTER NUMBER</span></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">PERSON RECEIVING/RECEIVING SAMPLES</th> <th style="width: 15%;">TIME TO FILL IN FORM</th> <th style="width: 15%;">TOTAL COUNT OF MICROSCOPE SLIDES</th> <th style="width: 15%;">SIGNATURE (CONFIRMING THAT EACH SLIDE IS PRESENT - SEE BACK OF FORM)</th> <th style="width: 15%;">SIGNATURE (CONFIRMING COUNT OF MICROSCOPE SLIDES IN COLUMN 3)</th> <th style="width: 10%;">DATE</th> <th style="width: 20%;">NOTES (NOTE ANY DISCREPANCY IN NUMBERS OF SLIDES)</th> </tr> <tr> <th>(1)</th> <th>(2)</th> <th>(3)</th> <th>(4)</th> <th>(5)</th> <th>(6)</th> <th>(7)</th> </tr> </thead> <tbody> <tr> <td>BIOMARKER TECHNICIAN</td> <td>AFTER BIOMARKER TECHNICIAN HAS DONE HIS/HER COUNT</td> <td style="text-align: center;">□ □</td> <td></td> <td style="background-color: #cccccc;"></td> <td></td> <td></td> </tr> <tr> <td>TEAM SUPERVISOR</td> <td>WHEN CLUSTER IS COMPLETED</td> <td style="text-align: center;">□ □</td> <td></td> <td style="background-color: #cccccc;"></td> <td></td> <td></td> </tr> <tr> <td>FIELD COORDINATOR</td> <td>WHEN SAMPLES ARE PICKED UP IN FIELD</td> <td style="text-align: center;">□ □</td> <td style="background-color: #cccccc;"></td> <td></td> <td></td> <td></td> </tr> <tr> <td>RECEIVER AT IMPLEMENTING AGENCY</td> <td>UPON ARRIVAL AT PROJECT OFFICE</td> <td style="text-align: center;">□ □</td> <td style="background-color: #cccccc;"></td> <td></td> <td></td> <td></td> </tr> <tr> <td>LAB</td> <td>UPON ARRIVAL AT LAB</td> <td style="text-align: center;">□ □</td> <td></td> <td style="background-color: #cccccc;"></td> <td></td> <td></td> </tr> </tbody> </table>	PERSON RECEIVING/RECEIVING SAMPLES	TIME TO FILL IN FORM	TOTAL COUNT OF MICROSCOPE SLIDES	SIGNATURE (CONFIRMING THAT EACH SLIDE IS PRESENT - SEE BACK OF FORM)	SIGNATURE (CONFIRMING COUNT OF MICROSCOPE SLIDES IN COLUMN 3)	DATE	NOTES (NOTE ANY DISCREPANCY IN NUMBERS OF SLIDES)	(1)	(2)	(3)	(4)	(5)	(6)	(7)	BIOMARKER TECHNICIAN	AFTER BIOMARKER TECHNICIAN HAS DONE HIS/HER COUNT	□ □					TEAM SUPERVISOR	WHEN CLUSTER IS COMPLETED	□ □					FIELD COORDINATOR	WHEN SAMPLES ARE PICKED UP IN FIELD	□ □					RECEIVER AT IMPLEMENTING AGENCY	UPON ARRIVAL AT PROJECT OFFICE	□ □					LAB	UPON ARRIVAL AT LAB	□ □				
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Two paper handouts are available to parents/responsible adults:

1. **Malaria pamphlet:** a one sheet document designed to inform the parent/responsible adult about the malaria test results within the household, dosages of treatment and contact information. See [Appendix X](#) for an example of the malaria pamphlet.
2. **Severe malaria referral form:** a slip of paper given to the parent/responsible adult of a child with severe malaria (defined as a child who tested positive for malaria and has symptoms of severe malaria See [Appendix X](#) for an example of the severe malaria referral form).

**NOTE:** Provision of [FIRST LINE ACT] is a requirement of the survey. Children should not be tested for malaria if [FIRST LINE ACT] is unavailable.

#### 4.D. Handling and storage of SD Bioline P.f rapid diagnostic test (RDT) kit



The SD Bioline P.f RDT is a rapid, qualitative test for malaria. It tests for one antigen, the histidine-rich protein II (HRP-II), specific to *Plasmodium falciparum* (P.f), the major cause of malaria in

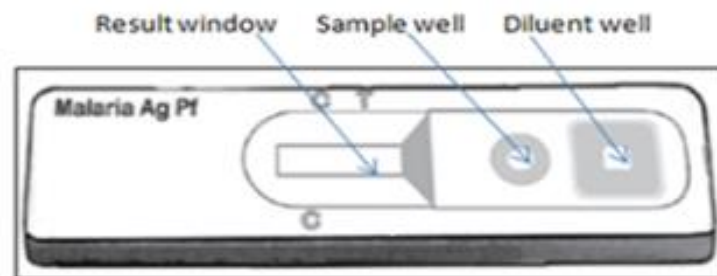


[COUNTRY].

Each SD Bioline P.f RDT comes in a self-contained pouch. The kit includes:

- Test cassette
- Desiccant packet
- Sample collection cup
- Assay diluent in a dropper bottle
- Instructions

### SD Bioline P.f RDT



1. The sample collection cup is used to collect and deposit the blood sample from the finger (heel) prick into the **sample well** in the test device.
2. Assay diluent is added to the **diluent well** to aid the lateral flow of the blood and reagents along the strip.
3. After 15 minutes, a control band (C) and test band (T), will appear in the **result window** if malaria is detected.

There are handling and storage requirements that should be observed for accurately performing the SD Bioline P.f RDT:

- Do not use the device after the expiration date.
- The test device must remain in the sealed pouch until use. **Once the device is open, it must be used immediately.** Do not open the sealed pouch more than 5 minutes before doing the test as the device is sensitive to humidity.
- **Never** mix reagents from different lots.
- Do not use the device if the pouch or device is damaged or if any lines are visible on the device before contact with the sample.

#### 4.E. Determine eligibility and obtain informed consent for malaria testing

**Children:** Follow the steps below for malaria testing of eligible children age 6-59 months.

Biomarker technicians will not fill in anything prior to [Q. 106; Q. 118] and onwards are for the biomarker technician to complete.

[Q.118]: NAME OF PARENT/RESPONSIBLE ADULT FOR THE CHILD

In [Q. 118], record the name of the parent/responsible adult (over the age of 18) for the child. This person will be asked for their informed consent for malaria testing for that child. You will notice that below the space for the name is space for a line number. You are **NOT** responsible for filling in the line number. The line number of the parent/responsible adult will be populated when the questionnaire is entered into CAPI.

**Do Not Enter Life Number**

118	RECORD NAME AND LINE NUMBER OF PARENT/RESPONSIBLE ADULT FOR THE CHILD.	NAME _____ LINE NUMBER OF PARENT/RESPONSIBLE ADULT <input type="text"/> <input type="text"/>
-----	------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------

**[Q. 120]: ASK CONSENT FOR MALARIA TEST FROM PARENT/RESPONSIBLE ADULT**

120	ASK CONSENT FOR MALARIA TEST FROM PARENT/RESPONSIBLE ADULT:  As part of this survey, we are asking children all over the country to take a test to see if they have malaria. Malaria is a serious illness caused by a parasite transmitted by a mosquito bite. This survey will assist the government to develop programs to prevent and treat malaria. We ask that all children age 6 months through 4 years take part in malaria testing. The tests require a few drops of blood from a finger or heel. The equipment used to take the blood is clean and completely safe. It has never been used before and will be thrown away after each test.  The blood will be tested for malaria immediately, and the results will be told to you right away. [A few blood drops will be collected on slide(s) and taken to a laboratory for testing. You will not be told the results of the laboratory testing.] All results will be kept strictly confidential and will not be shared with anyone other than members of our survey team.  Do you have any questions? You can say yes or no. It is up to you to decide. Will you allow {NAME OF CHILD} to participate in the malaria test?	GRANTED ..... 1 REFUSED ..... 2 NOT PRESENT/OTHER ..... 3   <div style="border: 1px solid black; width: 100px; height: 20px; margin: 0 auto;"></div> [FIELDWORKER] NUMBER
-----	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

After reading the consent statement, record the parent/responsible adult’s response to the request to allow the child to participate in the testing. If the parent/responsible adult agrees, circle ‘1’ (GRANTED). If the parent/responsible adult refuses to allow the child to participate in the testing, circle ‘2,’ (REFUSED).

**[Q. 121]: SIGN NAME AND ENTER [FIELDWORKER] NUMBER**

After recording the outcome of the consent process, you must affirm that you have read the statement to the parent/responsible adult and recorded the results accurately by signing your name and entering your fieldworker number in the space provided.

**[Q. 123]: IF CONSENT GRANTED, PREPARE EQUIPMENT AND SUPPLIES FOR THE TESTS AND PROCEED WITH THE TESTS**

At this point, set up your station and proceed with the malaria testing.

## 4.F. Steps in performing malaria testing

### 1. Prepare the supplies

Following instructions in Chapter X, prepare blood collection supplies. Remove one malaria RDT from the kit, [one glass slide for the thick smear, another slide to spread the blood drop,] and timer. Open your capillary blood collection supplies in the order mentioned in Chapter X.



### 2. Place barcode labels:

- Take the **first** barcode label from the first complete row on the sheet of barcode labels and affix it in [Q. 123] of the Biomarker Questionnaire.
- Take the second barcode label from the same row on the sheet of barcode labels and affix it on the microscope slide (with the unique identifier facing outwards).
- Take the third barcode label from the same row on the sheet of barcode labels and affix it on the Microscope Slide Transmittal Form for the cluster in which you are working.

123 PREPARE EQUIPMENT AND SUPPLIES FOR THE TEST(S) AND PROCEED WITH TESTING.

(3) PLACE 1ST BAR CODE LABEL FOR MALARIA LAB TEST IN SPACE TO THE RIGHT. PUT THE 2ND BAR CODE LABEL ON THE SLIDE AND THE 3RD ON THE TRANSMITTAL FORM.

PUT THE 1ST BAR CODE LABEL HERE.

REFUSED ..... 99995  
OTHER ..... 99996




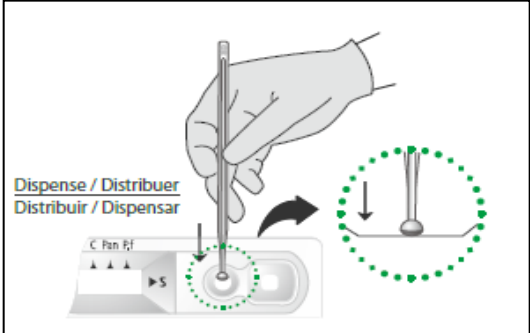
135






[YEAR] [COUNTRY] [MALARIA INDICATOR] SURVEY  
MICROSCOPE SLIDE TRANSMITTAL FORM (FRONT SIDE)

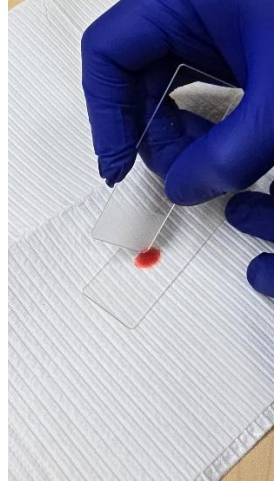
FIELDWORKER NUMBER: [ ][ ][ ][ ] CLUSTER NUMBER: [ ][ ][ ][ ]

PERSON RECEIVING SAMPLES	TIME TO FILL IN FORM	TOTAL COUNT OF MICROSCOPE SLIDES	SIGNATURE (CONFIRMING THAT EACH SLIDE IS PRESENT - SEE BACK OF FORM)	SIGNATURE (CONFIRMING COUNT OF MICROSCOPE SLIDES IN COLUMN 3)	DATE	NOTES (NOTE ANY DISCREPANCY IN NUMBERS OF SLIDES)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
BIOMARKER TECHNICIAN	AFTER BIOMARKER TECHNICIAN HAS DONE HIS/HER COUNT	[ ][ ]				
TEAM SUPERVISOR	WHEN CLUSTER IS COMPLETED	[ ][ ]				
FIELD COORDINATOR	WHEN SAMPLES ARE PICKED UP IN FIELD	[ ][ ]				
RECEIVER AT IMPLEMENTING AGENCY	UPON ARRIVAL AT PROJECT OFFICE	[ ][ ]				
LAB	UPON ARRIVAL AT LAB	[ ][ ]				

<p><b>3. Organize your station – Malaria</b></p> <ul style="list-style-type: none"> <li>■ Open the RDT pouch and retrieve the test cassette, the sample collection cup and desiccant packet, taking care not to touch the membrane area of the device. Once the device is open, it must be used immediately!</li> <li>■ Check the color of the desiccant packet, it should be blue. If it is colorless or pink, discard the device and use another one.</li> </ul>	
<p><b>4.</b> If consent was granted, collect a blood sample from the respondent following the procedure described in Chapter X. Use a sterile gauze pad to <b>wipe away the FIRST large blood drop from the finger or heel.</b> Use the <b>SECOND large blood drop for the malaria RDT.</b></p>	
<p><b>5.</b> Touch the sample collection cup to the blood drop at the puncture site, ensuring that blood fills the entire cup (5 µL) to run the RDT. Do not release the finger.</p>	
<p><b>6.</b> Transfer the blood sample to the sample well immediately. Ensure the blood from the sample collection cup has been completely absorbed by the sample pad. Put the sample collection cup in the Sharps container.</p>	

<p>7. Without delay, dispense four drops of the assay diluent into the developer well while holding the bottle vertically.</p>	
<p>8. Start the timer for 15 minutes.</p>	
<p>9. Collect the <b>THIRD</b> drop of blood for the preparation of the thick blood smear. The blood drop should be about 5 µl or about this size •. Pick up a slide with a barcode by its edge. Turn the slide so the barcode is facing the respondent's finger or heel. Touch the center of the slide to the blood drop three times to collect three small blood drops in the shape of a triangle. Place the slide on the absorbent sheet.</p> <p>DO NOT LET THE SLIDE TOUCH THE FINGER!</p>	

**10. Prepare the thick smear.** Use the corner of a beveled edge clean slide to blend the three drops of blood. Do not “stir” the blood; instead, the blood should be spread evenly in 3 to 5 circular motions in the same direction. Start from the inside and work your way out. Bring the edge/corner of the mixing slide back to the center of the blood drop and lift. The blood smear should have a diameter of about 1 cm in size. Put the mixing slide in the sharps container.



**The following shows how thick smears should look:**



A thick smear is made by placing three drops of blood (5  $\mu$ l each) on a clean, grease-free slide and spreading blood evenly over a small area such that the blood cells are layered on top of each other. If the thick smear is made correctly, letters can be barely read if the slide is placed over newsprint.

The following illustrate some common errors in **thick blood smear** preparation which you should avoid:

**Corner of mixing slide chipped:**



**Too little blood:**



**11.** After you have finished blood collection, **wipe any remaining blood from the prick site with a sterile gauze pad.** Press the gauze pad against the prick site until the blood flow has stopped completely.



**12. Apply an adhesive bandage to the prick site.** Advise the parent or responsible adult, especially when the child is a toddler, to carefully watch that the child does not take off the bandage and put it

**Children age 12-59 months (Finger)**

in his/her mouth as the child may choke on it.



Children age 6-11 months (Heel)

**13. After 15 minutes, read the malaria result.** Record the result code of malaria testing in [Q. 124] of the Biomarker Questionnaire and the malaria pamphlet. If the child was tested, circle '1'. If the child was not present, the parent/responsible adult refused to consent to the test, or there was some other problem, circle the appropriate code. **The test results should not be interpreted after 30 minutes.**

124	CONDUCT TEST AND RECORD RESULT OF THE MALARIA RDT HERE AND IN THE [INFORMATIONAL PAMPHLET]	[TEST POSITIVE] .....	1	} → 135
		[TEST NEGATIVE] .....	2	
		NOT PRESENT .....	4	
		REFUSED .....	5	
		OTHER .....	6	

**14. Place the blood smears in the cardboard slide tray.** Each smear should be placed in one independent slot. Make sure the smear is facing upwards and not down. Close the cardboard slide tray to protect the blood smears from flies and dust. The blood smears will dry while in the cardboard tray in a horizontal position.



**15. Give the malaria pamphlet to the parent/responsible adult.** Inform the parent/responsible adult of the result and provide him/her with the pamphlet. When reporting the result, briefly explain to the parent/responsible adult what his/her child's malaria result means, using the informational pamphlet as a guide.



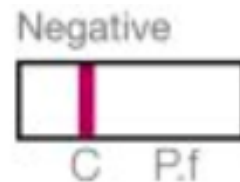
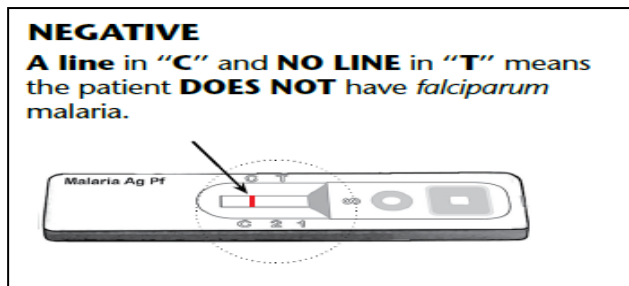
**16. Provide a written referral to the parent/responsible adult of a child with severe malaria,** defined as any child with severe malaria symptoms and/or any child who tested positive for malaria. Inform the parent/responsible adult about the effects of severe malaria. Record the RDT result on the severe malaria referral form and encourage the parent/responsible adult to seek follow-up medical attention for their child.

**17. Provide the parent/responsible adult with treatment for a child with malaria.** Any child with malaria who does not have any severe malaria symptoms is eligible for treatment if the parent/responsible adult consents. Children who are taking or have taken a first line ACT in the past 2 weeks are not eligible for treatment. Instead, the parent/responsible adult is instructed to seek care if the child has a fever for 2 days after the last dose of the ACT was given.

#### 4.G. Interpreting the results of SD Bioline P.f RDT

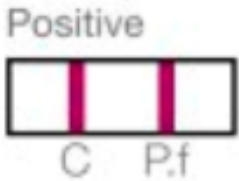
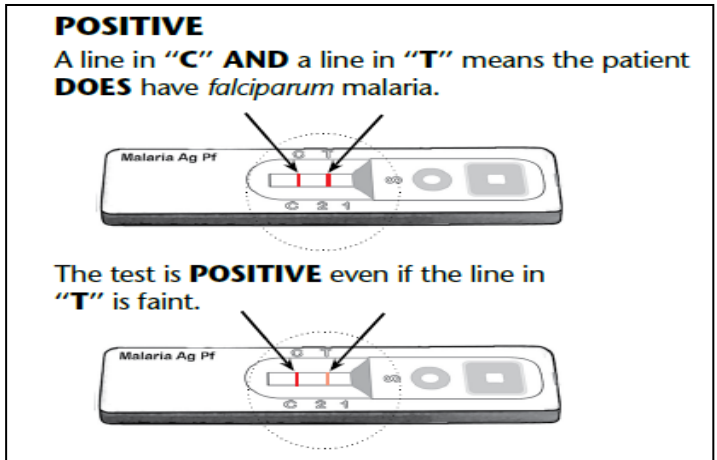
There are three possible outcomes of the SD Bioline P.f RDT: **negative**, **positive**, and **invalid**. A test that is positive will be classified as *P. falciparum* malaria positive.

The result is **NEGATIVE** for *P. falciparum* malaria if **only a single pink/pink-purple band** corresponding to the **control "C"** is observed.

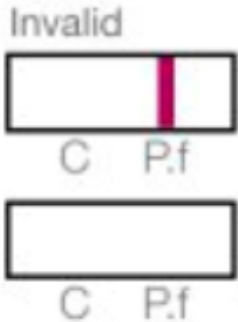
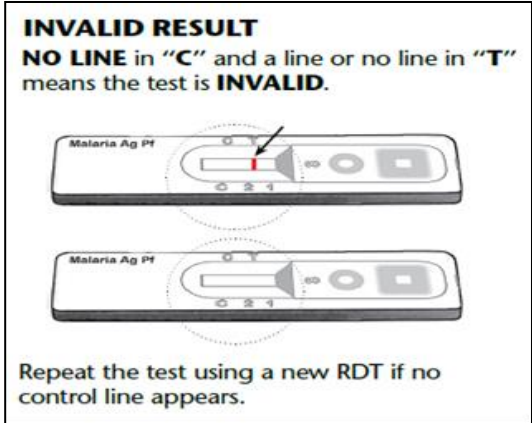


The result is **POSITIVE** for *P. falciparum* malaria if there is a **pink/pink-purple band** in **both** the **test** and **control** areas of the result window.





If **no control band** is observed on the device, the test is **invalid**. It must be repeated with consent from the parent/responsible adult using a new device.



**4.H. Treatment protocol for malaria positive children**

Malaria treatment will be provided to children testing malaria positive in the [YEAR] XMIS. Following the national malaria treatment guidelines, children will be treated with [FIRST LINE ACT]. Prior to treating children, it must be determined whether or not the child is in need of treatment. If the child has taken [ACT] within the previous 2 weeks or is currently taking [ACT] to treat the malaria, it is not appropriate to give him/her additional medication. Rather, if the child has already received medication, read the following statement to the parent/responsible adult and skip to [Q. 129]:

129	<p>ALREADY TAKING [FIRST LINE MEDICATION] REFERRAL STATEMENT</p> <p>You have told me that {NAME OF CHILD} had already received [FIRST LINE OF MEDICATION] for malaria. Therefore, I cannot give you additional [FIRST LINE OF MEDICATION]. However, the test shows that he/she has malaria. If your child has a fever for 2 days after the last dose of [FIRST LINE MEDICATION], you should take the child to the nearest health facility for further examination.</p>	
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For each child with a positive malaria test and who hasn't taken [FIRST LINE ACT] in the past 2

weeks, request consent from the parent/responsible adult to provide [FIRST LINE ACT] using the following language:

131	<p>ASK CONSENT FOR MALARIA TREATMENT FROM PARENT/RESPONSIBLE ADULT:</p> <p>The malaria test shows that {NAME OF CHILD} has malaria. We can give you free medicine. The medicine is called [FIRST LINE OF MEDICATION]. [FIRST LINE OF MEDICATION] is very effective and in a few days it should get rid of the fever and other symptoms. You do not have to give {NAME OF CHILD} the medicine. This is up to you. Please tell me whether you accept the medicine or not.</p>	<p>ACCEPTED MEDICINE ..... 1          REFUSED MEDICINE ..... 2          OTHER ..... 6</p>	
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The correct dosage of [ACT] depends on the child’s weight/age:

***[ACT] dosage guidelines for children with positive malaria tests***

**[INSERT APPROPRIATE ACT DOSAGE HERE]**

The first dose of [FIRST LINE ACT] should be administered to the child by the biomarker technician. The nurse/health technician should advise the parent/responsible adult on how to administer the subsequent doses of [ACT]. The parent/responsible adult should also be told that the child must be given the **full** 3 days of medication so that the infection will be cleared. The nurse/health technician should also advise the parent that additional [ACT] tablets must be obtained and given to the child if the child vomits within an hour of taking a tablet.

The nurse/health technician should also tell the parent/responsible adult to take the child to a health facility immediately if the child experiences a fever for 2 days after taking the last dose of medication.

**4.1. Storage and transport of thick blood smears**

The blood smears you make in the field for malaria testing must be properly stored. They must be allowed to dry thoroughly, protected from dust, flies, debris and other contaminants and kept from high levels of humidity. Follow the guidelines below to maintain high quality blood smears during storage.

1. After returning from the field each day, you should inspect the slides you collected that day to check their quality. Be sure to wear gloves during your inspection.
2. You should also check that you have one thick smear for each eligible child you tested that day, and that each slide has a barcode label. Check that the barcode label in the Biomarker Questionnaire ([Q. 123]) matches one placed on the **Microscope Slide Transmittal Form**. Note any discrepancies and try to resolve them. If you are missing slides for any child for whom you have recorded that a smear was prepared, you must go back to the household and ask permission to test the child again.
3. Make sure that you do not touch the smears accidentally with your fingers or with any materials you carry in the field and that there is no dust or dirt particles embedded in the

blood. If you touch the smear before it has dried thoroughly, you must go back to the household and ask permission to collect another blood smear.

The next morning before going to the field, you must:

4. Check the thick smears to make sure that they have dried completely.
5. Transfer the thick blood smears from the cardboard tray into the slide slots of blue slide storage box, beginning with the first column.
6. Place the blue slide storage box in a Ziploc bag containing about 3 to 5 sachets of desiccant. It is very important that the zip-loc bag remained sealed. The buildup of humidity can damage blood smears. Monitor the desiccants for color change from blue to pink. As necessary, remove pink desiccants and replace with new desiccant packets. Each morning that you are in the cluster, add the additional smears you have collected to the slide box. You will use one blue slide storage box per cluster. Mark both the slide box and the Ziploc bag with the cluster number.

### ***Transferring the thick smears to the laboratory***

Periodically, field coordinators or other members of the [YEAR, COUNTRY MIS] team will visit to pick up the blood smears and transfer them to the central office and then to the laboratory for further processing. **You will transfer slides for completed clusters only.**

To make sure that all the slides are transferred, you must check the slides against the **Microscope Slide Transmittal Form** and the Biomarker Questionnaires for each cluster. Please see an example of the **Microscope Slide Transmittal Form** in **Appendix X**. Follow these steps for in preparation for transferring the slides:

1. **Put on Gloves.** Remove the blue slide storage box from the Ziploc bag. Check the barcode on each thick smear slides against the barcodes on the **Microscope Slide Transmittal Form**. Put a check mark in the column labelled TECHNICIAN for each slide with corresponding barcode found on the **Microscope Slide Transmittal Form**.
2. Complete the **Microscope Slide Transmittal Form**. Count the total number of blood smears (slides) and record the number in Column (3).
3. Sign your name in Column (4) and record the date in Column (6). Note any discrepancies in Column (7).
4. The team supervisor will re-verify that the barcodes on the smears match the barcodes on the **Microscope Slide Transmittal Form**.
5. Fold the **Microscope Slide Transmittal Form** along the dotted lines (so that the bar-coded labels are not folded) and keep it with the slides in the blue slide storage box or Ziploc bag until the slides are collected by the field coordinator or other staff member who is picking up the slides for all completed clusters.

6. When the field coordinator collects the slides for completed clusters from the teams, he/she will verify the number of slides on the **Microscope Slide Transmittal Form** with the field supervisor. They will then be taken to the central survey office for checking before being transferred to the laboratory for processing.

#### **4.J. Precautions to take during malaria testing**

The following are common mistakes made during malaria testing:

- **Inadequate filling of the malaria RDT.** The blood collection device should be filled correctly with the recommended volume by the RDT kit manufacturer. The entire volume of blood should be blotted in the sample collection well.
- **Improperly stored RDTs should not be used for testing.** RDTs have specific storage requirements and should not be used if these storage requirements were not followed. The containers must be kept closed when not in use to avoid exposure to moisture, which may destroy the reagents or alter the properties of the test.
- **Using kit components with different lot numbers.** Always use the reagents that are supplied with the RDT kits. Do not swap buffers or cassettes from different kits.
- **Not labelling the slide.** As the blood smear will be taken to another location where the microscopic examination will be done, it is critical that the smears are labelled with a barcode so the result can be matched to the child.
- **Not using free-flowing blood.** It is important that the blood be free flowing, especially the drops used for preparing the blood smear.
- **Touching the glass slide with fingers wet with alcohol.** This can result in alcohol and dirt contamination of the glass slide preventing the proper spread and drying of the blood smear.
- **Using greasy slides to prepare thick smears.** Preparing blood smears on greasy slides results in smears with holes and streaks, as the grease does not allow the blood to spread evenly on the slide. These slides cannot be properly read.

## Chapter 5. BIOHAZARDOUS WASTE DISPOSAL

### *Learning objectives*

- Define biohazardous waste
- Define biohazardous waste disposal
- How to collect and store biohazardous waste during training and fieldwork
- Procedures for field disposal of biohazardous waste
- Methods of destroying biohazardous waste

### **5.A. Introduction**

Any material that has come in contact with blood or other bodily fluids such as lancets, alcohol swabs, gauze, and gloves are considered to be biohazardous waste (hazardous to other humans). Safe disposal of such material (biohazardous waste disposal) is crucial to prevent the transmission and spread of various bloodborne diseases, such as hepatitis B and HIV, among survey personnel and survey respondents. Biohazardous waste must be collected in biohazardous waste bags or sharps containers immediately following blood collection and testing, securely stored and transported, and safely disposed of prior to leaving a cluster. Both biohazardous waste bags and sharps containers have a special logo warning about biohazardous content. Sharps containers should be securely closed for safe storage and transportation of used sharp materials.

### **5.B. Collecting and storing waste during trainings and fieldwork**

During training and while in the field/during data collection, all soiled (containing blood) biomarker supplies (for example: absorbent sheets, gloves, gauze, etc.), and their packaging will be placed in a biohazardous waste bag. Items identified as sharps, posing a personal health risk to biomarker technicians, respondents and anyone disposing of waste (for example: safety-engineered lancets) will be collected in a sharps container.

#### ***Biohazardous Waste Bags***

For the [YEAR] [COUNTRY] MIS, three sizes of biohazardous waste bags are provided: **small** 2-3 gallon (7.5-11.3 liters), **medium** 7-10 gallon (26.5-37.8 liters) and **large** 12-14 gallon (45.4-52.9 liters). The **small** “household” waste bag will be used to collect all the non-sharps biohazardous waste from one household. Once the biomarker technician has completed processing all eligible respondents within a single household, the small biohazardous waste bag should be tied in a knot making sure to remove any excess air. When traveling from one household to another, all individually knotted small biohazardous waste bags should be stored in a **medium** “field” waste bag for easier transport. Thus, the biomarker technician can carry around one medium biohazardous waste bag instead of five or so small waste bags. At the team space or vehicle (wherever the biohazardous waste is being stored), all used medium biohazardous waste bags should have the excess air removed from them and be transferred for storage into a **large** “cluster” waste bag. The large biohazardous bag should hold all the waste collected within a cluster. If

not, a second cluster bag may be used. See the table below for each biohazardous waste bag and their appropriate use.

Biohazardous Waste Bag	Appropriate Use	Storage When Filled
<b>2 to 3-gallon</b>	Small household biohazardous waste bag	Store inside of medium biohazardous bag
<b>7 to 10-gallon</b>	Stores the small biohazardous waste bags used in households for easier transport though the field	Store inside of large biohazardous bags
<b>12 to 14-gallon</b>	Stores the medium biohazardous waste bags per cluster	Store at the team space until disposal at a local health facility

If all the waste from one household will not fit into one 2-3 gallon small biohazardous waste bag, please use another small bag to collect the remaining household waste. Generally, 1-2 large cluster bags are enough to hold all the waste from one cluster.

### ***Sharps Containers***

For the [YEAR] [COUNTRY] MIS, [SIZE] sharps containers are provided. Sharps are any items used to measure biomarkers (and as a result are contaminated with biohazardous bodily fluids or blood) that can puncture through the thin plastic biohazardous waste bags. All sharps containers used in the [XMIS] are made of puncture-proof plastic so any item placed inside of them will not puncture through the material. This is not the case for the plastic biohazardous waste bags. Sharp items include, but are not limited to, safety-engineered lancets. [For an MIS, glass slides, cartridges and pipettes should be considered sharps]. To protect both the biomarker technicians and the respondents, safety-engineered lancets are used to reduce exposure to blood and injuries. These lancets are one-time use and thus, the blade permanently retracts into the casing after being triggered. However, if these lancets are tampered with after use (i.e., taken apart), it is possible to recover the blade inside the casing, so we place lancets inside the sharps container. Unlike the biohazardous waste bag, items cannot be recovered from the sharps container once they are sealed.

**Note: you should NEVER attempt to remove any biohazardous waste material once it is discarded in the biohazardous waste bag or sharps container!**

See the table below for sharps containers and their appropriate use.

Sharps Containers	Appropriate Use	Storage When Filled
<b>5 quarts (4.7 liters)</b>	Sharp biohazardous waste from a cluster	Store at the team space until disposal at a local health facility

All sharps containers recommended by The DHS Program have a fill line printed on the outside.

Do not fill the sharps containers with material past this line. Sharps containers once sealed cannot be reused. So once a sharps container is filled, close the lid and dispose of at a designated health facility. Start each cluster with a new sharps container even if the last sharps container from the previous cluster has yet to reach the fill line.

***Sharps container labels***



**5.C. Procedures for disposal of biohazardous waste**

Biohazardous waste is generated at three stages during the [YEAR] [COUNTRY] MIS: during the training, during field practice, and during fieldwork. Prior to generating any biohazardous waste, [Implementing Agency] in partnership with the [Ministry of Health, NACP or other country specific agencies] must identify health facilities that will dispose of the biohazardous waste collected according to [Country] national standards. A list of these health facilities and their contact information should be provided to the team supervisors by the [implementing agency] along with a letter from the MOH detailing the mission of the survey, introducing the team, and outlining the services needed from that facility.

At the end of training and after each blood collection within the household, all the non-sharps materials used during the testing (i.e., gloves, alcohol swabs, and gauze pads) are to be placed in a 2-3 gallon household biohazardous waste bag. All sharp materials (i.e., lancets and glass slides) are to be placed in the sharps container. All biohazardous materials should be immediately placed in the appropriate waste bag or container after use. For instance, once you have pricked the finger or heel with the lancet, you should place the lancet directly into the sharps container, do not place the lancet back on the absorbent sheet.

Before proceeding to a new cluster, team supervisors should identify (from the list of facilities provided by [implementing agency]), the local health facility where the waste can be safely destroyed. Team supervisors should contact the health facility prior to or soon after entering the cluster to introduce themselves and inform the local health facility that the team intends to dispose of the biohazardous waste from the cluster(s) there. One health facility may be used for the disposing of waste from multiple clusters; hence it is considerate to inform the local health facility ahead of time.

## **5.D. Methods of destroying/decontaminating biohazardous waste**

It is likely that the local health facilities identified by the government for safe disposal of biohazardous waste during the [YEAR] [COUNTRY] MIS will use one or a combination of the following methods to destroy or decontaminate the biohazardous waste. The two methods listed below are the best management options for solid infectious waste for small-scale activities.

### ***Incineration***

Incineration is the process of burning biohazardous waste and reducing the waste volume by about 80%. Incineration can take place in a chamber or drum/brick furnace. Through this method, 99% of microorganisms on biohazardous waste and contaminated sharps are destroyed. However, the sharps found in ashes can still pose a physical hazard. Open-air incineration is less effective at disinfecting and has the potential for incomplete burning (leaving behind infectious material), is more hazardous to the staff involved and runs a greater risk of unburned supplies being scavenged by people and animals.

### ***Autoclave***

Autoclaving is the process of sterilizing waste with steam treating at high temperature and pressure. In order to be effective, the steam needs to be able to penetrate the waste. Autoclaving can also be used to sterilize reusable medical waste. We do not autoclave and reuse any of the materials used in the [YEAR] [COUNTRY] MIS.

A few points to remember when you are collecting and storing biohazardous waste in the field:

- **NEVER** leave biohazardous waste in households
- Biohazardous waste should **NEVER** be disposed of in general solid waste containers or facilities
- Never store anything in the biohazardous waste bags or sharps containers other than biohazardous waste
- Once closed, the sharps containers cannot be reopened, so take care when moving through the field not to close the container prior to reaching the fill line



## Chapter 6. APPENDIX

### 6.A. Malaria brochure

replace with <b>LOGO</b>	[NAME OF SURVEY]	replace with <b>LOGO</b>	
Name of the Household Head: _____			
Name:	Name:	Name:	Name:
<i>Malaria diagnosis:</i>  Positive    Negative	<i>Malaria diagnosis:</i>  Positive    Negative	<i>Malaria diagnosis:</i>  Positive    Negative	<i>Malaria diagnosis:</i>  Positive    Negative
<i>TREATMENT FOR MALARIA PROVIDED:</i>  YES        NO	<i>TREATMENT FOR MALARIA PROVIDED:</i>  YES        NO	<i>TREATMENT FOR MALARIA PROVIDED:</i>  YES        NO	<i>TREATMENT FOR MALARIA PROVIDED:</i>  YES        NO
<b>TREATMENT WITH FIRST LINE: [FIRST LINE ACT]</b>			
Weight in KG	Age	Content	Dosage*
≥4.5kg < 9 kg	6-11 months	25 mg XX + 67.5 mg XX	1 tablet once a day for 3 days
≥9kg < 18 kg	1 - 4 years	50 mg XX + 135 mg XX	1 tablet once a day for 3 days
<small>* If the child has a fever for two days after completing the last dose of [FIRST LINE ACT], you should take him or her to a health professional for treatment right away</small>			
<p><b>⚠</b> If your child develops the following symptoms you should go to the health facility:</p> <ul style="list-style-type: none"> <li>• Extreme weakness</li> <li>• Loss of consciousness</li> <li>• Rapid or difficult breathing</li> <li>• Seizures</li> <li>• Jaundice or yellow skin</li> <li>• Dark urine</li> <li>• Abnormal bleeding</li> </ul>		<p>For questions concerning the survey please contact the following:</p> <p>National Malaria Control Program</p> <p>[NAME: CELL NUMBER]</p> <p>[NAME: CELL NUMBER]</p> <p>[OTHER RELEVANT AGENCY]</p> <p>[NAME: CELL NUMBER]</p>	

**6.B. Severe malaria referral**

**[COUNTRY] MALARIA INDICATOR SURVEY: Severe Malaria Referral**

During the YEAR COUNTRY MIS \_\_\_\_\_ (Name), age \_\_\_\_  
months / years, was tested for malaria on \_\_\_\_/\_\_\_\_/\_\_\_\_, with a Rapid Diagnostic Test (RDT).

He/she tested positive for malaria, and is displaying the following signs of severe malaria:

\_\_\_ EXTREME WEAKNESS

\_\_\_ HEART PROBLEMS

\_\_\_ LOSS OF CONSCIOUSNESS

\_\_\_ RAPID OR DIFFICULT BREATHING

\_\_\_ SEIZURES

\_\_\_ ABNORMAL BLEEDING

\_\_\_ JAUNDICE OR YELLOW SKIN

\_\_\_ DARK URINE

He/she appears to be very ill and did not receive treatment for the malaria. **THIS CHILD NEEDS TO BE TAKEN TO A HEALTH FACILITY RIGHT AWAY.**

## 6.C. Slide transmittal form

**[YEAR] [COUNTRY] [MALARIA INDICATOR] SURVEY**  
**MICROSCOPE SLIDE TRANSMITTAL FORM (FRONT SIDE)**

[FIELDWORKER] NUMBER <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px; margin-bottom: 2px;"></div> <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px; margin-bottom: 2px; margin-left: 5px;"></div> <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px; margin-bottom: 2px; margin-left: 5px;"></div> <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px; margin-bottom: 2px; margin-left: 5px;"></div>	CLUSTER NUMBER <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px; margin-bottom: 2px;"></div> <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px; margin-bottom: 2px; margin-left: 5px;"></div> <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px; margin-bottom: 2px; margin-left: 5px;"></div>
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PERSON SENDING/ RECEIVING SAMPLES	TIME TO FILL IN FORM	TOTAL COUNT OF MICROSCOPE SLIDES	SIGNATURE (CONFIRMING THAT EACH SLIDE IS PRESENT - SEE BACK OF FORM)	SIGNATURE (CONFIRMING COUNT OF MICROSCOP SLIDES IN COLUMN 3)	DATE	NOTES (NOTE ANY DISCREPANCY IN NUMBERS OF SLIDES)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
BIOMARKER TECHNICIAN	AFTER BIOMARKER TECHNICIAN HAS DONE HIS/ HER COUNT	<div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div>				
TEAM SUPERVISOR	WHEN CLUSTER IS COMPLETED	<div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div>				
FIELD COORDINATOR	WHEN SAMPLES ARE PICKED UP IN FIELD	<div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div>				
LAB	UPON ARRIVAL AT LAB	<div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div>				

### INSTRUCTIONS

**BIOMARKER TECHNICIAN:** Upon completion of a cluster, verify that the barcode label on each slide collected in that cluster corresponds to a barcode label pasted to the back of this transmittal form and vice-versa. Note any discrepancies in Column (7). Count and record the total number of blood smears (slides) in Column (3). Sign your name in Column (4) and record the date in Column (6). Fold and store this transmittal form in the Ziploc bag with the box containing the slides.

**TEAM SUPERVISOR:** After the biomarker technician has verified the slides, the team supervisor will conduct a second verification. Verify that the barcode label on each slide collected in that cluster corresponds to a barcode label pasted to the back of this transmittal form and vice-versa. Note any discrepancies in Column (7). Count and record the total number of slides in Column (3). Sign your name in Column (4) and record the date in Column (6). Fold and store this transmittal form in the box containing the slides.

**FIELD COORDINATOR:** Before returning to the laboratory with the slides, you will count and record the total number of blood smears (slides) in Column (3). Sign your name in Column (5) and record the date in Column (6). Note any discrepancies in Column (7). Fold and store this transmittal form in the box containing the slides.

**RECEIVER AT THE LABORATORY:** Upon receiving the blood smears (slides) from the [FIELD COORDINATOR], verify that the barcode label on each blood smear (slide) collected in that cluster corresponds to a barcode label pasted on the back of this transmittal form and vice-versa. Count and record the total number of slides in Column (3). Sign your name in Column (4) and record the date in Column (6). Note any discrepancies in Column (7) and inform the [IMPLEMENTING AGENCY].

**Note:** This form will be destroyed under the direction of the Lab Director after all blood smears have been stained and read and a final result has been determined for each usable sample.

[YEAR] [COUNTRY] [MALARIA INDICATOR] SURVEY  
 BLOOD SMEAR (SLIDE) TRANSMITTAL FORM (BACK SIDE)

CLUSTER NUMBER

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NO.	SLIDE BAR CODE	TECH.	LAB		NO.	SLIDE BAR CODE	TECH	LAB
1				:	17			
2				:	18			
3				:	19			
4				:	20			
5				:	21			
6				:	22			
7				:	23			
8				:	24			
				Fold here				
9				:	25			
10				:	26			
11				:	27			
12				:	28			
13				:	29			
14				:	30			
15				:	31			
16				:	32			