

Standard Operating Procedures for the LAKANA trial  
**SOP Proc-07 Preparation of sample collection material for DBS, stool samples, and CRP and Hb**

Version 1.0. (2022-03-15)

**1. Purpose and overview:**

This Standard Operating Procedure (SOP<sup>1</sup>) describes how to assemble a sample pack for the collection of dry blood spot (DBS) samples in the mechanistic sub-study (MDA4) of the LAKANA trial.

**2. Applicability to and responsibilities of various staff members**

Staff member	Responsibility
Laboratory technician/scientist	<ul style="list-style-type: none"> <li>- Maintaining enough materials and reagents</li> <li>- Preparing reagents</li> <li>- Preparing the sampling packs</li> <li>- Keeping track of expiry dates</li> <li>- Sending the sampling packs to sample collection team</li> </ul>

**3. Required materials**

Item	Number	Specification
QuikRead go® instrument	1/field team	For measuring CRP+Hb. AIDIAN
Extra battery	1	For QuikRead go® instrument
QuikRead go® wrCRP+Hb reagent kit box	<i>Number required to meet the daily target</i>	For measuring CRP and Hb. 1 kit includes 50 tests with capillaries (10 µl) and plungers. Storage of unopened kit at 2-25°C until the expiry date of the kit. Unopened cuvettes after opening the foil pouch: storage at 2-8°C for 6 months, storage at 18-25°C for 3 months.
Lancet for heel prick blood collection	1 lancet/participant <i>Number required to meet the daily target</i>	For making the skin incision for DBS sample collection and blood for measuring CRP and Hb. Blood lancets VITREX® STERIHEEL® Baby II, 2.00 x 3.00 mm
Alcohol wipes	2 wipes/participant <i>Number required to meet the daily target</i>	For cleaning the skin before and after the blood prick tests (CRP+Hb and DBS on DBS card)

<sup>1</sup> Abbreviations: CRP = C-reactive protein, DBS = Dry blood spot, Hb = Hemoglobin, LAKANA = Large-scale assessment of the key health-promoting activities of two new mass drug administration regimens with azithromycin, MDA = Mass drug administration, SOP = Standard operating procedure,

Item	Number	Specification
Adhesive bandage/plaster	1 /participant <i>Number required to meet the daily target</i>	Adhesive bandage 19x72 mm
QuikRead go® wrCRP control	1	Unopened vials at 2-8°C until the expiry date. Opened vial at 2-8°C up to two months.
QuikRead go® Hb control	1	Unopened vials at 2-8°C until the expiry date. Opened vial at 2-8°C up to one months.
Dry blood spot card	<i>Number required to meet the daily target</i>	For collecting dry blood spot and later malaria PCR analyses. PerkinElmer PKI RUO Spot Saver Card
Dry Rak	<i>Number required to meet the daily target</i>	Whatman 903 DRY RAK with Velcro, safely and properly air-drying multiple collected DBS specimen cards in a suspended horizontal position.
Indicating desiccant packet	1 desiccant/zip lock bag <i>Number required to meet the daily target</i>	QIAGEN WB100003, 1 g, to keep the DBS card dry in the bag during transport/storage. Desiccant change from blue to pink to indicate absorption of moisture.
Plastic zip lock bag	1/DBS card	To pack DBS card for transport.
Stool container	<i>Number required to meet the daily target</i>	For collecting whole stool sample. Sterile Faeces Container includes a spoon, 60ml (red cap with a spoon)
Disposable diaper	1 diaper/participant <i>Number required to meet the daily target with different size</i>	For collecting whole stool sample. Muumi 2-5 kg, 5-8 kg and 7-14 kg
Nappy liner	1 sheet/participant <i>Number required to meet the daily target</i>	For collecting whole stool sample.
Extra bag of DBS cards	1 bag/village	Extra bag of DBS cards – one bag of DBS cards (20pcs) for DBS specimen collection
Extra bag of desiccant	1 bag/village	Extra bag of desiccants – one bag of desiccants (20pcs) for DBS specimen collection
Extra bag of stool containers	1 bag/village	Extra bag of stool containers (10pcs) for whole stool specimen collection

Item	Number	Specification
Disposable gloves	Change as needed	None
Printed barcode label	1 printed label/ stool container (126 labels/ sheet) <i>Number required to meet the daily target</i>	For collected whole stool sample, the nurse will affix the label to the contained when received in pop-up facility and fill the participant information and scan the barcode (or manually enter if scanning is not working) to tablet
Disinfectant	500 – 1000 mL	10% bleach and 70% ethanol

#### 4. Definitions and general instructions

##### 4.1. Definitions

- 4.1.1.** Laboratory technician/Scientist: a LAKANA staff member responsible for AMR and mechanistic sub-study sample collection, sample log and arranging transport to the laboratory.

##### 4.2. General Instructions

Diagram on how to assemble DBS specimen collection pack

Dry blood spot card - PerkinElmer  
PKI RUO Spot Saver Card

Indicating desiccant packet  
- QIAGEN WB100003, 1 g



#### 5. Step-by-step procedures

##### 5.1. Assembling of DBS sample collection bag

- 5.1.1.** Label 1 zip bag with “DBS”.

**5.1.2.** Place 1 dry blood spot card (PerkinElmer PKI RUO Spot Saver Card) and 1 desiccant packet (QIAGEN indicating desiccant packet, 1g) in a zip bag and close, making sure all bags have the two material mentioned above.

**5.1.3.** The collection bag is now ready.

## **5.2. Assembling of extra bags of DBS cards, desiccants and stool containers**

**5.2.1.** Label 1 zip bag with ‘extra DBS card’.

**5.2.2.** Place 20 individual dry blood spot cards (PerkinElmer PKI RUO Spot Saver Card) in the labelled ‘extra DBS card’ bag and close.

**5.2.3.** Label 1 zip bag with ‘extra desiccant’.

**5.2.4.** Place 20 desiccants (QIAGEN indicating desiccant packet, 1g), in the labelled ‘extra desiccants’ bag and close.

**5.2.5.** Label 1 plastic bag with “extra stool container”

**5.2.6.** Place 10 stool container (Sterile Faeces Container includes a spoon, 60ml, red cap with a spoon), in the labelled ‘extra stool container’ bag and close.

## **6. Occupational Safety Issues**

All study team members undertaking this SOP must be trained in good clinical laboratory practice.

## **7. Quality Assurance / Quality Control**

All involved study personnel who will prepare the sample bags will undergo practical training. Study personnel will not be approved to assemble bags until a supervisor has assessed their competency and signed off in the training log.

## **8. Version history, authors and approvals**

<b>Version (date)</b>	<b>Edits to the SOP text (author)</b>
0.1 (2022-03-01)	Authored by Yuemei Fan, Rikhard Ihamuotila, Dagmar Alber, Jane Juma and Awa Traore.
1.0 (2022-03-15)	Authored by Yuemei Fan, Rikhard Ihamuotila, Dagmar Alber, Jane Juma and Awa Traore.