## **KENYA MEDICAL SUPPLIES AUTHORITY**

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All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

KEMSA/OIT10/2021-2023

Date: 17th September, 2021

**CLARIFICATION 3** 

To: All bidders,

Dear Sir/Madam,

REF: TENDER NO: KEMSA/OIT10/2021-2023: - FOR SUPPLY OF LABORATORY CONSUMABLES

The following questions were raised by interested bidders and responses provided:

## **QUESTION 1:**

Item No-29-NL05TES117- Hepatitis B (HBsAg) Test strips- clarification 2 stated it is rapid test kits not ELISA please give us the specifications for the rapid kit.

#### RESPONSE

(See attached appendix 1)

## **QUESTION 2:**

All the items are grouped as Lot 1, Can we bid for a single item?

#### RESPONSE

For the lotted items (Lot 1), tenderers will be required to tender for both items as they will be awarded to one tenderer.

## **QUESTION 3:**

As per the attached technical specification for item no. 5-EDTA-K Blood Collection Tubes (Purple) 4mls:

a) The specifications are not clear, please send clear specifications as the page is cut from the edges as seen in the attached.

#### **RESPONSE**

(See attached appendix 2)

b) Packaging is for a pack of 1000's, while our standard packaging is for a pack of 100's. Please clarify.



## RESPONSE

Packaging required is 100x 10 packs to make a Thousand not more for easier marketing to our customers

Submit a pack of 100's with all manufacturer details for evaluation

c) The tender specification states that: "Manufacturer's instructions for use must be on the tube"

Please note that the tube size is 13x75mm and our tube label size is 46x19mm which accommodates all the necessary required information. The label size does not suffice to have the instructions for use on the tube but we can include instructions for use in the secondary packaging

#### **RESPONSE**

The manufacturer's user instructions must be briefly on the final product for friendly use during blood sample collection

## **QUESTION 4:**

Item No. 15 – Stool Occult Blood Test – In the Price Schedule Form, UOM is Pack of 20s while in the Specifications, packaging is 100s. Please clarify.

## **RESPONSE**

Submit a pack of 20's for evaluation

Yours faithfully

EDWARD BULUMA

FOR: AG. CHIEF EXECUTIVE OFFICER

#### APPENDIX 1

# Hbasg strips tests technical specifications

Pack of 100 tests or per manufacturers unit of Measures

Packed in moisture proof aluminum foil that remains sealed until immediately prior to use.

Method of detection: Lateral Flow

Detection: invitro, visually read, qualitative immunoassay for the detection of antibodies to Hepatitis B

Immunochromatographic

Sample type: Test suitable for whole blood, serum and plasma

Sensitivity - Minimum 99%

Specificity -minimum 99%

Results in 5-30 minutes or less

Inserts of relevant literature, including pictorial description of test preparation, explaining the test procedure, reading and interpretation of results and storage conditions

Shelf-life: Upon delivery of the product, it should have remaining shelf life of at least 75 %.

Bidders to provide 1 pack for evaluation

Should use diluent or Chase buffer -1 per Kit

Capillary tubes-100pcs per kit

Lancet provided

Labeling should be in English•Must be evaluated locally by KMLTTB

Bidders to provide 1 full kit for evaluation

**PACKAGING** 

All packaging to be labelled "GOK-Not for Sale"

Manufacturer's Name and Address, Country of Origin, Model Number or Name

Should conform to KEBS/ISO standards or equivalent2Hepatitis B vaccine1 Vial per Pack

Sterile suspension purified

Non-infectious major surface antigen of the hepatitis-B virus.

Cesium chloride free

Uses Recombinant DNA technology

Bidders to provide 1 pack for evaluation

FDA or WHO-prequalified



# APPENDIX 2

ITEM	SPECIFICATION	
DESCRIPTION		
	EDTA RI OOD	COLLECTION TUBES
EDTA-K Blood Collection Tubes (Purple) 4mls	Charles (All Charles Self Self Self Self Self Self Self Self	
	Drawing volume	Capacity of 4 mL
	Size in mm	13x75mm
	Туре	Vacuum tubes
	Color code	Lavender cap
	Tube cap	Slip-on type of cap for one-hand opening.
		Should have a rubber stopper which is recessed inside an outer plastic
		shield.
		Outer plastic shield must not separate from the rubber on opening the tube.
		Manufacturer's instructions for use must be on the tube
		Temperature range should be indicated on the final product (tube)
		The pack of 100 should be packed in well holding material
	Additives	Di-potassium EDTA salt ( K2EDTA) dry spray coated
	Material	Made of transparent Polyethylene Terephthalate (PET)
	Clotting time	Not clotting
	Operational features	
	Operating	2-25°C
	temperature	
	Storage	4-25°C (RT)
	condition	
		Printed with all necessary information (Manufacturer, Mfg&Exp.date,
	Label type	Batch/Lot number.

