health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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HM09-2014RTK: SUPPLY AND DELIVERY OF RAPID HIV TEST KITS TO THE DEPARTMENT OF HEALTH FOR PERIOD 1 APRIL 2014 T0 31 MARCH 2017

1. The attached contract circular for your information.

2. This contract will be subject to the General Conditions of Contract issued in accordance with Chapter 16A of the Treasury Regulations published in terms of the Public Finance Management Act, 1999 (Act 1of 1999). The Special Conditions of Contract are supplementary to that of the General Conditions of Contract. Where, however, the Special Requirement and Conditions of Contract are in conflict with the General Conditions of the Contract, the Special Requirements and Conditions will prevail.

2. The following provincial Departments of Health will participate in this contract

PARTICIPANTS	CONTACT PERSONS	TEL NO	FAX NO
National Department of Health	T Chidarikire – Director HIV Prevention J Honwani – Acting Director HCT	012 395-9153 012 395-9187	086 632 2443
Eastern Cape	X Somahela -Hast Manager L Lunyawo - HCT Contact R Harris - Pharmaceutical Depot)	(040) 608 1223 (040 608-1734 (041) 408-9814	086 505 2871
Free State	Y Tsibolane - Hast Manager T Stofile - HCT Contact K Mosikare - Pharmaceutical Depot	(051) 408 1429 (051) 408-595 (051) 411 0544	(051) 430-5344
Gauteng	N Mmope - Hast Manager L Katane - HCT Contact D Malele - Pharmaceutical Depot	(011) 355 3340 (011) 355 3029 (011) 628 9001	(011) 628- 9130

Kwa Zulu -Natal	Dr T Mayise - Hast Manager) T Ndabandaba - HCT Contact D Ogunsanwo - Pharmaceutical Depot	(033) 341-4001 (033) 341-4018 (033) 846-7269	 (033) 846-7280
Limpopo	E Kobola - Hast Manager M Makwela - HCT contact S Rasekele - Pharmaceutical Depot	0823490310 (015) 293 6000 (015) 223 9000	 086 604 7766
Mpumalanga	E Nkosi - Hast Manager R Mbi - HCT Contact B Thela - Pharmaceutical Depot	(013) 766- 3442 0713614721 ((013) 283 9002	 (013) 283- 9043
North West	T Isaacs - Hast Manager L Phuduhudu - HCT Contact S Mokgatlha - Pharmaceutical Depot	(018) 397- 2601 (018) 397- 2601 (018) 384 2977	 (018) 384 3529
Northern Cape	Ms.N Mazibuko - Hast Manager M Motlhaudi -HCT Contact H Bothma - Pharmaceutical Depot	053) 830 -0524 (053)830- 0517/ (053) 830 2784	 086 228 7074
Western Cape	J Arendse - Hast Manager M Dyeshana - HCT Contact N Mia - Pharmaceutical Depot	021- 4833334 021- 4839881T 021-483 5800	 (086) 6691294

H ZEEMAN
DIRECTOR: AFFORDABLE MEDICINES
For: DIRECTOR-GENERAL: HEALTH
DATE: 18.06.14

HM09-2014RTK: SUPPLY AND DELIVERY OF RAPID HIV TEST KITS TO THE DEPARTMENT OF HEALTH FOR PERIOD 1 APRIL 2014 T0 31 MARCH 2017

1. IMPORTANT GENERAL INFORMATION:

1.1 Please note that the delivered price is for the unit of measure (UOM) as offered. Units of Measure, National Stock Numbers and prices should be carefully matched when placing or executing orders.

1.2 All prices are inclusive of 14 % VAT.

1.3 All prices are on a delivered basis.

1.4 Should an order be placed by any institution other than the provincial medical depots, the validity of the order must first be confirmed with the relevant depot manager.

1.5 Contact persons and e-mail addresses indicated hereunder are to be used for contract enquiries and not for orders.

2. NAMES AND ADDRESSES OF CONTRACTORS AND CONTACT DETAIL

Supplier Name	**Supplier Code**	**Supplier Address**	**Contact Detail** **----------** **Telephone Number** **Fax Number**	**Contact Person** **E-mail Address**
Titima Medical (Pty) Ltd	V3G38	Po Box 7743 Halfway House 1685	Tel: 0861848462 Fax: 086 548 8956	Lincoln Phakisi lincolnp@titimagroup.com
Armada Health (Pty) Ltd	V0J09	PO Box 1869 Juksei	Tel: 011 706- 5500 Fax: 086 503 3900	Richard Wormersely armadahealth@telkom.net
Fit Health Care & Diagnostics (Pty) Ltd	V3EC1	PO Box 201422 Durban North 4016	Tel:031 564 -1396 Fax: 086 402-7799	Nomali Hlatswayo nomali@fithealthcare.co.za

Description	Split	Quantity awarded	Supplier Name	Supplier Code	Brand name	Delivered Price in ZAR	Lead Time (Days)	MOQ	Total Points	National Stock Number	Unit of Measure
HIV RAPID TEST KITS, highly sensitive and specific (≥ 99% Sensitivity and Specificity) for HIV-1 and HIV-2 antibodies. Refrigeration not required. Shelf-life of at least 12 months upon delivery. Kits of 25 test devices must contain sufficient buffer/diluent, 25 pipettes, 25 Lancets, 25 Swabs and a package insert with instructions. Kit of 25	Screening: According to provincial allocation	16 005 600	Titima Medical (Pty) Ltd	V3G38	One Step Advanced Quality	R100.50 per kit of 25 R4.0200 per test	7	1 Kit	90.00	18-191-6239	Single tests in kit
		12 074 400	Armada Health (Pty) Ltd	V0J09	Advanced Quality	R132.00 per kit of 25 R5.2800 per test	30	10 x 25 (250 tests)	66.79	18-191-6239	Single tests in kit
	Confirmation	10 920 000	Fit Healthcare & Diagnostics (Pty) Ltd	V3EC1	Abon	R285.00 per kit of 50 R5.7000 per test	25	1 Kit (50 pack size)	61.39	18-191-6240	Single tests in kit

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Special Requirements and Conditions of Contract

HM09-2014RTK

SUPPLY AND DELIVERY OF RAPID HIV TEST KITS TO THE DEPARTMENT OF HEALTH

FOR PERIOD

1 APRIL 2014 T0 31 MARCH 2017

VALIDITY PERIOD 120 DAYS

National Department of Health

CONTENTS

1. BACKGROUND

SPECIAL CONDITIONS OF CONTRACT

This bid and all contracts emanating there from will be subject to the General Conditions of Contract issued in accordance with Treasury Regulation 16A published in terms of the Public Finance Management Act, 1999 (Act 1 of 1999). The Special Conditions of Contract are supplementary to that of the General Conditions of Contract. Where, however, the Special Conditions of Contract are in conflict with the General Conditions of Contract, the Special Conditions of Contract will prevail.

2. EVALUATION CRITERIA

Preference Points System

a. In terms of regulation 6 of the Preferential Procurement Regulations pertaining to the Preferential Procurement Policy Framework Act, 2000 (Act 5 of 2000), responsive bids will be adjudicated by the Department of Health on the 90/10-preference point system in terms of which points are awarded to bidders on the basis of:

The bid price (maximum 90 points)

Broad Based Black Economic Empowerment (B-BBEE) status level of contributor (maximum 10 points)

b. The following formula will be used to calculate the points for price:

$$Ps = 90\left(1 - \frac{Pt - P\min}{P\min}\right)$$

Where

Ps = Points scored for comparative price of bid under consideration

Pt = Comparative price of bid under consideration

Pmin = Comparative price of lowest acceptable bid

A maximum of 10 points may be allocated to a bidder for attaining their B-BBEE status level of contributor in accordance with the table below:

B-BBEE Status Level of Contributor	Number of Points
1	10
2	9
3	8
4	5
5	4
6	3
7	2
8	1
Non-compliant contributor	0

c. Bidders are required to complete the preference claim form (SBD 6.1) in order to claim the B-BBEE status level points.

d. The points scored by a bidder in respect of the level of B-BBEE contribution will be added to the points scored for price.

e. Only bidders who have completed and signed the declaration part of the tender documentation may be considered.

f. The Department of Health may, before a bid is adjudicated or at any time, require a bidder to substantiate claims it has made with regard to preference.

g. The points scored will be rounded off to the nearest 2 decimals.

h. In the event that two or more bids have scored equal total points, the contract will be awarded to the bidder scoring the highest number of preference points for B-BBEE.

i. Should two or more bids be equal in all respects, the award will be decided by the drawing of lots.

j. A contract may, on reasonable and justifiable grounds, be awarded to a bid that did not score the highest number of points.

k. The Department of Health reserves the right to negotiate prices.

l. The Department of Health reserves the right not to award a line item.

3. PRE AWARD SUPPLIER DUE DILIGENCE

The Department of Health reserves the right to conduct supplier due diligence prior to final award. This may include site visits.

4. PARTICIPATING AUTHORITIES

The National Department of Health and the following Provincial Departments will participate in this contract:

a. Provincial Departments of Health: Eastern Cape, Free State, Gauteng, KwaZulu-Natal, Limpopo, Mpumalanga, Northern Cape, North West and Western Cape.

5. CONTRACT PERIOD

The contract period shall be for a period of 36 months commencing 1 April 2014 to 31 March 2017.

6. RESPONSE FIELDS

It is imperative that bidders submit responsive bids by completing all the mandatory response fields for the individual items. In this regard bidder's attention is drawn to the response field and price structure explanations and examples supplied in the bid document.

Non-compliance with this condition may invalidate the bid for the item/s concerned**.**

7. VALUE ADDED TAX

All bid prices must be inclusive of 14% Value-Added Tax.
Failure to comply with this condition may invalidate the bid

8. TAX CLEARANCE CERTIFICATE

An original and valid Tax Clearance Certificate issued by the South African Revenue Services certifying that the tax affairs of the bidder are in order must be submitted at the closing date and time of bid.

Copies or certified copies of the Tax Clearance Certificate will not be acceptable. Failure to comply with this condition will invalidate the bid.

9. AUTHORISATION DECLARATION AND DOCUMENTATION OF UNDERTAKING

9.1 DECLARATION OF AUTHORISATION

a. In the event of the bidder not being the actual manufacturer and will be sourcing the product(s) from another company (third party), a signed letter from the source company to the bidder committing to firm supply arrangement(s) for each item, including lead times in this regard, must accompany your bid at closing date and time. The Bid Authorization Form (Form AD1) must be completed and signed giving full details of the declaration of authorisation and be submitted with bid documents at the closing date and time of the bid.

b. The said company/manufacturer/supplier issuing such a letter must confirm that it has familiarised itself with the item description/specification, lead times and bid conditions and if the bid consists of more than one item, it should be clearly indicated in respect of which item(s) the supportive letter has been issued.

c. The Department reserves the right to verify any information supplied by the bidder in the Authorisation Declaration and should the information be found to be false or incorrect, the Department of Health will exercise any of the remedies available to it in the bid documents.

d. The bidder must ensure that all financial and supply arrangements for goods, including lead times, have been mutually agreed upon between the bidder and the third party. No agreement between the bidder and the third party will be binding on the Department of Health.

e. It must be indicated in the letter that all the terms and conditions are mutually agreed upon.

f. Failure to submit a duly completed and signed Authorisation Declaration, with the required annexure(s), in accordance with the above provisions may invalidate the bid for such goods offered.

9.2 DOCUMENTATION OF UNDERTAKING AND LEGISLATIVE REQUIREMENTS

a. The Bidder to provide evidence from their Manufacturer of operating under a quality management system

b. The Bidder must provide evidence of an agreement with the manufacturer to ensure that the post market requirements of ISO 13485 (Sections 8.2 Monitoring and

Feedback, Section 8.3 Control of Non-conforming Product and Section 8.5 Improvement) will be met.

c. Proof of Evaluation Information by the following organisations CDC (USAID list), WHO (**have completed at least the registration and two other stages**), FDA, CE marking. Only data for the product / brand appearing on the afore-mentioned lists will be accepted for traceability purposes (i.e. no re-branding of the original product)

d. It must be indicated in the letter that all the terms and conditions are mutually agreed upon.

9.3 NON COMPLIANCE

Non compliance with the above mentioned (Paragraphs 9.1 and 9.2) special conditions may invalidate the bid for such products offered.

10. CONTRACT ADMINISTRATION

a. Successful bidders must advise the Cluster Manager: Sector-Wide Procurement immediately when unforeseeable circumstances will adversely affect the execution of the contract. Full particulars of such circumstances as well as the period of delay must be furnished within a week of identifying such a problem.

b. The administration and facilitation of the contract will be the responsibility of National Department of Health and all correspondence in this regard must be directed to one of the following addresses:

Director: Affordable Medicine

Department of Health

Postal: Private Bag X828, Pretoria, 0001

Physical: Room 501 South Tower, 242 Struben Street, Pretoria, 0001

and

Director: HIV & AIDS and STI's Prevention Strategies

Department of Health

Postal: Private Bag X 828, Pretoria, 0001

Physical: Room 417 North Tower, 242 Struben Street, Pretoria, 0001

c. The Department of Health may communicate with bidders where clarity is sought after the closing date of the bid and prior to the award of the contract, or to extend the validity period of the bid, if necessary.

d. All communication between the bidder and the Department of Health must be done in writing.

e. Any communication to any government official or a person acting in an advisory capacity for the Department in respect of this bid between the closing date and the award of the bid by the bidder is discouraged.

11. COUNTER CONDITIONS

Bidders' attention is drawn to the fact that amendments to any of the Bid Conditions or setting of counter conditions by the bidders may result in the invalidation of such bids.

12. FRONTING

a. The National Department of Health supports the spirit of broad based black economic empowerment and recognizes that real empowerment can only be achieved through individuals and businesses conducting themselves in accordance with the Constitution and in an honest, fair, equitable, transparent and legally compliant manner. Against this background the National Department of Health condemns any form of fronting.

b. The National Department of Health, in ensuring that bidders conduct themselves in an honest manner will, as part of the bid evaluation processes, conduct or initiate the necessary enquiries/investigations to determine the accuracy of the representation made in bid documents. Should any of the fronting indicators as contained in the Guidelines on Complex Structures and Transactions and Fronting, issued by the Department of Trade and Industry, be established during such enquiry /investigation, the onus will be on the bidder/contractor to prove that fronting does not exist. Failure to do so within a period of 14 days from date of notification may invalidate the bid/contract and may also result in the restriction of the bidder /contractor to conduct business with the public sector for a period not exceeding ten years, in addition to any other remedies the National Department of Health may have against the bidder / contractor concerned.

13. PRODUCT COMPLIANCE

13.1 PRE AWARD PRODUCT COMPLIANCE PROCEDURES

The following pre-award product compliance procedures will apply:

a. Proof of Evaluation Information by one of the following organisations CDC (USAID list), WHO, FDA, European Union, USFDA, Australian TGA, Health Canada, Japanese PMDA

b. CE marking

c. ISO 13485 Certification

d. Test report from NICD

14. PRICE QUALIFICATION AND CONTRACT PRICE ADJUSTMENT PROCEDURE

14.1 Pricing Structure

a. Prices submitted for this bid will be regarded as non-firm and subject only to adjustment(s) in terms of the formula under paragraph 14.2, defined areas of cost and defined periods of time

b. Bidders should quote a final delivered price.

c. Prices quoted must be furnished on the basis of “delivered into store” country-wide

d. Bids must be for the supply ex duty paid stocks held in the Republic of South Africa during the contract period.

e. Prices quoted must be per unit as per specification of each item as advertised.

f. Prices submitted for this bid must be entered on the relevant fields on the bid response document.

g. Price structures that do not comply with this requirement may invalidate the bid.

14.2 PRICE ADJUSTMENTS

a. The Department of Health reserves the right to accept or reject any application for price adjustment

b. Bidders are required to complete the price breakdown in the relevant response fields as per diagram below. Failure to provide such breakdown may exclude the bidder from any price adjustments during the contract period.

Cost component (For fully imported or finished products offered from another manufacturer, materials and manufacturing components may be combined)		**% of total product value** (values in this column must add up to 100%)	**Value** (Value for "% imported" and "% local" must add up to 100% for each cost component)	
			% imported	**% local**
Cost of raw materials				
Manufacturing cost	Labour			
	Other			
Transportation cost	Fuel		N/a	
	Freight			
Margin			N/a	N/a

c. Applications for price adjustments must be accompanied by documentary evidence in support of any adjustment.

d. The process for price adjustment will be as follows:

- Identify the cost component(s) to be adjusted. Margins above cost cannot be adjusted, thus eligible cost components include:
  - Cost of raw materials
  - Costs related to manufacture (labour and other)
  - Costs related to transport (fuel and freight)
- Calculate price adjustment using the following formula:

$$Pa = Pt\left(D_A \frac{R_{A1}}{R_{A0}} + D_L \frac{R_{L1}}{R_{L0}} + D_M \frac{R_{M1}}{R_{M0}} + D_T \frac{R_{T1}}{R_{T0}} + D_F \frac{R_{F1}}{R_{F0}} + PM \right)$$

Pa	=	The new adjusted price to be calculated
Pt	=	Original bid price. Note that Pt must always be the original bid price and not an adjusted price
D_A	=	The proportion of the award price attributable to raw materials
R_{A1}	=	New cost of raw materials

R_{A0}	=	Base cost of raw material
D_L	=	The proportion of the award price attributable to labour
R_{L1}	=	New cost of labour
R_{L0}	=	Base cost of labour
D_M	=	The proportion of the award price attributable to manufacturing costs - other
R_{M1}	=	New cost of manufacturing costs - other
R_{M0}	=	Base cost of manufacturing costs - other
D_T	=	The proportion of the award price attributable to fuel
R_{T1}	=	New cost of fuel
R_{T0}	=	Base cost of fuel
D_F	=	The proportion of the award price attributable to freight
R_{F1}	=	New cost of freight
R_{F0}	=	Base cost of freight
PM	=	The proportion of the award price that is attributable to margin above cost; **this variable is not adjustable**

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e. Costs associated with normal business risk are not eligible for adjustment, but unforeseen costs that may impact continuous supply will be considered.

f. Applications for price adjustments may be submitted by the half-yearly review dates stipulated in section 14.3 and must be accompanied by documentary evidence of the circumstances that are claimed to warrant a price adjustment.

g. Information required to assess price adjustment requests is as follows:

- For adjustments related to raw material price changes, suppliers must submit the following:
  - Documentation of the current cost of the raw materials
  - Documentation of the new cost of the raw materials
  - Supplier / Manufacturer invoice(s) and remittance advice(s)
- For adjustments related to manufacturing or transport price changes, suppliers must submit the following:
  - A description of why the adjustment is necessary
  - Documentation of the current cost of the cost component
  - Documentation of the new cost of the cost component
  - Relevant local indices (e.g. Stats SA PPI or transport index) will only be considered regarding applicable declared local content.

h. Successful bidders can apply for adjustments relating to one or more than one combination of the above factors.

i. Contracted suppliers are expected to continue to supply the product without interruption at the contracted price until advised of the outcome of a price adjustment application.

j. . No retroactive price increases will be permitted for purchase orders already issued to and accepted by the manufacturer.

k. Where the Department of Health is not satisfied with the documentation submitted, it could grant a lower adjustment or deny the request altogether.

l. All requests for price adjustments will be based on the original award price – and not on any previously adjusted price.

m. Should the Department of Health choose to initiate a price adjustment (decrease) for a particular product, the following factors will be taken into account to determine the revised prices:

- Material reductions in the cost of the raw materials, as determined by a composite index of raw materials linked to international prices for products in question;
- Other material reductions in the cost of production based on changes in technology or alternate routes of production becoming available or substantially higher volumes than anticipated resulting in a drop in fixed manufacturing costs.
- Known substantial drops in international freight or fuel prices.

n. The applicable index refers to the relevant market index, which is a true reflection of price movement(s) in the cost over time. The base index date applicable to the formula is defined as a date at which the price adjustment starts. In this bid the base index date is November 2014.

14.3 PRICE ADJUSTMENT PERIODS

Adjustment to contract prices may be applied for at the following dates:

Adjustment	**Application for price adjustment to reach the office by the following dates**	**Dates *from* which adjusted prices will become effective**
1st Adjustment	5 November 2014	1 December 2014
2nd Adjustment	5 May 2015	1 June 2015
3rd Adjustment	5 November 2015	1 December 2015
4th Adjustment	5 May 2016	1 June 2016

14.4 RATES OF EXCHANGE (RoE) – BASE AND AVERAGE RATES

In the event where material and/or finished products are imported the following will apply:

a. The formula described in par. 14.2 will be used and ONLY the imported cost component of the bid price will be adjusted taking into account the base RoE and the average RoE rate over the period under review indicated in paragraph (d) below.

b. Rate(s) of exchange to be used in this bid in the conversion of the price of the item(s) to South African currency.

Currency	**Rates of exchange** Average for the period 1 May 2013 to 31 October 2013
US Dollar	R 9.8776
Pound Sterling	R 15.3761
Euro	R13.0999

c. Should the bidder make use of any other currency not mentioned above, the bidder is requested to calculate the average for the period 1 May 2013 to 31 October 2013 using the South African Reserve Bank published rates for the specific currency. Visit www.reservebank.co.za to obtain the relevant rates.

d. Contract price adjustments due to rate of exchange variations are based on average exchange rates as published by the Reserve Bank for the periods indicated hereunder:

Adjustment	Average exchange rates for the period:
1st Adjustment	3 March 2014 – 31 August 2014
2nd Adjustment	1 Sept 2014 – 28 February 2015
3rd Adjustment	2 Mar 2015 – 31 August 2015
4th Adjustment	1 Sep 2015 – 29 Feb 2016

14.5 GENERAL

a. Unless prior approval has been obtained from National Department of Health, no adjustment in contract prices will be made.

b. Contract Price Adjustment (CPA) applications will be applied strictly according to the specified formula and variables above as well as the cost breakdown supplied by successful bidders in their bid documents.

c. In the event where the supplier's CPA application, based on the above formula and parameters, differs from National Department of Health's verification, National Department of Health will consult with the supplier to resolve the differences.

d. Bidders are referred to paragraph 11 of the Special Conditions regarding counter conditions.

e. An electronic price adjustment calculator will be made available on the Department of Health's website and will be communicated.

15. QUANTITIES, ORDERS AND DELIVERY

15.1 DELIVERY ADHERENCE

a. For each product, bidders must explicitly indicate in the response fields the minimum and maximum volumes that they can supply on a monthly, quarterly (3-monthly) and annual basis.

b. Bidders must indicate and provide assurance of ability to maintain delivery lead time (time from placement of the order to delivery at the identified delivery point) for the duration of the contract in compliance with paragraph 28.

c. Products must be evaluated by NICD on arrival in the country (1 box per batch) and results of the evaluation must be sent to NDoH for approval before distribution of test kits to provinces.

d. Products must have the same batch number on the outer box as the inner boxes.

e. Delivery of products must be made in accordance with the instructions appearing on the official order forms emanating from the above mentioned Participating Authorities and institutions placing the orders.

f. All deliveries or dispatches must be accompanied by a delivery note stating the official order number against which the delivery has been effected.

g. In respect of items awarded to them, contractors must adhere strictly to the delivery periods quoted by them in their bids.

h. The instructions appearing on the official order form regarding the supply, dispatch and submission of invoices must be strictly adhered to.

i. All invoices should be delivered / posted to reach the institution that placed the order timeously. The invoices should be original and accompanied by proof of delivery.

j. Deliveries must be in accordance with official orders and any deviation will be returned to the contractor at the contractor's expense.

k. Deliveries must conform to cold chain distribution requirements, if applicable. Normal storage conditions (25 degrees Celsius) must not be exceeded.

15.2 QUANTITIES AND ORDERS

a. The ordered quantities are required for delivery as indicated by the particular participating departments.

b. Suppliers should under no circumstances deviate from the orders issued by the departments.

c. The Department of Health is under no obligation to purchase any stock, which is in excess of the indicated quantities for any item.

d. The quantity indicated against each item represents the total estimated off-take of all participating departments as per paragraph 4.

e. Bidders should note that the order/s will be spread out throughout the contract period and that delivery points will be to the individual Provincial Depots or institutions.

f. Bids must be for supply ex duty paid stocks held in the Republic of South Africa during the contract period.

g. The quantities reflected in the bid documents are estimated quantities and no guarantee is given or implied as to the actual quantity which will be ordered.

h. The Department of Health also reserves the right to purchase its requirements elsewhere outside the contract in terms of clause 21 of the General Conditions of Contract if:

- Minimum order quantity specified by the contractor be more than that of the purchaser's requirements
- The item(s) are urgently required and not immediately available
- An emergency arises
- If the contractor fails to perform in terms of this contract

i. The Department of Health reserves the right to allocate products for screening and for confirmatory purposes.

j. The Department of Health reserves the right to arrange contracts with more than one contractor for the same item but not exceeding six contractors subject to the following condition:

- In a split or multiple awards a single bidder will not be awarded more than one portion for the same line item.
- The Department of Health reserves the right not to split award amongst bidders using the same source and / or manufacturer.

k. The allocation of volumes between two suppliers will be determined based on the difference in points, as follows:

Category	Difference between points	Recommended percentage split
A	Equal points	50/50
B	0,1% – 5 %	60/40
C	5,1% - 10%	70/30
D	10,1% – 20 %	80/20

l. The Department of Health reserves the right to determine the number of awards per line item.

m. For multiple awards of the same item to three or more bidders the volume will be allocated according to the following formula in line with paragraph 15.2 k:

Supplier portion = [1/N * 100]% + [Supplier score – Mean score] *0 .23 %

where N= the number of bids accepted.

n. The Department of Health reserves the right to invite bids on supplementary tender should it be necessitated by developing circumstances.

15.3 MANUFACTURING INFORMATION

Bidders must disclose the manufacturing site(s) as well as suppliers of raw material.

Bidders must be able to substantiate their bid price.

16. SAMPLES

a. Do not submit samples to the National Department of Health.

b. A sample must be submitted for testing to the National Institute of Communicable Diseases (NICD) before the closing date and time of bid. The purpose is to obtain a test report for the items being offered in the bid.

c. Samples for initial assessment must be submitted to the National Institute for Communicable Diseases (NICD) by closing date and time of bid. Samples must be placed in a clear plastic bag and marked on the outside with the bid number, item number and bidder's name.

d. Samples must be submitted to: National Institute for Communicable Diseases (NICD) 1 Modderfontein Road, Sandringham, 2131, for attention: Dr Adrian J. Puren, tel: 011-386 6328 fax: 011 386 6333.

e. The NICD requires 900 samples for both the initial assessment and full evaluation from all bidders to conduct sample evaluation.

f. Successful bidders on the initial assessment evaluation will be contacted by contract management to submit further samples if need be for full evaluation within 10 working days.

g. Samples of all products accepted against this bid will be retained for the duration of the contract period.

h. Proof of submission of samples obtainable from the NICD should be submitted with the bid at the time and close of the bid.

i. Test reports should be issued in the name of the bidder. Should the test report be issued in the name other than that of the bidder, such test reports must be accompanied by a letter of authority from the manufacturer / authorising importer.

j. Unsuccessful bidders who have submitted samples must collect such items within 3 months of the commencement of the contract. Samples not collected within this 3 month period will be disposed off at the discretion of the Department.

k. The successful bidders must submit a further 150 samples for post marketing surveillance at their cost. Any batch that does not comply with the post marketing surveillance cannot be distributed.

l. Marking of samples for submission to testing institutions should be done according to the following requirements:

- Samples must be placed in suitable containers and be clearly marked on the outside with the bid number(s), and the bidder's name.

m. Failure to comply with these conditions may invalidate the bid against the relevant item.

17. STANDARDS FOR TESTING OF SAMPLES

a. Items must comply with standards as stated in the specification documents and as stated in paragraph 9.2.

b. Manufacturers and suppliers of rapid HIV test kits shall follow an appropriate code of quality management, including good quality management system as required in the manufacturing and packaging of the products.

c. Labelling shall be performed in accordance with specification of products in Annexure A.

18. CONTAINERS

The function of a container is to maintain the quality, safety and stability of its contents. The condition of container must be acceptable to purchaser at the point of delivery. The materials of construction should have no chemical or physical effect on the product. Containers should withstand the mechanical hazards of handling, transport and storage, prevent leakage and provide appropriate level of protection to the environmental conditions or contact with metal.

19. BARCODES

a. The packaging of all products supplied to the Department of Health must include a barcode (number plus symbology). Both the outer case and the specification pack must be marked with the appropriate number and symbology. The European Article Numbering Code 13 (EAN 13) has been accepted as the standard. The batch number and the expiry date should be included in the barcode, if possible.

b. Bidders who are already in possession of the necessary block of numbers are requested to submit the EAN 13 numeric code(s) for each of the products offered as well as the outer case coding applicable to the distribution pack(s) (ITF 14) together with the quantity of items contained in such packs.

20. INSPECTIONS

a. The purchaser, as part of the purchase agreement and before delivery of the product, must approve any variance in the properties for compliance with specification requirements in Annexure A

b. Packaging will be tested for compliance by inspection. Inspections or verifications will generally be carried out at the pre-qualification stage, lot-by-lot compliance testing and during periodic inspections / audits.

21. QUALITY

Quality assurance requirements of the Rapid HIV test kits shall comply with those indicated in the products specification in Annexures A.

22. PERFORMANCE REQUIREMENTS

Performance requirements of Rapid HIV test kits shall comply with those indicated in the products specification in Annexure A.

23. SHELF-LIFE

Where applicable, products, upon delivery must have at least greater or equals to 12 months of shelf-life before date of expiry..

24. MANUFACTURING INFORMATION

a. Bidders must disclose the manufacturing site(s)

b. Any intention to change the manufacturing source prior to the commencement of the contract or during the lifetime of the contract must be approved by the Bid Adjudication Committee, National Department of Health.

25. PACKAGING

a. Products must have the same batch number on the outer box as in the inner box

b. The number of “PACK” items in the commercial packing must appear on the bid documents. The packaging must be uniform for the duration of the contract period, i.e.:

- The number of “PACK” items per commercial packing.
- The number of commercial packing per carton.
- The number of cartons per bulk packing.
- The condition under which the product must be stored.

c. The following information shall be clearly and indelibly printed on all inner and outer bulk packaging and containers in letters not less than 10pt in height:

  - the description and quantity of the contents;

- The expiry date; where only numerals are used the year shall be given in four digits;
- The batch identification, prefixed by the word "LOT";
- The trade name or trademark of the manufacturer; and
- A product code as relevant.

d. All containers, packing and cartons must be clearly labelled.

e. Care should be taken to assure that the packaging (presentation) of products as samples be those supplied by the manufacturer.

26. POST AWARD PRODUCT COMPLIANCE PROCEDURES

Consignment/Batch Testing

a. All contractors /successful bidder must submit a further 150 samples for post marketing surveillance at their cost. Any batch that does not comply with the post marketing surveillance cannot be distributed.

b. It is compulsory for all winning Bidders to participate in the Post Marketing surveillance as follows:

Prior to any batches/lot numbers being distributed to testing sites the supplier will provide a minimum of 150 test devices of the final batch to the NICD for assessment.

I) No batch/lot number may be distributed in South Africa without the necessary Post Marketing Surveillance Report from the NICD.

II) A compulsory fee for the assessment will be applied by the NICD and paid for by the supplier

a. NDOH will circulate copies of these Post Marketing Surveillance certificates to all provinces prior delivery of any stock..

b. Test results are final and no requests for testing by other testing laboratories will be entertained by the Department of Health. Any performance failure will result in immediate and non-negotiable rejection of the batch.

27. COMPLIANCE TESTED STOCK LEVELS

a. Contractors will be required to have in-country, and immediately available for delivery, at least two month's compliance certified stock at the commencement date of the contract and this minimum stock level must be maintained through the end of quarter seven of the contract. (Stock level estimated from the anticipated requirements of the procurer and as indicated in the contract award unless

otherwise instructed in writing by the procurer). This stock level requirement for compliant product may be adjusted by the Department of Health to respond to changing programmatic requirements.

b. Suppliers will be expected to deliver according to orders generated by provinces.

The supplier must inform delivery sites by phone at least 24 hours in advance as to when they should expect a delivery. Deliveries must be made within reasonable working hours, before 15:00 on week days. Delivery staff must ensure all cartons are stacked neatly, with all labels right side up, in the respective storage areas. It will be the supplier's responsibility to ensure that adequate material offloading labour is provided. Delivery site staff is not obliged to assist with the materials offloading.

28. POST AWARD MONITORING

Any change in the status in supply performance during the contract period must be reported within seven (7) days of receipt of such information:

Cluster: Sector-wide Procurement, Affordable Medicines, Department of Health,

And

Cluster: HIV & Aids and STI's for attention:Ms Sesupo Makakole-Nene Acting Cluster Manager: HIV & Aids and STI's	Ms Thato Chidarikire Directorate: HIV Prevention Strategies	Mr Joseph Honwani Cluster: HIV & Aids and STI's
Tel : 012 395 9157	Tel : 012 395 9153	Tel : 012 395 9187
Fax: 012 395 8422	Fax: 012 395-8506	Fax: 086 632 7609
nenes@health.gov.za	ChidaT@health.gov.za	honwaj@health.gov.za

29. REPORTING AND HISTORICAL DATA

29.1 HISTORICAL DATA

Historical value and volume reports are required to be submitted monthly preferably via e-mail to the Department of Health for attention of Mr J Honwani (honwaj@health.gov.za), Ms M Rasengane (rasenm@health.gov.za) and Ms K Sethole (Sethok@health.gov.za) by all successful bidders. For this purpose

electronic templates which will include orders received and deliveries made will be supplied to successful bidders. The reports must be submitted on or before the 10th of each month.

30. PERFORMANCE MEASURES

30.1 SUPPLIERS MEASURES

a. Delivery period adherence
b. Product quality adherence

30.2 END USER MEASURES

On time payment

31. CONTACT DETAILS

Chief Directorate: Pharmaceutical Policy and Planning, Private Bag X828, Pretoria, 0001 or Physical address: 242 Struben Street, Civitas Building, Pretoria,0001.

Bid Enquiries:

Ms Phuti Moloko	Mamma Rasengane
Tel: (012) 395 8439	Tel: (012) 395-9452
Fax: (012) 395 8823	Fax: (012) 395 8823
Molokp@health.gov.za	rasenm@health.gov.za

For specification/ technical enquiries

Joseph Honwani	Thato Chidarikire
Tel: (012) 395-9187	Tel : (012) 395-9153
Fax: 086 632 7609	Fax : (012) 395-8506
E-mail : honwaj@health.gov.za	E-mail : chidat@health.gov.za