

Ministry of Health & Family Welfare
National AIDS Control Organization
Through
RITES LIMITED
(Procurement Agent)
Materials System Management Division
RITES Office Complex, Annex Building, 4th Floor,
Plot No.144, Sector 44, GURGAON, INDIA

Dated: 04.04.2016

AMENDMENT No. 1

National HIV/AIDS Control Programme
National Competitive Bidding
IFB No.: RITES/MSM/NACP/06/2015/REBID, due for opening on 19.04.2016
for Procurement of HIV (RAPID) 2nd & 3rd ANTIGEN AND WHOLE BLOOD FINGER PRICK TEST KITS.

The following amendments in the subject bid document are hereby authorized:-

Sl. No.	Reference	Existing	Modified
Section III. Schedule of Requirements			
1.	Schedule I to IV - HIV (Rapid) Kits for 1 st Antigen (Page 55)	Schedule I to IV - HIV (Rapid) Kits for 1st Antigen	Schedule I to IV - HIV (Rapid) Kits for 1st Antigen has been deleted as these schedules are already approved. Amended Schedules are mentioned in Annexure I below.
2.	Sch. V to VIII- HIV (Rapid) Kits for 2 nd Antigen (Page 55)	Total quantity required for these schedules is 1,082,820 tests	Total revised quantity required for these schedules is 5,41,410 tests. Amended Schedule wise quantity is mentioned in Annexure I below and Schedule wise quantity distribution mentioned in Annexure II below.
3.	Sch. IX to XII- HIV (Rapid) Kits for 3 rd Antigen (Page 55)	Total quantity required for these schedules is 1,082,820 tests	Total revised quantity required for these schedules is 5,41,410 tests. Amended Schedule wise quantity is mentioned in Annexure I below and Schedule wise quantity distribution mentioned in Annexure II below.
4.	Delivery Schedule for HIV (Rapid) Kits for 2 nd & 3 rd Antigen	i) 1st Lot quantity within 75 days after the issue of NOA, (ii) 2nd Lot quantity between 180-240 days after the issue of NOA (iii) 3 rd Lot quantity between 360-420 days after the issue of NOA and (iv) balance 4 th Lot quantity between 540-600 days after the issue of NOA (Notification of Award).	Revised Delivery Schedule is mentioned below: (i) 1st Lot of 2,70,705 quantity to be supplied between 360-420 days and (ii) 2nd Lot of balance 2,70,705 to be supplied between 540-600 days after the issue of NOA (Notification of Award).
5.	Note SN. 2 (i), (ii) & (iii) of Schedule of Requirement (Page 55)	Existing Note SN. 2 (i), (ii) & (iii)	The Note SN. 2 (i), (ii) & (iii) are revised as mentioned below: The following Principles for HIV Rapid test kit are required- a). Lateral Flow/ Immunocytoflow/ Immunochromatography- HIV 2nd Test Kit b) Immuno Flow through (Immuno- concentration) - HIV 3rd Test Kit c) Principle w.r.t. Whole Blood Finger Prick Test Kits is not related with HIV 1st, 2nd, & 3rd Test kits.

6.	Consignee address and Consignee-wise Quantity distribution for HIV (Rapid) Kits for 2nd & 3rd Antigen (Page 56-59)	Existing Consignee address and Consignee-wise Quantity distribution for HIV (Rapid) Kits for 2nd & 3rd Antigen	Amended Schedule wise quantity distribution mentioned in Annexure II below. (Page 4-7)
7.	Appendix 'A'	Existing Appendix 'A'	Modified Appendix 'A' is mentioned below at Annexure III. (page-8)
8.	Appendix 'B'	Existing Appendix 'B'	Existing Appendix 'B' is mentioned below at Annexure IV. (page-9)
Section IV. Technical Specifications			
9.	Technical Specification for HIV (Rapid) Kits for 2nd & 3rd Antigen (Page 71-73)	Existing Technical Specification for HIV (Rapid) Kits for 2nd & 3rd Antigen	Modified Technical Specification is mentioned below at Annexure V (page-10-11)

All other terms and conditions of the Bid Document shall remain unchanged.

ADDRESS FOR COMMUNICATION:

General Manager/MSM, RITES Ltd.,
RITES Office Complex, Annex Building,
4th Floor, Plot No. 144, Sector 44, Gurgaon - 122003 (Haryana)-
India
Tel: 0124 2728 408/440/405,
Fax: 0124 2571659/ 2571660
E mail: rites_naco@rediffmail.com, rites_naco@rites.com

SECTION III

SCHEDULE OF REQUIREMENTS

Schedule No.	DESCRIPTION	UNIT	FUNDING BODY	REQUIRED QUANTITY	BID SECURITY IN (INDIAN RUPEES)	
V	HIV (Rapid) Kits for 2nd Antigen	Tests	Domestic Budget	136,950	31,000	
VI	HIV (Rapid) Kits for 2nd Antigen	Tests		96,720	22,000	
VII	HIV (Rapid) Kits for 2nd Antigen	Tests		218,940	50,000	
VIII	HIV (Rapid) Kits for 2nd Antigen	Tests		88,800	20,000	
	Total:			541,410	123,000	
IX	HIV (Rapid) Kits for 3rd Antigen	Tests		136,950	25,000	
X	HIV (Rapid) Kits for 3rd Antigen	Tests		96,720	17,000	
XI	HIV (Rapid) Kits for 3rd Antigen	Tests		218,940	40,000	
XII	HIV (Rapid) Kits for 3rd Antigen	Tests		88,800	16,000	
	Total:			541,410	98,000	
XIII	HIV (Rapid) Whole Blood Finger Prick	Tests		15,421,350	2,500,000	
XIV	HIV (Rapid) Whole Blood Finger Prick	Tests		10,029,050	1,625,000	
XV	HIV (Rapid) Whole Blood Finger Prick	Tests		12,602,950	2,043,000	
	Total:			38,053,350	6,168,000	
			Grand Total:	6,389,000		

HIV (Rapid) Kits for 2nd Antigen Tests:

Sl.	Schedule	SACS/MACS	1st Lot Quantity	2nd Lot Quantity	Grand Total	Total Qty
1	Schedule V	Dadra & Nagar Haveli	35	35	70	136,950
2		Daman & Diu	120	120	240	
3		Goa	840	840	1680	
4		Gujarat	14,400	14,400	28800	
5		Maharashtra (Total)	36,700	36,700	73400	
5.1		MSACS, Mumbai	4,080	4,080	8160	
5.2		Thane	4,080	4,080	8160	
5.3		Aurangabad	4,080	4,080	8160	
5.4		Nagpur	4,060	4,060	8120	
5.5		Akola	4,080	4,080	8160	
5.6		Nasik	4,080	4,080	8160	
5.7		Satara	4,080	4,080	8160	
5.8		Pune	4,080	4,080	8160	
5.9		Latur	4,080	4,080	8160	
6		Mumbai	9,450	9,450	18900	
7		Rajasthan	5,520	5,520	11040	
8		Sikkim	420	420	840	
9		Andaman & Nicobar Islands	990	990	1980	
1		Schedule VI	Chandigarh	1,170	1,170	
2	Chhattisgarh		3,480	3,480	6960	
3	Delhi		5,580	5,580	11160	
4	Haryana		2,970	2,970	5940	
5	Himachal Pradesh		1,410	1,410	2820	
6	Jammu & Kashmir		1,080	1,080	2160	
7	Madhya Pradesh (Total)		4,860	4,860	9,720	
7.1	Bhopal		1,200	1,200	2400	
7.2	Indore		1,200	1,230	2430	
7.3	Jabalpur		1,230	1,200	2430	
7.4	Gwalior		1,230	1,230	2460	
8	Punjab		5,100	5,100	10200	
9	Uttar Pradesh (Total)		16,830	16,830	33660	
9.1	Gomti Nagar, Lucknow		3,390	3,360	6750	
9.2	Aishbagh, Lucknow		3,360	3,390	6750	
9.3	University chowk, Lucknow		3,360	3,360	6720	
9.4	Aligarh		3,360	3,360	6720	
9.5	Varanasi		3,360	3,360	6720	
10	Uttarakhand		1,500	1,500	3000	
11	Manipur	2,700	2,700	5400		
12	Mizoram	1,680	1,680	3360		
1	Schedule VII	Assam	2,850	2,850	5700	218,940
2		Bihar	6,240	6,240	12480	
3		Jharkhand	4,800	4,800	9600	
4		Nagaland	3,150	3,150	6300	

Sl.	Schedule	SACS/MACS	1st Lot Quantity	2nd Lot Quantity	Grand Total	Total Qty
5		Orissa	6,810	6,810	13620	
6		Tripura	990	990	1980	
7		West Bengal	7,740	7,740	15480	
8		Andhra Pradesh	36,150	36,150	72300	
9		Karnataka (Total)	40,740	40,740	81480	
9.1		Bangalore Urban	2,910	2,910	5820	
9.2		Kolar	2,910	2,910	5820	
9.3		Tumkur	2,910	2,910	5820	
9.4		Hassan	2,910	2,910	5820	
9.5		Mysore	2,910	2,910	5820	
9.6		Bellary	2,910	2,910	5820	
9.7		Mangalore	2,910	2,910	5820	
9.8		Raichur	2,910	2,910	5820	
9.9		Shimoga	2,910	2,910	5820	
9.1		Davanagere	2,910	2,910	5820	
9.11		Bijapur	2,910	2,910	5820	
9.12		Belgaum	2,910	2,910	5820	
9.13		Gulbarga	2,910	2,910	5820	
9.14	Dharwad	2,910	2,910	5820		
1	Schedule VIII	Kerala (Total)	4,950	4,950	9900	88,800
1.1		Trivandrum	1,650	1,650	3300	
1.2		Thrissur	1,650	1,650	3300	
1.3		Kozhikode	1,650	1,650	3300	
2		Lakshadweep	30	30	60	
3		Pondicherry	1,260	1,260	2520	
4		Tamil Nadu	23,880	23,880	47760	
5		Telengana	12,300	12,300	24600	
6	Arunachal Pradesh	1,110	1,110	2220		
7	Meghalaya	870	870	1740		
			270,705	270,705	541,410	541,410

HIV (Rapid) Kits for 3rd Antigen Tests:

Sl.	Schedule	SACS/MACS	1st Lot Quantity	2nd Lot Quantity	Grand Total	Total Qty
1	Schedule IX	Dadra & Nagar Haveli	35	35	70	136,950
2		Daman & Diu	120	120	240	
3		Goa	840	840	1680	
4		Gujarat	14,400	14,400	28800	
5		Maharashtra (Total)	36,700	36,700	73400	
5.1		MSACS, Mumbai	4,080	4,080	8160	
5.2		Thane	4,080	4,080	8160	
5.3		Aurangabad	4,080	4,080	8160	
5.4		Nagpur	4,060	4,060	8120	
5.5		Akola	4,080	4,080	8160	
5.6		Nasik	4,080	4,080	8160	
5.7		Satara	4,080	4,080	8160	
5.8		Pune	4,080	4,080	8160	
5.9		Latur	4,080	4,080	8160	
6		Mumbai	9,450	9,450	18900	
7		Rajasthan	5,520	5,520	11040	
8		Sikkim	420	420	840	
9		Andaman & Nicobar Islands	990	990	1980	
1		Schedule X	Chandigarh	1,170	1,170	
2	Chhattisgarh		3,480	3,480	6960	
3	Delhi		5,580	5,580	11160	
4	Haryana		2,970	2,970	5940	
5	Himachal Pradesh		1,410	1,410	2820	
6	Jammu & Kashmir		1,080	1,080	2160	
7	Madhya Pradesh (Total)		4,860	4,860	9,720	
7.1	Bhopal		1,200	1,200	2400	
7.2	Indore		1,200	1,230	2430	
7.3	Jabalpur		1,230	1,200	2430	
7.4	Gwalior		1,230	1,230	2460	
8	Punjab		5,100	5,100	10200	
9	Uttar Pradesh (Total)		16,830	16,830	33660	
9.1	Gomti Nagar, Lucknow		3,390	3,360	6750	
9.2	Aishbagh, Lucknow		3,360	3,390	6750	
9.3	University chowk, Lucknow		3,360	3,360	6720	
9.4	Aligarh		3,360	3,360	6720	
9.5	Varanasi		3,360	3,360	6720	
10	Uttarakhand		1,500	1,500	3000	
11	Manipur	2,700	2,700	5400		
12	Mizoram	1,680	1,680	3360		
1	Schedule XI	Assam	2,850	2,850	5700	218,940
2		Bihar	6,240	6,240	12480	
3		Jharkhand	4,800	4,800	9600	
4		Nagaland	3,150	3,150	6300	
5		Orissa	6,810	6,810	13620	
6		Tripura	990	990	1980	

Sl.	Schedule	SACS/MACS	1st Lot Quantity	2nd Lot Quantity	Grand Total	Total Qty
7		West Bengal	7,740	7,740	15480	
8		Andhra Pradesh	36,150	36,150	72300	
9		Karnataka (Total)	40,740	40,740	81480	
9.1		Bangalore Urban	2,910	2,910	5820	
9.2		Kolar	2,910	2,910	5820	
9.3		Tumkur	2,910	2,910	5820	
9.4		Hassan	2,910	2,910	5820	
9.5		Mysore	2,910	2,910	5820	
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9.8		Raichur	2,910	2,910	5820	
9.9		Shimoga	2,910	2,910	5820	
9.1		Davanagere	2,910	2,910	5820	
9.11		Bijapur	2,910	2,910	5820	
9.12		Belgaum	2,910	2,910	5820	
9.13	Gulbarga	2,910	2,910	5820		
9.14	Dharwad	2,910	2,910	5820		
1	Schedule XII	Kerala (Total)	4,950	4,950	9900	88,800
1.1		Trivandrum	1,650	1,650	3300	
1.2		Thrissur	1,650	1,650	3300	
1.3		Kozhikode	1,650	1,650	3300	
2		Lakshadweep	30	30	60	
3		Pondicherry	1,260	1,260	2520	
4		Tamil Nadu	23,880	23,880	47760	
5		Telengana	12,300	12,300	24600	
6	Arunachal Pradesh	1,110	1,110	2220		
7	Meghalaya	870	870	1740		
			270,705	270,705	541,410	541,410

Annexure III

Schedule No.	Minimum value of completed contract (In Million Indian Rupees or equivalent)	Similar Product
V	1.00	Diagnostic kits
VI	1.00	Diagnostic kits
VII	2.00	Diagnostic kits
VIII	1.00	Diagnostic kits
IX	1.00	Diagnostic kits
X	1.00	Diagnostic kits
XI	2.00	Diagnostic kits
XII	1.00	Diagnostic kits
XIII	20.00	Diagnostic kits
XIV	7.00	Diagnostic kits
XV	16.00	Diagnostic kits

Annexure IV

Schedule No.	Annual Turnover (in Million Indian Rupees or equivalent)
V	3.00
VI	3.00
VII	6.00
VIII	3.00
IX	3.00
X	3.00
XI	6.00
XII	3.00
XIII	120.00
XIV	78.00
XV	96.00

SECTION IV: TECHNICAL SPECIFICATIONS**PART A**

Bidders are required to mention “Comply”/ “Not comply” or specific information requested against each criteria of the following Technical Specification for the items being supplied.

Schedule: V to VIII
HIV (RAPID) TEST KIT 2nd ANTIGEN

1. By Principle of Lateral Flow/ Immunocytoflow/ Immunochromatography

Sl.	<i>Specification</i>	Your Offer (Please fill-in “Comply”/ “Not comply”)
1.	Should be solid phase /particle coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.	
2.	The assay should detect HIV 1 & 2 antibodies in plasma, serum or whole blood	
3.	Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 & 2 , bio-safety methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each Kit.	
4.	The Kit should have approval of the statutory authority form the country of origin.	
5.	In case of Imported kits it should be registered and licensed by the DCG(I) .	
6.	In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centres approved by the DCG(I).	
7.	The kit should have minimum 60% or more of the shelf life at the port of discharge of consignees.	
8.	The time required for performing the test should not be more than 30 minutes.	
9.	The control dot/band should be able to detect the presence of human immunoglobulins and should not be just a "procedural control" or meant for merely checking the flow or reagents or integrity of the antigen except in kits using " lateral flow (Immunocytoflow) " technology.	
10.	The manufacturers should ensure that: <ol style="list-style-type: none"> 1. The test kit should be packed such that there is a provision to conduct single test at a time; 2. The assay components should include HIV positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls); and <u>For 2nd & 3rd Antigens:</u> <ol style="list-style-type: none"> 3. The pack size of HIV rapid test kits should not be more than 30 tests per kit. 	
11.	The assay should have sensitivity of $\geq 99.5\%$ and specificity of $\geq 98\%$.	
12.	The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8°C. The cumulative time temperature indicator technology should be pre qualified by WHO.	

Schedule: IX to XII
HIV (RAPID) TEST KIT 3rd ANTIGEN

1. By Principle of Flow through (Immuno- concentration)

Sl.	<i>Specification</i>	Your Offer (Please fill-in “Comply”/ “Not comply”)
13.	Should be solid phase /particle coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.	
14.	The assay should detect HIV 1 & 2 antibodies in plasma, serum or whole blood	
15.	Adequate documents detailing the principle, components, details of antigen for antibody detection of HIV 1 & 2 , bio-safety methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing & expiry dates should be provided with each Kit.	
16.	The Kit should have approval of the statutory authority form the country of origin.	
17.	In case of Imported kits it should be registered and licensed by the DCG(I) .	
18.	In case of indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 & also be evaluated by the Centres approved by the DCG(I).	
19.	The kit should have minimum 60% or more of the shelf life at the port of discharge of consignees.	
20.	The time required for performing the test should not be more than 30 minutes.	
21.	The control dot/band should be able to detect the presence of human immunoglobulins and should not be just a "procedural control" or meant for merely checking the flow or reagents or integrity of the antigen except in kits using " Flow through (Immuno- concentration) " technology.	
22.	The manufacturers should ensure that: <ol style="list-style-type: none"> 1. The test kit should be packed such that there is a provision to conduct single test at a time; 2. The assay components should include HIV positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls); and <p><u>For 2nd & 3rd Antigens:</u></p> <ol style="list-style-type: none"> 3. The pack size of HIV rapid test kits should not be more than 30 tests per kit. 	
23.	The assay should have sensitivity of $\geq 99.5\%$ and specificity of $\geq 98\%$.	
24.	The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2-8°C. The cumulative time temperature indicator technology should be pre qualified by WHO.	