**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 1st 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.<br><br>**Amended Schedules are mentioned in Annexure I below**. |
| 2. | Sch. V to VIII- HIV (Rapid) Kits for 2nd 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.<br><br>**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 3rd 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.<br><br>**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 2nd & 3rd 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) 3rd Lot quantity between 360-420 days after the issue of NOA and (iv) balance 4th Lot quantity between 540-600 days after the issue of NOA (Notification of Award). | **Revised Delivery Schedule is mentioned below:**<br><br>**(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:<br><br>**The following Principles for HIV Rapid test kit are required-**<br><br>**a). Lateral Flow/ Immunocytoflow/ Immunochromatography- HIV 2nd Test Kit**<br><br>**b) Immuno Flow through (Immuno- concentration) - HIV 3rd Test Kit**<br><br>**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

**Annexure I**

# 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** |

**Annexure II**

**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 | **2340** | **96,720** |
| 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** | |
| 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** | **88,800** |
| 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 | **2340** | **96,720** |
| 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** | |
| 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 XII** | **Kerala (Total)** | **4,950** | **4,950** | **9900** | |
| 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** | **88,800** |
| 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 |

**Annexure V**

## 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. | *Specification* | 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:<br>1. The test kit should be packed such that there is a provision to conduct single test at a time;<br>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<br>**For 2nd & 3rd Antigens:**<br>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 ≥ 99.5% and specificity of ≥ 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. | *Specification* | 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:<br>1. The test kit should be packed such that there is a provision to conduct single test at a time;<br>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<br>**For 2nd & 3rd Antigens:**<br>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 ≥ 99.5% and specificity of ≥ 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. | |