Minutes of Meeting Technical Specification Committee, NACO for review and revision of specifications of the programmatic commodities under BSD and STI components of NACP

Date: 02nd & 30th March 2022
Venue: NACO Office/ virtual cum physical

A Meeting on Technical Specification for Commodities under the BSD & STI division, was conducted in two steps using virtual & hybrid modes under the Chairpersonship of Dr. Sunil Gupta, Principal Consultant, NCDC, Government of India. First meeting was held on 02 March 2022 to finalize the technical Specification of HIV test kit 1, HIV test kit 2, HIV test kit 3 & RPR test kit for syphilis.

In continuation of above second part of meeting was done on 30th March 2022 to finalize the technical specifications of Whole Blood Finger prick test kit for HIV, STI colour coded drugs kit 1, 2, 4, 5, 6 and 7, Injection Benzathine Penicillin, Tab Azithromycin, Syrup Nevirapine, Syrup Zidovudine, Syrup Lopinavir & Ritonavir, DBS card & DSB consumables, Ice Lined Refrigerator & Draft specification for Mobile van), under BSD & STI division:

All members were present and quorum was complete. After due discussions and deliberations, the committee approved the technical specifications as detailed Agenda wise.

Agenda 1:

Technical Specifications of HIV (Rapid) Test kits -1 By the Principal Dot Immune Assay:

1. Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail 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 statuary authority from the country of origin.
5. Imported kits, it should be registered and licensed by the DCG(I).
6. Indigenous manufacturer should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.
8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The Control dot / band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of ≥98%.
11. The manufacturer should ensure that:
    a. The test kit should be packed such that there is a provision to conduct the single test at a time.
    b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls)
    c. The pack size of HIV rapid test kits should be not more than 50 tests per kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2 - 8^0 C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

Agenda 2:

Technical Specification of HIV (Rapid) Test kits -2, (Principal Agglutination)

1. Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect & differentiate HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail 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 statuary authority from the country of origin.
5. In case of Imported kits, it should be registered and licensed by the DCG(I).
6. Indigenous manufacturers should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.
8. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The Control dot / band should be able to detect the presence of human immunoglobulin's and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of ≥98%.
11. The manufacturer should ensure that:
    a. The test kit should be packed such that there is a provision to conduct the single test at a time.
    b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls)
    c. The pack size of HIV rapid test kits should be not more than 30 tests per kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2 - 8^0 C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

Agenda 3:

Technical Specification of HIV (Rapid) Test kits -3 (Principle excluding Agglutination and (Dot Immune Assay)

1. Should be solid phase coated HIV 1 & 2 recombinant and / or synthetic peptide antigens.
2. The assay should detect HIV 1 & 2 antibodies in serum, plasma or whole blood.
3. Adequate documents detailing the principal component, detail 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 statuary authority from the country of origin.
5. In case of Imported kits, it should be registered and licensed by the DCG(I).
6. Indigenous manufacturers should be licensed by the competent authority defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rule 2017.
7. The time required for the performing the test should not be more than 30 minutes.
8. The kits should have a shelf life of 24 months, at least $5/6^{th}$ of the minimum shelf life must remain at the time of dispatch to the consignee.
9. The Control dot / band should be able to detect the presence of human immunoglobulin's and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow.
10. The assay should have sensitivity of 100% and specificity of ≥98%.
11. The manufacturer should ensure that:
    a. The test kit should be packed such that there is a provision to conduct the single test at a time.
    b. The assay component should include HIV positive & negative serum controls, sufficient for conducting 20% of the test (10% negative & 10% positive controls)
    c. The pack size of HIV rapid test kits should be not more than 30 tests per kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage & transport the kits at 2 - 8^0 C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

Agenda 4:

Technical Specification of Whole Blood Finger Prick test kit for HIV, kit -4

1. The assay should be able to detect antibodies to HIV 1 & HIV 2, including all the subtypes by the rapid test in whole blood/ and serum/ plasma.
2. The assay should have sensitivity of 100% and specificity of ≥98%.
3. The clinical data to determine the performance characteristics of the kit on whole blood sample should be made available by the manufacturer.
4. The assay should have solid phase/particles coated with synthetic and or recombination or both types of antigens of HIV 1 and HIV 2.
5. Total procedure time should not be more than 30 minutes
6. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee
7. The Control dot / band should be able to detect the presence of human immunoglobulins and should not merely check the flow of reagents or integrity of the antigen except for the kits based on the principal of lateral flow
8. Adequate documents detailing the principal component, detail 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.
9. 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 used should be pre - qualified by WHO.
10. Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics Act 1940 & Rule 1945 and/or Medical device rule 2017
11. The imported rapid test kits should have the approval of the statutory authority in the country of Origin/ manufacturers and should satisfy the requirements of Drugs & Cosmetics Act in India. The imported kits should also get evaluated in our country
12. The manufacturers should ensure that:

    a) The test kit should be packed such that there is a provision to conduct single test at a time

    b) The assay components should include HIV positive and negative serum controls sufficient for conducting 20% of the test (10% negative and 10% positive controls); and

    c) The pack size of HIV rapid test kits should not be more than 50 tests per Kit

Agenda 5:

Technical Specification of Rapid Plasma Reagin (RPR) for Syphilis Testing

1. The indigenous RPR (Rapid Plasma Reagin) kits should have been manufactured under manufacturing license issued by the State Licensing Authority under the Drugs and Cosmetics Act, the imported kits should have been imported under import license issued by the DCG(I) under the Drugs and Cosmetics Act 1940 & Rule 1945 and / or medical devices rule 2017.
2. Literature detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing, limitations and expiry date should be provided with each kit.
3. The assay should be calibrated to WHO reference standards from a third party accredited laboratory.
4. The assay should be suitable to perform with either serum or plasma.
5. The assay should allow for qualitative and semi quantitative determination of Reagin antibodies in serum or plasma for sera-diagnosis of syphilis based on flocculation principle using non - treponemal antigens.
6. The assay should have sensitivity of ≥85% or more in primary syphilis and a specificity of ≥93% or more.
7. The test should be able to yield results within 30 minutes.
8. The pack size of RPR test kit should be less than or equal to 50 tests per kit.
9. The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls).
10. The kit should have all essential accessories required for the test such as cards, droppers, applicator, etc. in adequate quantities for the number of tests to be performed.
11. The kits should have a shelf life of 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.
12. The kit should have a storage temperature of 2° C to 8°C and supplier/ local agent should have the facility to store kits at 2° C to 8°C.
13. Cumulative Time Temperature Indicator should be part of the kit as per specifications defined in the terms and conditions.

Agenda 6:

Technical Specification of pre – Packed Colour Coded STI/ RTI drug kits

KIT Description:

S. No.	Colour	Description of Kit	Unit
1	Grey	Tab Azithromycin 1 gm and Tab Cefixime 400 mg	One Tablet of each drug in one kit
2	Green	Tab Secnidazole 1 gm and Tab Fluconazole 150 mg	Two Tablets of Secnidazole and One Tablet of Fluconazole
4	Blue	Cap/tab Doxycycline 100 mg and Tab Azithromycin 1 gm	Thirty Tablets of Doxycycline and One Tablet of Azithromycin in each drug in one kit
5	Red	Tab Acyclovir 400 mg	Twenty one tablets of drug in one kit
6	Yellow	Tab Cefixime 400 mg and Tab Metronidazole 400 mg and Cap/Tab Doxycycline 100 mg	One tablet of Cefixime and Twenty Eight Tablets of Metronidazole and Doxycycline each drug in one kit
7	Black	Cap/Tab Doxycycline 100 mg and Tab Azithromycin 1 gm	Forty Two Tablets of Doxycycline and One tablet of Azithromycin in each drug in one kit
3	White	Inj. Benzathine Penicillin 2.4 MU with equal number of sterile water 10 ml	Vial
3	White	Tab Azithromycin 1 gm	Tablet
3	White	Disposable syringe 10 ml with disposable needle	Number

Product Code Number	Product Name (Generic)	Pharmacopeia standards	Strength	Dosages Form	Number of generic product per each kit	Product Description
Product code 1: STI/RTI treatment kit 1 for UD; ARD and Cervicitis, PT	Azithromycin	I.P. or Equivalent	1 gm	Tablet	1	Treatment kit 1 for UD; ARD and Cervicitis, PT. Colour of Pouch is Grey (25%).
	Cefixime	I.P. or Equivalent	400 mg	Tablet	1	
Product code 2: STI/RTI treatment kit 2 for Vaginitis	Secnidazole	I.P. or Equivalent	1 gm	Tablet	2	Treatment kit 2 for Vaginitis. Colour of Pouch is Green.
	Fluconazole	I.P. or Equivalent	150 mg	Capsule / Tablet	1	
Product code 3: STI/RTI treatment kit 3 for GUD (Genital Ulcer Diseases)	Azithromycin	I.P. or Equivalent	1 gm	Tablet	1	Treatment kit 3 for GUD (Genital Ulcer Diseases). Colour of Pouch is White.
	Benzathine Penicillin	I.P. or Equivalent	2.4 MU	Vial	1	
	Disposable Syringe	-	10 ml capacity	NA	1	
	Disposable Needle	-	21 gauze	NA	1	
	Distilled Water	I.P. or Equivalent	10 ml	Plastic Phial	1	
Product code 4: STI/RTI treatment kit 4 for GUD (Genital Ulcer Diseases)	Azithromycin	I.P. or Equivalent	1 gm	Tablet	1	Treatment kit 4 for GUD (Genital Ulcer Diseases). Colour of Pouch is Blue.
	Doxycyclin	I.P. or Equivalent	100 mg	Capsule / Tablet	30	
Product code 5: STI/RTI treatment kit 5 for GUD (Genital Ulcer Diseases)	Acyclovir	I.P. or Equivalent	400 mg	Tablet	21	Treatment kit 5 for GUD (Genital Ulcer Diseases). Colour of Pouch is Red.