Minutes of Meeting of the Technical Specification Committee, NACO for review and revision of Technical Specifications of Dual test kit for HIV & Syphilis and Mobile ICTC Van

Date: 25th May 2022
Venue: NACO (Hybrid mode)

A Meeting of the Technical Specification Committee was conducted on 25th May 2022 under the Chairpersonship of Dr. Sunil Gupta, Principal Consultant, NCDC, GoI. List of the participants is placed at Annexure: 1

At the outset, chairperson gave the opening remarks and set the context for meeting and briefed the agenda points.

- Agenda 1: Review & approval of Technical Specification for Dual Test Kit for HIV & syphilis
- Agenda 2: Review & approval of Technical Specification for Mobile Testing Van
- Agenda 3: Any other point of discussion with the permission of chair

It was briefed to Technical Specification Committee members that last Technical Specification committee meeting was conducted on 2nd March 2022 & 30th March 2022. In this meeting committee approved the Technical Specification of Commodities used under BSD [HIV kit I, II, III, WBFPT, DBS Card & Consumable, Pediatric drug Lopinavir & Ritonavir, RPR for syphilis testing, ARV Syrup Zidovudine & Nevirapine, Vertical Ice Line Refrigerator(ILR)]. The Committee has suggested to put the technical specification for Mobile ICTC van in next Technical Specification Committee meeting with two separate specifications for Diesel based & CNG based ICTC Mobile ICTC van.

In order to review and revision of Technical Specification of Dual testing kits (HIV & Syphilis), was informed to committee members, that TRG-HCTS has recommended the use/scale up of Dual testing kits under NACO for Screening of Pregnant Women, HRGs, Bridge population and STI patients at DSRC

Both the agenda for the meeting were discussed in detail by the committee members and experts and the technical specifications for the dual kit was finalized. Approved Technical Specification of Dual testing kits for HIV & Syphilis is mentioned below:

Technical Specifications of Dual test kit for HIV & syphilis

1. The kit should be able to individually detect antibodies to all subtypes of HIV1 & HIV 2 and Treponema pallidum by the rapid test, in human whole blood/ & serum / plasma.
2. The assay should have following synthetic and/or recombinant antigens coated on solid phase
   a. Multiple Treponema pallidum antigens, and
   b. Multiple Antigens of HIV 1 (including gp41) and HIV 2 (including gp36)
3. The clinical performance evaluation data of the kit on whole blood sample should be made available by the manufacturer.
4. The assay should be based on any of the rapid test principles such as flow-through (Immunoconcentration), or lateral flow (Immunochromatography).
5. The assay should have an in-built control for testing the validity of the test procedure.
6. The Control dot / band (in-built control), 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 principle of lateral flow.
7. The assay should have following performance characteristics:
   a. For HIV, sensitivity of 100% and specificity ≥98%.
   b. For Treponema pallidum, sensitivity ≥85% and specificity ≥93%
8. The time required for performing the test should not be more than 30 minutes.
9. 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.
10. The manufacturer should ensure that:

a) The test device should be packed (along with the desiccant) such that there is a provision to conduct single test at a time.
b) The pack size of rapid test kits should be not more than 50 tests per kit.
c) The assay component should include sufficient amount of positive and negative controls.
d) The kit should be supplied with a sufficient number of droppers to deliver the required amount of specimen as specified in the kit literature

11. Adequate documents detailing the principal components, details of antigen used / coated for detection of HIV 1 & 2 as well asTreponema pallidum antibodies, biosafety compliance, validity criteria, interpretation of results, performance characteristics, storage condition and limitation of assays should be provided, Also the manufacturing and expiry dates should be provided with each kit.
12. The manufacturer/authorized agent should ensure maintenance of cold chain during storage and transportation of the kits at 2 - 8° C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.

13. Indigenous manufacturers should be licensed by the licensing authorities as the case may be, defined under Drugs & Cosmetic Act 1940 & Rule 1945 and / or medical devices rules 2017.
14. In case of Imported kits, it should be licensed by the DCG(I).

In respect to Technical specifications of the Mobile testing van required further deliberations and will be taken up in the next meeting.

The meeting ended with a vote of the thanks.

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Gmail YouTube Maps Mental Health - Bur... PDF2WORD - Chan...

Gmail Search mail

Compose

Inbox 14
Starred
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Important
Chats
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Scheduled
More

3 of 2,872

Re: MoM Dual Test kit: Reminder

Inbox ×

Madhuri Thakar 12:29 (31 minutes ago)
to me

I agree with the final minutes .thanks
Madhuri Thakar

On Mon, Jun 20, 2022 at 11:51 AM Shailendra Gandharva <shailendra.naco@gmail.com> wrote:

Respected Ma'am

This is a gentle reminder, to please give your concurrence on the attached meeting of Minutes for Dual test kit (HIV & syphilis).

Thanks.
Shailendra Gandharva

NACO

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Meet
New meeting
Join a meeting

Hangouts
Shailendra

No recent chats
Start a new one

Annexure: 1-List of Participants

Members and experts of Technical Specification Committee:

Sr. No.	Name	Designation and affiliation
1	Dr. Sunil Gupta	Principal Consultant, NCDC, Delhi
2	Dr. Ravi Kant Sharma	Deputy Drug Controller of India, MoH&FW, Govt. of India
3	Dr. Sumit Agrawal	Scientist 'D', Indian Council of Medical Research (ICMR) Delhi
4	Dr. Madhuri Thakkar	Scientist 'F' National AIDS Research Institute (NARI), Pune, (MH)
5	Dr. AkankshaBisht	Scientist Grade II, National Institute of Biologicals, Noida (U.P)
6	Dr. Sumathi Murlidhar	Professor & Microbiologist, Apex Regional STD Centre & SRL for HIV, Safdarjung, Delhi
7	Dr. Manju Bala	Additional Director & HoD, Division of Microbiology, CA & ZD, Centre for AIDS & related Disease, NCDC, Delhi
8	Dr. Rohit Chawla	Professor, Dept. of Microbiology, MAMC, Delhi
9	Dr. Shobini Rajan	Member Secretary, (SAG), DDG, NACO, Delhi
	Invitee	
10	Dr. Parveen Kumar	Asst. Director, DSACS, Delhi
11	Dr. Tauqueer Ahmad	Dy. Director, Plan India
12	Mr. Kumar Swamy	AD ICTC, Tamilnadu

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Members of Technical Specifications Committee

Sr. No.	Name	Designation and affiliation	Signature
1	Dr. Sunil Gupta	Principal Consultant, NCDC, Delhi	
2	Dr. Ravi Kant Sharma	Deputy Drug Controller of India, MoH&FW, Govt. of India	
3	Dr. Sumit Agrawal	Scientist 'D', Indian Council of Medical Research (ICMR) Delhi	23/08/22
4	Dr. Madhuri Thakkar	Scientist 'F' National AIDS Research Institute (NARI), Pune, (MH)	
5	Dr. Akanksha Bisht	Scientist Grade II, National Institute of Biologicals, Noida (U.P)	
6	Dr. Sumathi Murlidhar	Professor & Microbiologist, Apex Regional STD Centre & SRL for HIV, Safdarjung, Delhi	
7	Dr. Manju Bala	Additional Director & HoD, Division of Microbiology, CA & ZD, Centre for AIDS & related Disease, NCDC, Delhi	
8	Dr. Rohit Chawla	Professor, Dept. of Microbiology, MAMC, Delhi	
9	Dr. Shobini Rajan	Member Secretary, (SAG), DDG, NACO, Delhi	