

Minutes of the meeting of the Technical Specifications Committee held on 6th.Aug.2015 to review the specifications of Point of Care (POC) CD4 machines

- A meeting of the Technical Specifications Committee for review the specifications of CD4 machines was held under the chairmanship of Dr. B. D. Athani (Spl. DGHS) on 6th.Aug.2015 at 3:00 P.M at room no. 439A, A Wing, Nirman Bhawan, New Delhi.
- The following members attended the meeting:
 1. Dr. B.D. Athani (Spl. DGHS) (Chairman)
 2. Dr. Ravikant Sharma , ADC(I), CDSO (Member)
 3. Dr. Manjula Singh, Scientist C, ICMR (Member)
 4. Dr. Lalit Dar, Professor, AIIMS (Member)
 5. Dr. Charoo Hans, Specialist Grade 1, RML Hospital (Member)
 6. Dr. Sumathi Muralidhar, Associate Professor, Safdarjung Hospital (Member)
 7. Dr. Madhuri Thakar, Scientist E, NARI Pune (Member)
 8. Dr. Naresh Goel, DDG (LS), NACO (Member Secretary)
- The agenda of the meeting was to finalize technical specifications for POC CD4 machines.
- The agenda was discussed in the meeting and following decision were taken:
The committee approved the technical specification for POC CD4 machines as follows:

Technical specifications for Point of Care (POC) CD4 machines

Characteristics		SPECIFICATIONS
1	Model type	Table top
2	Certification	FDA/CE & IVD
3	Validation	WHO pre - qualified or validated in India in NACO designated laboratory
4	Principle	The POC can be based on different principles
5	Type of measurement	Absolute CD4 count with or without percentage
6	Sample Type	Blood- both venous and finger prick
7	Throughput	minimum 10 samples/ 8 hours working day
8	Temperature for functioning of machine	The machine should be functional at 10-40 °C
9	Power supply	a)The machine should have in-built or external rechargeable battery with a power back up of minimum 4 hours and optional ability to draw power from alternate sources such as solar energy, car battery, etc








		b)When working on the electric current, the machine should work on 220-240 volts and 50 Hz frequency and should be provided with compatible stabilizer to withstand voltage fluctuation if required
10	Data Analysis and display	Machine should have automated data analysis, data display system
11	Data printing	Inbuilt or external printer with printer paper should be supplied free of cost
12	UPS	If the equipment does not have an inbuilt power source, a compatible UPS with power back-up of 30 minutes shall be supplied with the system
13	Training	Supplier shall provide onsite hands on training at the time of installation and annual refresher training
14	Operating Manual	Original instruction manual /product literature must be provided by the manufacturer in English.
15	Market standing and service	Principals should have marketing, sales and after-sales service network in India
REAGENTS		
16	Certification	DCGI approved and IVD
17	Reagent supply	Manufacturer must ensure provision of uninterrupted supply of reagents that can measure absolute CD4 count with or without percentage, and all necessary consumables, including controls or calibrators, in addition to the equipment.
18	Reagent stability	10-30°C
19	Reagent shelf life	Minimum 9 months at the time of delivery to testing sites
OTHER CONDITIONS:		
20	Warranty	2 years warranty + 3 years CAMC(comprehensive annual maintenance Contract)
21	Evaluation	Robust data through credible performance evaluations of the technology should be made available for review by the NACO designated expert group OR the company should be prepared to undergo evaluation of its technology against established reference CD4 technology at a NACO nominated reference lab
22	Installation	Company will provide at the time of installation a log book for maintenance of equipment at no extra cost

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23	Repair and trouble shooting	(a) Commitment to troubleshoot (or availability of swap out model) and address breakdowns within 48 hours in major cities and within 72-96 hours in relatively remote areas. Failure to meet these requirements would make the manufacturer liable to penalty as in the contract document
		(b) Maintain an inventory of all critical spares/ repairs/back up devices in country to minimize downtime
		(c) Provide six monthly feedback to NACO on breakdowns, repairs and other troubleshooting assistance



Dr. Ravkant Sharma

Dr. Lalit Dar 


Dr. Madhuri Thakar

Dr. Charoo Hans 


Dr. Sumathi Muralidhar
6/8/15


Dr. Manjula Singh


Dr. Naresh Goel


Dr. B.D. Athar