Minutes of the meeting of the Technical Specifications Committee held on 24th. Feb. 2015 to review the specifications of 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 24th. Feb. 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. Chandrashekhar Ranga, DDC(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. A.S. Rathore DDG (CST), NACO (Member)
9. Dr. Naresh Goel, DDG (LS), NACO (Member Secretary)

The agenda of the meeting was to review technical specifications of CD4 machines.

The agenda was discussed in the meeting and following decision were taken:

The committee approved the technical specification of CD4 machines as follows:

1. It shall be a table top model and should be FDA/CE approved for in-vitro diagnostic (IVD) use.
2. The working principle shall be single platform fluorescence based flow cytometry.
3. Machine shall be capable of measuring absolute number of CD4 cells (absolute CD4 count) and CD4 percentage precisely in whole blood.
4. Should have throughput of at least 20 samples per hour.
5. Machine shall have automated data analysis, data display system and provision for printing out results with an inbuilt printer and / or external printer.
6. The system should work on 220-240 volts and 50 Hz frequency and should be provided by with compatible stabilizer to withstand voltage fluctuation.
7. A compatible UPS with power of 30 minutes shall be supplied with the system.
8. Supplier shall provide original operating manual (English language) with CD/DVD (English language), software for result analysis and onsite hands on training with annual refresher training.
9. The product should have good market standing of at least three years’ duration.
10. Principals should have marketing, sales and after-sales service center/s in India.
11. The manufacturer must ensure provision of uninterrupted supply of approved IVD reagents that can measure both absolute CD4 count and percentage, and all necessary consumables.

Other conditions

1. The supplier will provide 5 years' warranty that will include Comprehensive Annual Maintenance Contract (CAMC)
2. Purchasers reserve the right to subject the equipment for independent evaluation of performance.
3. The company will provide installation qualification, operational qualification and performance qualification with log book for maintenance of the equipment at no extra cost
4. Maximum downtime of two working days for machine repair will be given after which penalty clause will apply.

Dr. Chandrashekhar Ranga
CDSCO

Dr. Gauri Shankar

Dr. Lail Dar, AIIMS

Dr. Sumathi Muralidhar,
Safdarjung Hospital

Dr. Manjula Singh, ICMR

Dr. Naresh Goel
DDG (LS), NACO
as Member secretary

Dr. A.S. Rathore DDG (CST), NACO

Dr. Charoo Hans, RML Hospital

Dr. Madhuri Thakar, NARI

Dr. B.D. Athani (Spl. DGHS) as Chairman