File No. 1/06/ADG(Med)/CAPFs/Pathology/2012

Government of India/भारत सरकार

Ministry of Home Affairs/गृह मंत्रालय

Police Modernization Division/पुलिस आधुनिकीकरण प्रभाग

Prov.I Desk/संभरण-I डेस्क

26, Mansingh Road,
Jaisalmer House, New Delhi.
Dated: 11th April, 2013

To,

DsG : AR(through LOAR)/BSF/CISF/CRPF/ITBP/NSG/SSB & BPR&D

Subject: Trial Directives of Auto CD3/CD4/CD8 Flowcytometer.

The Trial Directives in respect of Auto CD3/CD4/CD8 Flowcytometer as per annexure have been accepted by the competent authority in MHA.

2. Henceforth, all the CAPFs should trial evaluate the above items strictly as per the laid down Trial Directive/Technical Specifications/QRs.

Issued on 15/4/2013

Yours faithfully,

(Smt. S B Nanda)
Under Secretary to the Govt. of India
Tel No. 23381278

Copy to :

O/C

1. SO, NIC, MHA: It is requested to host the Trial Directives (Soft copy attached) on the MHA website (under the page of organizational set up, Police Modernization Division) Qualitative Requirements.
2. Director(Procurement), MHA
3. PS to JS(PM) – for information.

Board Proceedings

Proceedings of	:	A board of officers of Sub-group of technical experts
Assembled on	:	7.12.2012 & 21.01.2013
Assembled at	:	Office of ADG (Medical), CAPFs, NSG & ARs
By the order of	:	ADG (Medical) Order no. I-45024/1/EC-VII/1/2012-2446 30.11.2012
For the purpose of	:	To formulate the QRs & Trial Directives of Auto CD/CD4/CD8 flowcytometer

Composition of the board:

Presiding Officer- Dr. A.K. Trivedi, CMO (SG), BSF

Member CRPF- Dr. Manisha Garg, CMO (SG)/Pathologist

Member, ITBP- Dr. D.K. Verma, Splst Gr-II (Sr. Scale)

Member, SSB- Dr. B.K. Nigam, CMO (SG)

In compliance to the order of ADG (Medical), CAPFs, NSG and ARs vide above reference , the meeting of sub-group of technical experts were conducted on 7.12.2012 and 21.1.2013 to formulate trail directives of QRs approved by MHA vide letter No. I/06/ADG (Med)/CAPFs/Pathology/2012 dated 2nd Jan, 2013.

After detailed deliberations the board sub-group has formulated the trial directives which is placed as Annexure-A

Encl: as above

(Dr. A.K. Trivedi, CMO (SG), BSF)
Presiding officer

Dr. B.K. Nigam
CMO (SG), SSB

Dr. Mansiha Garg
CMO (SG), CRPF/Pathologist

Dr. D.K. Verma
Spl Gr-I, ITBP

Approved/~~Not approved~~

ADG (Medical) CAPFs, NSG & ARs

Introduction:

Auto CD3/CD4/CD8 Flowcytometer is an equipment used to measure CD3, CD4 and CD8 cells in the whole blood of HIV/AIDS patients

Aim

To frame trial Directive to facilitate Board of officers to carry out physical and technical evaluation of tender sample of Auto CD3/CD4/CD8 Flowcytometer

General Instructions

1. The Trial Directive is issued to assist and guide the Evaluation Committee. Nothing in this Trial Directive absolves the BOO from their responsibility to ensure that the evaluation is carried out strictly as per the specification in every respect.
2. The evaluation Committee may carry out additional tests which they consider necessary after seeking approval of Competent Authority, to verify the quality of Tender Sample with the specifications.
3. The evaluation committee should ensure proper safety of man and equipments during evaluation to avoid any damage
4. Trial/evaluation will be conducted in the presence of representative of the firm

Composition of the Board

The physical Evaluation of the Tender Sample of Auto CD3/CD4/CD8 flowcytometer will be carried out by the Board of Officers detailed by the Competent Authority.

General Requirements

Following instruments should be available during trial evaluation

1. Whole blood sample of HIV positive patients
2. Laser meter
3. Automated Pipettes 50µl, test tubes, Test Tube Stand etc.

Trial Directives of Auto CD3/CD4/CD8 Flow-cytometer

S No	Specifications asked	Procedure Suggested for Trial for board of Officers	Result Expected/Desired	Complied/not Complied
1	The system should be portable bench top flowcytometer, occupying minimum space.	The same can be physically reviewed on site during Demo, and details can be taken from printed literature confirming dimensions. The printed literature / technical specs attached in the bid should be original and not photocopied	Should be benchtop occupying minimum space	
2	The detection system should have a Green laser for high sensitivity. Emission wave length should be in the range of 500-750nm. Their excitation & emission optics should be fixed aligned.	The reagents used with the system includes CD4 PE, CD8 PE, CD3 PE-Cy5 which is excited by the said Green laser and emits in the range of 500-750nm. The same can also be measured through Laser meter. (To be provided by suppler) The quoted instrument literature or supporting printed brochure can also be checked for laser & wave length details.	System should run properly and test conducted Laser meter should conform the the wave length Shoud verify the findings	
3	The system should be capable of measuring the absolute no of CD4/CD8 Lymphocytes precisely & accurately in whole blood samples. The system should be able to report the absolute no of CD8 T Lymphocytes only when required.,	1. Modes for running the CD4/CD8 and absolute CD8 to be mentioned clearly in the literature submitted by bidder. Certified blood controls with known results may be run on the system to check the accuracy of the absolute no	Result should comply with standards	

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		of CD4/CD8 Lymphocytes, measured by the instrument. 2. A performance demonstration can be done. 3. The same controls may be evaluated externally. The instrument supplier should be also able to supply the controls to ensure consistency of performance.	Should prove the test results Results should match	
4	Software may preferably be provided for reporting on the same platform CD4 T Cell as a percent of total lymphocytes for pediatric patient	Software to be provided for reporting on the same platform CD4 T Cell as a percent of total lymphocytes. The report can be checked /printed during demo. Modes for running the CD4 T cells as a percentage of total lymphocytes to be mentioned clearly in the literature submitted by bidder and can be checked during demo	After installation of software % of T cell lymphocytes should be available	
5	The optical system used in the system should not require any user alignment & it should not require any user intervention. Photomultiplier tubes should be used as a part of the system for fluorescence detection	The entire demo can be monitored for the same. (No user intervention & alignment) Undertaking or details of PMT for florescence detection should be provided.	Demo requires no intervention for testing and results obtained	
6	Fluidics should be such that reagents consumption is minimum.	Pre-filled/measured reagent cartridges To ensure no wastage & minimum usage of reagents. Pack insert of reagent usage/consumption per test should be provided/Demonstrated.	Prefilled cartridges used completely	
7	The system shall have capacity of performing minimum 03 parameters measurement with two Florescence detectors.	The same can be checked by certified documents /undertaking/literatures/printed brochures	3 parameters checked and results shown, undertaking to be checked.	

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8	The system should be supplied with data workstation (computer) which should be connectable and compatible with built in printer of the machine or external printer or may have integrated/inbuilt computer with printer. It should be able to store data files for subsequent review analysis.	Inbuilt computing with printer should be checked during demo. Or External computer & Printer should be checked during demo. The ability to store data on external computer should be there for external connectivity.	Seen physically, confirms the findings	
9	The system should be able to work on sample volumes less than 50 microlitre with minimal wastage	To be checked at the time of demo with samples.	Amount confirmed	
10	The system should preferably be upgradable	Undertaking to be provided by the manufacturing firm	Undertaking tro be checked	
11	Calibration check should be there.	The system calibration check should be there/Flagging of error message or SOP/Manual should be provided/demonstrated for calibration with IVD certified protocol	Flagging or error message seen physically	
12	Accessories :- a. Required automated pipettes of reputed company having calibration certificate b. Vortex Mixure c. Compatible UPS with back up of atleast 30 minute	The quoted bidder should list the accessories & verify during demo /The usage of accessories can be checked during demo. (Vortex mixer, Electronic Pipette & UPS) The dispensing (calibrated & Certified) pipettes can be checked for exact sample volume of 50 microlitre dispensing. The instrument supplier should also supply precision electronic pipette to dispense 50ul of sample and the same also needs to be periodically calibrated with certification.	Accessories seen & physically verified	
Quality Assurance/Safety/Terms & Conditions/Training				
13	Should be BIS/FDA/CE complaint	Certificate to be produced	Certificates must be ensured	
14	Certificate of calibration and inspection	Certificates and undertaking from firm to be obtained	Certificates /undertakings must be ensured	
15	Quoted model should have been in use at Government/Reputed private institutions. List of user with address and phone numbers to be provided	Undertakings/List tobe provided	undertakings must be ensured	

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16	Comprehensive Warranty for two years and next 5 CMC charges after warranty	Undertakings to be provided by the firm	undertakings must be ensured	
17	On site comprehensive training for the technical staff to make them familiar with machine	Undertakings to be provided by the supplier	undertakings must be ensured	
Documents				
18	User /Technical/ maintenance manuals to be supplied in English	To be provided by the firms and inspected by the board	Must satisfy the board	
19	List of equipments available for providing calibration and routine preventive maintenance support, as per manufacturer documentation in service/technical manual	To be provided by the firms and inspected by the board	Must satisfy the board	
20	List of Important spare parts and accessories with their part number and costing	To be provided by the firms and inspected by the board	Must satisfy the board	
21	Compliance report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue /data sheet. Any pint, if not substantiated with authenticated catalogue, will not be considered.	To be provided by the firms and inspected by the board	Must satisfy the board	

21/01/13

(Dr. A.K. Trivedi, CMO (SG), BSF)
Presiding officer

21.1.13

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