

Subject: Minutes of the meeting Technical Specifications Committee for review of technical specification of 'Blood collection tubes for collection of whole blood sample for CD4/ Viral Load testing , Microtubes for collection of whole blood samples for PCR in Early Infant Diagnosis (EID) programme and Safety Lancet for drawing heel prick blood samples from infants in EID program ' held on 16.7.2014

A meeting of the Technical Committee for specifications of 'Blood collection tubes for collection of whole blood sample for CD4 testing, Micro-tubes for collection of whole blood samples for PCR in Early Infant Diagnosis (EID) programme and Safety Lancet for drawing heel prick blood samples from infants in EID program ' was held under the chairmanship of Dr. B.D. Athani, Addl. DGHS & Medical Superintendent in room no. 439 B, A Wing, Nirman Bhawan, New Delhi on 16.7.2014.

The following members attended the meeting:

1. Dr. B.D. Athani, Spl. DGHS, New Delhi. **CHAIRMAN**
2. Dr.R.Chandrashekhar, Dy. Drug Controller General of India, MOH & FW
3. Dr. Abhijit Kadam , Scientist B, NARI, Pune.
4. Dr. Manjula Singh, Scientist C, ICMR HQ, New Delhi
5. Dr. Naresh Goel, DDG(LS), DAC , New Delhi **Member Secretary**
6. Dr.Lalit Dar , Prof & in-charge of Virology Section, Department of Microbiology, AIIMS, New Delhi
7. Dr. Rajeev Thakur, Professor and Head of the Department of Microbiology, IHBAS, New Delhi
8. Dr..Reba Chhabra, Scientist Grade II, Head of Diagnostics Division, National Institute of Biologicals, NOIDA
9. Dr. Namita Singh, Director Labs , CHAI India

The agenda of the meeting was as follows:

1. Review of technical specifications of blood collection tubes for collection of whole blood samples for CD4 testing/ Viral Load testing.
2. Review of technical specifications of Micro-tubes for collection of whole blood samples for PCR test for EID .
3. Review of technical specifications of Safety Lancet for drawing heel prick blood sample from infants and children in EID program

All three agenda items were discussed in the meeting and following decisions were taken:

Handwritten signatures and dates of the meeting participants. The signatures are: 1. Kadam 16/7/14, 2. M.S., 3. B.D. Athani, 4. Chandrashekhar, 5. Naresh Goel, 6. Lalit Dar, 7. Rajeev Thakur, 8. Reba Chhabra, 9. Namita Singh.

a). Agenda item No.1 was review of technical specifications of blood collection tubes for collection of whole blood samples for CD4 testing/ Viral load testing. The committee approved the technical specifications for the same as follows :

- Evacuator tubes
- Made of Polyethylene terephthalate(PET)/ Polystyrene
- Sterile
- Coated with Spray Dried K2 or K3 EDTA appropriate for volume drawn
- 3 ml draw volume.
- Pierceable cap
- Leak- proof cap.
- CE/FDA approved
- Toxicity Certificate and batchwise sterility/pyrogenicity certificate should be provided.
- Adequate combustion data to prove that it is safe for the environment upon incineration
- Equal no of needles with safety mechanism to prevent needle stick injury and spillage post usage, should be provided along with the tubes.
- One holder per 50 tubes should be supplied.
- Expiry of tube at time of delivery should be at least nine months.

b) Agenda item No.2 was review of technical specifications for Micro-tubes for collection of whole blood samples for PCR test for EID.The committee approved the technical specifications for the same as follows:

- Made of Polyethylene terephthalate(PET)/ Polystyrene
- Sterile
- EDTA coated with Spray Dried K2 or K3 EDTA appropriate for volume drawn
- Should have a 500 µl volume.
- Should have integrated lip/ rim for facilitating heel prick/capillary blood collection.
- Leak free closure cap
- CE/FDA approved
- Toxicity Certificate and batch-wise sterility/pyrogenicity certificate should be provided.
- Adequate combustion data to prove that it is safe for the environment upon incineration.
- Expiry of tube at time of delivery should be at least nine months.

c) Agenda item No.3 was review of technical specifications for Safety Lancet for drawing heel prick blood sample from infants and children in EID program .The committee approved the technical specifications for the same as follows:

- Single use
- Sterile blade
- 1-2 mm blade for drawing blood volume equal to or more than 500 micro-litre.

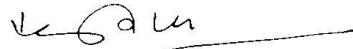
Adem
16/11/14

[Signature]
M.L.

[Signature]
16/11/14

[Signature]

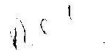
- Blade with protective removable tab/cover
- Rust proof blade
- Auto-retractable



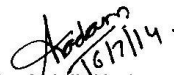
Dr. Naresh Goel
DDG(Labservices), DAC
as Member Secretary



Dr. B.D. Atharji
Addl. DGHS & MS,
Safdarjung Hospital,
New Delhi as Chairman



Dr. R Chandrashekhar (Dy DCGI)



16/7/14

Dr. Abhijit Kadam (NARI).



Dr. Manjula Singh, (ICMR)



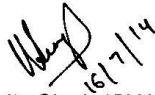
Dr. Lalit Dar , (AIIMS)



Dr. Rajeev Thakur (IHBAS) .



Dr. Reba Chhabra (NIB)



16/7/14

Dr. Namita Singh (CHAI)