Minutes of Meeting of Technical Specification Committee of "equipment, test kits and drugs underNational Viral Hepatitis Control Program (NVHCP)" held on August 24, 2018 at Room Number 455~~439~~A, Nirman Bhawan, New Delhi.

A meeting of the Technical Specification Committee of "equipment, test kits and drugs under National Viral Hepatitis Control Program (NVHCP)" was held on August 24, 2018 at Room Number 445A, Nirman Bhawan, New Delhi under the Chairmanship of Dr B.D. Athani, Principal Consultant, Dte.GHS. The committee was apprised about the program through a presentation by the member secretary. It was also informed that all technical specifications had already been reviewed by the relevant technical resource groups under the program.

The following members attended the meeting:

1. Dr.R.Gangakhedkar, Head ECD, ICMR, Delhi
2. Mr.Somnath Basu, ADC, CDSCO (HQ)Representative, Drug Controller General of India
3. Mr. Vinod Kumar, Drug Inspector, CDSCO (HQ) Representative, Drug Controller General of India
4. Dr. Somnath Karmakar, Representative of Director,NCDC,Delhi
5. Dr.R.S.Gupta,DDG NACO
6. Dr. Aashish Choudhary, Dept of Microbiology,AIIMS,Delhi
7. Dr.Sandhya Kabra,Addl Director,NCDC/MoHFW
8. Dr. R. K. Sharma, Representative of DirectorNIB,Noida
9. Dr.Vandana Roy,HOD,Dept of Pharmacology,MAMC,Delhi
10. Dr. Vaishali Bharadwaj, Professor,Dept of Gastroenterology,PGIMER &Dr.RML Hospital, Delhi
11. Dr.S.Anuradha,Professor,Dept of Medicine,MAMC, Delhi
12. Dr. Partha Rakshit, Deputy Director, NCDC/MoHFW& Member Secretary, Technical Specification Committee of equipment, test kits and drugs under NVHCP

The agenda of the meeting was as follows

Agenda 1

- *To discuss and finalize the technical specifications of Equipment for use in the NVHCP and other related programs.*
- All annexures with respect to the items of equipment were reviewed and the following decisions were taken:

1. ELISA READER :

Technical specifications

1. Should be able to supportall plate formats U bottom, V bottom and flat bottom with reading capacity of 1 to 96-well microplates individually
2. Optical systems: LED lamp.
3. Detection: Absorbance based.
4. Reading Time: <15 Seconds for96-wells .
5. Wavelength range: 340nm to 750nm or more and should have easy access 8 position filter wheel
6. Should have automatic filter selection
7. Suitable LCD display
8. Wave length selection should be double monochromatic with 1nm increment
9. System should have capability to do qualitative, quantitative, kinetics with any formulae including validation, transformation, and factors and floating cut off.
10. Should have linear measurement range of : 0- 4OD (optical density)

24/8/18 (SOMNATH BASU) ADC I/C CDSCO

11. Resolution: 0.001Abs.
12. Photometric Accuracy: 1%±1%
13. Should have a resolution of 0.001OD
14. Repeatability: 0.5% +/ -0.005OD
15. Photometric method-single/dual
16. Should have facility for sorting atleast 50 assay protocols
17. Should be capable of doing multi standard tests and controls
18. Should have blanking facility- air wise and well wise
19. System should perform self-check before every measurement and should have automatic calibration before each plate reading and facility for storage of calibration curves.
20. Power requirements:220-240 V AC, 50Hz
21. Inbuilt shaking mode
22. PC based system.
23. PC Requirements: Intel core i5 processor, 2 GB RAM, 500GB hard disc, LED monitor 17", USB PORT, key board and mouse, Microsoft Window with MS office licensed,
24. PC Software packages (windows compatible and should be licensed) for on board data analysis.
25. Two way interface with Laboratory Information System
26. Compatible UPS-microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. The manufacture should specify Installation qualifications, Operational Qualifications and Performance qualifications at site. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable in-built voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage

corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:

a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.

8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Additional requirements:
    a) Cover for the instruments to be provided
    b) Compliance certification of relevant section(s) of 21 CFR.

The committee approved the technical specifications of the ELISA reader

2. ELISA WASHER:

Technical specifications

1. Should have capability to wash flat, U or V bottom microplates.
2. Fully automatic platewasher.
3. Should have removable and autoclavable plate carrier
4. Should have strip selection option which allows to wash selected strips only
5. Should have inbuilt vacuum and dispensing pumps/peristaltic pumps to ensure accurate and quiet washing
6. Dispensing and aspirating needles should be separate
7. Washer should have 8 or 12 channel wash head
8. Should have 2-4 independent liquid channels
9. Wash volume per well should be programmable
10. Should have more than 50 wash programme memory
11. Programmable washing time, volume and soaking time.
12. Should have residual volume of<5µl
13. Alarm for monitoring the overflow and wash solution.
14. Should provide additional 2 numbers- each of wash buffer bottle and waste bottle along with the tubing
15. Compatible UPS- microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer
16. Power input 220-240VAC, 50 Hz

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. The manufacture should provide Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.

4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in- lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable in-built voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:

a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.

8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Additional requirements:
    a)Cover for the instruments to be provided

The committee approved the technical specifications of the ELISA Washer
The committee decided that the two items ELISA reader and ELISA washer should be procured separately

3. <u>TABLE TOP CENTRIFUGE (swing out)</u>

<u>Technical specifications:</u>

1. Body should be made of strong fabricated & corrosion resistant steel.
2. Microprocessor controlled with touch keypad LED.
3. Display of time, speed and temperature. Should have digital timer.
4. Control panel – for start/stop switch, dynamic brakes, step less speed regulator with zero start switch and protective fuses.
5. Swing out rotor with 4 round buckets of 180 ml and 4 aerosol tight caps to accommodate atleast 8 tubes in each bucket.
6. Autoclavable rotors
7. Automatic rotor recognition and automatic imbalance detector. Programmable speed with separate short spin key (in seconds).
8. Adaptor for accommodating 7ml tube must be supplied with rotor

9. Brushless maintenance free motor drive with low noise levels less than 60 dBAat Max speed with exact speed pre selection and display. Speed range from 100-5000 rpm accuracy 1 rpm with increment of 100.
10. Double lid locking system for maximum safety.
11. Automatic imbalance cut out, rotor over speed protection feature
12. Acceleration /breaking time should be 50/35secs
13. Stable speed output even under unstable voltage conditions.
14. The unit should be capable of operating in ambient temperature of 10-40 °C and relative humidity of 15-90%.
15. Power supply requirements: Supply voltage: 220- 240 V, AC, 50 Hz.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. The manufacture should specify Installation qualifications, Operational Qualifications and Performance qualifications on site. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation : the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the technical specifications of the Table Top Centrifuge (Swing Out)

4. **Refrigerated Microfuge**

Technical specifications

1. Bench top, compact, refrigerated
2. Robust metal housing; compact design with chemical-resistant (coated) housing.
3. Low access height (≤23 cm) and space-saving design (≤24 cm × 32 cm; W ×D).
4. Maximum speed: 18000 rpm. Speed adjustable in 100 rpm steps.
5. Max. RCF: Approximately 30,000 g or more
6. 45^0 fixed angle rotor.
7. Control system: Microprocessor control (brushless motor), LCD display protected; showing time and relative centrifugal force or speed in rcf or rpm.Speed, rcf, time, g.sec, acceleration & deceleration, temperature, 20 channel or more memories.
8. Temperature setting & Indication: Cooling range: -10°C to 40°C; Fast Pre cooling and should maintain +4°C at maximum speed
9. Easy-to-clean, smooth rotor chamber that is resistant to acids, alkali, disinfectants used in the laboratory.
10. Autoclavable rotors
11. Rotors should have autoclavable lids for minimizing aerosolization
12. Automatic lid lock, starting with and during run of rotor.
13. Option: Automatic opening at the end of the run.
14. Emergency unlock for electricity blackout.
15. Abnormality Detection: Lid open, Imbalance, over speed and Temperature shoot sensor, abnormal rotor mounting, electric abnormality.
16. Acceleration/Deceleration: Three level selectors: Rapid, slow and super slow.
17. Integrator setting & indication: Digital display: From 1, 00 to 9.99 x 10^9 g-sec.
18. Timer setting & indication: Digital display with hold and flashing in 1sec, 10sec, 1min,10min increment, showing rpm, RCF and time
19. Refrigerant: CFC / HCFC free should be environment friendly
20. The centrifuge must have a minimum of 4 "direct recall" program keys
21. Rotors: 24 x 1.5-2ml rotor aerosol-tight (chemical-resistant coated); exchangeable.
22. Adaptors for 0.5 ml and 0.2 ml tubes requirements.
23. Auto balancing in situation of minor imbalance.
24. Noise level: ≤60 dBA.
25. Power supply requirements: Supply voltage: 220- 240 V, AC, 50 Hz.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included (within two years of submission of bid).
2. The manufacture should specifyInstallation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)

5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the technical specifications of the Refrigerated Microfuge

5. LABORATORY REFRIGERATOR

Technical specifications:

1. Capacity 400±20 Liters.
2. Temperature range: 2-8°C
3. Internal: Durable unbreakable interior stainless steel
4. External: Durable rust free exterior.MS powder coated, scratch free
5. Should have one transparent door with light inside main chamber. Door with lock.
6. Preferably roller mounted
7. Microprocessor based controller
8. Control panel with temperature alarm, on/off switch, digital thermometer, temperature display
9. Refrigerant: CFC / HCFC free should be environment friendly
10. Stainless steel trays, with minimum four adjustable shelves Adequate circulation of air to ensure even cooling by duct system
11. Electronic automatic temperature control,
12. Hermetically sealed heavy duty compressor unit. Should have all the accessories required for the functioning of the equipment.
13. Power supply requirements: Supply voltage: 220- 240 V, AC, 50 Hz.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included (within two years of submission of bid).
2. The manufacturer should specify Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp).
5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:

a. Capacity/rating: 10 KVA: As per the requirement of the equipment.

b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.

8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the technical specifications of the Laboratory refrigerator

6. DEEP FREEZER (-20^{0}C) VERTICAL

<u>Technical Specifications</u>

1. Internal minimum capacity 350 to 400 L
2. Temperature Range up to -10°C to -30°C (adjustable)
3. Vertical Cabinet (upright mode)
4. **Outer Panels:** Outer panels are made of GI coated/ CPRCA sheet/Stainless Steel
5. **Interior Panels:** Interior panels are made of Stainless Steel
6. Adjustable feet for leveling with lockable castor wheels.

7. **Door:** Standard hinged door with Double gasket seal between the door and the cabinet . Option includes dual door system or vacuum insulated glass door.
8. **Door closing and locking Adjustment:** Self closing door with key door lock .
9. Control System: Micro-processor based temperature controller with digital temperature display LED/LCD with temperature recorder.
10. Temperature monitoring:
    a. Digital temperature (LED) display with 0.1 °C graduation
    b. Temperature recording device: temperature recorder with data logger compatible with LIS
    c. Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. There should be a method to check alarm system.
    d. Provision to connect with central (temperature) monitoring system
    e. The temperature indicator of deep freezer shall be calibrated with the help of master calibrator which shall be certified for its accuracy by NABL approved lab.
11. **Insulation:** High density polyurethane or equivalent gaskets – double seal silicon, fungus resistant
12. **Trays:** Adjustable stainless steel trays with perforated design
13. **Inner shelf:** 4-6 shelves/drawers. Each to be closed with a freezing flap.
14. Refrigeration system
    a. Should have a stable and reliable refrigeration system high efficiency energy saving environmental friendly Industry- grade refrigeration compressor, CFC / HCFC free
    b. should be environment friendly with an enhanced condenser and washable condenser filter for optimum cooling:
    c. Heavy Duty refrigeration system, maintenance free, hermetically sealed dual compressor, noise free and vibration free
    d. Should have dual compressors with evaporators and cooling fans.
    e. Refrigeration SystemAlarm: It should also have audio visual Electronic Alarm System independent of power supply for malfunction warning.
15. Security lock to prevent unintentional switch off shall be supplied
16. Alarm for audible & visual fault acknowledgement, low & high temperature audio visual alarms, condenser fault alarm, remote contact alarm, open door alarm, clean filter Indicator and power failure alarm.
17. Noise factor should not exceed 60 dBA
18. System should include inventory system like racks/boxes/plastic crates two for each shelf.
19. The unit shall be capable of operating continuously in ambient temperature of 10 – 40^{0}C and relative humidity of 15-90%.
20. **Power Supply:**Power input to be 220-240V AC, 50Hz, 3 Phase
21. Resettable over current breaker shall be fitted for protection.
22. Maintenance free temperature backup system to retain temperature in sub zero condition for period of minimum 5 hours with full load and in close door conditions in case of power failure or any other shut down.
23. Compatible UPS- microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. The manufacturer should specify Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(15Amp)
5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.I)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the technical specifications of the Deep Freezer (-20^{0}C) VERTICAL

7.DEEP FREEZER (-80 ^{O}C) VERTICAL

Technical specifications

1. Internal minimum Capacity : 450-500L
2. Temperature range: -65^{0}C to -85^{0}C
3. Internal : Stainless steel (minimum 22g) (S.S. grade 304)
4. External: Solid Outer Cabinet Corrosion Resistant (at least 1mm thickness) adjustable feet for leveling with lockable castor wheels.
5. Design: Upright Type

6. Door: Triple silicon section seal, Fitted with decompression valve facility to lower air pressure inside the freezer for easy door opening.Self- closing door with key door lock adjustable feet for leveling (optional casters). Casing & door should have insulation panel with polyurethane foam. Advanced remote monitoring: Should have independent High/Low alarm, Door open alarm, and power failure alarm;
7. Refrigeration :
    a) Dual Compressors with evaporators
    b) freezer with CFC / HCFC free refrigerant.
    c) Optimized cascade freezing technology. High efficiency, energy saving, environmental friendly, industry- grade refrigeration compressor, CFC free refrigeration with an enhanced condenser and washable condenser filter for optimum cooling.
    d) Heavy duty hermetically sealed dual compressor air cooled cascade refrigeration system, maintains inner temperature below -80° C
    e) Option for duct from equipment to connect to common main duct to throw hot air out of the room
8. External Ambient Temperature : Performs in an ambient temperature of +10 to +40° **C**
9. Temperature Monitoring :
    - Electronic temperature control
    - Operating temperature reachable lowest up to -86° at room temperature of 35° C with settling accuracy of ± 1° C whatever the load.
    - Digital temperature (LED) display with 0.1 ° C graduation
    - Temperature recording device: temperature recorder with data logger compatible with LIS
    - Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. There should be a method to check alarm system.
    - Provision to connect with central (temperature) monitoring system
10. The temperature indicator of deep freezer shall be calibrated with the help of master calibrator which shall be certified for its accuracy by NABL accredited lab.
11. Alarm for audible & visual fault acknowledgement, low & high temperature audio visual alarms, condenser fault alarm, remote contact alarm, open door alarm, clean filter Indicator and power failure alarm.
12. Noise factor should not exceed 60 dBA
13. Power supply:
    a. Power input to be 220-240V AC, 50Hz, 3 Phase
    b. Resettable over current breaker shall be fitted for protection.
    c. Maintenance free temperature backup system to retain temperature in sub zero condition for period of minimum 5 hours with full load and in close door conditions in case of power failure or any other shut down.
    d. Compatible UPS- microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included (within two years of submission of bid).
2. The manufacturer should specifyInstallation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.

3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(15Amp)
5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the technical specifications of the Deep Freezer (-80^{0}C) VERTICAL

8. FULLY AUTOMATED IMMUNO ANALYSER

System shall have the facility to test immunoassays for Hepatitis A/E, Hepatitis B surface antigen, Hepatitis C . There should be a provision of up gradation of the system for infectious/noninfectious markers.

Technical specifications

1. Fully automated, bench top/floor analyzer to perform the qualitative and quantitative assays from serum and plasma samples.
2. System should be discrete, fully sensitive random access with a provision to test STAT samples.
3. System should be based on chemiluminiscence, enhanced CLIA/ electro CLIA/ latest chemiluminescence etc. technology for measuring the assays with very high sensitivity, specificity and linearity.
4. Onboard loading capacity should be at least 50-60 samples or more at one time with a procedure for continuous loading.
5. System should have throughput of at least 80 tests/hr and the machine should have provision for up-gradation.

6. System should have reagent slots for a minimum of 15 - 20 assays
7. System should have on-board cooling facility to maintain the temperature of the reagents
8. Sample volumes should be < 100 µl per test.User defined onboard sample dilution is needed
9. System must use ~~disposable cups and tips for all immuno assays~~ mechanisms to prevent any carryover contamination to have reliable patient results.
10. System to use latest mixing probe technology to mix the samples and reagents to have complete uniformity with clot detection facility.
11. Flexibility to use different sample containers like primary tube with different sizes; sample cups etc for easy processing.
12. H A M A interferences should be taken care of with Chimeric antibodies.
13. Systems should have the facility to test infectious and non infectious markers
14. On-board reagent stability should be up to two months and calibration of the parameter should be typically lot based. Calibration frequency should be as per quality control requirements/lot specific.No daily calibration should be required by the system to conserve reagents.
15. System should have on-board windows based data control work station with (Thin Film Transistor)TFT LCD/LED color touch screen monitor for programming the tests and entering the patient data.
16. System should have the facility to store minimum of 2000 test results
17. System should have external laser printer to take printout of patient results and QC reports.
18. On-board barcode scanner for easy operation needed.
19. Two way interface with LIS.
20. System should have comprehensive software with calibration management, management of internal control, management of external control and customized patient data management. System must have extensive quality control like Westgard rules, Levey – Jennings graphical representation.
21. The system should be upgradable.
22. All materials required for Maintenance, calibration and upgrades including software would be provided free of cost.
23. System should have facility to collect both liquid and solid waste for disposal.
24. Power supply 220- 240 V AC,50Hz.
25. Company should provide a backup system (throughput of at least 80 test/hour) using same kits and consumables.
26. UPS - microprocessor controlled, line interactive, compatible pure sinewave online continuous transducercompatible with the system with maintenance free batteries with at least one hour backup to be provided.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included (within two years of submission of bid).
2. The manufacturer should specifyInstallation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies., efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance.

Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)

5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.I)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)
9. Additional requirements
    a. Bidder to be responsible for site preparation (minor modifications), installation, commissioning, trial run etc of the system in laboratory. All reagents to make the machine functional along with trial runs (minimum of 100 tests for each parameter) to user satisfaction should be provided free of cost.
    b. Lab staff should be comprehensively trained on all the operational function of equipment. Satisfactory working report of machine will only be provided once the lab staff is trained to our satisfaction
    c. The supplier should be authorized dealer for the principal firm & should produce original certificate for the same
    d. The principal firm should provide certificate stating the machine is brand new.
    e. All related plumbing for installation with suitable diameter pipes for input as well as drain should be done by company if required. Also suitable/compatible water treatment plant system and storage tank should be provided if required. It is the responsibility of the vendor to maintain the water quality for equipment irrespective of the quality of the tap water supplied in the site

The committee approved the technical specifications of the fully automated immunoanalyser and agreed for procurement of the same under reagent rental model wherein the kits procured for hepatitis diagnostic assistance as per algorithm or use in the program would be compatible with the platform.

9. NEXT GENERATION SEQUENCER

The equipment is a high end equipment and will be deliberated upon separately

10. REAL TIME PCR

Technical specifications

1. Table top model
2. Automated for both real time and post PCR analysis.
3. Complete system including basic system, essential accessories, the state-of-art computer workstation, acquisition and analysis software, startup kit inclusive of calibration standards etc. The system should support applications including SNP Genotyping, Gene Expression profiling, Micro RNA expression, Translocation analysis, Gene detection and Viral load analysis.
4. Real Time PCR with Peltiers for uniform heating and cooling and with temp range between 4°C-100°C with 96 well block. The Relative Quantitaion software should be provided along with the system and should provide facility of viewing Ten, 96 well plates together for gene expression
5. Standard optical 96 well plates, 0.1/0.2 ml strips, 0.1/0.2ml tubes compatibility. Min sample value requirement - 5µl; Min sample value requirement - 10µl. Should cover 20- 50µl reaction volume
6. Thesystemshouldbeenabledtorunfastchemistryandmusthaveapeakblockramprate of 4.4°C/secor more.
7. Should complete a minimum of 40 cycles within 2 hours
8. Temperature range of 4-100°C. Temperature accuracy +/- 0.25°C
9. CCD camera with LED or Tungsten halogen or high intensity Xenon lamp (No PMT System acceptable) and at least five excitation and five emission filters (covering wavelengths from 515-700 nm.). Multiplexing ability up-to five dyes in a single run.
10. Calibrated dyes at installation: FAM/SYBR Green, VIC/JOE, NED/TAMRA/Cy3, ROX/Texas Red and Cy5, Should offer flexibility in dye selection. Facility to calibrate new dye within the wavelength range without addition of new filters; Passive reference dye ROX or any other calibrated dye and should be optional.
11. The system should be capable of multiplexing 5 targets per well.
12. Should support all real time PCR chemistry like Taqman, SYBR Green, molecular beacons and all other fluorescent dye based Chemistries and should be calibrated for Multiple dyes.
13. Licensed version of primer probe designing software and relative gene expression software should be provided along with the system.
14. The system should include a licensed high resolution melting curve analysis software
15. The instrument should have software that can analyze multiple perspective in the multiple plot view, with side by side view of all data aspects including amplification plot, standard curve, multi-component data plot and raw data.
16. Software for absolutequantitation, relative quantitation, multiplex PCR, allelic discrimination (SNP), plus/ minus assay
17. Normalization to multiple endogenous controls.System should have facilities for system control, analysis, net-working of multiple systems.
18. Sensitivity: Detection of less than 10 copies of template
19. USB port for data export to Powerpoint, Excel or JPG file formats
20. Compatible UPS- microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer with ≥4 hours backup and maintenance battery
21. Power input 220-240VAC, 50/60 Hz
22. Additional requirements

a. One startup kit and consumables of each parameter should be provided by the firm free of cost for the training and installation purposes.
b. Branded non assembled PC with the following configuration or better to be included: OS Windows 7 or 10, 64-bit, Intel i7,4 GB RAM processor with Intel H87 chip set or better, minimum 3.5 GHz, minimum 3 Mb cache, hard disk minimum 500GB, 7200 r.p.m. SATA, Intel HD graphics 4400, atleast 4 USB ports, 1KVa UPS with 30 min backup.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included (within two years of submission of bid).
2. The manufacturer should specify Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation : the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report .
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
7. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
8. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the technical specifications of the Real time PCR

11. FULLY AUTOMATED NUCLEIC ACID EXTRACTOR

Technical specifications

Features	
Automated system for Nucleic Acid extraction	The system should be automated **for DNA and RNA** to provide a very high quality of extract for sensitive detection
Chemistries	It should work with proven magnetic bead based or spin column chemistries for all applications
Sample type	The system should be compatible with a wide variety of sample types like: blood, body fluids, serum, plasma, sputum, urine, CSF, stool, saliva, cultures etc. to use with different downstream molecular biology applications
Minimum sample volume	100µl and varies till 1000µl
Through-put	The system should be able to extract upto 20±5 per run, with option to run one sample per run also if and when needed.
Pre-treatment	The system should be able to do complete process including the pre-treatment steps like lysis etc.
Pipetting system	Pipetting system should avoid cross contamination. Should have a robust robotic system. No manual pipetting required.
Elution volume	50-200µl
Load-check	A comprehensive load check should be performed prior to sample processing to check work table setup and to help to ensure correct loading of the instrument.
Reliability and reproducibility in results	Results should be reliable and reproducible.
LIS compatibility	System should be LIS compatible Software should be upgradeable free of cost by company
Additional	1. Run time is 20-45 minutes depending upon sample and batch size 2. All desired samples can be isolated by instrument and free from cross contamination and can be used for PCR/RT PCR reactions. 3. Don't require external device like vacuum pump or tubing/pumps 4. All products are pre installed and require no external device 5. Instrument should have integrated HEPA filter,UV decontamination and bar code scanning facility 6. Meets the desired power requirement (220-240V,50Hz)
General specifications:	1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included (within two years of submission of bid). 2. The manufacturer should specify Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards. 3. Original product catalogue should be provided by the firm. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.

4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty including preventive maintenance followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.

a. Complete with comprehensive set of spare parts.
b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive action shall be taken in case of failure to maintain the desirable downtime.
d. Preventive maintenance plan and technical support to be provided.

7. After installation must provide IQ/OQ/PQ report. The bidder must arrange for calibration as and when required.
8. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
9. Capacity/rating: 10 KVA: As per the requirement of the equipment.
10. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
11. Certifications:

a. Product Certification : CE Class II A or US FDA certified
b. Quality Certification : ISO certified
c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the technical specifications of the fully automated nucleic acid extractor

12.GEL DOCUMENTATION SYSTEM
13. ADJUSTABLE VOLUME DIGITAL MULTIPLE CHANNEL MICROPIPETTES
14. MICROPIPETTES SINGLE CHANNEL OF VARIOUS VOLUMES
15.BIOLOGICAL SAFETY CABINET (CLASS II TYPE A2).
16.HOT AIR OVEN
17.WATER BATH
18.BOD INCUBATOR
19.VORTEX MIXER
20. VERTICAL AUTOCLAVE

Due to paucity of time, the committee felt the technical specifications of Equipment at S.No.12-20 will be deliberated in the next meeting

21.QUANTITATIVE VIRAL LOAD TESTING PLATFORM FOR HBV AND HCV

Technical specifications

1: Closed HCV and HBV nucleic acid extraction and Viral Load Testing Platform using human whole blood derived serum/plasma

2: Technology Platform should be based on real time PCR chemistry like TaqMan, molecular beacon probes, SYBR Green and all other fluorescent dye based chemistries and should be calibrated for multiple dyes. .

3:The Assay should be FDA-approved and CE-IVD marked. The quoted test shall be licensed to bidder in India by DCGI(I).

4: The limit of detection must be -

HCV RNA: 15 IU/ml or lower for 0.5 ml input

HBV DNA: 20 IU/ml or Lower for 0.5 ml input

5: Dynamic range of the quoted assay shall be

HCV: 15 – 1 X 10^8 IU/mL or better

HBV: 20 – 1.7 x 10^8 IU/ml or better

6: Specificity of the assay shall be 100%

7: Genotype coverage: Assay shall cover HCV genotypes 1 to 6& HBV genotype A to H plus Pre-Core Mutants.

8: The assay shall have inclusion of reagents/enzymes (either built in or external addition) to remove the carry over contamination by degrading of Nucleic Acid templates amplified in previous runs.

9: Capable of completing a cycle of extraction and testing within 8 hrs.

10: Automated sample extraction and the testing should have a throughput of up to 96 specimens in batches of 24 to 96.

11: The platform shall have barcode system for specimen tube identification

General Specifications:

1. The bidder will provide installation qualification, operational qualification and performance qualification at the time of installation with all certificates and log book for maintenance of the equipment at no extra cost.
2. The agency shall provide an EQAS on a 6-monthly basis provided by any ISO 17043 approved provider which should be part of the package with two sets of proficiency testing panels for HBV DNA and HCV RNA.
3. Yearly preventive maintenance and calibration, shall be the responsibility of the bidder as per requirement of quoted system/assay. Timely upgradation of the facility with respect to hardware/ software/reagent/workflow shall be provided free of cost.
4. The manufacturer should provide 95% uptime of the HCV & HBV viral load testing facility
5. The bidder shall provide free of cost replacement of the viral load platform in case new model or upgraded version is released by the manufacturer.
6. The bidder shall submit the details of engineer and application support team
7. The bidder will be responsible for training of laboratory staff on operation of equipment at the time of installation and subsequently every year for optimal utilization of the equipment.The cost of refresher trainings will be borne by the government but the technical aspects will have to be dealt with by the vendor.
8. The bidder shall set up the operational facility as per the requirement of proposed system and assay such as refrigeration (4/-20/-80 degree Celsius), centrifuge, Air conditioner, biosafety cabinets, HEPA filters, Pipettes or any other equipment/consumables required for running of quoted assay. The same shall be calibrated by the bidder as per requirements of NABL.

9. Compatible (5 to 10 KVA) UPS for nucleic acid extraction and testing equipment with back-up to complete one cycle atleast..
10. Electrical Requirement:
    a) Output voltage:220 volts +/- 10% volts.Input voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
    b) Electrical safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
11. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and provide alternative to ensure uninterrupted testing services. Punitive actions shall be taken in case of failure to maintain the desirable downtime.
12. Satisfactory report from atleast three government sites which have the equipment installed in last three years.

The committee approved the technical specifications of the quantitative viral load testing platform for HBV and HCV and agreed for procurement of the same under reagent rental model wherein the kits procured for HBV DNA and HCV RNA would be compatible with the platform.

22. WATER PURIFICATION SYSTEM

23. THERMAL CYCLER

Due to paucity of time, the committee felt the technical specifications of Equipment at S.No.22&23 will be deliberated in the next meeting

Cumulative Time Temperature Indicator for diagnostic test kit

1. The cumulative time/temperature indicator should indicate the exposure to temperature in the range of 2-8^0 C
2. The cumulative time-temperature indicator technology used should be pre qualified by WHO
3. The indicator should change colour uniformly, irreversibly and the rate of reaction should be predictable by appropriate kinetic parameters
4. The colour change should have a well defined start point and end point that can be correlated to the heat stability of the kit

The committee approved the specifications for Cumulative Time Temperature Indicator for diagnostic test kits

Cartridges for HCV RNA Assays using Cartridge based Nucleic Acid Amplification Test, (CBNAAT)

Technical Specifications

1. An HCV Viral Load assay designed for the quantification of hepatitis C virus (HCV) RNA in human serum or plasma (EDTA) from HCV-infected individuals.
2. The test must utilize automated reverse transcriptase polymerase chain reaction (RT-PCR) using fluorescence to detect the RNA of interest for the quantification of HCV.
3. Assay components must be contained within a single-use, disposable cartridge which performs RNA extraction, reverse transcription, and real-time PCR targeting the 5'untranslated region (UTR) of the HCV genome. Reagents must all be contained within the cartridge.
4. The test cartridge must contain atleast two internal controls to ensure accurate test performance and to quantify HCV viral load.
5. The software for running tests and viewing the results must be provided and uploaded on the lab system
6. HCV Viral Load test must quantify HCV genotypes 1–6 over the range of at least 10 to 10^8 IU/mL and a limit of detection of 15 IU/ml or lower in serum/plasma.Specificity of the assay shall be 100%
7. The test must automate and integrate specimen purification, nucleic acid amplification, and detection of the target sequence in simple or complex specimens using real-time reverse transcriptase PCR (RT-PCR) which uses fluorescence to detect the RNA of interest.
8. The assay performance characteristics must be aligned with limited hands-on time, short run time, random access testing, and uncomplicated operator input to enable rapid, same day evaluation and reporting of HCV status.
9. The type of assay should not require more than general laboratory equipment such as centrifuge, vortex and must be able to be performed in laboratories with limited facilities. No requirements for PCR room settings.
10. A volume of not more than 1000µl (1.0 ml) of plasma or serum should be needed to perform the assay.
11. The HCV VL Assay kit must contain cartridges in packs of not more than 10/pack.
12. The assay kits provided should have an expiry date of not less than 10 months at the time of delivery.
13. The assay must be CE-marked / FDA approved *in vitro* diagnostic (IVD) test.
14. Scheduled, periodic, on- site training on the use of assay to be provided to the laboratory staff.

The committee approved the specifications for Cartridges of CBNAAT HCV RNA Assays and was informed that as on date validated HCV RNA detection by this method is only available from a single vendor.

Agenda 3: ***The committee deliberated on the drug specifications for use in the program and finalised the technical specifications of the same for use in the NVHCP and other related programs. The committee approved the specifications for the following drugs:***

A. Sofosbuvir 400mg
B. Sofosbovir +Velpatasvir(FDC 400mg+100mg)
C. Daclatasvir60mg
D. Daclatasvir30mg
E. Ribavirin 200mg

1. Sofosbuvir

Technical specifications

1. Each tablet contains Sofosbuvir 400mg.
2. Number of tablets per container: 28---30 tablets
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (tablet) and the drug content, interactions adverse effect and contraindications. The product should conform to standards of Indian Pharmacopoeia or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates, specific storage requirements, batch number and manufacturer's address and other requirements as per Drugs and Cosmetics Act, India.

General specifications

1. Standard Shelf Life: at least 18months at the place of dispatch to the consignee
2. Primary Container: Suitable, Opaque Plastic Bottle to contain28---30tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap.
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by Division of Viral hepatitis, NHM should be used. Each label should have clearly marked as "Government of India Supply, Not for sale" on primary packaging. The packaging and labeling requirements must meet the GMP practices.
4. Each batch shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

2. Sofosbuvir and Velpatasvir (FDC 400mg+100mg)

Technical specifications

1. Each tablet contains: Sofosbuvir 400mg and Velpatasvir 100mg
2. Number of tablets per container: 28---30tablets
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (tablet) and the drug content, interactions adverse effect and contraindications. The product should conform to standards of Indian Pharmacopoeia or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates, specific storage requirements, batch number and manufacturer's address and other requirements as per Drugs and Cosmetics Act, India.

General specifications

1. Standard Shelf Life: at least 18 months at the place of dispatch to the consignee

2. Primary Container: Suitable, Opaque Plastic Bottle to contain 28---30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap.
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by Division of Viral hepatitis, NHM should be used. Each label should have clearly marked as "Government of India Supply, Not for sale" on primary packaging. The packaging and labeling requirements must meet the Good manufacturing practices
4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

3. Daclatasvir 60 mg

Technical specifications

1. Each tablet contains Daclatasvir 60mg.
2. Number of tablets per container:28---30 tablets
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (tablet) and the drug content, interactions adverse effect and contraindications. The product should conform to standards of Indian Pharmacopoeia or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates, specific storage requirements, batch number and manufacturer's address and other requirements as per Drugs and Cosmetics Act, India.

General specifications

1. Standard Shelf Life: atleast 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable, Opaque Plastic Bottle to contain 28---30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap.
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by Division of Viral hepatitis, NHM should be used. Each label should have clearly marked as "Government of India Supply, Not for sale" on primary packaging. The packaging and labeling requirements must meet the GMP practices
4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

4. Daclatasvir 30 mg

Technical specifications

1. Each tablet contains Daclatasvir 30mg. Indian Pharmacopoeia or any other pharmacopeia.
2. Number of tablets per container:28---30 tablets
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (tablet) and the drug content, interactions adverse effect and contraindications. The product should conform to standards of Indian Pharmacopoeia or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates, specific storage requirements, batch number and manufacturer's address and other requirements as per Drugs and Cosmetics Act, India.

General specifications

1. Standard Shelf Life: at least 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable, Opaque Plastic Bottle to contain 28---30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap.
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by Division of Viral hepatitis, NHM should be used. Each label should have clearly marked as "Government of India Supply, Not for sale" on primary packaging. The packaging and labeling requirements must meet the GMP practices
4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

5. Ribavirin

Technical specifications

1. Each tablet/capsule contains ribavirin 200mg.
2. Number of tablets per container:100 tablets
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules There under.
4. The product insert must indicate dosage form (tablet) and the drug content, interactions adverse effect and contraindications. The product should conform to standards of Indian Pharmacopoeia or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates, specific storage requirements, batch number and manufacturer's address and other requirements as per Drugs and Cosmetics Act (India) and Rules There under 24/8/18

General specifications

1. Standard Shelf Life: at least 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable, Opaque Plastic Bottle to contain 100 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screwcap/Box with strips of Ribavirin
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by Division of Viral hepatitis, NHM should be used. Each label should have clearly marked as "Government of India Supply, Not for sale" on primary packaging. The packaging and labeling requirements must meet the GMP practices
4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

For Ribavirin, explore the possibility of a pack of 50 tablets and include if available.

The meeting ended with a vote of thanks to the Chair.

Dr.R.Gangakhedkar, , Head ECD, ICMR, Delhi		Dr.R.S.Gupta,DDG NACO	
Mr. Vinod Kumar, Drug Inspector, CDSCO (HQ)	24/7/18	Mr.Somnath Basu, ADC, CDSCO (HQ)	24/8/18
Dr. Somnath Karmakar, Addl Director NCDC		Dr. Aashish Choudhary, AIIMS,Delhi	
Dr.Sandhya Kabra,Addl Director,NCDC/MoHFW		Dr. R. K. Sharma, NIB,Noida	
Dr.Vandana Roy, MAMC,Delhi	V. Roy 24/8/18	Dr. Vaishali Bharadwaj, RML, Delhi	
Dr.S.Anuradha,Professor, MAMC, Delhi		Dr. Partha Rakshit, DD,NCDC/MoHFW	
Dr B. D. Athani, Principal Consultaant, DteGHS & Chairman			