Annexure A

Personal Protection Equipment (PPE) - Specifications
(for Contact & Airborne precautions)

1. PPE Kit
   1.1 Gloves
       * Nitrile
       * Non-sterile
       * Powder free
       * Outer gloves preferably reach mid-forearm (minimum 280 mm total length)
       * Different sizes (6.5 & 7)
       * Quality compliant with the below standards, or equivalent:
         a. EU standard directive 93/42/EEC Class I, EN 455
         b. EU standard directive 89/686/EEC Category III, EN 374
         c. ANSI/SEA 105-2011
         d. ASTM D6319-10

1.2 Coverall (medium and large)*
       * Impermeable to blood and body fluids
       * Single use
       * Avoid culturally unacceptable colors e.g. black
       * Light colors are preferable to better detect possible contamination
       * Thumb/finger loops to anchor sleeves in place
       * Quality compliant with following standard
         a. Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent

1.3 Goggles
       * With transparent glasses, zero power, well fitting, covered from all sides with elastic band/or adjustable holder.
       * Good seal with the skin of the face
       * Flexible frame to easily fit all face contours without too much pressure
       * Covers the eyes and the surrounding areas and accommodates for prescription glasses
       * Fog and scratch resistant
       * Adjustable band to secure firmly so as not to become loose during clinical activity
       * Indirect venting to reduce fogging
       * May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable
       * Quality compliant with the below standards, or equivalent:
         a. EU standard directive 86/686/EEC, EN 166/2002
         b. ANSI/SEA Z87.1-2010
1.4. **N-95 Masks**
- Shape that will not collapse easily
- High filtration efficiency
- Good breathability, with expiratory valve
- Quality compliant with standards for medical N95 respirator:
  - a. NIOSH N95, EN 149 FFP2, or equivalent
  - Fluid resistance: minimum 80 mmHg pressure based on ASTM F1862, ISO 22609, or equivalent
- Quality compliant with standards for particulate respirator that can be worn with full-face shield

1.5. **Shoe Covers**
- Made up of the same fabric as of coverall
- Should cover the entire shoe and reach above ankles

1.6. **Face Shield**
- Made of clear plastic and provides good visibility to both the wearer and the patient
- Adjustable band to attach firmly around the head and fit snugly against the forehead
- Fog resistant (preferable)
- Completely covers the sides and length of the face
- May be re-usable (made of material which can be cleaned and disinfected) or disposable
- Quality compliant with the below standards, or equivalent:
  - b. ANSI/SEA Z87.1-2010

3. **Triple Layer Medical Mask**
- Three layered medical mask of non-woven material with nose piece, having filter efficiency of 99% for 3 micron particle size.
  - a. ISI specifications or equivalent

4. **Gloves**
- Nitrile
- Non-sterile
- Powder free
- Outer gloves preferably reach mid-forearm (minimum 280mm total length)
- Different sizes (6.5 & 7)
- Quality compliant with the below standards, or equivalent:
  1. EU standard directive 93/42/EEC Class I, EN 455
  2. EU standard directive 89/686/EEC Category III, EN 374
  3. ANSI/SEA 105-2011
  4. ASTM D6319-10
5. **Body Bags - Specifications**

1) Impermeable  
2) Leak proof  
3) Air sealed  
4) Double sealed  
5) Disposable  
6) Opaque  
7) White  
8) U shape with Zip  
9) 4/6 grips  
10) Size: 2.2 x 1.2 Mts  
11) Standards:  
   a) ISO 16602:2007  
   b) ISO 16603:2004  
   c) ISO16604:2004  
   d) ISO/DIS 22611:2003

All items to be supplied need to be accompanied with certificate of analysis from national/ international organizations/labs indicating conformity to standards  

All items: Expiry 5 years

* Due to scarcity of coveralls, and risk versus benefit, that as an emergency temporary measure in larger public interest, in present given circumstances, the fabric that cleared/passed "Synthetic Blood Penetration Resistance Test" (ISO 16603) and the garment that passed 'Resistance to penetration by biologically contaminated solid particles (ISO 22612:2005) may be considered as the benchmark specification to manufacture Coveralls." The Coveralls should be taped at the seams to prevent fluid/droplets/aerosol entry.

The test for these two standards (ISO 16603 and ISO 22612:2005), which can be performed in Indian laboratories are as per WHO Disease Commodity Package (Version 4.0)