

Guidelines for diagnostic laboratories pertaining to requirements of infrastructure for testing of specimens for Pandemic Influenza A (H1N1) virus infection (based on CDC/WHO guidelines¹)

General Bio-safety measures: Gloves (latex), shoe cover, head cover, goggles, triple layered mask, mask with N-95 specification, front closed full length apron, puncture resistant autoclavable yellow coloured bio-safety bag with bio-safety symbols, hypochlorite solution. (As per bio-safety manual attached as Document 2).

Civil Infrastructure: Separate dedicated areas for sample handling and PCR testing as per recommended guidelines (Document 3).

Sample collection kit: Throat/Nasal swab with synthetic up (polyester or Dacron) and aluminium or plastic shaft sample collection vials or tubes (leak proof and autoclavable) containing 1-3 ml. virus transport media (with protein stabilizer and antibiotics) as primary container.

Sample storage: Refrigerator (4-8⁰ C) for storage up to 48 hrs. Deep freeze (-70⁰C) for longer storage.

Back up sample for future testing etc. should be kept at -70⁰ C.

Sample Transport: Absorbent cotton, tissue paper or waste newspaper for wrapping primary container. Secondary container to hold the primary container i.e. bigger tube or sealed plastic bag. Insulated ice box with ice pack, sample proforma fastened on to the secondary container.

Sample handling and testing:

Handling: In BSL-3 Bio-safety or BSL-2+ facility with BSL-3 precautions.

Testing: Real time RT-PCR test, by Real Time PCR machine using validated reagents accessories and protocol as per CDC/WHO guidelines/testing protocols³ and subsequent amendments published from time to time.

Reporting of Results: Standardized uniform reporting proforma. PC with internet facilities, fax machine.

1. http://www.cdc.gov/swineflu/specimen_collection.htm

2. http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

3. <http://www.who.int/csr/resources/publications/swineflu/realtimeptpcr/en/index.html> dated 28th April 2009 and 30th April,2009