

Directorate of National Vector Borne Disease Control Programme

Technical Specification of Dengue NS1 Antigen detection kit by ELISA under NVBDCP

- 1) The ELISA kit should be designed for qualitative detection of dengue NS1 antigen of all 4 dengue serotypes in human serum.
- 2) The kit should be provided with the following materials and reagents:
 - a) Anti- NS1 Antibody Coated Breakway Microwells (12*8=96 wells). Desiccant should be provided for storing the unused microwells which are to be resealed immediately.
 - b) Horseradish peroxidase conjugated Anti-NS1 monoclonal antibody with preservatives
 - c) Chromogenic substrate in buffer
 - d) Positive Control in the form of recombinant antigen with preservatives and antibiotics
 - e) Negative control in the form of confirmed negative human serum with preservatives and antibiotics
 - f) Calibrators in the form of recombinant antigen with preservatives and antibiotics
 - g) Sample diluents
 - h) Wash buffer
- 3) The time required for performing the test for detection of dengue NS1 antigen by ELISA should range between 2-4 hours.
- 4) The ELISA kit for detection of dengue NS1 antigen should have a sensitivity of >90% and a specificity of >95% taking RT-PCR as the gold standard.
- 5) The kit should have a shelf-life of at least 6 months when stored at an ambient temperature of 2°C - 8°C.
- 6) Transportation should be under cold chain.

The Technical Specification of Dengue NS1 Antigen detection kit by ELISA under NVBDCP approved by Technical Specification Committee in the meeting held on 26.09.2011